United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA-738-R-96-016
August 1996

Reregistration Eligibility Decision (RED)

Cryolite

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical and active ingredient cryolite, case number 0087. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It also includes requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses are due 90 days from the date of your receipt of this letter. The second set of required responses are due 8 months from the date of your receipt of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that this RED was finalized and signed prior to August 3, 1996. On that date, the Food Quality Protection Act of 1996 ("FQPA") became effective, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED does not address any issues raised by FQPA, and any tolerance-related statements in the RED did not take into account any changes in tolerance assessment procedures required under FQPA. To the extent that this RED indicates that a change in any tolerance is necessary, that determination will be reassessed by the Agency under the standards set forth in FQPA before a proposed tolerance is issued. To the extent that the RED does not indicate that a change in a

tolerance is necessary, that tolerance too will be reassessed in the future pursuant to the requirements of FQPA.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative, Jeff Billingslea, (703) 308-8004. Address any questions on required generic data to the Special Review and Reregistration Division representative, Dana Lateulere, (703) 308-8044.

Sincerely yours,

Lois A. Rossi, Director
Special Review
and Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

Cryolite

CASE 0087

LIST A

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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CRYOLITE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Assessment

William Gross	Biological Analysis Branch
Gabe Patrick	Biological Analysis Branch
Eric Maurer	Economic Analysis Branch

Environmental Fate and Effects Assessment

Karen Angulo	Science Analysis and Coordination Staff
Alex Clem	Environmental Fate and Groundwater Branch
Allen Vaughan	Ecological Effects Branch

Health Effects Assessment

William Greear	Toxicology Branch I
Stephen Funk	Reregistration Support Chemistry Branch
John Leahy	Occupational and Residential Exposure Branch
Tom Myers	Risk Characterization and Analysis Branch
Brian Steinwand	Science Analysis Branch

Risk Management Assessment

Marilyn Mautz	Insecticide-Rodenticide Branch
Peg Perreault	Insecticide-Rodenticide Branch
Dana Lateulere	Reregistration Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration

GLOSSARY OF TERMS AND ABBREVIATIONS

NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
ug/L	Micrograms per liter
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision of the pesticide cryolite. This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. Cryolite is an insecticide used on many fruits, vegetables and ornamental crops to protect against leaf eating pests. Currently, the predominant uses are on grapes, potatoes and citrus. Cryolite is formulated as dusts, wettable powders, granulars and water dispersable granulars and can be applied by ground or air equipment. The Agency has concluded that all supported uses, except strawberries, as prescribed in this document, will not cause unreasonable risks to humans or the environment and therefore, are eligible for reregistration. Additional residue data are required to confirm the Agency's risk assessment and conclusions. Additional residue data are required before an eligibility decision can be made for the use of cryolite containing products on strawberries.

Cryolite was first registered as a pesticide in the U.S. in 1957. EPA issued a 1983 Guidance Document and a superseding 1988 Final Registration Standard and Tolerance Reassessment (FRSTR) requiring environmental, toxicological and residue data needed to determine cryolites reregistration eligibility. A 1990 Data Call-In (DCI) required additional ecological effects, toxicological, residue and product chemistry data.

In studies using laboratory animals, cryolite generally has been shown to be slightly to practically non-toxic on an acute basis. The acute dermal LD_{50} in rats is 2.1 g/kg, placing cryolite in Toxicity Category III (the second lowest of four categories) for this effect. Cryolite was considered a moderate irritant in eye irritation studies. Cryolite was classified in Toxicity Category IV for acute oral exposure, acute inhalation and skin irritation. Cryolite was classified as a non-sensitizer after dermal sensitization tests were conducted with Guinea pigs.

People may be exposed to residues of cryolite through their diet. Tolerances or maximum residue limits have been established for the fluorine compounds cryolite and synthetic cryolite in or on raw agricultural commodities. These include a regional registration tolerance for kiwi-fruit and a time-limited tolerance to expire May 6, 1996 on potatoes. EPA has reassessed the cryolite tolerances and found that some are acceptable, others must be revoked because the registrants have chosen not to support the uses, and new tolerances must be established for cabbage, citrus, collards, eggplant, lettuce (head and leaf), peaches and tomatoes. Food additive tolerance (FAT) increases must be established for raisins and tomato paste and data must be submitted to determine appropriate FAT levels for prunes. The Agency has completed its review of the data needed to establish a permanent tolerance for potatoes. The Agency will propose in the Federal Register permanent tolerances for potatoes at 2 ppm and potato waste at 22 ppm.

EPA has assessed the dietary risk posed by cryolite. A qualitative dietary risk assessment was performed to include the daily intake of fluoride from other sources, i.e. fluorinated public water sources. The Agency concluded that levels of fluoride in/on food from agricultural use of cryolite plus fluoride levels in U.S. drinking water supplies results in a high-end daily dietary

intake of fluoride of approximately 0.085 mg/kg/day. This is less than the Agency's determined Maximum Concentration Limit Goal (MCLG) of 4.0 mg/L [0.114 mg/kg/day], a level which provides no known or anticipated adverse health effects. The MCLG has been reviewed and is supported by the Surgeon General.

Cryolite has been classified as a Group "D" chemical, "not classifiable as to human carcinogenicity". It has been the subject of a comprehensive review by the National Research Council (National Academy of Sciences Subcommittee of Health Effects of Ingested Fluoride) who concluded that "...the available data are insufficient to demonstrate a carcinogenic effect of fluoride in animals." and that "..the weight of evidence from more than 50 epidemiological studies does not support the hypothesis of an association between fluoride exposure and increased cancer risk in humans." The Agency is in agreement with the conclusion reached by the National Academy of Sciences.

Acute risk is not expected to birds, mammals, aquatic organisms or beneficial insects from exposure to cryolite. Chronic ecological risk is also not expected because in the presence of sufficient water, cryolite is quickly converted to near natural background levels of simple inorganic compounds containing its constituent elements (sodium, aluminum, fluorine). Once cryolite dissolves and penetrates to shallow depths in the soil or is transported to natural waters, any minor chemical imbalances caused by its insecticidal application are offset by the mineral buffering capacity of the environment and standard agricultural practices (i.e., calcium applications, pH adjustments to the soil). Ground or surface water effects are expected to be negligible.

EPA is requiring the following additional generic studies for cryolite to confirm its regulatory assessments and conclusions: Residue crop field trials for cranberries and plums. The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration. Residue field trials are needed to determine the eligibility of cryolite use on strawberries.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of cryolite. The document consists of six sections. Section I is the introduction. Section II describes cryolite, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for cryolite. Section V discusses the reregistration requirements for cryolite. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient(s) are covered by this Reregistration Eligibility Decision:

- **Common Name:** Cryolite
- **Chemical Name:** Sodium aluminofluoride or sodium aluminum fluoride or sodium hexafluoroaluminate
- **Chemical Family:** Inorganic fluorine compound.
- **CAS Registry Number:** 15096-52-3
- **OPP Chemical Code:** 75101
- **Empirical Formula:** Na_3AlF_6
- **Trade and Other Names:** Kryocide®, Prokil®, Cryolite
- **Basic Manufacturers:** Gowan Company and Elf Atochem North America Inc.

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of the current uses of cryolite is in Appendix A. Cryolite is registered for use on Terrestrial Food, Terrestrial Food and Feed and Terrestrial Non-food sites. Cryolite is predominantly used by commercial growers and is not registered for greenhouse use.

Type of Pesticide: Fluorine Insecticide

Use Sites: Terrestrial Food Crops - Cucurbits (melons, cantaloupe, water melon, pumpkins, all types of squash), fruiting vegetables (eggplant, pepper, broccoli, Brussels sprouts, cabbage, cauliflower, collards, head and leaf lettuce, kohlrabi), kiwi (in California only), pears, radish, cranberry and peaches.

Terrestrial Food and Feed Crops - grapefruit, lemon, lime, orange, tangelo, tangerines, tomatoes, apples, potatoes, beans and grapes.

Terrestrial Non-food Crops - Ornamental herbaceous plants, ornamental nonflowering plants, ornamental woody shrubs and vines, ornamental and/or shade trees.

Target Pests: Cabbage looper, cutworms, corn earworm, spotted cucumber beetle, diamondback moth, flea beetles, imported cabbage worms, yellow-striped armyworm, melonworm, pickleworm, citrus cutworm, fruit-tree leafroller, Fuller rose beetle, garden tortrix, katydids, orange tortrix, orangedog, variegated cutworm, blue-green citrus root weevil, omnivorous leafroller, grape leaffolder, Western grapeleaf skeletonizer, grape berry moth, armyworm, tobacco budworm, pepper weevil, Colorado potato beetle, blister beetles, tomato pinworm, codling moth, gypsy moth and plum curculio.

Formulation Types Registered:

END USE PRODUCTS

Granular	20.0%

The granular formulation is registered only for Special Local Need uses [24(c)'s] and is applied as a "mulch-like" bait.

Dust	96.0%
Wettable powder/dust	93.0 and 96.0%
Water Dispersable Granules	93%

Method and Rates of Application: Cryolite products may be applied by hydraulic ground sprayers and/or aircraft. The maximum single application rate is 30 lbs ai/A, applied as a liquid to citrus and ornamentals; the maximum seasonal application rate from multiple applications is 154 lbs ai/A, applied as a liquid to lettuce. See Appendix A for required rates and restrictions.

Timing: For most crops cryolite is applied during the early part of the growing season when insects are first seen, or their presence is impending. Potato applications are usually made mid to late season. Grapes are predominantly treated pre-bloom through the early part of the season. Grape vines may also be treated post-harvest.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of cryolite. These estimates are derived from a variety of published and proprietary sources

available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

The table below summarizes the percent of various U.S. crops treated annually with cryolite, 1992 - 1994:

Site/1	Acres Grown/[2] (x000)	Acres Treated (x000)/[3]	Percent Crop Treated[4]	Pounds AI Applied[5] (x000)	Major Region or State
Apples	457.1	1 - 2	<1 - <1	1 - 10	Nationwide
Cabbage	99.4	1 - 1	1 - 1	5 - 10	Nationwide
Cantaloupes	111.2	1 - 1	1 - 1	5 - 10	CA
Cauliflower	55.3	1 - 1	2 - 2	5 - 10	Nationwide
Cucumbers	172.4	1 - 1	1 - 1	5 - 10	Nationwide
Grapes	757.4	250 - 475	33 - 63	1,500 - 4,000	CA
Kiwi	7.1	1 - 1	14 - 14	5 - 10	CA
Lemons	62.4	1 - 1	2 - 2	1 - 1	CA
Lettuce	269.4	1 - 4	<1 - 1	5 - 35	CA and AZ
Oranges	646.2	5 - 10	1 - 2	50 - 200	CA
Peaches	176.4	1 - 1	1 - 1	1 - 1	CA
Peppers	118.4	1 - 1	1 - 1	5 - 10	CA
Potatoes	1,379.5	40 - 100	3 - 7	400 - 900	Mid Atlantic
Squash	69.0	<1 - <1	<1 - <1	<1 - <1	CA
Strawberries	49.7	1 - 1	2 - 2	1 - 1	CA
Tangerines	23.5	1 - 1	4 - 4	1 - 1	CA
Tomatoes	449.7	1 - 1	<1 - <1	10 - 15	Nationwide
Watermelons	246.1	1 - 2	<1 - <1	10 - 30	CA
Totals		310 - 605		2,011 - 5,255	

[1] - Site identification based on OPP's Reference Files System (REFS).
[2] - 'Acres grown' based on USDA, Agricultural Census, and state statistics.
[3] - 'Acres treated' represents a range of the annual number of acres treated times the number of applications.
[4] - 'Percent crop treated' figure may represent a high estimate due to the definition of 'acres treated'.
[5] - 'Pounds of active ingredient' (AI) represents a range of the annual number of pounds of AI applied.

Data based on proprietary and non-proprietary sources, USDA, and state statistics.

Note: All other sites had either no known usage or no available data. Where data typically exist, there are no known usage on beans, broccoli, eggplant, grapefruit, limes, ornamentals, pears, and tangelos; those with no available data include collards, cranberries, mustard, radishes, and turnip.

D. Data Requirements

Data to support the continuing registration of cryolite were required in the 1983 Registration Standard and in the superseding 1988 Final Registration Standard and Tolerance Reassessment (FRSTR). Data were required on ecological effects, environmental fate, residue chemistry, chronic toxicity, oncogenicity and reproduction, as well as product-specific product chemistry and acute toxicity for both natural and synthetic cryolite. A 1990 DCI required additional ecological effects, acute and chronic toxicity, residue and product chemistry data. These data were required to support those uses listed in the 1983 and 1988 Registration Standards. Appendix B includes all data requirements identified by the Agency needed to support reregistration of currently registered uses.

E. Regulatory History

Cryolite has been registered in the United States since 1957 for use as an insecticide. A Registration Standard was issued in June 1983 for all pesticide products containing the active ingredient, cryolite. This document identified the additional generic data required to support the continued registration of cryolite for terrestrial outdoor food and non-food uses. The 1983 Registration Standard also specified the product-specific product chemistry and acute toxicity data required for manufacturing use products. At the time the 1983 Registration Standard was issued, the Agency's data base for cryolite was extremely poor and extensive data gaps existed in all disciplines.

The Agency reviewed all of the data submitted in response to the data requirements outlined in the 1983 Registration Standard and subsequently issued a Final Registration Standard and Tolerance Reassessment (FRSTR) in April 1988. In the 1988 Registration Standard, the Agency concluded that additional data were required to make a full assessment regarding the continued registration of all uses of cryolite. Existing data gaps resulted from a determination that certain submitted studies were unacceptable, and changes in data status from "reserved" to "required" based on results of lower tier studies, and/or expanded CFR Part 158 data requirements. A Data Call-In (DCI) for cryolite was issued in 1990 which required ecological effects and toxicological data and additional residue data to reassess current tolerances for cryolite.

In response to the DCI and Product and Residue Chemistry Update, the basic registrants chose not to support certain registered food uses. On March 12, 1996, a Generic Data Exemption (GDE) revocation letter was sent to the remaining end-use product registrant, who also opted not to support those same registered food uses. Amended labels showing the removal of these unsupported uses are required to be

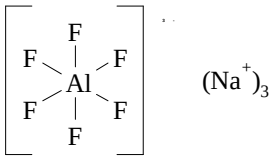
submitted within sixty days from the date of issuance of this Reregistration Eligibility Document. The supported and unsupported food uses are listed in Table 17 of this document. This Reregistration Eligibility Decision reflects a reassessment of all data submitted in response to the Registration Standards for cryolite, as well as assessments of data recently submitted in response to the DCI and Product and Residue Chemistry Update.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Cryolite (sodium aluminum fluoride, sodium aluminofluoride or sodium hexafluoroaluminate) is a fluorine insecticide which is a naturally occuring inorganic mineral that can also be produced synthetically. [The human and environmental science assessments that follow deal predominantly with the effects of fluoride as it was found to be the main component of concern.]

Structural Formula of Cryolite:



Empirical Formula:	Na_3AlF_6
Molecular Weight:	209.97
CAS Registry No.:	15096-52-3
OPP Chemical Code:	075101

IDENTIFICATION OF ACTIVE INGREDIENT

Natural cryolite is a white, black, purple, or violet crystalline solid with a melting point of 1009 C; synthetic cryolite is a white crystalline solid with a melting point ranging from 960-1027 C. Cryolite was found to be soluble in water at a range of 400 - 1200 ppm (at 25 C), insoluble in alcohol and to decompose in basic (alkaline) environments. Cryolite's insecticidal mode of action is predominantly as a stomach poison. Cryolite is formulated as a dust, water dispersable granule or wettable powder and applied as a liquid spray or dust. There is also a mulch-like granular formulation applied as a bait for use in two Special Local Need (SLN) registrations.

MANUFACTURING-USE PRODUCTS

The Cryolite Reregistration Standard Update (5/16/91) identified two 96% technical products registered to Elf Atochem North America, Inc. (previously Pennwalt Corporation; EPA Reg. No. 4581-116) and Gowan Company (EPA Reg. No. 10163-41). These products are currently registered as end-use products (EPs). A list of registered cryolite EPs is presented in Table 1.

Table 1. Registered cryolite products.

Formulation	EPA Reg. No.	Registrant
96% wettable powder/dust	4581-116	Elf Atochem North America, Inc. [a]
96% dust	10163-41	Gowan Company
93% wettable powder/dust	5481-132	Amvac Chemical Corporation
93% water-dispersible granules	10163-185	Gowan Company
20% granular/bait	OR95000800 WA95001800	Gowan Company

[a] The name of the registrant has changed from Pennwalt Corporation to Elf Atochem North America, Inc. without change in company number.

B. Human Health Assessment

1. Toxicology Assessment

The available toxicological database for cryolite is adequate and supports a reregistration eligibility determination for the currently registered uses. Although fluoride (a component of cryolite) is accumulated at all dose levels in several subchronic and chronic animal studies, the accumulation itself is not considered an adverse effect. The LOEL in these studies is based on the biological effects resulting from the fluoride accumulation.

a. Acute Toxicity

Results of the acute toxicity studies conducted with technical cryolite are summarized below in Table 2:

Table 2. Acute Toxicity Values of Technical Cryolite.

Route	Species	Results	Toxicity Category
Oral[a]	Rat	LD_{50}: >5 g/kg	IV
Dermal[b]	Rabbit	LD_{50}: 2.1 g/kg	III
Inhalation[c]	Rat	LC_{50} >2.06 mg/L and < 5.03 mg/L	IV
Eye Irritation[d]	Rabbit	Moderate Irritant	III
Skin Irritation[e]	Rabbit	No Effects	IV
Dermal Sensitization[f]	Guinea Pig	Non sensitizer	N/A

[a] MRID No. 00138096.
[b] MRID No. 00128107.
[c] MRID No. 00128107.
[d] MRID No. 00128106. Not required for TGAI, however, presented here for informational purposes.
[e] MRID No. 00128106. Not required for TGAI, however, presented here for informational purposes.
[f] MRID No. 00138097. Not required for TGAI, however, presented here for informational purposes.

Dental fluorosis is noted as an endpoint in several toxicology studies. Dental fluorosis is defined as a cosmetic mottling of tooth enamel caused by fluoride or its compounds and is not considered an adverse health effect.

b. Subchronic Toxicity

In a 3-month feeding study in rats, cryolite (96%) was administered to groups of 40 male and 40 female Charles River Crl:CD(SD)BR rats in the diet at levels of 0, 50, 5000 or 50,000 ppm (corresponding to 0, 3.8, 399.2 and 4172.3 mg/kg/day in males and 0, 4.5, 455.9 and 4758.1 mg/kg/day in females). At 5000 ppm and above, the stomachs of male and female rats exhibited thickened walls, dark contents, raised focal areas, glandular thickened walls, non-glandular light focal areas, glandular dark focal areas and red glandular areas of the stomach at necropsy. Histological examination revealed submucosal lymphoid foci, epidermal hyperplasia, hyperkeratosis/acanthosis, erosion/ulcerations, mucosal atrophy and chronic submucosal inflammation. Male and female rats at 50,000 ppm exhibited reduced body weights and decreases in hemoglobin and hematocrit. The NOEL is 50 ppm (3.8 mg/kg/day) for effects other than fluoride accumulation. The LOEL is 5000 ppm (399.2 mg/kg/day) based on lesions observed in the stomach. Fluoride accumulated at all dose levels (MRID 00158000).

In a 28-day subchronic feeding study, groups of 5 Sprague-Dawley rats/sex were administered cryolite (97.6%) at dose levels of 0, 250, 500, 1000, 2000, 4000, 10,000, 25,000 or 50,000 ppm in the diet (representing approximately 0, 25, 50, 100, 200, 400, 1000, 2500 and 5000 mg/kg/day). The teeth were whiter and the enamel became soft and granular at all dose levels and there was a dose-

response relationship. A NOEL was not determined. The LOEL is 250 ppm (25 mg/kg/day) based on dental fluorosis (MRID 00128109).

In a 3-month feeding study in dogs, cryolite (97.3%) was administered to groups of 7 male and 7 female dogs at 0, 500, 10,000 or 50,000 ppm (corresponding to 0, 17, 368 and 1692 mg/kg/day). One male and one female dog/group were interim sacrificed at 45 days. At 50,000 ppm, there was decreased food consumption, body weight, body weight gain and red blood cells (RBC), hemoglobin (Hgb), hematocrit (HCT), mean corpuscular volume (MCV) and mean corpuscular hemoglobin (MCH). Fluoride accumulated in bone at all dose levels. The NOEL is 10,000 ppm (368 mg/kg/day). The LOEL is 50,000 ppm (1692 mg/kg/day) for effects other than fluoride accumulation. Fluoride accumulation occurred at all dose levels (MRID 00157999).

In a 21-day subchronic dermal toxicity study, cryolite (96% a.i.) was administered dermally to 5 New Zealand White Rabbits/sex at dose levels of 0, 25, 250, or 1000 mg/kg/day. Exposure was for 6 hours per day, 5 days per week. The following signs were probably due to inadvertent oral exposure (rabbits were observed licking their fur during the study). Signs of toxicity included: mortality in males (3/5) and females (1/5) at 1000 mg/kg/day; clinical signs of toxicity (thin appearance, hypoactivity); actual decreases in absolute body weight (up to 400 gms) throughout the study; anemia and changes in several clinical chemistry parameters. At 250 mg/kg/day, body weight was only decreased on day 5 with weight gain returning to normal for the duration of the study. The systemic LOEL and NOEL due to dermal exposure can not be determined. Signs and mortality were probably due to oral exposure (MRID 41224801).

This 21-day subchronic dermal toxicity study is unacceptable because there is a high possibility that cryolite was ingested during the study. Given the extreme sensitivity of the rabbit to oral doses of cryolite and the observations of oral exposure, it is likely that the toxicity observed was due to oral ingestion. It does not satisfy the guideline requirement for a 21-day subchronic dermal study (82-2). However this guideline requirement (82-2) is waived and an additional study is not required on the technical. An additional study in the rat or rabbit is not necessary. Based on its chemical/physical properties, cryolite would not be absorbed through the skin to an appreciable extent to justify requiring an additional study.

c. Chronic toxicity/Carcinogenicity

The National Toxicology Program (NTP) conducted a 2-year rat carcinogenicity study with sodium fluoride (99%) 80, 50, 50, 50 and 80 F344/N rats/sex/group at dose levels of 0, 0 (paired control), 25, 100 or 175 ppm in water,

representing 0, 0, 1.3, 5.2 and 8.6 mg/kg/day in males and 0, 0, 1.3, 5.5 and 9.5 mg/kg/day in females (HED DOC NO. 009682; NTP, 1990).

Animals in the 100 and 175 ppm groups exhibited attrition, deformity, discoloration, and mottling of the teeth. Animals in the 25 ppm groups exhibited only mottling of the teeth. Serum, urine, and bone fluoride levels were increased in all treated animals. The fluoride levels showed a dose-response relationship. Osteosclerosis was increased in females in the 175 ppm group. Dentine incisor dysplasia was increased in males and females in all treated groups. Incisor odontoblast degeneration was increased in males in all treated groups and in females in the 175 ppm group. Incisor ameloblast degeneration was increased in males in all treated groups and in females in the 100 and 175 ppm groups. Osteosarcoma of the bone was only observed in one male in the 100 ppm group and in three males in the 175 ppm group. NTP considers this to be equivocal evidence of carcinogenicity in male F344/N rats. Other tumors present were squamous cell neoplasms of the epithelium of the oral mucosa, follicular cell adenomas and carcinomas and benign tumors arising from stratified squamous epithelium. The occurrence of these tumors was not associated with administration of the test material. The NOEL is less than 25 ppm (1.3 mg/kg/day). The LOEL is 25 ppm (1.3 mg/kg/day) based on mottling of teeth, dentine incisor dysplasia, increased serum, urine and bone fluoride levels in males and females and incisor odontoblast and incisor ameloblast degeneration in males. There was "equivocal evidence" of carcinogenic activity in male rats and "no evidence" of carcinogenic activity in female rats.

NTP conducted a 2-year mouse carcinogenicity study with sodium fluoride (99%) in groups of 80, 50, 50, 50 and 80 $B_6C_3F_1$ mice/sex at dose levels of 0, 0 (paired control), 25, 100 or 175 ppm in water, representing 0, 0, 2.4, 9.6 and 16.7 mg/kg/day in males and 0, 0, 2.8, 11.3 and 18.8 mg/kg/day in females (HED DOC NO. 009682; NTP,1990).

Attrition of the teeth ("grinding down by friction") was increased in females in the 175 ppm group and in all treated male groups. The incidence of discoloration and mottling ("spotted tooth enamel caused by excessive fluorides during the time teeth are calcifying") of the teeth was increased in all male and female treated groups. Alkaline phosphatase was increased in females in the 175 ppm group when compared to controls. Bone fluoride levels were increased in males and females in all NaF treated groups. The incidence of dentine dysplasia was increased in males in the 175 ppm group. It was concluded by NTP that there was "no evidence" of carcinogenic activity in male or female mice administered sodium fluoride in drinking water for 2 years. The NOEL is less than 25 ppm (2.4 mg/kg/day). The LOEL is 25 ppm (2.4 mg/kg/day) based on attrition of the teeth

in males, discoloration and mottling of the teeth in males and females and increased bone fluoride in both sexes.

Cryolite (97.3-97.4%) was tested in a one-year chronic feeding study in beagle dogs (4/sex/group) at dose levels of 0, 3000, 10,000 or 30,000 ppm, representing 0, 95, 366 and 1137 mg/kg/day in males and 0, 105, 387 and 1139 mg/kg/day in females. In terms of fluoride the doses are 0, 51, 198, or 614 mg F/kg/day for males and 0, 57, 209 or 615 mg F/kg/day for females (MRID 42575101).

At 3000 ppm, there were slight increases in the incidence of emesis (vomiting; white and yellow froth in both males and females), nucleated red cells in males, and renal lesions (regeneration of the tubular epithelium, interstitial fibrosis, tubular dilation, interstitial infiltration with lymphocytes) in 1-2 males and/or females. Females also showed a decrease in specific gravity of the urine.

At 10,000 ppm, decreased red cell count, hemoglobin, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, and platelets, and increased incidence of abnormal red cells (anisokaryocytes, microcytes, macrocytes, target cells, hypochromic cells, nucleated red cells, basophilic stippling, and Howell-Jolly bodies), hematopoiesis in the liver and spleen, megakaryocytosis in the spleen, and myelofibrosis in the bone marrow were observed in males and/or females. Also, increased leukocytes (primarily segmented neutrophils and eosinophils) were observed in females. Dilation of Bowman's space was observed in one male and one female at this dose. Clinical chemistry showed a decrease in total serum protein in males and in serum albumin in females. In addition, decreased serum calcium was observed in males.

Body weight gain was increased in males at 30,000 ppm. Increased lactate dehydrogenase was observed in both males and females and decreased blood sodium was observed in males. The NOEL (in terms of Cryolite) is less than 3000 ppm (95 mg/kg/day in males and 105 mg/kg/day in females). The LOEL is 3000 ppm (95 mg/kg/day) based on increases in emesis, nucleated cells in males, renal lesions and a decrease in urine specific gravity in females.

d. Developmental Toxicity

Cryolite was tested by gavage in a developmental toxicity study in Sprague-Dawley derived fBR Simonsen albino rats (30/group) at dose levels of 0, 750, 1500 or 3000 mg/kg/day during gestation days 6-15 inclusive. At 3000 mg/kg/day, well above the limit dose, the only observation was whitening of the teeth of dams. The NOEL for maternal toxicity is 3000 mg/kg/day. The LOEL

is greater than 3000 mg/kg/day. The NOEL for developmental toxicity is 3000 mg/kg/day. The LOEL is greater than 3000 mg/kg/day (MRID 00128112).

Cryolite (97.3%) was tested by gavage in a developmental toxicity study in female CD-1 mice (25/group) at dose levels of 0, 30, 100 or 300 mg/kg/day. There was increased mortality at 300 mg/kg/day. The glandular portion of the stomach was red beginning at 100 mg/kg/day. In addition, females in the 300 mg/kg/day group exhibited dark red contents of the stomach. The NOEL for maternal toxicity is 30 mg/kg/day and the LOEL is 100 mg/kg/day based on the occurrence of dark red contents of the stomach. Fetuses at 300 mg/kg/day exhibited bent ribs and bent limb bones. The NOEL for developmental toxicity is 100 mg/kg/day. The LOEL is 300 mg/kg/day based on an increase in bent ribs and bent limbs (MRID 42297902).

Cryolite (97.3%) was tested by gavage in a range-finding developmental toxicity study in female New Zealand White rabbits (5/group) at dose levels of 0, 10, 30, 100, 300 or 1000 mg/kg/day. Mortality was increased in the 30, 100, 300 and 1000 mg/kg/day groups. Toxic signs including decreased defecation, decreased urination, soft stool and black colored feces were increased in the treated groups when compared to controls. Food consumption was decreased in all treated groups. Most animals studied in the 30, 100, 300 and 1000 mg/kg/group exhibited dark red areas, dark red contents and/or reddened mucosa of the stomach. The NOEL for maternal toxicity is 10 mg/kg/day and the LOEL is 30 mg/kg/day based on an increased incidence of soft stool and dark colored feces and decreased defecation and urination. The NOEL for developmental toxicity is 30 mg/kg/day. The LOEL could not be assessed due to excessive toxicity at dose levels of $\geq$ 30 mg/kg/day (MRID 42297901).

This study is unacceptable and will not satisfy the guideline requirement for a non-rodent developmental study. This study suggested that severe maternal toxicity occurred at lower doses than external developmental toxicity. However, following an extensive literature evaluation, the National Research Council (National Academy of Sciences Subcommittee of Health Effects of Ingested Fluoride) (NAS) has determined the following:

"There have been reports of adverse effects on reproductive outcomes associated with high levels of fluoride intake in many animal species. In most of the studies, however, the fluoride concentrations associated with adverse effects were far higher than those encountered in drinking water. ...

"Based on these findings, the subcommittee concludes that the fluoride concentrations associated with adverse reproductive effects in animals are far higher than those to which human populations are exposed. Consequently, ingestion of fluoride at current concentrations should have no adverse effects on human reproduction."

A new rabbit developmental study is not required at this time since there are two acceptable rodent developmental studies (rat and mouse) showing no specific adverse developmental effects. In addition, the NAS report supports this decision. It is unlikely that an additional rabbit developmental study would alter the risk evaluation for Cryolite.

e. Reproductive Toxicity

In a two-generation reproduction study, Sprague-Dawley rats (30 per group) were administered cryolite (96%) in the diet at dose levels of 0, 200, 600, or 1800 ppm (representing 0, 14, 42, and 128 mg/kg/day for males and 0, 16, 49, and 149 mg/kg/day for females, respectively, during premating). Compound-related systemic toxicity was observed in a dose related manner among both sexes and generations at all dose levels as evidenced by clinical signs of dental fluorosis. Whitening of the upper and/or lower incisors was observed in most treated animals of both generations. Beveled anterior edge of the lower incisor was observed in $\geq$67% of animals from both generations at 1800 ppm. Mottled appearance of lower incisor was noted at dose levels $\geq$600 ppm in 6%-40% of F_1 animals; however, this sign was not dose related. The NOEL was not determined. The LOEL for systemic toxicity was 200 ppm (15 mg/kg/day) based on dental fluorosis.

Reproductive toxicity was observed at 1800 ppm as evidenced by significantly decreased pup body weights during lactation days 7, 14, and 21 (82%-88% of control in F_1 offspring) and days 4, 7, 14, and 21 (74%-89%) of control in F_2 offspring). Gross findings were also observed in pups at 1800 ppm by the time of weaning. They were manifested as pale kidneys, pale livers and enlarged hearts and were considered to be compound related. No effects were observed on parental reproductive performance. The NOEL and LOEL for reproductive toxicity were 600 and 1800 ppm, respectively (46 and 138 mg/kg/day) based on decreased pup body weights (MRID 43387501).

f. Mutagenicity

Cryolite was tested in an (Ames) reverse mutation test using Salmonella typhimurium with and without activation at dose levels of 167, 500, 1670, 5000, 7500 and 10000 μg/plate. The results were negative (MRID 41838401).

Cryolite produced negative results when tested at 100, 500 and 1000 μg/ml with and without activation in an in vitro chromosomal aberration study using human lymphocytes (MRID 41838402).

Cryolite was negative for inducing unscheduled DNA repair in primary rat hepatocytes at dose levels up to and including 50 μg/ml (MRID 41838403).

g. Metabolism

A general metabolism study is not required. It has been demonstrated that toxicologically, cryolite behaves as free fluoride. There are numerous references in the literature on the metabolism of cryolite and other fluoride salts. The National Research Council, in their 1993 report on fluoride concluded that fluoride is readily absorbed by the gut and rapidly becomes associated with teeth and bones. The remaining fluoride is eliminated almost exclusively by the kidneys with the rate of renal clearance related directly to urinary pH.

h. Dose Response Assessment

The OPP's Health Effects Division's RfD/Peer Review Committee (document dated December 22, 1995) concluded the following for cryolite:

For acute dietary exposure, no endpoint of concern could be found from which an acute dietary risk assessment (1 day) should be conducted. There was no endpoint for acute dietary exposure since acute toxicity in animal studies is absent until very high doses of cryolite were used.

Based upon review of the toxicology database for cryolite there are no short-term (1-7 days) or intermediate-term (7-90 days) occupational or residential endpoints identified or risk assessments required.

Cryolite has been classified as a Group "D" chemical, "not classifiable as to human carcinogenicity". It has been the subject of a comprehensive review by the National Research Council (National Academy of Sciences Subcommittee of Health Effects of Ingested Fluoride) who concluded that "... the available laboratory data are insufficient to demonstrate a carcinogenic effect of fluoride in animals." and that "... the weight of evidence from more than 50 epidemiological studies does not support the hypothesis of an association between fluoride exposure and increased cancer risk in humans." The Agency is in agreement with the conclusions reached by the National Academy of Sciences (NAS).

i. Reference Dose

The OPP's Health Effects Division's RfD/Peer Review Committee (document dated December 22, 1995) determined that a weight-of-the-evidence risk assessment for chronic dietary exposure to fluoride residues as a result of

agricultural uses of cryolite would be more appropriate than a traditional RfD approach for the following reasons:

- National and International regulatory organizations (U.S. EPA Office of Water, U.S. Department of Health and Human Services (DHHS), the Canadian Government, and the World Health Organization) have assessed potential health risks from exposure to fluoride. The endpoints and estimated effect levels documented by these organizations are similar.

- The U.S. Surgeon General (Koop, 1984 and Elders, 1994) has recommended a guideline level of exposure that should provide an adequate "margin of safety" based on a large amount of human data, including epidemiology studies.

- Animal data considered by the RfD Committee are consistent with human data with respect to dose related skeletal effects.

Regulatory Background

Fluoride levels in public drinking water are regulated under the Safe Drinking Water Act. The Agency has established a Maximum Concentration Limit Goal (MCLG) at 4.0 mg/L [0.114 mg/kg/day; note that all conversions from mg/L of fluoride in drinking water to mg/kg body weight/day are based on 70 kg body weight and 2 L/day water consumption as taken from Drinking Water Criteria Document on fluoride, October 21, 1985] to protect against crippling skeletal fluorosis, Federal Register (FR) 11396 (Vol. 51, No. 63, 4/2/86). The MCLG established on 4/2/86 finalizes interim regulations set in FR47142 (Vol. 50, No. 220, 11/14/85) and proposed in FR20164 (Vol. 50, No. 93, 5/14/85). In addition, these FR notices established a Secondary Maximum Contaminant Level (SMCL) at 2.0 mg/L [0.057 mg/kg/day] for cosmetic effects (objectionable dental fluorosis) which are not considered to be adverse health effects. The MCLG has been reviewed and is supported by the Surgeon General.

The Agency's Office of Drinking Water issued a Drinking Water Criteria Document on Fluoride (October 21, 1985) which presents summaries of experimental and clinical data on the health effects of fluoride in animals and humans. In general, the health effects of fluoride include dental fluorosis and skeletal fluorosis.

Dental fluorosis is a mottling of tooth enamel. The relationship between fluoride intake and the incidence of dental fluorosis has been demonstrated in both animals and humans.

"At the request of the Agency, the U.S. Surgeon General examined the relationship of fluoride in drinking water and the aspects of dental fluorosis. The results of that evaluation (Koop 1982, Albertini et al. 1982) led to the general conclusions that, while not considered an adverse health effect, the undesirable cosmetic effects to teeth could be minimized by limiting the fluoride concentration to twice the optimum for the reduction of dental caries. The Surgeon General encouraged communities to limit water to twice optimum (about 2 mg F/L [0.057 mg/kg/day]) to provide this protection for children up to age nine, but emphasized that there is no sound evidence to indicate that adverse effects on general or dental health (dental fluorosis was not judged to be an adverse effect) are associated with concentrations of fluoride that are naturally found in U.S. public water supplies." (Water Criteria Document p. IX-13).

Skeletal fluorosis results from the incorporation of excessive fluoride into bone. Skeletal fluorosis increases in severity with both dose and duration of exposure to fluoride. In its mildest form, it is characterized by an increase in bone density (osteosclerosis) that is detectable only through X-ray examination. The most severe form (crippling skeletal fluorosis) is characterized by irregular bone deposits.

"At the request of the Agency, the U.S. Surgeon General examined the nondental health aspects associated with fluoride in drinking water. An ad hoc advisory committee met in April, 1983 in Bethesda, MD and provided their report (Shapiro 1983) and a later formal response from the Surgeon General (Koop 1984) to EPA. The Surgeon General concluded that he did not consider changes in bone density to be an adverse health effect and that adverse effects (arthralgias) are not likely to occur at human dose levels below 20 mg F/day (10 mg F/L for an adult consuming 2 L water/day [0.29 mg/kg/day]). The ad hoc committee concluded that four times the optimal fluoride concentration (approximately 4 mg F/L [0.114 mg/kg/day]) in drinking water should provide an adequate margin of safety for preventing adverse health effects which were not documented to occur in the U.S. population below 8 mg F/L [0.23 mg/kg/day]." (Water Criteria Document p. IX-21).

Other Regulatory Assessments

Canada Environmental Protection Act (CEPA) (1993) concluded that inorganic fluorides are not present in the environment at levels that may result in adverse effects to human health.

"Based on available information, the estimated average daily intakes of inorganic fluoride ..... are less than the level at which adverse effects upon the skeleton (the

end-point considered most sensitive on the basis of available data) are anticipated (i.e. ≥200 ug/kg/bw/day fluoride [0.2 mg/kg/day]."

The 1993 World Health Organization (WHO) Guidelines for Drinking-Water Quality addresses fluoride exposure and concludes the following:

"There is no evidence to suggest that the guideline value of 1.5 mg/L set in 1984 needs to be revised. Concentrations above this value carry an increasing risk of dental fluorosis, and much higher concentrations lead to skeletal fluorosis. The value is higher than that recommended for artificial fluoridation of water supplies."

2. Exposure Assessment

Cryolite (sodium aluminofluoride, fluorine expressed as elemental--50 percent), is an insecticide formulated as a wettable powder or dust containing 93% or 96% active ingredient, a 20% granular bait and as a water dispersible granular containing 93% active ingredient. Cryolite is applied by aerial equipment and ground sprayers. Depending on the crop and insect situation, applications are made from one to several times per season.

Tolerances are established for combined residues of the insecticidal fluorine compounds cryolite and synthetic cryolite in/on the following raw agricultural commodities (RACs): broccoli, cabbage, cauliflower, brussels sprouts, kohlrabi, cucumber, squash, cantaloupe, watermelon, grapefruit, grapes, kiwi (in California only), lettuce head, lettuce leaf, peppers, potatoes, tomatoes, eggplant, cranberries, collards, and peaches. *[Source: 40 CFR §180.145 (a), (b), and (c)]*. All RAC tolerances are currently set at 7 ppm, except 15 ppm in/on kiwifruit and 2 ppm in/on potatoes (time-limited tolerance to expire on 5/6/96). There are no tolerances for residues in animal products. A feed additive tolerance (FAT), time-limited to expire on 5/6/96, is established for potato waste, process (wet or dry) *[40 CFR §186.3375]* at 22.0 ppm. The Agency has completed its review of the data needed to establish a permanent tolerance for potatoes. The Agency will propose in the Federal Register permanent tolerances for potatoes at 2 ppm and potato waste at 22 ppm.

Cryolite was the subject of a Registration Standard Guidance Document (6/83), a Final Registration Standard and Tolerance Reassessment (FRSTR) Residue Chemistry Chapter (1/22/88), and a Reregistration Standard Update dated (5/16/91). These documents summarized the regulatory conclusions of available residue chemistry data and specified what additional data were required for reregistration.

a. Dietary Exposure

GLN 171-3: Directions for Use

As of 12/95 there were three cryolite end-use products (EPs) with food/feed uses registered to Gowan Company and Elf Atochem, the primary registrants. These EPs are presented below in Table 3.

Table 3. Cryolite End-Use Products registered by **Basic Producers**

Registrant Reg. No.	Most Recent Label Acceptance Date	Formulation Class	Product Name
Gowan Co.			
10163-41	August 17, 1995	96% Dust	Prokil Cryolite 96
10163-185	March 11, 1994	93% WDG	Prokil Cryolite WDG
OR95000800	March 24, 1995	20% G	Gowan Cryolite Bait
WA95001800	March 28, 1995	20% G	Gowan Cryolite Bait
Elf Atochem, Inc.			
4581-116	November 12, 1995	96% WP/D	Kryocide Insecticide

The conclusions listed below regarding the reregistration eligibility of cryolite food/feed uses are based on the use patterns registered by the basic producers, Gowan Company and Elf Atochem North America, Inc.; all data to support the food/feed uses were based on the above registered label rates and restrictions. All end-use product labels which rely on these data must be amended such that they are consistent with the basic producers labels.

GLN 171-4 (a): Plant Metabolism

The qualitative nature of the residue in plants is adequately understood. Uptake and translocation of cryolite from soil is unlikely owing to the low water solubility of cryolite. Plant residues are inorganic surface residues of cryolite. The residues of concern are cryolite fluoride residues.

GLN 171-4 (b): Animal Metabolism

The requirement for animal metabolism studies was waived, as the Agency determined that cryolite metabolism in animals manifests itself as free fluorine. The qualitative nature of the residue in animals is adequately understood. Total fluoride is the residue of concern.

GLN 171-4 (c) and (d): Residue Analytical Methods - Plants and Animals

Adequate methodology is available for data collection and tolerance enforcement. Atochem methods BR-006-02 for plant residues and BR-010-00 for animal tissues have undergone successful Agency validation and will be published in PAM, Vol. II. Using these methods, total fluoride is determined using a pH/ion meter with a fluoride-specific electrode. The limit of quantitation is 0.05 ppm. Because cryolite is an inorganic ionic compound, recovery of residues using FDA Multiresidue Protocols is not expected and the requirement for such data is waived.

GLN 171-4 (e): Storage Stability in Plant and Animal Commodities

Storage stability is not of concern as cryolite is a naturally occurring mineral and breakdown (ionization or dissolution) of residues in plant or animal tissues is not expected.

GLN 171-4 (k): Magnitude of the Residue in Plants

Pending required label amendments and/or revised tolerances (as prescribed in this document or previous Agency correspondence), reregistration data requirements are fulfilled for broccoli, Brussels sprouts, cabbage, cauliflower, citrus fruit, collards, cucumbers, eggplant, grapes, kiwifruit, kohlrabi, lettuce, melons, peaches, peppers, potatoes, pumpkins, squash (winter and summer), and tomatoes.

Additional residue data are required for cranberries, plums and strawberries. There are no registered uses on apricots, beets, carrots, caneberries (blackberries, boysenberries, dewberries, loganberries, youngberries), corn, nectarines, okra, peanuts, peas, quinces, and rutabagas; these tolerances are proposed for revocation. The registrants intend to cancel the registered uses on apples, beans, kale, mustard greens, pears, radishes, and turnips; these tolerances are proposed for revocation.

Data to support the tolerances for cryolite on blueberries, raspberries and strawberries are being generated by Interregional Research Project No. 4 (IR4), but are currently not available. These tolerances will not be proposed for revocation at this time. The reregistration eligibility for the use of cryolite on strawberries will be determined when the data are reviewed and found acceptable. There are currently no registered uses for cryolite on blueberries and raspberries, therefore, these uses are not subject to a reregistration decision. The Agency will make a decision regarding the registration of the blueberry and raspberry uses when the data are made available.

A summary of the available data and reregistration data requirement status by crop group are summarized below. (See Section IV for the tolerance reassessment summary, recommendations and proposed revocations).

Root and Tuber Vegetables Group

Beets, carrots, radishes, rutabagas, turnips: There are no registered uses on beets, carrots, and rutabagas. The registrants have proposed to cancel uses on radishes and turnips. The Agency will propose to revoke these tolerances.

Potatoes: The tolerance for cryolite residues in/on potatoes is time-limited to expire 5/6/96. A petition for permanent tolerance is pending. A label (10163-41) has been approved (08/17/95) for foliar application to potatoes at up to 11.5 lbs. a.i/acre, with a maximum seasonal application of 92 lbs. a.i./acre. The PHI is 0 days. The Agency has reviewed the data needed to establish a permanent tolerance for potatoes and will be proposing a permanent tolerance of 2 ppm in the Federal Register.

Leaves of Root and Tuber Vegetables Group

Beet tops, radish tops, rutabaga tops, turnip tops: There are no registered uses on beets and rutabagas. The registrants have proposed to cancel uses on radishes and turnips. The Agency will propose to revoke these tolerances.

Leafy Vegetables Group

Lettuce (head): Residue data on head lettuce were reviewed in the 1991 Update. Cryolite residues were 8.12-174.87 ppm in/on head lettuce with wrapper leaves and 1.1-3.66 ppm in/on head lettuce without wrapper leaves harvested 14 days following the last of eight applications of the 96% WP/D formulation using ground and aerial equipment at 19.2 lb ai/A/application (1x the maximum single application rate). The data indicate that the established 7 ppm tolerance is too low and that a tolerance of 180 ppm would be appropriate. The Agency will propose a tolerance of 180 ppm for cryolite residues in/on head lettuce.

Lettuce (leaf): Residue data on leaf lettuce were reviewed in the 1991 Update. Cryolite residues were 27.1-36.8 ppm in/on untrimmed leaf lettuce and 11.6-17.5 ppm in/on trimmed leaf lettuce harvested 14 days following the last of eight applications of the 96% WP/D formulation using ground and aerial equipment at 19.2 lb ai/A/application (1x the maximum single application rate). The data indicate that the established 7 ppm tolerance is too low and that a tolerance of 40 ppm would be appropriate. The data support the proposed use pattern (4581-116, 08/95) of 8 - 20 lbs. a.i./acre/application, 160 lbs. a.i./acre/year, 14 day PHI. The Agency will propose a tolerance of 40 ppm for cryolite residues in/on leaf lettuce.

Brassica Leafy Vegetables Group

Broccoli: Residue data on broccoli were reviewed in the 1988 FRSTR. Cryolite residues were 0.5-6.0 ppm in/on broccoli harvested 7 or 14 days following the last of six applications of the 96% WP/D formulation at 15.4 lb ai/A/application (1.3x the maximum single application rate). The available data support the established 7 ppm tolerance for cryolite residues in/on broccoli.

Brussels sprouts: Residue data on Brussels sprouts and broccoli were reviewed in the 1988 FRSTR. Cryolite residues were 2.9-5.7 ppm in/on Brussels sprouts harvested 7 or 14 days following the last of six applications of the 96% WP/D formulation at 16 lb ai/A/application (1.3x the maximum single application rate). The available data, including data on broccoli support the established 7 ppm tolerance for cryolite residues in/on Brussels sprouts.

Cabbage: Residue data on cabbage were reviewed in the 1991 Update. Cryolite residues were 1.56-40.52 ppm in/on cabbage with wrapper leaves and 0.52-2.76 ppm in/on cabbage without wrapper leaves harvested 14 days following the last of eight or nine applications of the 96% WP/D formulation using ground and aerial equipment at 16 lb ai/A/application (1x the maximum single application rate). The data indicate that the established 7 ppm tolerance is too low and that a tolerance of 45 ppm would be appropriate. The Agency will propose a tolerance of 45 ppm for cryolite residues in/on cabbage.

Cauliflower: Residue data on cauliflower and broccoli were reviewed in the 1988 FRSTR. Cryolite residues were 3.9-5.2 ppm in/on cauliflower harvested 7 or 14 days following the last of eight applications of the 96% WP/D formulation at 15.4 lb ai/A/application (1.3x the maximum single application rate). The available data, including data on broccoli support the established 7 ppm tolerance for cryolite residues in/on cauliflower.

Collards: Residue data on collards were reviewed in the 1991 Update. Cryolite residues were 0.46-34.47 ppm in/on collards harvested 14 days following the last of six applications of the 96% WP/D formulation using ground and aerial equipment at 15.4 lb ai/A/application (1x the maximum single application rate). The data indicate that the established 7 ppm tolerance is too low and that a tolerance of 35 ppm would be appropriate. The Agency will propose a tolerance of 35 ppm for cryolite residues in/on collards.

Kohlrabi: No field residue data are available for kohlrabi. However, the Cryolite Update concluded that no data are required for reregistration purposes as the existing data for broccoli can be used to support the tolerance for kohlrabi. The registered use patterns for

the 96% WP/D formulation are identical for broccoli and kohlrabi. The available data for broccoli indicate that the established 7 ppm tolerance is acceptable.

Kale, mustard greens: The registrants propose to cancel uses on kale and mustard greens. The Agency will propose to revoke these tolerances.

Legume Vegetables Group

Beans and peas: There is no registered use on peas. The registrants propose to cancel uses on beans. The Agency will propose to revoke these tolerances.

Fruiting Vegetables (except Cucurbits) Group

Eggplant: Data reviewed in the FRSTR indicate that cryolite residues were 2.7 and 3.9 ppm in/on eggplant harvested on the day of the last of four foliar spray applications of the 96% WP/D formulation at 11.5 lb ai/A (1x the maximum single application rate). These data must be supplemented by the translation of tomato residue data, including cherry tomatoes, to support the proposed label for the WP/D (4581-116): 15.4 lbs. a.i./acre/application, 61.4 lbs. a.i./acre/season, 14 day PHI. The tomato data indicate that the existing tolerance of 7 ppm is inadequate, and that a tolerance of 30 ppm is required (see tomato).

Peppers: Cryolite residues were 2.0-5.8 ppm in/on peppers harvested 14 days following the last of two applications at 7- to 9-day intervals of the 96% WP/D formulation at 11.5 lb ai/A/application (1x the maximum single application rate). The available data support the established 7 ppm tolerance for cryolite residues in/on peppers.

Tomatoes: Cryolite residues were 1.22-6.06 ppm in/on tomatoes and 1.87-27.39 ppm in/on cherry tomatoes harvested 14 days following the last of four applications of the 96% WP/D formulation using ground and aerial equipment at 15.4 lb ai/A/application (1x the maximum single application rate). The data indicate that the established 7 ppm tolerance would be adequate if all pertinent labels specify a restriction on cherry tomatoes. However, in order to alleviate the need for this restriction the registrant has agreed to the Agency proposing in the Federal Register a tolerance of 30 ppm for cryolite residues in/on all tomatoes.

Cucurbit Vegetables Group

Cucumbers: Data indicate that cryolite residues were 0.3-5.2 ppm in/on cucumbers harvested 7 days following the last of three to five applications of the 96% WP/D formulation at 7.7-15.5 lb ai/A/application (>1x the maximum single application rate). The available data support the established 7 ppm tolerance for cryolite residues in/on cucumbers.

Melons: Data reviewed in the Update indicate that cryolite residues were 1.7-2.56 ppm in/on melons harvested 14 days following the last of four or five applications of the 96% WP/D formulation using ground and aerial equipment at 15.4 lb ai/A/application (1x the maximum single application rate). The available data support the established 7 ppm tolerance for cryolite residues in/on melons.

Pumpkins: Data on melons will be translated to pumpkins.

Squash (winter): Data on melons will be translated to winter squash.

Squash (summer): Data reviewed in the Update indicate that cryolite residues were 1.73-5.41 ppm in/on summer squash harvested 7 days following the last of four applications of the 96% WP/D formulation using ground and aerial equipment at 15.4 lb ai/A/application (1x the maximum single application rate). The available data support the established 7 ppm tolerance for cryolite residues in/on summer squash.

Citrus Fruits Group

Data reviewed in the Update indicate that cryolite residues were 1.3-30.39 ppm in/on grapefruit harvested 14-16 days following the last of three or six foliar applications of the 96 WP/D formulation made with ground equipment at 28.8 lb ai/A (1x the maximum registered single application rate). Residues were 0.74-38.45 ppm in/on lemons harvested 13-16 days following the last of three or six foliar applications of the 96 WP/D formulation made with ground equipment at 28.8 lb ai/A (1x the maximum registered single application rate). Residues were 0.81-93.18 ppm in/on oranges harvested 15 days following the last of three foliar applications of the 96 WP/D formulation made with ground equipment at 28.8 lb ai/A (1x the maximum registered single application rate). The data indicate that the established 7 ppm tolerance is too low and that a tolerance of 95 ppm would be appropriate. The Agency will propose a tolerance of 95 ppm for cryolite residues in/on citrus fruit.

Pome Fruits Group

Apples, pears, quinces: There is no registered use on quinces. The registrants propose to cancel uses on apples and pears. The Agency will propose to revoke these tolerances.

Stone Fruits Group

Apricots, nectarines, plums (fresh prunes): There are no registered uses on apricots, nectarines, and plums (fresh prunes) although a tolerance of 7 ppm is currently established; the registrants do not support the apricot and nectarine use. Cryolite residues were <0.5-1.4 ppm in/on plums harvested 45 days following two applications of a 96% WP/D formulation using ground equipment at 12 lbs. a.i./A/application. The four trials

were conducted in California; additional trials are required before an adequate tolerance can be determined for plums (fresh prunes).

Peaches: Cryolite residues were 4.84-8.90 ppm in/on peaches harvested 45 days following the two applications of the 96% WP/D formulation using ground equipment at 11.5 lb ai/A/application (1x the maximum single application rate). The data indicate that the established 7 ppm tolerance is too low and that a tolerance of 10 ppm would be appropriate. The Agency will propose a tolerance of 10 ppm for cryolite residues in/on peaches.

Small Fruits and Berries Group

Blackberries, boysenberries, dewberries, loganberries, raspberries, youngberries: There are currently no registered uses on caneberries; however, there is an established tolerance of 7 ppm for each of these crops. IR4 is generating the data to support the tolerances for blueberry and raspberry use in the Pacific Northwest and may also conduct field trials in other regions around the country to support the uses nationally. These uses are not subject to a reregistration decision; when the data are available, the Agency will make a registration decision.

Blueberries (huckleberries): There is no registered use on blueberries; however, see note above for caneberries.

Cranberries: There are no data to support the currently registered use: 9.6 - 11.5 lbs. a.i./acre/application, 35 lbs. a.i./acre/season maximum, 30 day retreatment interval and 30 day PHI. Data must be submitted for five trials [region 1 (2), region 5 (2), region 12 (1)] conducted at the maximum label rate and minimum PHI. Currently IR4 is generating the necessary data to support this use. An interim report from IR4 showed there was sufficient varietal and geographically representative field trial data to show that fluoride from cryolite residues are not expected to exceed the established 7 ppm tolerance when Gowan Bait is used as directed. The studies in progress will support both the wettable powder and bait formulation use of cryolite on cranberries.

Grapes: Data reviewed in the FRSTR indicate that cryolite residues were 0.6-5.5 ppm in/on grapes harvested 31 days following one or two applications of the 96% D formulation at 9.6 lb ai/A (spray) or 15.4 lb ai/A (dust). Labels specify an additional postharvest application may be made to grape vines at a rate of 7.7 lbs. a.i./acre. The combined seasonal application rate may not exceed 27 lbs. a.i./acre. These data support the established tolerance of 7 ppm for residues in/on grapes.

Strawberries: The current tolerance for strawberries is 7 ppm. IR4 is generating the data to support the tolerance for cryolite on strawberries in the Pacific Northwest and may also conduct field trials in other regions around the country to support the use nationally.

When the data are available, the Agency will reassess the tolerance and make an eligibility decision for the use of cryolite on strawberries.

Cereal Grains Group

Corn: There is no registered use on corn. The Agency will propose to revoke this tolerance.

Miscellaneous Commodities

Kiwifruit (CA): Residues were 2.7-10.6 ppm in/on kiwifruit harvested 29 days following four foliar spray applications of the 96% WP/D at 9.6 lb ai/A/application (1x the maximum rate). These data support the established 15 ppm tolerance for residues in/on kiwifruit grown in California.

Okra: There is no registered use on okra. The Agency will propose to revoke this tolerance.

Peanuts: There is no registered use on peanuts. The Agency will propose to revoke this tolerance.

GLN 171-4 (l): Magnitude of the Residue in Processed Food/Feed

Reregistration data requirements for processing studies are satisfied for citrus fruits, grapes, potatoes, and tomatoes. As registered uses on apples are to be canceled, processing studies are not required for this commodity. A summary of cryolite processing studies is presented below.

Potatoes: An acceptable potato processing study has been submitted and reviewed. This study indicates that cryolite residues concentrated 11x in potato peels/potato waste processed from potatoes treated at a 6.7x exaggerated rate. These data support the established food additive tolerance (FAT) for cryolite in potato waste, provided that the time-limited tolerance for residues on potatoes is sustained or a permanent tolerance is established. The Agency will propose the establishment of a permanent tolerance for potatoes. Residues did not concentrate in potato chips, flakes, or granules; no FAT is required for any of these commodities.

Tomatoes: An acceptable tomato processing study was reviewed in the Update. This study indicates that residues concentrated in tomato paste (1.6X). A food additive tolerance of 45 ppm will be proposed for tomato paste.

Citrus fruit: An acceptable orange processing study was reviewed in the Update. Cryolite residues did not concentrate in pulp, oil, or juice processed from oranges treated at 5x the

maximum registered rate.

Grapes: Acceptable processing studies were reviewed in the FRSTR. Fluorine residues from cryolite concentrated 10x in raisins processed from grapes bearing measurable residues. The registrants have proposed a food additive tolerance for cryolite residues in raisins. The Agency ruled favorably on the proposed FAT, 70 ppm. However, under the modified procedure for calculating food/feed additive tolerances, the appropriate FAT is 55 ppm, the product of the maximum average field trial residue and the average processing factor. [Memo S. Irene to D. Barolo, OPP, 9/12/95; re: Update to Subdivision O, Residue Chemistry Guidelines.]

Plums: A processing study is not required in this particular case because cryolite does not metabolize or degrade and is not systemic; also, there is only one product of processing, which is prunes. The processing represents a loss of water, and cryolite would be stable under such conditions. Prunes are a ready-to-eat food, and a food additive tolerance is required. A value of 7 ppm may be appropriate, but additional field trials must be evaluated.

GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

The Agency has concluded that there is no reasonable expectation of finite fluoride residues in ruminant or poultry tissues as a result of livestock ingestion of cryolite. As this situation falls under 40 CFR §180.6 (a) (3), tolerances for cryolite residues in meat, milk, poultry, and eggs are not required.

GLN 165-1: Confined Rotational Crops

The requirement for data on confined rotational crops was waived. The residue available to rotational crops is expected to be negligible with respect to the amount of free fluorine occurring naturally in soil.

b. Occupational and Residential

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete.

Occupational-use products and homeowner-use products

At this time no products containing cryolite are intended primarily for homeowner use; all product are intended primarily for occupational use.

Handler (Mixers, Loaders, Applicators) Exposures and Assumptions

The Agency has determined that there is a potential for exposure to mixers, loaders, applicators, or other handlers resulting from usual use-patterns associated with cryolite. There are potential exposures to: mixer/loaders supporting ground and aerial applications of wettable powder, dusts, granular and water-dispersible granular formulations; applicators using ground and aerial equipment to apply sprays; and flaggers participating in aerial applications.

However, an exposure assessment was not performed because there were no toxicological endpoints identified for cryolite.

Post-Application Exposures and Assumptions

The Agency has determined that there is potential exposure to persons entering treated sites after application is complete. Post-application exposures may occur to agricultural workers following applications to registered food and ornamental crops during hand-labor tasks and other crop-production activities. Post-application exposures may also occur to residential workers following applications on plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit.

However, a post-application exposure assessment was not performed because there were no toxicological endpoints identified for cryolite.

3. Risk Characterization

a. Dietary

Cryolite is an inorganic fluoride-containing insecticide. Plant residues are inorganic surface residues of cryolite which are measured as total fluoride using a pH/ion meter with a fluoride-specific electrode. The residues of toxicological concern are fluoride residues.

Fluoride occurs at low levels in food and air as well as in drinking water (FR20167, Vol. 50, No. 93, 5/14/85). Atmospheric levels of fluoride contribute relatively little to the average level of dietary fluoride exposure and are not further considered in this exposure estimate. Incidental dietary exposures to fluoride as a toothpaste additive or as a dental treatment are also not included in this exposure estimate. This exposure is regulated by the Food and Drug Administration and is expected to be negligible.

As a part of the Reregistration Eligibility Decision for Cryolite, the Agency recently (2/96) conducted a chronic exposure analysis using the Dietary Risk Evaluation

System (DRES). This analysis was performed using recommended tolerance increases and raw agricultural commodity (RAC) tolerance revocations. Percent crop treated data were used to calculate the anticipated residue concentration. The results are summarized below in Table 4.

Table 4. Dietary Exposure Evaluation for Cryolite.

Population Subgroup	Exposure of Fluoride (mg/kg/day) Food from agricultural use of Cryolite[1]
U.S. Population	0.020
Children 1-6	0.024
Children 7-12	0.015
Females 13+ years, nursing	0.028

[1]DRES analysis based on reassessed tolerances and %crop treated.

Weight-of-the-Evidence Dietary Risk Assessment

A weight-of-the-evidence dietary risk assessment for cryolite has been conducted as recommended by the RfD Committee.

- "... There exists no directly applicable scientific documentation of adverse medical effects at levels of fluoride below 8 mg/L [0.23 mg/kg/day]. (FR20166, Vol. 50, No. 93, 5/14/85)

- Less than 0.4% of the U.S. population (on public water supplies) is exposed to greater than 2 mg/L fluoride [0.057 mg/kg/day] in the public water supply. (Water Criteria Document, pg. IV-3, Table IV-1.)

- Dietary exposure estimates using reassessed tolerances and percent of crops treated are approximately 0.020 mg/kg/day for the U.S. population and 0.028 mg/kg/day for the highest exposed subgroup (females 13 years and older and nursing).

  [Note: Dietary exposures from food sources are high-end estimates, since tolerance values (which estimate high-end values on treated crops) were used in the residue estimate.]

Therefore, it can be concluded that levels of fluoride in/on food from the agricultural use of cryolite plus fluoride levels in U.S. drinking water supplies results in a high-end daily dietary intake of fluoride of approximately 0.085 mg/kg/day. This is less than the MCLG of 4.0 mg/L [0.114 mg/kg/day], a level which provides no known or anticipated adverse health effects. The MCLG has been reviewed and is supported by the Surgeon General.

b. Occupational

Although occupational exposure to cryolite is expected, an occupational quantitative risk assessment is not required because there were no toxicological endpoints of concern identified for cryolite.

C. Environmental Assessment

1. Ecological Toxicity Data

At present, the available ecological toxicity database is adequate to assess the hazard of cryolite to nontarget terrestrial organisms.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of cryolite to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail).

TABLE 5: Avian Acute Oral Toxicity Findings

Species	% A.I.	LD_{50} mg/kg	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	96	>2150	00152375 Fletcher, 1984	Practically nontoxic	Yes

TABLE 6: Avian Subacute Dietary Toxicity Findings					
Species	**% A.I.**	**LC_{50} ppm**	**MRID No. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Northern Bobwhite	96	>10,000	00084001 Fink, 1975	Practically nontoxic	Yes
Mallard	96	>10,000	00084002 Fink, 1975	Practically non-toxic	Yes

These results indicate that cryolite is practically nontoxic to avian species on an acute oral (TABLE 5) and subacute dietary (TABLE 6) basis. The guideline requirements are fulfilled (MRIDs 00152375, 00084001, and 00084002).

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Many uses of cryolite allow for multiple applications. However, due to the physicochemical properties (naturally occurring mineral, readily soluble in water), and the relative lack of acute toxicity to birds, avian reproduction studies are not required for this chemical.

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. In most cases, however, an acute oral LD_{50} from the Agency's OPP Health Effects Division (HED) is used to determine toxicity to mammals. This LD_{50} is reported below.

TABLE 7: Mammalian Acute Oral Toxicity Findings			
Species	**LD_{50} mg/kg**	**MRID #**	**Toxicity Category**
Rat (small mammal surrogate)	>1500	00071392	Slightly toxic

The available mammalian data (TABLE 7) indicate that cryolite is no more than slightly toxic to small mammals on an acute oral basis (MRID 00071392).

(4) Insects

A honey bee acute contact LD_{50} study is required if the proposed use will result in honey bee exposure.

TABLE 8: Nontarget Insect Acute Contact Toxicity Findings

Species	% AI	LD_{50} μg a.i./bee	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Honey Bee	Technical	>217	00036935 - Atkins, 1975	Practically nontoxic	Yes

There is sufficient information to characterize cryolite as practically nontoxic to bees (TABLE 8). The guideline requirement is fulfilled (MRID 00036935).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish).

TABLE 9: Freshwater Fish Acute Toxicity Findings

Species	% A.I.	LC_{50} ppm a.i.	MRID No.	Toxicity Category	Fulfills Guideline Requirement
Rainbow trout	96	47	40094602 Johnson & Finley, 1980	Slightly toxic	Yes
Rainbow trout	98	>100	00147306 Bailey, 1984	Practically nontoxic	Yes
Bluegill sunfish	96	>400	40094602 Johnson & Finley, 1980	Practically nontoxic	Yes
Bluegill sunfish	98	>100	00147306 Bailey, 1984	Practically nontoxic	Yes

TABLE 10: Formulated Product Testing					
Species	**% A.I.**	**LC_{50} ppm a.i.**	**MRID No.**	**Toxicity Category**	**Fulfills Guideline Requirement**
Rainbow trout	50	42.5	00073803 McCann, 1971	Slightly toxic	Yes
Bluegill sunfish	50	>100	00073804 McCann, 1972	Practically nontoxic	Yes

The results of the 96-hour acute toxicity studies (TABLES 9 and 10) indicate that cryolite is no more than slightly toxic to fish. The guideline requirements are fulfilled (MRIDs 40094602, 00147306, 00073803, and 00073804).

Data from fish early life-stage tests may be required if the product is applied directly to water or is expected to be transported to water from the intended use site, and when certain other conditions apply. Registered uses of cryolite do not fulfill these conditions, therefore, data from these studies are not required.

The fish life-cycle test is required when an end-use product is intended to be applied directly to water or is expected to transport to water from the intended use site, when any of the following conditions apply: the estimated environmental concentration (EEC) is equal to or greater than one-tenth of the NOEL in the fish early life-stage or invertebrate life-cycle test, or if studies of other organisms indicate the reproductive physiology of fish may be affected. Registered uses of cryolite do not fulfill these conditions, therefore, data from this study are not required.

(2) Freshwater Invertebrates

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

TABLE 11: Freshwater Invertebrate Toxicity Findings					
Species	**% A.I.**	**EC_{50} (ppm ai)**	**MRID NO. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Simocephalus	96	5.0	40094602 - Johnson and Finley, 1980	Moderately toxic	No; supplemental study[1]
Daphnia pulex	96	10.0	40094602 - Johnson and Finley, 1980	Moderately toxic	Yes

[1] Simpcephalus is not a recommended test species.

There is sufficient information to characterize cryolite as moderately toxic to aquatic invertebrates (TABLE 11). The guideline requirement is fulfilled (MRID 40094602).

Data from an aquatic invertebrate life-cycle test may be required if the product is applied directly to water or is expected to be transported to water from the intended use site, and when certain other conditions apply. In view of the environmental fate conclusions (see 2(a)(2), Exposure and Risk to Nontarget Aquatic Animals, below), data from this study are not required for cryolite.

The following Daphnia life-cycle study was submitted and reviewed:

TABLE 12: Freshwater Invertebrate Toxicity Findings				
Species	**% A.I.**	**MATC (ppm ai)**	**MRID NO. Author/Year**	**Fulfills Guideline Requirement**
Daphnia magna	96.0	>5.1, <9.9 for survival	41207701 Battelle, 1989	No; supplemental study[1]

1. This study was determined to be supplemental because MATC's for reproduction and growth were not established.

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. In view of the environmental fate conclusions (see 3(a)(2), Exposure and Risk to Nontarget Aquatic Animals), data from these studies are not required for cryolite.

The usual requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters. The following shrimp study was submitted and reviewed:

TABLE 13: Estuarine/Marine Acute Toxicity Findings					
Species	**% A.I.**	**LC_{50}/EC_{50} (ppm ai)**	**MRID No. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Pink Shrimp	96	>14	00073805 - Heitmuller, 1975	Slightly toxic	No; supplemental study[1]

[1]Study was conducted to test the limits of solubility; actual EC50 was not determined.

There is sufficient information to characterize cryolite as no more than slightly toxic to estuarine/marine shrimp (TABLE 13). (MRID 00073805).

c. Toxicity to Plants

(1) Terrestrial

Terrestrial plant testing (seedling emergence and vegetative vigor) is required for herbicides that have terrestrial non-residential outdoor use patterns and appear to move off site of application through volatilization (vapor pressure $\geq 1.0 \times 10^{-5}$mm Hg at 25C) or drift (aerial or irrigation), and/or that may have endangered or threatened plant species associated with the site of application. The above conditions do not apply for cryolite, therefore, plant data are not required.

(2) Aquatic

Aquatic plant testing is required for any herbicide or fungicide that has outdoor non-residential terrestrial uses that may move off-site of application by runoff (solubility >10 ppm in water), by drift (aerial or irrigation), or is applied directly to aquatic use sites (except residential). The above conditions do not apply for cryolite, therefore, aquatic plant data are not required.

2. Environmental Fate

a. Environmental Fate Assessment

Cryolite is a naturally occurring inorganic substance; however, most present day supplies of cryolite are synthetically produced. The Agency primarily based its assessment of the environmental fate of cryolite on various published sources of information on its chemical constituents and fundamental chemistry. In addition, two studies submitted by the registrant contained some useful information on hydrolysis and leaching/adsorption. Because cryolite is an inorganic substance, the complement of environmental fate studies normally required for organic chemicals are not appropriate. However, enough is known about is chemical nature from the open literature and the two studies submitted by the registrant to complete the fate assessment without requiring additional testing.

The Agency believes that once cryolite dissolves and penetrates to shallow depths in soil solution (which is likely to occur as a result of watering of crops) or is transported to natural waters, its constituent ions (Al and F) will rapidly reach or be quickly converted to near background levels of numerous solvated or complex ions containing aluminum and/or fluorine, or into insoluble minerals such as fluorite and gibbsite. Standard agricultural practices to maintain soil fertility, particularly pH regulation and maintenance of sources of readily available calcium and other minerals, insure that the extreme excursions in the amounts of aluminum or fluorine species present in some natural environments do not occur. Therefore, the use of cryolite should have negligible impacts on ground and surface water quality and there should be no difference in the accumulation of aluminum or fluorine moieties in plants or animals.

b. Environmental Fate and Transport

Two laboratory studies were submitted to the Agency by the registrants. The study containing hydrolysis information served only to show that "free" fluoride concentrations increase with pH, and that in pure or laboratory buffered water, less than half of the total fluorine is usually available in the form of free fluoride ion. In the hydrolysis study, aluminum speciation with fluoride or hydroxide was not determined, equilibrium constants were not measured, and the results were not compared with those expected from the chemical literature. The Agency interprets the study on leaching and adsorption as being consistent with precipitation of fluoride. In addition to the information given in the two studies, the Agency also used information reported in scientific journals and published in standard references and textbooks in order to determine the fate of cryolite in soils. No additional data are required at this time.

Environmental Chemistry

Cryolite's crystal lattice is composed of sodium ions (Na^{+}) and hexafluoroaluminate ions (AlF_6^{3-}). When dissolved in soil solution, many different aqueous species are possible and their relative concentrations depend greatly on pH and on the presence and concentration of other soil ions or ligands. Sodium ion will not be discussed here because it is well-known that it exchanges freely in the environment and is considered non-toxic at concentrations far above those that would result from cryolite application. This assessment, therefore, considers the principal simple and complex solvated ions or neutral species derived from the dissociation and hydrolysis of the hexafluoroaluminate ion, and their chemical reactions with other ubiquitous environmental species.

In order to determine the fate of the hexafluoroaluminate ion, the relationships and interactions of the ion with naturally occurring soil chemicals

must be considered. Forms of the elements aluminum, calcium, and fluorine are naturally abundant in the earth's soils, and their relative concentrations are subject to considerable natural variation. These elements occur principally as insoluble minerals with but a small fraction available for soil solution.

Fluoride. In the presence of calcium ion, fluoride is precipitated as calcium fluoride (the insoluble mineral fluorite). This precipitation equilibrium shifts such that the more dissolved calcium that is available, the less fluoride will be in solution. Other even less soluble minerals (e.g., fluorapatite, fluorphlogopite) and complexation with aluminum or other ions can further depress fluoride. All processes depend on pH, prevailing mineral composition, and even the presence of organic matter. Various literature sources suggest that levels of calcium in natural soil solution are between 8 to 300 ppm. Simple Agency calculation shows that for a soil with calcium ion at the lowest concentration of 8 ppm, fluoride is limited by calcium fluoride solubility to a maximum concentration range of approximately 4 to 16 ppm.

The Agency's calculations indicate that the natural soil background equilibrium concentrations of fluoride would be approached if the fluoride from cryolite, when cryolite is applied at the maximum yearly application rate of 172 kg/ha (154 lb/acre), were to penetrate the soil to a maximum depth of around 40 to 50 cm (15 to 20 inches) (these calculations assumed that the soil has a uniform horizon and a bulk density of 1.5 g/cm^3, and half of the fluorine from cryolite was conservatively complexed and the other half "free" fluoride). Soil factors such as inhomogeneous wetting or preferential flow would allow relatively deeper movement. These calculated values for concentration and leaching depth compare well with the four registrant-tested soils for which background (control) fluoride content varied from about 2 to 14 ppm and leaching depth after cryolite addition was well within the expected range.

Aluminum. An analysis of aluminum ions conducted by the Agency indicates that aluminum ions or complexes are generally considered much less toxic than fluoride. The aqueous amphoteric aluminum ion ($Al(H_2O)_6^{3+}$) strongly and actively complexes with numerous other ions, including "free" fluoride (F^-) and hydroxide (OH^-). These components are always present in soils, with or without the application of cryolite. Concentrations of aluminum ions or complexes are generally more stringently restricted by natural processes and by less soluble clays and other minerals (for example, gibbsite, a form of aluminum hydroxide) than those for calcium or fluorine.

Conclusion. The theoretically possible slight increases in equilibrium concentrations of exchangeable aluminum or fluorine species in natural soils or waters due to insecticidal application of cryolite are insignificant when compared

to the existing background concentrations and the buffering capacity of the environment for these specific minerals. In addition, any potential increase in environmental concentrations may be offset by standard agricultural practices (e.g., calcium applications, pH adjustments).

(1) Dissociation in Water

Hydrolysis. Synthetic cryolite (Na_3AlF_6, sodium hexafluoroaluminate, 97.3% pure) at an initial concentration of 200 ppm yielded "free" fluoride ion concentrations (as measured by a fluoride ion specific electrode) of 16.8, 40.0, and 47.0 ppm at pH's 5, 7, and 9, respectively. These concentrations correspond to approximately 15.5, 37 and 43% of the total available fluorine.

Speciation (identification) of aluminum and fluorine complexes was not attempted. No equilibria were measured or discussed (MRID 00142836).

(2) Mobility

The Agency interprets the leaching and adsorption study submitted by the registrant as being consistent with precipitation of fluoride ion as calcium fluoride (CaF_2), rather than sorption in the usual sense. This interpretation is based upon Agency calculations using the registrant's data and the properties that they gave for four soils (mainly cation exchange capacity). Simple assumptions, approximations, and use of controlling equilibria enable a good estimate of the range of fluoride concentrations that could be expected in soil solution in field situations.

Column Leaching. In a column leaching study using four different soils with cryolite at an equivalent application rate of 16 lb/acre, fluoride (the only species monitored) showed little mobility. A fluoride ion specific electrode was used for quantitation. Background fluoride concentrations from the control soils, which varied from about 2 to 14 ppm, were subtracted from the treated soils. Most fluoride remained within the top 24 cm of the columns. Some extraneous leaching did occur to a maximum depth interval of 36-42 cm, but was probably an artifact of method limitations and/or natural soil variation. No fluoride was detected in the leachate of the 42 cm columns. For comparison, sodium fluoride, which was run through equivalent soil columns at equivalent fluoride concentration, showed virtually the same leaching profile for fluoride as cryolite (MRID 00142837).

Adsorption. A batch equilibrium adsorption study was conducted for the fluoride ion from cryolite with the same four soils used for column leaching above. Desorption was not investigated. Cryolite soil treatment rates were 5, 10,

20 and 50 ppm. A fluoride ion specific electrode was again used for quantitation. Only simple sorption coefficients were calculated, not Freundlich coefficients.

The data show two striking features. First, there are large soil-dependent differences in sorption, with "apparent" simple Kd's ranging from 1 to 53 in standard units (calculated range of apparent Koc's is from approximately 600 to 6400). Second, there is a pronounced, regular concentration-dependent spread of Kd values within three of the four individual soils. For these three soils the higher the concentration, the lower the Kd. For example, in Lakeland sand with 5 ppm of cryolite, the Kd is 6.6, but at 50 ppm of cryolite, the Kd is only 1.4.

These features prompted the Agency to conduct a Freundlich analysis using the registrant's data. Results yielded exponents (1/n values) of approximately 1/2 for three soils (exponents of 0.56, 0.49, and 0.69 for sand, sandy loam, and silt loam soils, respectively). The exponent of about 1/2, the seeming approach to "saturation" of fluoride, and the apparent lack of correlation with organic matter in these soils suggested that the mineral precipitation with a divalent cation is responsible for the observed behavior.

As calcium is usually a dominant exchangeable cation in soils, and also forms insoluble calcium fluoride, the Agency tested the precipitation hypothesis using registrant adsorption data, the solubility product constant for calcium fluoride (the mineral fluorite), and the assumptions that approximately half of the fluorine in cryolite is available as fluoride and that exchangeable calcium ion in many soils usually accounts for about 0.1 to 0.2 of the maximum CEC (the registrants did not report individual exchangeable cations). Calculations using the various measured Kd's and water to soil ratios showed fluoride concentrations consistent with those predicted.

Unlike the other three soils, the fourth soil (Aguila clay loam) had uniform sorption coefficients for all four of the tested concentrations. Kd's averaged approximately 8.9 ± 1.3 in standard units, the pH is 8.0, and its CEC is given as 43.6 meq/100 g. These high values are typical of a calcarious soil and require special interpretation. With a large reserve of calcium, small changes in its equilibrium concentration due to precipitation with fluoride are offset, and the soil is far from being saturated with fluoride. Additional calcium ion available from equilibrium with abundant solid carbonate opposes any shifts in dissolved calcium concentration. Thus, the observed sorption behavior is again explainable if calcium fluoride precipitation occurs (MRID 00142837).

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOC's. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration, (EEC) by an appropriate toxicity test effect level, e.g. the LC_{50}. The acute effect levels typically are:

-EC_{25} (terrestrial plants),
-EC_{50} (aquatic plants and invertebrates),
-LC_{50} (fish and birds), and
-LD_{50} (birds and mammals)

The chronic test results are the:

-NOEL (sometimes referred to as the NOEC) for avian and mammal reproduction studies, and either the NOEL for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration (MATC), the geometric mean of the NOEL and the LOEL (sometimes referred to as the LOEC) for chronic aquatic studies.

When the risk quotient exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOC's.

Levels of Concern (LOC) and associated Risk Presumption

Mammals, Birds

IF THE	LOC	PRESUMPTION
acute RQ>	0.5	High acute risk.
acute RQ>	0.2	Risk that may be mitigated through restricted use.
acute RQ>	0.1	Endangered species may be affected acutely.
chronic RQ>	1	Chronic risk, endangered species may be affected chronically.

Fish, Aquatic invertebrates

IF THE	LOC	PRESUMPTION
acute RQ>	0.5	High acute risk.
acute RQ>	0.1	Risk that may be mitigated through restricted use.
acute RQ>	0.05	Endangered species may be affected acutely.
chronic RQ>	1	Chronic risk, endangered species may be affected chronically.

Plants

IF THE	LOC	PRESUMPTION
RQ>	1	High risk.
RQ>	1	Endangered plants may be affected.

Currently, no separate criteria for restricted use or chronic effects for plants exist.

(1) Exposure and Risk to Nontarget Terrestrial Animals

(a) Birds

Residues found on dietary food items following cryolite application may be compared to LC_{50} values to predict hazard. The maximum concentration of residues of cryolite that may be expected to occur on selected avian or mammalian dietary food items following a single application rate is provided in TABLE 14 below:

TABLE 14: Estimated Environmental Concentrations on Avian and Mammalian Dietary Food Items in PPM		
Food items	**EEC**	**RQ**
Range Grasses (short)	6960	0.696
Fruit/Vegetable Leaves (other than legumes)	2079-2592	0.208-0.259
Seeds	144-435	0.014-0.043
Fruits	144-435	0.014-0.043

Based on TABLE 14 above, the maximum expected residue (6960 ppm) would occur on the short grass cover in citrus groves. The acute RQ for this use (0.696) exceeds the LOC of 0.5, indicating acute risk to birds. Residues on fruit and vegetable leaves (2079-2592 ppm) provide RQ's of 0.208-0.259, which exceed the LOC of 0.2 for risk that may be mitigated through restricted use.

However, acute risk to birds is not expected from any registered use of cryolite. It is unlikely that birds would receive significant dietary exposure. Although many bird species will eat grasses, they generally provide a relatively poor quality food when compared with the other potential food items listed in TABLE 10. A more reasonable "worst case" scenario for cryolite ingestion by birds is exemplified by contaminated grapes. This residue level is much less than 10% of the avian LC50 value (i.e., the criterion for concern about endangered species). Therefore, it is unlikely that cryolite use poses any significant acute risks to avian species, including those designated as endangered.

Avian reproduction data are not available for cryolite. Ordinarily, any pesticide with multiple applications generates a concern for chronic risk to birds. Although most cryolite uses allow for multiple applications, chronic risk is not a concern in this case for the following reasons:

1) Cryolite is soluble in water (400 - 1200 ppm).
2) Cryolite is not persistent.

In view of the above, it is unlikely that cryolite residues will accumulate on foliage. Any significant rainfall or irrigation would also serve to decrease the probability of accumulation on foliage.

(b) Mammals

Small mammal exposure is addressed using acute oral LD_{50} values converted to estimate a LC_{50} value for dietary exposure. The estimated LC_{50} is derived using the following formula:

$$LC_{50} = \frac{LD_{50} \times \text{body weight (g)}}{\text{food consumption per day (g)}}$$

These estimated LC_{50}s are shown in TABLE 15, below.

TABLE 15: Small Mammal Food Consumption in PPMs (Based on an LD_{50}> mg/kg)[1]

Small Mammal	Body Weight in Grams	% of Weight Eaten Per Day	Food Consumed Per Day in Grams	Estimated LC_{50} Per Day in PPMs
Meadow vole	46 gms	61 %	28.1 gms	>2456 ppm
Adult field mouse	13 gms	16 %	2.1 gms	>9286 ppm

1. The above table is based on information contained in Principles of Mammalogy by D. E. Davis and F. Golly, published by Reinhold Corporation, 1963.

The estimated LC_{50} is then compared to the residues listed in TABLE 14 to calculate a risk quotient (EEC/LC_{50}). TABLE 16 below shows the risk quotients for each of the following application rates:

TABLE 16: Mammalian Dietary Risk Quotients (Based on Dietary RQ = EEC/Lowest LC_{50})

Small Mammal	Application Rates in lbs. a.i./A	
	15.4 (vegetables)	29 (citrus, ornamentals)
Meadow vole consuming range grasses	0.846	2.843
Adult field mouse consuming seeds	0.224	0.750

Figures from the above table indicate that RQ's will exceed LOC's for small mammals. It should be noted, however, that these calculations are estimates based on the value LD50> 1500 mg/kg, which is the "lowest" value available. The data also show longer studies (28-day and 3-month) with rats, with no mortality at levels as high as 50,000 ppm in the diet. Based on all the available information, acute risk to small mammals is not expected from the use of cryolite.

For the same reasons listed above in the discussion on birds, chronic risk to mammals is not expected from the use of cryolite.

(c) Insects

With an acute contact LD50 of >217 micrograms per bee, cryolite is considered practically nontoxic to honey bees. Risk to honey bees is not expected.

(2) Exposure and Risk to Nontarget Aquatic Animals

Expected Aquatic Concentrations. Cryolite displays only slight acute toxicity to freshwater fish. Acute toxicity to Daphnia and shrimp is no more than moderate.

Because of the unique nature of cryolite, and the fact that it is a naturally occurring mineral, the standard EEC calculations are not appropriate for this pesticide. This conclusion is based upon the fact that in the presence of sufficient water, cryolite is quickly converted to near natural background levels of its constituents. Once cryolite dissolves and penetrates to shallow depths in soil solution or is transported to natural waters, any minor chemical imbalances caused by its insecticidal application are offset by the specific mineral buffering capacity of the environment and self-correcting agricultural practices. Ground or surface water effects should be negligible, and no significant difference in the accumulation of aluminum or fluoride moieties in plants or animals is expected to occur. Therefore, the use of cryolite is not expected to present significant risk to aquatic organisms.

(3) Exposure and Risk to Nontarget Plants

No data were required to support a nontarget plant risk assessment for cryolite.

(4) Endangered Species

No risks to endangered species have been identified.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing cryolite as the active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing cryolite. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of cryolite, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of cryolite and to determine that cryolite can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing cryolite as the active ingredient, labeled and used as specified in this document, are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all of the supported uses of cryolite, except strawberries, are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing cryolite, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change. The reregistration eligibility for the use on strawberries will be determined when the appropriate data are submitted and reviewed.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient cryolite, the Agency has sufficient information on the health effects of cryolite and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that cryolite products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing cryolite that are labeled for those uses that have been supported, except strawberries, are eligible for reregistration. The eligibility for the use on strawberries will be determined when the data are available and reviewed.

2. Eligible and Ineligible Uses

The Agency has determined that the following supported uses of cryolite are eligible for reregistration: broccoli, Brussels sprouts, cabbage, cauliflower, citrus fruits, collards, cranberries, cucumbers, eggplant, grapes, kohlrabi, lettuce (leaf and head), melons, peaches, peppers, plums (fresh prunes), pumpkins, squash (winter and summer), tomatoes (except cherry), kiwi, potatoes, ornamental herbaceous plants, ornamental nonflowering plants, ornamental woody shrubs and vines and shade trees. The use on strawberries is being supported by IR4 but the data are not currently available to reassess the eligibility. The use on blueberries

and raspberries is not subject to a reregistration decision because these uses have never been registered, although tolerances were historically set for these commodities. IR4 has indicated that they will be conducting the field trial data in 1996 to support the existing tolerances for the strawberries, blueberries and raspberries.

Uses that are not being supported and for which tolerances will be revoked include: apples, apricots, beans, beets, blackberries, boysenberries, carrots, corn, dewberries, kale, loganberries, mustard greens, nectarines, okra, peanuts, pears, peas, quinces, radish (roots and tops), rutabaga, turnips, and youngberries.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for cryolite. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Tolerance Reassessment

Tolerances Listed Under 40 CFR §180.145(a): Tolerances listed in 40 CFR §180.145 are for the combined residues of the insecticidal fluorine compounds cryolite and synthetic cryolite. A summary of cryolite tolerance reassessments is presented in Table 17. The established tolerances for broccoli, Brussels sprouts, cauliflower, cucumbers, grapes, kohlrabi, melons, peppers, pumpkins, and squash are adequate. The following tolerance proposals are pending approval with the Agency: increase for cabbage (45 ppm), citrus fruit (95 ppm), collards (35 ppm), peaches (10 ppm) and potatoes (2 ppm); separate tolerances proposed for head (180 ppm) and leaf lettuce (40 ppm). The established tolerances for tomatoes and eggplant must be increased to 30 ppm. Additional data are required to confirm the appropriate tolerance for cranberries and plums. Data are required to determine the appropriate tolerance for strawberries.

Tolerance Listed Under 40 CFR §180.145(b): The established tolerance for kiwifruit is adequate.

Tolerances Listed Under 40 CFR §180.145(c): A petition for a permanent tolerance for potatoes has been submitted and the Agency has reviewed the data. The Agency will propose the establishment of a permanent tolerance for potatoes at the same level as the current 2.0 ppm time-limited tolerance.

Tolerances Listed Under 40 CFR §186.3375 (time-limited tolerances): The current 22 ppm tolerance for potato waste is adequate, pending establishment of a permanent tolerance on potatoes.

Tolerances Needed Under 40 CFR §185.3375: Food additive tolerances are needed for prunes, raisins (55 ppm) and tomato paste (45 ppm).

Table 17. Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR 180.145(a):			
Apples	7	Revoke	Not supported
Apricots	7	Revoke	Not supported
Beans	7	Revoke	Not supported
Beets, roots	7	Revoke	Not supported
Beets, tops	7	Revoke	Not supported
Blackberries	7	Revoke	Not supported
Blueberries (huckleberries)	7	TBD[b]	Data are required.
Boysenberries	7	Revoke	Not supported
Broccoli	7	7	
Brussels sprouts	7	7	
Cabbage	7	45	New field trial data
Carrots	7	Revoke	Not supported
Cauliflower	7	7	
Citrus fruits	7	95	New field trial data
Collards	7	35	New field trial data
Corn	7	Revoke	Not supported
Cranberries	7	TBD[a]	Additional data are required.
Cucumbers	7	7	
Dewberries	7	Revoke	Not supported
Eggplant	7	30	New field trial data
Grapes	7	7	
Kale	7	Revoke	Not supported
Kohlrabi	7	7	
Lettuce	7	180	*Lettuce, head*. New field trial data
		40	*Lettuce, leaf.* New field trial data
Loganberries	7	Revoke	Not supported
Melons	7	7	
Mustard greens	7	Revoke	Not supported
Nectarines	7	Revoke	Not supported
Okra	7	Revoke	Not supported

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Peaches	7	10	New field trial data
Peanuts	7	Revoke	Not supported
Pears	7	Revoke	Not supported
Peas	7	Revoke	Not supported
Peppers	7	7	
Plums (fresh prunes)	7	TBD[a]	Additional data are required
Pumpkins	7	7	
Quinces	7	Revoke	Not supported
Radish, roots	7	Revoke	Not supported
Radish, tops	7	Revoke	Not supported
Raspberries	7	TBD[b]	Data are required.
Rutabaga, roots	7	Revoke	Not supported
Rutabaga, tops	7	Revoke	Not supported
Squash (winter)	7	7	
Squash (summer)	7	7	
Strawberries	7	TBD[a]	Data are required.
Tomatoes	7	30	New field trial data
Turnip, roots	7	Revoke	Not supported
Turnip, tops	7	Revoke	Not supported
Youngberries	7	Revoke	Not supported
Tolerances listed under 40 CFR 180.145(b):			
Kiwifruit	15	15	
Tolerances listed under 40 CFR 180.145(c)			
Potatoes	2.0 (Time-limited to expire on 5/6/96)	2.0	A permanent tolerance is pending.
Tolerances needed under 40 CFR 185.3375			
Prunes	none	TBD[a]	Additional data are required
Raisins	None	55	Processing study
Tomato paste	None	45	Processing study
Tolerances listed under 40 CFR 186.3375			
Potato waste, process (wet or dry)	22.0 (Time-limited to expire on 5/6/96)	22.0	A permanent tolerance petition has been submitted./ *Potatoes, waste from processing*

[a] TBD = to be determined; additional residue data are required.

[b] TBD = to be determined; additional residue data are required. Not currently a registered use.

CODEX HARMONIZATION

No Codex Maximum Residue Limits (MRLs) for fluorine compounds (Cryolite) exist. Therefore, there are no questions of compatibility with respect to Codex MRLs and U.S. tolerances.

2. Tolerance Revocations and Import Tolerances

As part of the Agency's reregistration eligibility decision for cryolite, several food uses will be voluntarily canceled. Once a pesticide use is no longer registered in the United States, the related pesticide residue tolerance and/or food/feed additive regulation generally is no longer needed. It is the Agency's policy to propose revocation of a tolerance, and/or food/feed additive regulation, following the deletion of a related food use from a registration, or following the cancellation of a related food-use registration. The Agency has the responsibility under the Federal Food, Drug and Cosmetic Act (FFDCA) to revoke a tolerance on the grounds that the Agency cannot conclude the tolerance is protective of the public health.

The Agency recognizes, however, that interested parties may want to retain a tolerance and/or food/feed additive regulation in the absence of a U.S. registration, to allow legal importation of food into the U.S. To assure that all food marketed in the U.S. is safe, under FFDCA, the Agency requires the same technical chemistry and toxicology data for such import tolerances (tolerances without related U.S. registrations) as are required to support U.S. food use registrations and any resulting tolerances. In addition, the Agency requires residue chemistry data (crop field trials) that are representative of growing conditions in exporting countries in the same manner that the Agency requires representative residue chemistry data from different U.S. regions to support domestic use of the pesticide and the tolerance and/or regulation.

Parties interested in supporting an existing cryolite tolerance as an import tolerance should ensure that all of the data noted above are available to the Agency, so that the Agency may determine whether maintenance of the tolerance and/or regulation would be protective of the public health.

3. Restricted Use Classification

Cryolite is not a Restricted Use pesticide and the Agency is not requiring a change in this classification.

4. Reference Dose and Cancer Classification

A weight-of-the-evidence dietary risk assessment for cryolite has been conducted as recommended by the Agency's OPP Reference Dose (RfD) Committee.

- "... There exists no directly applicable scientific documentation of adverse medical effects at levels of fluoride below 8 mg/L [0.23 mg/kg/day]. (FR20166, Vol. 50, No. 93, 5/14/85)

- Less than 0.4% of the U.S. population (on public water supplies) is exposed to greater than 2 mg/L fluoride [0.057 mg/kg/day] in the public water supply. (Water Criteria Document, pg. IV-3, Table IV-1.)

- Dietary exposure estimates using reassessed tolerances and percent of crops treated are approximately 0.020 mg/kg/day for the U.S. population and 0.028 mg/kg/day for the highest exposed subgroup (females 13 years and older and nursing). [Note: Dietary exposures from food sources are high-end estimates, since tolerance values (which estimate high-end values on treated crops) were used in the residue estimate.]

Therefore, it can be concluded that levels of fluoride in/on food from the agricultural use of cryolite plus fluoride levels in U.S. drinking water supplies results in a high-end daily dietary intake of fluoride of approximately 0.085 mg/kg/day. This is less than the MCLG of 4.0 mg/L [0.114 mg/kg/day], a level which provides no known or anticipated adverse health effects. The MCLG has been reviewed and is supported by the Surgeon General.

Cryolite has been classified as a Group "D" chemical, "not classifiable as a human carcinogen". It has been the subject of a comprehensive review by the National Research Council (National Academy of Sciences Subcommittee of Health Effects of Ingested Fluoride) who concluded that "... the available laboratory data are insufficient to demonstrate a carcinogenic effect of fluoride in animals." and that "... the weight of evidence from more than 50 epidemiological studies does not support the hypothesis of an association between fluoride exposure and increased cancer risk in humans." The Agency is in agreement with the conclusions reached by the National Academy of Sciences (NAS).

5. Endangered Species Statement

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation

measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

6. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift.

7. Environmental/Ecological Effects

The Agency has determined that it is unlikely that cryolite use poses any significant acute risks to avian or mammalian species, including those designated as endangered. Although most cryolite uses allow for multiple applications, avian and mammalian chronic risks are not a concern in this case because cryolite is not persistent and assuming any significant rainfall or irrigation during the application interval (7-30 days), cryolite residues will not accumulate on foliage. Because of the unique nature of cryolite, in the presence of sufficient water it is quickly converted to near natural background levels of its constituents. Ground or surface water effects are expected to be negligible, and no significant difference in the accumulation of aluminum or fluoride moieties in plants or animals is expected to occur. Therefore, the use of cryolite is not expected to present significant risk to aquatic organisms.

8. Occupational/Residential Labeling Rationale/Risk Mitigation

All cryolite products are intended primarily for occupational use. There are currently no cryolite products intended primarily for homeowner use.

The Worker Protection Standard (WPS)

On August 21, 1992 the Agency issued worker protection regulations effecting all pesticide products whose labeling reasonably permits use in the production of agricultural plants on any farm, forest, nursery or greenhouse. In general, products within the scope of the Worker Protection Standard (WPS) had to bear complying labeling when sold or distributed by the registrant after April 21, 1994.

The WPS labeling requirements pertaining to personal protective equipment (PPE), restricted entry interval (REI) and notification are interim. The interim WPS handler PPE requirements are based solely on the acute dermal and inhalation toxicity and skin and eye irritation potential of the end-use product. The interim WPS restricted-entry intervals for agricultural workers are based solely on the acute dermal toxicity and skin and eye irritation potential of the active ingredient. The interim WPS "double" notification requirement is imposed if the active ingredient is classified as toxicity category I for acute dermal toxicity or skin irritation potential. "Double" notification is the statement on the labels of some pesticide products requiring employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. These requirements are to be reviewed and revised, as appropriate during reregistration and other Agency review processes. During reregistration, the Agency reviews risks resulting from WPS uses as well as from all other occupational and residential uses.

Personal Protective Equipment for Handlers (Mixers, Loaders, Applicators, etc).

EPA has determined that occupational handler exposures and risks generally are the same for WPS and nonWPS uses of cryolite. Therefore, occupational handler exposures and risks are evaluated jointly. As a result of the reregistration evaluation of the acute and other adverse effects of cryolite, the Agency has determined that risks to handlers do not warrant the establishment of active-ingredient-based minimum personal protective equipment or engineering-control requirements that would apply to all cryolite end-use products. Handler PPE requirements for cryolite are to be based solely on the acute toxicity of individual end-use products.

Entry Restrictions

As a result of the reregistration evaluation of the acute and other adverse effects of cryolite, the Agency has determined that the risks from post-application exposures to cryolite by workers warrant the minimum WPS REI of 12 hours. Furthermore, since EPA has determined that the risks from adverse effects are minimal, EPA is establishing the minimum WPS early-entry PPE of coveralls, chemical resistant gloves, shoes and socks.

Post- application exposures associated with non-WPS outdoor uses generally involve less substantial, and briefer exposures than those associated with WPS uses.

Therefore, the Agency generally uses a different standard for reentry into treated areas following such uses. For nonWPS uses of cryolite, the Agency is requiring that reentry be prohibited following liquid applications until sprays have dried and following dry applications until dusts have settled. No PPE for nonWPS uses is specified since reentry is prohibited until sprays have dried and dusts have settled.

Worker Notification

Cryolite is not classified as toxicity category I for select acute dermal toxicity or skin irritation potential and is not classified as a severe skin sensitizer. EPA has no special concerns about cryolite for adverse effects where a single exposure can trigger the effect. EPA has not established an unusually long restricted-entry interval for cryolite. Therefore, at this time, EPA is not requiring a WPS "double" notification statement on the labeling of cryolite end-use products.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The following generic data are required before an eligibility decision can be made for the use of cryolite on strawberries:

171-4(k) Magnitude of Residue in Strawberries.

The generic data base supporting the reregistration of cryolite for the eligible uses has been reviewed and determined to be substantially complete for all uses. The following data are required on a confirmatory basis.

Product Chemistry

All TGAI data requirements are satisfied for the Gowan synthetic cryolite alternate formulations of the 96% EP/MP, except that data concerning the stability of the TGAI of alternate formulation 3 remain outstanding. Additional product-specific (MP) data are outstanding concerning both synthetic cryolite alternate formulations of the Gowan 96% EP/MP. Provided that the registrants submit the data required for the 96% EP/MPs, and either certify that the suppliers of beginning materials and the manufacturing processes for the cryolite TGAIs have not changed since the last comprehensive product chemistry

review or submit complete updated product chemistry data packages cryolite is eligible for reregistration with respect to product chemistry data requirements.

Residue Chemistry

171-3 Directions For Use - all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) must be amended such that they are consistent with the basic producer labels.

171-4(k) Magnitude of Residue in Plants:

Cranberries - Additional data are required to support the currently registered use: 9.6 - 11.5 lbs. a.i./acre/application, 35 lbs. a.i./acre/season maximum, 30 day retreatment interval and 30 day PHI. Data must be submitted for three trials conducted at the maximum label rate and minimum PHI.

Plums - Additional field trials are required to support the tolerance and proposed use patterns. Three additional trials are required, one each in regions 5, 11, and 12.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

> "Only for formulation into an [fill blank with Insecticide, Herbicide or the applicable term which describes the type of pesticide use(s)] for the following use(s) [fill blank only with those uses that are being supported by MP registrant."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under

> "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

(b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR 156.10 and other applicable notices. All end-use product labels [e.g. multiple active ingredient (MAI) labels, SLN's, and products subject to generic data exemption] must be amended such that they are consistent with the basic producer labels. See Appendix A for appropriate rates and restrictions for those supported uses.

a. Occupational/Residential Protection

PPE/Engineering Control Requirements for Pesticide Handlers

For sole-active-ingredient end-use products that contain cryolite, the handler personal protective equipment requirements set forth in this section must be incorporated on all cryolite product labels. Any conflicting PPE requirements on current labeling must be removed. There are currently no multiple-active-ingredient end-use products that contain cryolite.

Products Intended Primarily for Occupational Use (WPS and nonWPS)

Actual end-use product PPE requirements: PPE for handlers is to be established based on the acute toxicity of each end-use product, using the instructions in PR Notice 93-7.

Placement in labeling: The personal protective equipment must be placed on the end-use product labeling in the location specified in PR Notice 93-7 and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Entry Restrictions

For sole-active-ingredient end-use products that contain cryolite, product labels must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on current labeling must be removed. There are currently no multiple-active-ingredient end-use products that contain cryolite.

Products Intended Primarily for Occupational Use

WPS Uses

Restricted-entry interval: A 12-hour restricted entry interval (REI) is required for uses within the scope of the WPS (see tests in PR Notices 93-7 and 93-11) on all end-use products.

Early-entry personal protective equipment (PPE): The PPE required for early entry is:

-- coveralls,
-- chemical-resistant gloves, and
-- shoes plus socks.

Placement in labeling: The REI and early-entry PPE must be inserted into the standardized REI and early-entry PPE statements required by Supplement Three of PR Notice 93-7.

NonWPS uses

Entry restrictions: The entry restriction for all nonWPS uses is:

For liquid applications:
"Do not enter or allow others to enter the treated area until sprays have dried."

For dry applications:
"Do not enter or allow others to enter the treated area until dusts have settled."

Placement in labeling:

If WPS uses are also on label, follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box and place the appropriate nonWPS entry restriction in that box. If no WPS uses are on the label add the appropriate nonWPS entry restriction in the Directions-For-Use section on the end-use-product labeling.

b. Other Labeling Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing cryolite that are intended primarily for occupational use:

Application Restrictions

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

User Safety Requirements

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Environmental Hazard Statement

The labels of all cryolite end-use products must be revised to bear the following under the Environmental Hazard Section:

- "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment wash water or rinsate."

c. Spray Drift Labeling

The following language must be placed on each product label that can be applied aerially:

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.

The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.

2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they should be observed.

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.

The following aerial drift reduction advisory information must be contained in the product labeling:

> [This section is advisory in nature and does not supersede the mandatory label requirements.]

INFORMATION ON DROPLET SIZE

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

BOOM LENGTH

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT

Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT

When applications are made with a cross-wind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)

WIND

Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

C. Tolerance Revocation and Import Tolerances

The use of cryolite on apples, apricots, beans, beets, blackberries, boysenberries, carrots, corn, dewberries, kale, loganberries, mustard greens, nectarines, okra, peanuts, pears, peas, quinces, radish (roots and tops), rutabaga, turnips, and youngberries is being

voluntarily canceled as part of the Agency's reregistration eligibility decision regarding this pesticide. It is the Agency's policy to propose revocation of a tolerance, and/or food/feed additive regulation, following the deletion of a related food use from a registration, or following the cancellation of a related food-use registration. As a result, any parties interested in supporting the tolerance/regulation for import purposes in the absence of a registered U.S. use should notify the Agency as soon as possible.

In responding, the Agency will provide detailed information on the outstanding data requirements for these tolerances and/or regulations. The Agency will consider commitments made to generate data to support such tolerances/regulations and the timeliness of data submissions in its assessment of whether the tolerances/regulations should be retained. Persons interested in establishing a new tolerance for import purposes only, or retaining a current tolerance for import purposes following cancellation of the related use, must submit a petition, along with the appropriate supporting data.

D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell cryolite products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
The uses in Appendix A were evaluated for reregistration. These do NOT include changes in application rates, frequency or timing of applications, restricted entry intervals, etc. that may have been mandated in this document.													
FOOD/FEED USES													
APPLE				Use Group: TERRESTRIAL FOOD+FEED CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
BEANS				Use Group: TERRESTRIAL FOOD+FEED CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
BROCCOLI				Use Group: TERRESTRIAL FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	DF	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	14	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	7	.5			C46, CAE, H01(7)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
Appendix A does not reflect mandated changes in rates, timing, etc. for the uses													
FOOD/FEED USES (con't)													
BROCCOLI (con't)				Use Group: TERRESTRIAL FOOD CROP (con't)									
Spray, Foliar, Ground	DF	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	14	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	7	.5			C46, CAE, H01(7)
BRUSSELS SPROUTS				Use Group: TERRESTRIAL FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	DF	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	14	.5	CA		C46, CAG, CAU, H01(14)
	WP/D	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	7	.5			C46, CAE, H01(7)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	DF	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	14	.5	CA		C46, CAG, CAU, H01(14)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	7	.5			C46, CAE, H01(7)

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
Appendix A does not reflect mandated changes in rates, timing, etc. for the uses													
FOOD/FEED USES (con't)													
CABBAGE				Use Group: TERRESTRIAL FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	DF	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	14	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	15.36 lb A	*	NS	NS	122.88 lb	NS	7	.5			C46, CAE, H01(14)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	DF	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	14	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	15.36 lb A	*	NS	NS	122.88 lb	NS	7	.5			C46, CAE, H01(14)
CAULIFLOWER				Use Group: TERRESTRIAL FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
Appendix A does not reflect mandated changes in rates, timing, etc. for the uses											
FOOD/FEED USES (con't)											
CAULIFLOWER (con't)				Use Group: TERRESTRIAL FOOD CROP							
Spray, Foliar, Aircraft	DF	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	14	.5	C46, CAG, CAU, H01(14)
	WP/D	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	7	.5	C46, CAE, H01(7)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS	CAE
Spray, Foliar, Ground	DF	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	14	.5	C46, CAG, CAU, H01(14)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS	CAE
Spray, Foliar, Sprayer	WP/D	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	7	.5	C46, CAE, H01(7)
CITRUS FRUITS				Use Group: TERRESTRIAL FOOD+FEED CROP							
Spray, Foliar, Aircraft	DF	NA	19.2 lb A	*	NS	NS	86.4 lb	NS	30	.5	C46, CAG, CAU, H01(15)
CITRUS FRUITS (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
Spray, Foliar, Ground	DF	NA	19.2 lb A	*	NS	NS	86.4 lb	NS	30	.5	C46, CAG, CAU, H01(15)

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
Appendix A does not reflect mandated changes in rates, timing, etc. for the uses													
FOOD/FEED USES (con't)													
COLLARDS				Use Group: TERRESTRIAL FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	DF	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	10	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	10	.5			C46, CAE, H01(14)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	DF	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	10	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	10	.5			C46, CAE, H01(14)
CRANBERRY				Use Group: TERRESTRIAL FOOD CROP									
Bait application, Foliar, Ground	G	NA	6 lb A	*	2	NS	NS	NS	14	.5	OR		C46, CAU
	G	NA	6 lb A	*	2	NS	NS	NS	14	.5	WA		C46, CAU
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	WP/D	NA	11.52 lb A	*	NS	NS	NS	34.56 lb	NS	.5			C46, CAE, H01(30)

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
Appendix A does not reflect mandated changes in rates, timing, etc. for the uses													
FOOD/FEED USES (con't)													
CRANBERRY (con't)				**Use Group: TERRESTRIAL FOOD CROP (con't)**									
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	11.52 lb A	*	NS	NS	NS	34.56 lb	NS	.5			C46, CAE, H01(30)
CUCUMBER				**Use Group: TERRESTRIAL FOOD CROP**									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	DF	NA	11.52 lb A	*	NS	NS	46.08 lb	NS	10	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	DF	NA	11.52 lb A	*	NS	NS	46.08 lb	NS	10	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
EGGPLANT				**Use Group: TERRESTRIAL FOOD CROP**									
Spray, Foliar, Aircraft	DF	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5		CA	C46, CAG, CAU, H01(14)
	WP	NA	11.532 lb A	*	4	NS	NS	NS	NS	.5	NJ		C46, C92, H01(3)

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
Appendix A does not reflect mandated changes in rates, timing, etc. for the uses													
FOOD/FEED USES (con't)													
EGGPLANT (Con't)			**Use Group: TERRESTRIAL FOOD CROP**										
Spray, Foliar, Ground	DF	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5		CA	C46, CAG, CAU, H01(14)
	WP	NA	11.532 lb A	*	4	NS	NS	NS	NS	.5	NJ		C46, C92, H01(3)
Spray, Posttransplant, Aircraft	WP/D	NA	11.52 lb A	*	NS	NS	NS	NS	NS	.5	NJ		C46, CAE, CAG, CAU, H01(3)
	WP/D	NA	11.52 lb A	*	NS	NS	NS	NS	NS	.5	NJ		C46, CAE, H01(3)
Spray, Posttransplant, Ground	WP/D	NA	11.52 lb A	*	NS	NS	NS	NS	NS	.5	NJ		C46, CAE, CAG, CAU, H01(3)
	WP/D	NA	11.52 lb A	*	NS	NS	NS	NS	NS	.5	NJ		C46, CAE, H01(3)
GRAPEFRUIT			**Use Group: TERRESTRIAL FOOD+FEED CROP**										
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	28.8 lb A	*	NS	NS	86.4 lb	NS	30	.5			C46, CAE, H01(15)

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
Appendix A does not reflect mandated changes in rates, timing, etc. for the uses													
FOOD/FEED USES (con't)													
GRAPES				Use Group: TERRESTRIAL FOOD+FEED CROP									
Dust, Foliar, Aircraft	WP/D	NA	18.6 lb A	*	2	NS	NS	NS	NS	NS			CAE, H01(30)
Dust, Foliar, Ground	WP/D	NA	18.6 lb A	*	2	NS	NS	NS	NS	NS			CAE, H01(30)
Spray, Foliar, Aircraft	DF	NA	9.6 lb A	*	NS	NS	19.2 lb	NS	NS	.5			C46, CAG, CAU, H01(30)
	WP/D	NA	9.6 lb A	*	NS	NS	26.88 lb	NS	14	.5			C46, CAE, H01(30)
Spray, Foliar, Ground	DF	NA	7.68 lb A	*	NS	2/1 yr	NS	NS	NS	12 h	CA		C46, CAG, CAU, H01(30)
	DF	NA	9.6 lb A	*	NS	NS	19.2 lb	NS	NS	.5			C46, CAG, CAU, H01(30)
	WP/D	NA	9.6 lb A	*	2	NS	NS	NS	NS	.5	CA		C46, CAE, CAG, CAU, H01(30)
	WP/D	NA	7.44 lb A	*	2	NS	NS	NS	NS	NS			CAE, H01(30)
	WP/D	NA	9.6 lb A	*	NS	NS	26.88 lb	NS	14	.5			C46, CAE, H01(30)
Spray, Foliar, Helicopter	WP/D	NA	7.44 lb A	*	2	NS	NS	NS	NS	NS			CAE, H01(30)
Spray, Postharvest, Aircraft	DF	NA	7.44 lb A	*	NS	NS	18.6 lb	NS	NS	.5	CA		C46, C92, H01(30)
	DF	NA	7.68 lb A	*	NS	NS	7.68 lb	NS	NS	.5			C46, CAG, CAU, H01(30)
	WP/D	NA	7.68 lb A	*	NS	NS	26.88 lb	NS	14	.5			C46, CAE, H01(30)

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
Appendix A does not reflect mandated changes in rates, timing, etc. for the uses													
FOOD/FEED USES (con't)													
GRAPES (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP									
Spray, Postharvest, Ground	DF	NA	7.44 lb A	*	NS	NS	18.6 lb	NS	NS	.5	CA		C46, C92, H01(30)
	DF	NA	7.68 lb A	*	NS	NS	7.68 lb	NS	NS	.5			C46, CAG, CAU, H01(30)
	WP/D	NA	7.68 lb A	*	NS	NS	26.88 lb	NS	14	.5			C46, CAE, H01(30)
Spray, Preharvest, Aircraft	DF	NA	9.3 lb A	*	NS	NS	18.6 lb	NS	AN	.5	CA		C46, C92, H01(30)
Spray, Preharvest, Ground	DF	NA	9.3 lb A	*	NS	NS	18.6 lb	NS	AN	.5	CA		C46, C92, H01(30)
KIWI FRUIT				Use Group: TERRESTRIAL FOOD CROP									
Spray, Foliar, Ground	DF	NA	9.6 lb A	*	4	NS	38.4 lb	NS	15	.5	CA		C46, CAG, CAU, H01(30)
	WP/D	NA	9.6 lb A	*	4	NS	NS	NS	15	.5	CA		C46, CAE, H01(30)
KOHLRABI				Use Group: TERRESTRIAL FOOD CROP									
Spray, Foliar, Aircraft	DF	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	14	.5		CA	C46, CAG, CAU, H01(14)
Spray, Foliar, Ground	DF	NA	15.36 lb A	*	NS	NS	92.16 lb	NS	14	.5		CA	C46, CAG, CAU, H01(14)
LEMON				Use Group: TERRESTRIAL FOOD+FEED CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
Appendix A does not reflect mandated changes in rates, timing, etc. for the uses													
FOOD/FEED USES (con't)													
LEMON (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP									
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	28.8 lb A	*	NS	NS	86.4 lb	NS	30	.5			C46, CAE, H01(15)
LETTUCE				Use Group: TERRESTRIAL FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	DF	NA	19.2 lb A	*	NS	NS	153.6 lb	NS	7	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	27.9 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	DF	NA	19.2 lb A	*	NS	NS	153.6 lb	NS	7	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	27.9 lb A	*	NS	NS	NS	NS	NS	NS			CAE
LETTUCE, HEAD				Use Group: TERRESTRIAL FOOD CROP									
Spray, Foliar, Aircraft	DF	NA	19.2 lb A	*	NS	NS	153.6 lb	NS	7	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	19.2 lb A	*	NS	NS	153.6 lb	NS	7	.5			C46, CAE, H01(14)

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.		Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
Appendix A does not reflect mandated changes in rates, timing, etc. for the uses														
FOOD/FEED USES (con't)														
LETTUCE, HEAD (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)											
Spray, Foliar, Ground	DF	NA	19.2 lb A	*	NS	NS		153.6 lb	NS	7	.5			C46, CAG, CAU, H01(14)
Spray, Foliar, Sprayer	WP/D	NA	19.2 lb A	*	NS	NS		153.6 lb	NS	7	.5			C46, CAE, H01(14)
LIME			Use Group: TERRESTRIAL FOOD+FEED CROP											
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS		NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS		NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS		NS	NS	NS	NS			CAE
Spray, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS		NS	NS	NS	NS			CAE
MELONS, CANTALOUPE			Use Group: TERRESTRIAL FOOD CROP											
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS		NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS		NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	DF	NA	15.36 lb A	*	NS	NS		61.44 lb	NS	7	.5			C46, CAG, CAU, H01(7)
	WP/D	NA	15.36 lb A	*	NS	NS	76.8 lb		NS	7	.5			C46, CAE, H01(15)
	WP/D	NA	46.5 lb A	*	NS	NS		NS	NS	NS	NS			CAE

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
Appendix A does not reflect mandated changes in rates, timing, etc. for the uses													
FOOD/FEED USES (con't)													
MELONS, CANTALOUPE (con't)				Use Group: TERRESTRIAL FOOD CROP (con't)									
Spray, Foliar, Ground	DF	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5			C46, CAG, CAU, H01(7)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	15.36 lb A	*	NS	NS	76.8 lb	NS	7	.5			C46, CAE, H01(15)
MELONS, WATER				Use Group: TERRESTRIAL FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	DF	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5			C46, CAG, CAU, H01(7)
	WP/D	NA	15.36 lb A	*	NS	NS	76.8 lb	NS	7	.5			C46, CAE, H01(15)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	DF	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5			C46, CAG, CAU, H01(7)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	15.36 lb A	*	NS	NS	76.8 lb	NS	7	.5			C46, CAE, H01(15)

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Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes

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FOOD/FEED USES (con't)

MUSTARD				Use Group: TERRESTRIAL FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
ORANGE				Use Group: TERRESTRIAL FOOD+FEED CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
ORANGE (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	28.8 lb A	*	NS	NS	86.4 lb	NS	30	.5			C46, CAE, H01(15)
PEACH				Use Group: TERRESTRIAL FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE

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FOOD/FEED USES (con't)											
PEACH (Con't)				Use Group: TERRESTRIAL FOOD CROP							
Spray, Foliar, Aircraft	WP/D	NA	11.52 lb A	*	NS NS	23.04 lb	NS	10 .5			C46, CAE, H01(45)
	WP/D	NA	46.5 lb A	*	NS NS	NS	NS	NS NS			CAE
Spray, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS NS	NS	NS	NS NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	11.52 lb A	*	NS NS	23.04 lb	NS	10 .5			C46, CAE, H01(45)
PEAR				Use Group: TERRESTRIAL FOOD CROP							
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS NS	NS	NS	NS NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS NS	NS	NS	NS NS			CAE
Spray, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS NS	NS	NS	NS NS			CAE
Spray, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS NS	NS	NS	NS NS			CAE
PEPPER				Use Group: TERRESTRIAL FOOD CROP							
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	5 NS	NS	NS	5 NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	5 NS	NS	NS	5 NS			CAE
Spray, Bloom through foliar, Aircraft	WP/D	NA	9.6 lb A	*	4 NS	NS	NS	NS .5	CA		C46, CAE, CAG, CAU
Spray, Bloom through foliar, Ground	WP/D	NA	9.6 lb A	*	4 NS	NS	NS	NS .5	CA		C46, CAE, CAG, CAU

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Appendix A does not reflect mandated changes in rates, timing, etc. for the uses													
FOOD/FEED USES (con't)													
PEPPER (con't)				Use Group: TERRESTRIAL FOOD CROP (con't)									
Spray, Foliar, Aircraft	DF	NA	11.52 lb A	*	NS	NS	23.04 lb	NS	7	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	46.5 lb A	*	5	NS	NS	NS	5	NS			CAE
	WP/D	NA	11.52 lb A	*	NS	NS	23.04 lb	NS	7	.5			C46, CAE, H01(14)
Spray, Foliar, Ground	DF	NA	11.52 lb A	*	NS	NS	23.04 lb	NS	7	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	46.5 lb A	*	5	NS	NS	NS	5	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	11.52 lb A	*	NS	NS	23.04 lb	NS	7	.5			C46, CAE, H01(14)
POTATO, WHITE/IRISH				Use Group: TERRESTRIAL FOOD+FEED CROP									
Spray, Foliar, Aircraft	DF	NA	11.16 lb A	*	NS	NS	89.28 lb	NS	7	.5			C46, C92
	DF	NA	11.52 lb A	*	NS	NS	92.16 lb	NS	7	.5		CA	C46, CAG, CAU
	WP/D	NA	11.52 lb A	*	NS	NS	92.16 lb	NS	7	.5			C46, CAE, H01(0)
	WP/D	NA	11.52 lb A	*	NS	NS	92.16 lb	NS	7	.5	DE		C46, CAE, H01(0)

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Appendix A does not reflect mandated changes in rates, timing, etc. for the uses													
FOOD/FEED USES (con't)													
POTATO, WHITE/IRISH (con't)				**Use Group: TERRESTRIAL FOOD+FEED CROP (con't)**									
	WP/D	NA	11.52 lb A	* NS	NS		92.16 lb	NS	7	.5	NJ		C46, CAE, H01(0)
	WP/D	NA	11.52 lb A	* NS	NS		92.16 lb	NS	7	.5	PA		C46, CAE, H01(0)
	WP/D	NA	11.52 lb A	* NS	NS		92.16 lb	NS	NS	.5	MI		C46, CAE, H01(0)
Spray, Foliar, Ground	DF	NA	11.16 lb A	* NS	NS		89.28 lb	NS	7	.5			C46, C92
	DF	NA	11.52 lb A	* NS	NS		92.16 lb	NS	7	.5		CA	C46, CAG, CAU
	WP/D	NA	11.52 lb A	* NS	NS		92.16 lb	NS	7	.5	DE		C46, CAE, H01(0)
	WP/D	NA	11.52 lb A	* NS	NS		92.16 lb	NS	7	.5	NJ		C46, CAE, H01(0)
	WP/D	NA	11.52 lb A	* NS	NS		92.16 lb	NS	7	.5	PA		C46, CAE, H01(0)
	WP/D	NA	11.52 lb A	* NS	NS		92.16 lb	NS	NS	.5	MI		C46, CAE, H01(0)
Spray, Foliar, Sprayer	WP/D	NA	11.52 lb A	* NS	NS		92.16 lb	NS	7	.5			C46, CAE, H01(0)

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
Appendix A does not reflect mandated changes in rates, timing, etc. for the uses													
FOOD/FEED USES (con't)													
RADISH				Use Group: TERRESTRIAL FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
SQUASH (ALL OR UNSPECIFIED)				Use Group: TERRESTRIAL FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	DF	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	DF	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
SQUASH (WINTER)				Use Group: TERRESTRIAL FOOD CROP									
Spray, Foliar, Aircraft	WP/D	NA	15.36 lb A	*	NS	NS	76.8 lb	NS	7	.5			C46, CAE, H01(15)
Spray, Foliar, Sprayer	WP/D	NA	15.36 lb A	*	NS	NS	76.8 lb	NS	7	.5			C46, CAE, H01(15)

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes

Appendix A does not reflect mandated changes in rates, timing, etc. for the uses

FOOD/FEED USES (con't)

SQUASH (ZUCCHINI)				Use Group: TERRESTRIAL FOOD CROP								
Spray, Foliar, Aircraft	WP/D	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5		C46, CAE, H01(7)
Spray, Foliar, Sprayer	WP/D	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5		C46, CAE, H01(7)
STRAWBERRY				Use Group: TERRESTRIAL FOOD CROP								
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS		CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS		CAE
Spray, Foliar, Aircraft	WP/D	NA	9.3 lb A	*	NS	NS	NS	NS	NS	NS		CAE
Spray, Foliar, Ground	WP/D	NA	9.3 lb A	*	NS	NS	NS	NS	NS	NS		CAE
TANGELO				Use Group: TERRESTRIAL FOOD+FEED CROP								
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS		CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS		CAE
Spray, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS		CAE
Spray, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS		CAE
TANGERINES				Use Group: TERRESTRIAL FOOD+FEED CROP								
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS		CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS		CAE

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes

Appendix A does not reflect mandated changes in rates, timing, etc. for the uses

FOOD/FEED USES (con't)

TANGERINES (con't)					Use Group: TERRESTRIAL FOOD+FEED CROP								
Spray, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
TOMATO					Use Group: TERRESTRIAL FOOD+FEED CROP								
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	DF	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5			C46, CAE, H01(14)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	DF	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5			C46, CAG, CAU, H01(14)
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5			C46, CAE, H01(14)
Spray, Posttransplant, Aircraft	DF	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5			C46, CAG, CAU, H01(14)
Spray, Posttransplant, Ground	DF	NA	15.36 lb A	*	NS	NS	61.44 lb	NS	7	.5			C46, CAG, CAU, H01(14)

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes

Appendix A does not reflect mandated changes in rates, timing, etc. for the uses

FOOD/FEED USES (con't)

TURNIP				Use Group: TERRESTRIAL FOOD+FEED CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE

NON-FOOD/NON-FEED

ORNAMENTAL AND/OR SHADE TREES				Use Group: TERRESTRIAL NON-FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	DF	NA	23.04 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAG, CAU
	WP/D	NA	28.8 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAE
	P/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	DF	NA	23.04 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAG, CAU
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	28.8 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAE

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Dose	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
Appendix A does not reflect mandated changes in rates, timing, etc. for the uses													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL HERBACEOUS PLANTS				Use Group: TERRESTRIAL NON-FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	DF	NA	23.04 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAG, CAU
	WP/D	NA	28.8 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAE
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	DF	NA	23.04 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAG, CAU
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	28.8 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAE
ORNAMENTAL NONFLOWERING PLANTS				Use Group: TERRESTRIAL NON-FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	DF	NA	23.04 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAG, CAU
	WP/D	NA	28.8 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAE
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
Appendix A does not reflect mandated changes in rates, timing, etc. for the uses													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL NONFLOWERING PLANTS (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)									
Spray, Foliar, Ground	DF	NA	23.04 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAG, CAU
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	28.8 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAE
ORNAMENTAL WOODY SHRUBS AND VINES				Use Group: TERRESTRIAL NON-FOOD CROP									
Dust, Foliar, Aircraft	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Dust, Foliar, Ground	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Aircraft	DF	NA	23.04 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAG, CAU
	WP/D	NA	28.8 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAE
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Ground	DF	NA	23.04 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAG, CAU
	WP/D	NA	46.5 lb A	*	NS	NS	NS	NS	NS	NS			CAE
Spray, Foliar, Sprayer	WP/D	NA	28.8 lb A	*	NS	NS	NS	NS	NS	.5			C46, CAE

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]

LEGEND

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Re-Entry Intv.	: Reentry Intervals
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	: Non-specific
C	: Coarse
M	: Medium
F	: Fine
O	: Others

FORMULATION CODES

DF	: WATER DISPERSIBLE GRANULES (DRY FLOWABLE)
G	: GRANULAR
WP	: WETTABLE POWDER
WP/D	: WETTABLE POWDER/DUST

ABBREVIATIONS

AN	: As Needed
NA	: Not Applicable
NS	: Not Specified (on label)
UC	: Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPENDIX A REPORT

Case 0087[Cryolite] Chemical 075101[Cryolite]
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APPLICATION RATE
DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
U : Unknown whether PPM is given by weight or by volume
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES
C46 : Do not apply through any type of irrigation system.
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
CAE : Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes).
CAG : Do not apply where runoff is likely to occur.
CAU : Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
CA : California
DE : Delaware
MI : Michigan
NJ : New Jersey
OR : Oregon
PA : Pennsylvania
WA : Washington

REENTRY INTERVAL ABBREVIATIONS
.5 : day
h : hour(s)

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Cryolite covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Cryolite in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Cryolite

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY[1]			
61-1	**Chemical Identity**	ALL	42830201
61-2A	**Start. Mat. & Mnfg. Process**	ALL	41022901
61-2B	**Formation of Impurities**	ALL	41022901
62-1	**Preliminary Analysis**	ALL	4116701, 4161301
62-2	**Certification of limits**	ALL	42830201
62-3	**Analytical Method**	ALL	4116701, 41613101
63-2	**Color**	ALL	41022902
63-3	**Physical State**	ALL	41022902
63-4	**Odor**	ALL	41022902
63-5	**Melting Point**	ALL	41022902
63-6	**Boiling Point**	N/A	
63-7	**Density**	ALL	41022902
63-8	**Solubility**	ALL	41022902
63-9	**Vapor Pressure**	N/A	
63-10	**Dissociation Constant**	ALL	41022902
63-11	**Octanol/Water Partition**	N/A	
63-12	**pH**	ALL	41022902, 42830201
63-13	**Stability**	ALL	41022902, 42830201

Data Supporting Guideline Requirements for the Reregistration of Cryolite

REQUIREMENT		USE PATTERN	CITATION(S)
63-14	**Oxidizing/Reducing Action**	ALL	41022902
63-15	**Flammability**	N/A	
63-16	**Explodability**	ALL	41022902
63-17	**Storage stability**	ALL	41229101
63-18	**Viscosity**	N/A	
63-19	**Miscibility**	N/A	
63-20	**Corrosion characteristics**	ALL	41229101
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	A,B,C,D,K	00152375
71-2A	**Avian Dietary - Quail**	A,B,C,D,K	00084001
71-2B	**Avian Dietary - Duck**	A,B,C,D,K	00084002
71-3	**Wild Mammal Toxicity**	A,B,C	0071392
72-1A	**Fish Toxicity Bluegill**	A,B,C,D,K	40094602, 00147306
72-1B	**Fish Toxicity Bluegill - TEP**	A,B,C,D	00073804
72-1C	**Fish Toxicity Rainbow Trout**	A,B,C,D,K	40094602, 00147306
72-1D	**Fish Toxicity Rainbow Trout- TEP**	A,B,C,D	00073803
72-2A	**Invertebrate Toxicity**	A,B,C,D,K	40094602
72-3C	**Estuarine/Marine Toxicity - Shrimp**	A,B,C,D	00073805
141-1	**Honey Bee Acute Contact**	A,B,C,K	00036935

Data Supporting Guideline Requirements for the Reregistration of Cryolite

REQUIREMENT		USE PATTERN	CITATION(S)
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A,B,C,D,K	00138096
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	A,B,C,D,K	00128107
81-3	**Acute Inhalation Toxicity - Rat**	A,B,C,D,K	00128107
81-4	**Primary Eye Irritation - Rabbit**	A,B,C,D,K	00128106
81-5	**Primary Dermal Irritation - Rabbit**	A,B,C,D,K	00128106
81-6	**Dermal Sensitization - Guinea Pig**	A,B,C,D,K	00138097
82-1A	**90-Day Feeding - Rodent**	A,B,D	00158000
82-1B	**90-Day Feeding - Non-rodent**	A,B	00157999
82-2	**21-Day Dermal - Rabbit/Rat**	A,B	41224801
83-1A	**Chronic Feeding Toxicity - Rodent**	A,B,D	NTP Study
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	A,B,D	42575101
83-2A	**Oncogenicity - Rat**	A,B,D	NTP Study
83-2B	**Oncogenicity - Mouse**	A,B,D	NTP Study
83-3A	**Developmental Toxicity - Rat**	A,B,D	00128112
83-3B	**Developmental Toxicity - Rabbit**	A,B,D	42297901
83-4	**2-Generation Reproduction - Rat**	A,B,D	43387501
84-2A	**Gene Mutation (Ames Test)**	A,B,C,D,K	41838401

Data Supporting Guideline Requirements for the Reregistration of Cryolite

REQUIREMENT		USE PATTERN	CITATION(S)
84-2B	**Structural Chromosomal Aberration**	A,B,C,D,K	41838402
84-4	**Other Genotoxic Effects**	A,B,C,D,K	41838403
85-1	**General Metabolism**	A,B,D	N/A
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	A,B,C,D,K	00142836
163-1	**Leaching/Adsorption/Desorption**	A,B,C,D,K	00142837
163-2	**Volatility - Lab**	A,B	40279302
165-1	**Confined Rotational Crop**	A,B	42297903
RESIDUE CHEMISTRY			
171-3	**Directions for Use**	ALL	DATA GAP
171-4A	**Nature of Residue - Plants**	A,B,D	00158001
171-4B	**Nature of Residue - Livestock**	B	N/A
171-4C	**Residue Analytical Method - Plants**	A,B,D	00158001, 42630001
171-4D	**Residue Analytical Method - Animal**	B	N/A
171-4E	**Storage Stability**	N/A	N/A
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	B	00158001, 41694101, 41694102, 41694103, 41694104, 41694105, 41694106, 41694107, 41694108
171-4K	**Crop Field Trials**		

Data Supporting Guideline Requirements for the Reregistration of Cryolite

REQUIREMENT	USE PATTERN	CITATION(S)
Root and Tuber Vegetables		
Potatoes	A	00158001, 41021202, 42067901, 42126401, 42215901
Leafy Vegetables		
Lettuce	A	00102979, 00158001, 41380611, 42751701
Brassica (Cole) Leafy Vegetables		
Broccoli	A	00158001
Brussels sprouts	A	00158001
Cabbage	A	00158001, 41380610, 42751703
Cauliflower	A	00158001
Collards	A	00158001, 41380601, 42751702
Kohlrabi	A	00158001
Legume Vegetables		
Beans	A	00158001
Fruiting Vegetables		
Peppers	A	00158001, 42659301
Tomatoes	A	0015800, 41380608, 42751706, 42656901
Cucurbit Vegetables		
Cucumbers	A	00158001, 43867501
Melons	A	00158001, 41380602, 42751704
Pumpkins	A	00158001

Data Supporting Guideline Requirements for the Reregistration of Cryolite

REQUIREMENT		USE PATTERN	CITATION(S)
	Squash (summer, winter)	A	00158001, 41380603, 42751705
	Citrus Fruits Group	A	41380604, 41380605, 41380606, 42751709, 42751710, 42751711
	Stone Fruits		
	Peaches	A	43077601
	Plums (fresh prunes)	A	DATA GAP
	Small Fruits and Berries		
	Cranberries	A,D	DATA GAP
	Grapes	A	00130741, 00149815, 00158001
	Strawberries	A	00158001, DATA GAP
	Miscellaneous Commodities		
	Kiwifruit	A	40635601
171-4L	**Processed Food**		
	Citrus fruits	A	41380607, 42751708
	Potatoes	A	41021202, 41429801
	Tomaotes	A	41380609, 42751707

[1] The Product Chemistry Data Summary is represented by EPA Reg. No. 4581-116.

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

   c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 7; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-96).

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I	-	Why You are Receiving this Notice
Section II	-	Data Required by this Notice
Section III	-	Compliance with Requirements of this Notice
Section IV	-	Consequences of Failure to Comply with this Notice
Section V	-	Registrants' Obligation to Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries and Responses to this Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions (Form A)
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions (Form B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredients.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (Telephone number: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option.

Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice, which are contained in Section IV-C.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Reqistrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

b. Satisfying the Product Specific Data Requirements of this Notice.

There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Reqistrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and

Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant normally will be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly Met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3 'Raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must certify at the time of submitting the existing study that such GLP information is available for post May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted

according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option also should be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally, your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria, as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core-minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time-frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)

(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)

(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data

requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   i. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form.

   ii. Fulfill the commitment to develop and submit the data as required by this Notice; or

   iii. Otherwise take appropriate steps to meet the requirements stated in this Notice,

   unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1) EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2) EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3) EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding generally would not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You also must explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due, unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3-year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice must include completed Data Call-In Response Forms (Attachment 2)and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

CRYOLITE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing Cryolite.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Cryolite. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) a list of registrants receiving this DCI (Attachment 5) and (7) the Cost Share and Data Compensation Forms in replying to this Cryolite Product Specific Data Call-In (Attachment 6). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Cryolite are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Cryolite are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible Cryolite products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Jeff Billingslea at (703) 308-8004.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Jeff Billingslea
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Cryolite

CRYOLITE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing Cryolite.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Cryolite. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) a list of registrants receiving this DCI (Attachment 5), (5) the Cost Share and Data Compensation Forms in replying to this Cryolite Generic Data Call In (Attachment D). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Cryolite are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional product chemistry data on Cryolite are needed. These data are needed to fully complete the reregistration of all eligible Cryolite products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Dana Lateulere at (703) 308-8044.

All responses to this Notice for the generic data requirements should be submitted to:

Dana Lateulere, Chemical Review Manager
Reregistration Branch
Special Review and Reregistration Division (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Cryolite

Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Data Call-In Response Forms." Only registrants responsible for generic data have been sent the generic data response form. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a. **ON THE GENERIC DATA FORM:**Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Instructions For Completing The "Requirements Status and Registrant's Response Forms" For The Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites

TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum,

or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" for generic data.

Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must

be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this

EPA'S BATCHING OFCRYOLITE PRODUCTS FOR MEETING REREGISTRATION ACUTE TOXICITY DATA REQUIREMENTS

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing Cryolite as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Not with-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrant's option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data,

he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

PRS identified Federal Registration and Special Local Need (SLN) uses for batching purposes. The products in **bold print** represent Federal Registrations and the SLN uses are not in bold print.

Kryocide Insecticide 96.0% a.i. EPA Reg. No. 4581 -116
Kryocide Insecticide 96.0% a.i. EPA SLN No. CA77016700
Kryocide Insecticide 96.0% a.i. EPA SLN No. CA79012100
Kryocide Insecticide 96.0% a.i. EPA SLN No. CA80008100
Kryocide Insecticide 96.0% a.i. EPA SLN No. NJ90000-800

Prokil Cryolite 96 96.0% a.i. EPA Reg. No. 10163-0041
Prokil Cryolite 96 96.0% a.i. EPA SLN No. DE93000-300
Prokil Cryolite 96 96.0% a.i. EPA SLN No. MI9300-500
Prokil Cryolite 96 96.0% a.i. EPA SLN No. NJ93000-600
Prokil Cryolite 96 96.0% a.i. EPA SLN No. NJ90000-700
Prokil Cryolite 96 96.0% a.i. EPA SLN No. PA93000-500

Cryolite 93 93.0% a.i. EPA Reg. No. 5481-132

Prokil Cryolite WDG 93.0% a.i. EPA Reg. No. 10163-185
Prokil Cryolite WDG 93.0% a.i. EPA Reg. No. NJ94000-800

Gowan Cryolite Bait 20.0% a.i. EPA SLN No. OR95000-800
Gowan Cryolite Bait 20.0% a.i. EPA SLN No. WA95001-800

Sixteen products were found which contain Cryolite as an active ingredient. Fourteen products were placed in Batch 1 and two products were placed in Batch 2 (see graphs below).

Batch	EPA Reg. No.	% active ingredient	Formulation Type
1	**4581-116**	96	powder
	CA77016700	96	powder
	CA79012100	96	powder
	CA80008100	96	powder
	NJ90000800	96	powder
	10163-41	96	powder
	DE93000300	96	powder
	MI93000500	96	powder
	NJ90000700	96	powder
	NJ93000600	96	powder
	PA93000500	96	powder
	5481-132	93	powder
	10163-00185	93	powder
	NJ94000800	93	powder

Batch	EPA Reg. Number	% of active ingredient	Formulation Type
2	OR95000800	20	powder
	WA95001800	20	powder

Data from the HED Chapter on the technical can be used in support of all Batch 1 products.

The HED Chapter indicates that all the acute tox studies are Category III and/or IV; therefore, data on the technical can be bridged to support Batch 2 products.

New acute tox studies are not required since existing data on the technical may be used directly (Batch 1) and/or bridged (Batch 2) to all of the above listed products.

LIST OF REGISTRANTS SENT THIS DATA CALL-IN (REMOVE THIS PAGE AND INSERT MAILING LIST)

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
2070-0057
Approval Expires 3-31-96

Please fill in blanks below.

Company Name	Company Number
Product Name	**EPA Reg. No.**

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires 3-31-96

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date

Name and Title (Please Type or Print)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

APPENDIX E - LIST OF AVAILABLE RELATED DOCUMENTS

The following is a list of available documents for Cryolite that may further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Jeff Billingslea at (703)-308-8004.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for Cryolite.

The following documents are part of the Administrative Record for Cryolite and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria