UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

CERTIFIED MAIL

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Dear Registrant:

Enclosed is a **Reregistration Eligibility Document (RED)** for the pesticide active ingredient potassium bromide. The RED is the Environmental Protection Agency's evaluation of the potassium bromide data base and presents the Agency's conclusions on which uses are eligible for reregistration and under what conditions and requirements. Also enclosed is the **Pesticide Reregistration Handbook** which provides instructions to registrants on how to respond to any labeling and data requirements specified in the RED and how to reregister products.

The RED identifies outstanding product specific data requirements for end-use products and manufaturing-use products. These requirements are listed on the Requirements Status and Registrant's Response Form, which, along with the Data Call-In Response Form, listing all of your company's products subject to the RED, is included as an Appendix. Instructions for completing both forms are contained in the RED package. All product specific data must be submitted and found acceptable by EPA before a product can be reregistered.

Generic data requirements usually will have been fulfilled prior to making a reregistration eligibility decision. However, there may be some instances where additional generic data are required. If generic data requirements remain to be fulfilled, all registrants must complete the appropriate Data Call-In Response Form and Requirements Status and Registrant's Response Form. These forms are in the appendices to the RED.

The RED identifies any specific labeling requirements such as restricted use classification, groundwater hazard statements, endangered species precautions, etc., necessary for reregistration based on a review of the generic data for the active ingredient. In addition, in order to be reregistered all product labeling must be in compliance with format and content labeling as described in 40 CFR 156.10 and all labeling changes imposed by Pesticide Regulatory (PR) Notices.

The Pesticide Reregistration Handbook contains detailed instructions for compliance with the RED and must be followed carefully. There are several key points to remember in preparing your response to the RED:

- If generic or product specific data are required, registrants must submit an initial response within 90 days of receipt of the RED. Forms for generic data must be completed separately from forms for product specific data and must be marked with different internal distribution codes. (see page 6 of the Reregistration Handbook). Preprinted forms for each product have been included in the RED package.

- If expedited labeling changes are required, registrants must submit them within the time frame specified in the RED. Normally, however, labeling changes and applications for reregistration must be submitted within 8 months from the issuance of the RED. Refer to pages 3-5 of the Reregistration Handbook for instructions.

- Cite-all is no longer a valid response for fulfilling product-specific data requirements. You must commit to generate the data, cite specific data or select other allowable options. If you cite data, you must provide Master Record Identification Numbers (MRID) for each data requirement for each product. For previously submitted data each registrant must determine that the study meets the Agency's acceptance criteria for data, which are enclosed. If the data do not meet these criteria then the registrant must commit to generate data or choose an appropriate response option on the Requirements Status and Registrant's Response Form.

- Grouping of Products for Acute Toxicological Testing - In order to reduce the costs of testing, the Agency has "grouped" identical or similar products together for purposes of acute toxicity testing. This is discussed on page 9 of the Handbook and in an appendix to the data tables in the RED.

- The data requirements in the RED are issued under the authority of Section 3(c)(2)(B) of FIFRA. Failure to adequately respond to the data requirements specified in the RED within the timeframe provided may result in the issuance of a Notice of Intent to Suspend affecting products containing potassium bromide.

Questions on product specific data requirements and labeling (both End-Use Products and Manufacturing Use Products) should be directed to the Registration Division Product Manager Team for potassium bromide (Walter Francis, 703-557-3964).

The Agency is prepared to meet with any registrants who have questions about responding to the potassium bromide RED. If you want to meet with the Agency, you must contact Mr. Francis within two weeks of receipt of the RED. The Agency intends to have one combined meeting with interested registrants. If there are any requests for such a meeting, the Agency will notify all registrants who requested a meeting of the location and date. Requests for a meeting will not extend the 90 day or 8 month response deadlines.

Sincerely yours,

Allan S. Abramson

Allan S. Abramson, Ph.D
Acting Director
Special Review and Reregistration Division

Enclosures

REREGISTRATION ELIGIBILITY DOCUMENT (RED)
POTASSIUM BROMIDE

LIST A

CASE 0342

APRIL 1991

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION
WASHINGTON, D.C.

TABLE OF CONTENTS

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
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
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
K+CWHR	Kernel plus Cob with Husk Removed
LC50	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 or feed, e.g., mg/l or ppm.
LD50	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.
LDT	Lowest Dose Tested
LEL	Lowest Effect Level
MP	Manufacturing Use Product
MPT	Maximum Permissible Intake

GLOSSARY OF TERMS AND ABBREVIATIONS CONT'D

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts per Million
RfD	Reference Dose
RS	Registration Standard
TMRC	Theoretical Maximum Residue Contribution

EXECUTIVE SUMMARY

The Environmental Protection Agency (referred to as "the Agency") first registered potassium bromide as a final sanitizing rinse for food contact surfaces, food handling equipment and utensils in food processing establishments and later registered an additional use for control of bacteria and algae indoors in spas. Products which contain potassium bromide are eligible for reregistration.

In September 1984, the Agency issued a registration standard entitled "Guidance for the Reregistration of Pesticide Products Containing As the Active Ingredient Potassium Bromide." (NTIS # PB-89187256). The registration standard summarized the available data supporting the registration of potassium bromide and required additional data to assure that the proper use of the pesticide poses no unreasonable adverse effects to human health or the environment.

Recently, the Agency conducted a thorough review of the scientific database and all relevant information supporting the reregistration of potassium bromide, including the data submitted in response to the registration standard. The data base is substantially complete and consists of product chemistry, toxicology and ecological effects. No further generic data are required. No tolerances are required to cover the existing uses for the registered products.

The data are sufficient to allow the Agency to conduct a reasonable risk assessment for all registered uses of potassium bromide. The Agency has determined that for all currently registered uses of potassium bromide can be used according to label directions without resulting in unreasonable adverse effects. Based on the data reviewed, the Agency has determined that potassium bromide poses no unreasonable adverse effect to human health and the environment. Since the two registered products containing potassium bromide as an active ingredient also contain other active ingredients, they will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration. Labels and product specific data are required to be submitted. If these labels and data are acceptable, amendments to registration will be approved. When the other active ingredients are determined to be eligible for reregistration and when registrants properly respond to those Reregistration Eligibilty Documents (RED), EPA may proceed to reregister the two currently registered products.

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.

Section 4 (g) (2) (A) of FIFRA 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 of potassium bromide. The document consists of five sections. Section I is this introduction. Section II describes potassium bromide, its uses and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV discusses the reregistration decision for Potassium Bromide and Section V discusses product reregistration. Additional details concerning the Agency's review of available data are available on request.[1]

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[1] EPA's reviews of specific reports and information on the set of registered uses considered for EPA's analyses may be obtained from: EPA, Freedom of Information, 401, M St., S.W., Washington, D.C. 20460.

II. ACTIVE INGREDIENT COVERED BY THE REREGISTRATION DECISION DOCUMENT.

A. IDENTIFICATION OF ACTIVE INGREDIENT

The following active ingredient is covered by this Reregistration Eligibility Document:

Chemical Name: Potassium Bromide (KBr)

Common Name: None

CAS Number: 7758-02-3
Office of Pesticide Programs Chemical Code Number: 013903

B. USE PROFILE

Type of Pesticide: Antimicrobial Sanitizer and Bactericide Algaecide

Formulation Types Registered: Liquid and Tablets

Use Patterns: Indoor Food and Aquatic Non-Food Residential

Registered Use Sites: The registered use is as a final sanitizing rinse for food contact surfaces, food handling equipment and utensils in food processing establishments, eating establishments and for control of bacteria & algae indoors in spa water.

C. REGULATORY HISTORY

Potassium bromide was initially registered on August 15, 1960. Potassium bromide is a well known inorganic pesticide whose chemical and toxicological properties are extensively documented in published literature.

Potassium bromide is not registered as a manufacturing use product (MUP). The technical grade of the active ingredient is available as an unregistered material from chemical supply houses, at about 99% purity. The non-pesticidal uses for this chemical outnumber and outweigh in economic importance the pesticidal use. A Registration Standard, issued in September 1984, applied to the approved pesticidal uses of end-use products containing the active ingredient.

The Registration Standard was issued September 28, 1984 and at that time only one end-use product was registered:

SAF-SOL Brand For Institutional Use
EPA Reg No. 875-42
Diversey Wyandotte
1532 Biddle Ave.
Wyandotte, MI 48192

The approved label lists three active ingredients:

Sodium Hypochlorite	3.25%
Potassium Bromide	2.00%
Sodium Phosphate	89.75%

On May 15, 1987 Monsanto Chemical was granted approval for one end use product.

Convert-A-Clor One Inch Brominating Tablets
EPA Registration #524-378
Monsanto Chemical Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

The approved label lists two active ingredients:

Sodium Dichloro-S-Triazinetrione Dihydrate	52%
Bromide Source (KBr)	48%

The following data were required to be submitted for reregistration by the 1984 Registration Standard:

61-2	Statement of Composition
71-1	Avian Oral LD_{50}
71-2	Avian Dietary LC_{50}
72-1	Freshwater Fish LC_{50}
72-2	Acute LC_{50} Freshwater Invertebrates (48 hrs)

III. AGENCY ASSESSMENT

The Agency has conducted a thorough review of the scientific data base for potassium bromide. Based on the evaluation of these data, the findings are summarized below.

A. PRODUCT CHEMISTRY ASSESSMENT

The Merck Index, 9th Edition, provides the following information for this chemical: KBr, molecular weight 119.01, Br 67.15%, K 32.85%, colorless crystals or white granules, or powder; density 2.75, melting point 730°C; 1 gram dissolves in 1.5 ml water or in 250 alcohol. The aqueous solution is neutral.

B. HUMAN HEALTH ASSESSMENT

1. Toxicology Data Base

There are no outstanding generic toxicological data requirements for potassium bromide.

The toxicology chapter in the Registration Standard stated that no chronic tox data were required on technical KBr. Human toxicology of the compound is well understood and minimal. KBr dissolves in water and dissociates into potassium and bromide ions. Potassium ion is present in relatively large amounts in all living organisms and is essential for life. Bromide ion is present in small amounts, and is not known to concentrate, in man and all other organisms; and has no detectable effect at such concentrations. The use of bromide salts as tranquilizers has demonstrated the low and reversible toxicity of the bromine ion.

a. Acute Toxicity

The oral toxicity of the inorganic salts of bromine (potassium and sodium) is well known and is very low. The prominent effect of a high dose is nausea and vomiting. They are not skin irritants nor do they produce systemic toxicity by the dermal route. Additional acute toxicity data are not required because there is sufficient information available in public literature to show that potassium bromide is not acutely toxic and poses a low toxicity hazard.

The Potassium Bromide Registration Standard required acute oral, dermal, inhalation and delayed neurotoxicity data to support registration of a technical product. Based on the review of existing acute tox data in public literature and the conclusion that the toxicity of KBr is very low, no additional acute toxicity data are required.

b. Acute Delayed Neurotoxicity

The delayed neurotoxicity test is designed for testing a special toxicity found only in organophosphate cholinesterase inhibitors; this does not apply to KBr. Sodium and potassium salts of bromine were used, for many years, as tranquilizers and to assist in sleeping. Thus, the CNS depressant effect of the bromide salts in humans is well characterized. It requires repeated daily administration of doses in the order of 1 to 2 grams per day. The effect is slowly reversed when dosing is stopped. The Bromide ion acts in the organism by replacing the chloride ion and inhibiting depolarization and transmission in nerve cells.

c. Chronic Toxicity

A review of relevant information in the published literature on potassium bromide has raised no chronic or long term toxicology concerns for the approved pesticidal uses: as a final sanitizing rinse on food contact surfaces and swimming pools and spas. Potassium bromide, in combination with other chemicals generally recognized as safe, is cleared for final sanitizing use as an indirect food additive. (See section B.2.-Dietary Exposure)

2. Dietary Exposure

Sanitizing solutions for use on food-contact surfaces without the requirement for a final potable water rinse are considered to be indirect food additives and are regulated by the Food and Drug Administration under the Federal Food, Drug and Cosmetic Act as specified in Part 178 of 21 CFR.

Section 178.1010 (b)(1) allows the use of aqueous solutions containing potassium, sodium, or calcium hypochlorite, with or without the bromides of potassium, sodium, or calcium, for use on food-processing equipment, utensils, and articles. The registered formulation containing KBr is covered under this section. The EPA has not established any tolerances or exemptions for KBr per se and no tolerances are required.

3. Occupational and Residential Exposure

The 1984 Registration Standard did not require occupational or residential exposure data. Based on low toxicity and the current registered use patterns, potassium bromide does not meet the Agency's exposure criteria for requirement of reentry or mixer/loader/applicator exposure monitoring data. Since the registered use patterns are expected to provide only minimal human exposure, these data are not required to support the reregistration of potassium bromide.

C. ENVIRONMENTAL ASSESSMENT

All environmental fate and ecological effects data have been reviewed. No further environmental fate data were required in the 1984 Registration Standard. The following additional ecological effects data were required in the 1984 Guidance Document:

71-1 Avian Oral LD_{50}

71-2 Avian Dietary LC_{50} (one species only)

72-1 Freshwater Fish LC_{50}

72-2 Acute LC_{50}Freshwater Invertebrates (48 hrs.)

The Agency has sufficient data to support the conclusion that indoor use of potassium bromide will not result in unreasonable adverse effects to humans or the environment.

1. Environmental Fate Assessment

The Agency did not require environmental fate chemistry data in 1984 based on indoor use of KBr to sanitize food handling equipment and utensils in food processing establishments. Potassium bromide is used as a very dilute aqueous solution which goes to sewage treatment plants through the municipal sewer systems. Here the chemical is degraded with other components during the treatment process, going from there back to receiving natural bodies of water. The very diluted KBr dissociates into K+ and Br, elements that are present in nature as minerals and salts. Also very low levels are introduced into the environment after discharge from a sewage treatment plant. Therefore, potassium bromide is

not expected to produce any adverse effects. Based on this conclusion, environmental fate chemistry data (i.e., hydrolysis) are not required to support reregistration for this chemical.

2. Ecological Effects Data

The 1984 Guidance Document required the submission of certain ecological effects data to allow the Agency to characterize the toxicity of potassium bromide to avian and aquatic organisms.

When potassium bromide is mixed with an oxidant (chlorine gas, calcium hypochlorite, etc.),in water, it forms hypobromous acid (HOBr). Therefore fish and wildlife studies conducted with both hypobromous acid and technical grade material of potassium bromide were required to support reregistration of potassium bromide.

a. Effects on Birds

Potassium Bromide was found to be practically non-toxic to bobwhite quail with an acute oral LD_{50} value >2500 mg/kg and an 8-day dietary LC_{50} value for KBr in bobwhite quail was found to be >6,000 ppm. Avian studies with hypobromous acid are waived due to lack of exposure to birds (indoor use). Additionally, stability problems make dietary studies using hypobromous acid infeasible.

b. Effects on Fish

Since potassium bromide forms hypobromous acid when it comes into contact with water, aquatic studies employing hypobromous acid as the test material are appropriate to support the reregistration of potassium bromide. However, the Agency has determined that available data on bromine chloride satisfy aquatic testing requirements for hypobromous acid.

Bromine chloride, measured as bromine, was found to be highly toxic to bluegill sunfish with an LC_{50} 0.52 ppm based on 0-hour measured concentrations.

Although the 1984 Registration Standard required that only one species (bluegill sunfish or rainbow trout) be tested, data are available that indicate bromine chloride, measured as bromine, is highly toxic to rainbow trout with an LC_{50} of 0.31 ppm

based on 0-hour measured concentrations.

c. Effects on Aquatic Invertebrates

Bromine chloride, measured as bromine, is highly toxic to Daphnia magna with an LC_{50} of 1.07 ppm based on average (0-24 hours) concentrations. This study fulfills the requirement for a freshwater invertebrate testing for hypobromous acid.

Although these fish and aquatic invertebrate studies demonstrate the high toxicity of bromine to aquatic organisms, additional label precautions or restrictions for potassium bromide products are not required since the indoor use is not expected to result in significant exposure to aquatic organisms.

IV. REREGISTRATION DECISION FOR POTASSIUM BROMIDE

A. DETERMINATION OF ELIGIBILITY FOR REREGISTRATION

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 ingredient are eligible for reregistration. The Agency has previously identified and required the submittal of all the generic (i.e., active-ingredient specific) data required to support reregistration of products containing potassium bromide as an 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 potassium bromide. Appendix A identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of potassium bromide, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix A were sufficient to allow the Agency to conduct a reasonable risk assessment for all currently registered uses of potassium bromide and to determine for all such uses that potassium bromide can be used without resulting in unreasonable adverse effects to humans or the environment. The Agency, therefore, finds that all products containing potassium bromide as an active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document ("Product Reregistration").

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, and the data identified in Appendix A. Although the Agency has found that products containing potassium bromide 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 registration of products containing potassium bromide, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. ADDITIONAL GENERIC DATA REQUIREMENTS

The generic data base supporting the reregistration of products containing potassium bromide has been reviewed and determined to be complete. No further generic data are required to support reregistration.

C. LABELING REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING POTASSIUM BROMIDE

Currently there are no registered manufacturing-use products containing potassium bromide as the active ingredient.

V. PRODUCT REREGISTRATION

A. DETERMINATION OF ELIGIBILITY

Based on the reviews of the generic data for the active ingredient , potassium bromide, the products containing this active ingredient are eligible for reregistration. Section 4(g)(2)(B) of FIFRA requires the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Agency will review these data and determine whether to reregister individual products.

B. PRODUCT SPECIFIC DATA REQUIREMENTS

The product-specific data requirements are specified in the attached Data Call-In appendices.

C. LABELING REQUIREMENTS FOR END-USE PRODUCTS

The labels and labeling of all products must comply with EPA's current regulations and requirements. Follow the instructions in the Product Reregistration Handbook with respect to labels and labeling.

APPENDIX A

Generic Data Requirements for Reregistration of Potassium Bromide and Data Citations Supporting Reregistration

GUIDE TO APPENDIX A

Appendix A contains listings of data requirements which support the reregistration for the pesticide covered by this Reregistration Eligibility Document.

Appendix A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

The data table are generally organized according to 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 out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Use Pattern (Column 2). This column indicates the use patterns to which the data requirement applies. 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 crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Any other designations will be defined in a footnote to the table.

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 Appendices for a complete citation of the study.

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF POTASSIUM BROMIDE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERN	BIBLIOGRAPHIC CITATION
Product Chemistry			
61-1	Identity of Ingredients	G,L	00130901 00019750 00007445 GS0342-001
61-2a	Begin. Mat . and Mfg. Process	G,L	00147303 00130901 *
61-2b	Discussion of Impurities	G,L	00147303 00130901 *
63-2	Color	G,L	*
63-3	Physical State	G,L	*
63-4	Odor	G,L	*
63-5	Melting Point	G,L	*
63-6	Boiling Point	G,L	*
63-7	Density, Bulk Density or Specific Gravity	G,L	*
63-8	Solubility	G,L	*
63-12	ph	G,L	*
63-13	Stability	G,L	*

* CRC Press, Inc. Handbook of Chemistry & Physics

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF POTASSIUM BROMIDE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERN	BIBLIOGRAPHIC CITATION
Ecological Effects:			
71-1a	Acute avian oral - Quail	G,L	00151630
71-2a	Acute avain dietary - Quail	G,L	00151631
72-1a	Fish tox - Bluegill (HoBr)	G,L	40669903
72-1c	Fish tox - Rainbow trout (HoBr)	G,L	40669902
72-2a	Invertebrate tox (HoBr)	G,L	40669904

APPENDIX B

POTASSIUM BROMIDE BIBLIOGRAPHY

Citations Considered to be Part of the
Data Base Supporting Reregistration

GUIDE TO APPENDIX B

1. CONTENT 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, will be 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 attempted also 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 at any time 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 identifier 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 standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, 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

author. As a last resort, the Agency has shown the first submitter as author.

b. Document date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark the bibliographer deduced the date from evidence 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 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, following the phrase "submitted by." 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," standing 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. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REREGISTRATION ELIGIBILITY DOCUMENT
BIBLIOBRAPHY

CHEMICAL NAME: Potassium Bromide

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00019750 Vitands, A.; Carrera, R.T.; Kelly, M.J. (1961) Information on Conversion Rate of Bromide to Hypobromite in Solutions of Diversey PX-1216. (Unpublished study received Oct. 5, 1961 under 875-45; submitted by Diversey Chemical Co., Des Plains, IL; CDL: 231083-F)

00130901 US EPA (1983) Administrative Record of the Reregistration Standard for the Calcium and Sodium Hypochlorite Salts. Part 1. Unpublished File.

00147303 Diversey Wyandotte Corp. (1979) Product Chemistry Data of Potassium Bromide. Unpublished compilation. 58 p.

00151630 Shapiro, R. (1985) Acute Oral LD50 Limit Test with Bobwhite Quail: Potassium Bromide Technical. Report No.T-5462. Unpublished study prepared by Product Safety Labs. 16 p.

00151631 Shapiro, R. (1985) Acute Dietary LC50 with Bobwhite Qual:Potassium Bromide Tech. Report No. T-5461. Unpublished study prepared by Product Safety Labs. 12 p.

40669902 Surprenant, D. (1987) Acute Toxicity of Bromine Chloride to Rainbow Trout (Salmo gairdner): Rept. BW-87-3-2352; Study #11990387.6100.103. Unpublished study prepared by Springborn Bionomics, Inc. 61 p.

40669903 Surprenant, D. (1987) Acute Toxicity of Bromine Chloride to Bluegill (Lepomis macrochirus): Rept. #BW-87-3-2353; Study #11990387.6100.100. Unpublished study prepared by Springborn Bionomics, Inc. 36 p.

40669904 Hughes, J. (1987) The Acute Toxicity of Bromine Chloride to the Water Flea, Daphnia magna: Proj. ID 0950-02-1100-1. Unpublished study prepared by Malcolm Pirnie, Inc. 21 p.

GS-0342-001 Smith, M.K. (1983) Qualitative Assessment Document for Potassium Bromide

ATTACHMENT A

POTASSIUM BROMIDE: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Data Call-In Notice because you have products containing potassium bromide.

This attachment, the Data Call-In Chemical Status Sheet, contains the reregistration regulatory history of Potassium Bromide an overview of data required by this notice, and point of contact for inquiries. This attachment is to be used in conjunction with (1) the Data Call-In Notice, (2) Attachment B, the Data Call-In Response Form, (3) Attachment C, the Requirement Status and Registrant's Response Form, (4) Attachment D, List of all Registrant(s) sent this Data Call-In Notice, and (5) Attachment E, the Cost Share and Data Compensation Forms in replying to this Potassium Bromide Data Call-In. Instructions and guidance accompany each form.

REREGISTRATION HISTORY

In September 1984, EPA issued a Registration Standard on Potassium Bromide. In the Registration Standard, EPA identified data required to support existing uses of the pesticide and determined whether existing data were acceptable and sufficient to satisfy the requirement. Under the 1984 Registration Standard, registrants were required to generate data to supply missing data and to replace unacceptable studies.

The Agency has reviewed data submitted in response to the 1984 Registration Standard and has reevaluated its position on data needed to support the continued registration of Potassium Bromide.

DATA REQUIRED BY THIS NOTICE

The Agency's findings regarding the adequacy of the database for Potassium Bromide are contained in the Requirements Status and Registrant's Response, Attachment C.

The Agency has concluded that additional data on Potassium Bromide are needed in the following areas: product specific data. The required additional data are listed in Attachment C. These data are needed for the Agency to complete the reregistration decision for Potassium Bromide.

Depending on the results of the studies required in this Notice, additional testing may be required.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Walter Francis at (703) 557-3964.

All response to this Notice should be submitted to:

Walter Francis,Product Manager
Registration Division
Antimicrobial Branch H7505C
Office of Pesticide Programs
U,S. Environmental Protection Agency
401 - M St. S.W.
Washington, D.C. 20460
RE: Potassium Bromide

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DATA CALL-IN NOTICE

CERTIFIED MAIL

APR 21 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

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 A through E; or

2. why you believe you are exempt from the requirements listed in this Notice and in Attachment C, 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 B, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment D).

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 (expiration date 12-31-92).

This Notice is divided into six sections and five 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:

Attachment A - Data Call-In Chemical Status Sheet
Attachment B - Data Call-In Response Form
Attachment C - Requirements Status And Registrant's Response Form
Attachment D - List Of All Registrants Sent This Data Call-In Notice
Attachment E - Cost Share And Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in Attachment C, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional 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 Attachment C, Requirements Status and Registrant's Response Form, 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 (tel: 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, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

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 160.3(a)(6)].

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice 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

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose 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 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.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, Attachment B and the Requirements Status and Registrant's Response Form, Attachment C. The Data Call-In Response Form must be submitted as part of every response to this Notice. 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 Registrant'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 identified in Attachment A.

1. 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 the Data Call-In Response Form. If you choose this option, this is the only form 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.

2. 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, 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 on the Requirements Status and Registrant's Response Form. 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 and Emergency Response Branch, Registration Division, (703) 557-2126.

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, must bear an amended label.

3. 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:

a. 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;

b. 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

c. 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 B 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 product specific data.

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 the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in 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.

4. Satisfying the Data Requirements of this Notice There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and option 6b and 7 on the Data Call-In Response Form. If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

5. Request for Data Waivers. Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on 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.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), 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 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. A 90-day progress report must be submitted for all studies. 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 your 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 E. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a costsharing 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 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 burdens 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 will normally 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(j) " '[r]aw 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(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also 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 are usually 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 A. 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 should also 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.

III-D REQUESTS FOR DATA WAIVERS

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 inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver -- Option 8 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 as low volume pesticides 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:

a(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.

b. 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.

c. 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.

d(i). 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.

ii. 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.

e. 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.

f. 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.

2. Request for Waiver of Data -- Option 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 corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also 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 do not apply 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.

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:

a. 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;

b. fulfill the commitment to develop and submit the data as required by this Notice; or

c. 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 would generally 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 must also 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 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 listed in Attachment A, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Attachment B) and a completed Requirements Status and Registrant's Response Form (Attachment C) and any other documents required by this Notice, and should be submitted to the contact person identified in Attachment A. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely,

Allan S. Abramson

Allan S. Abramson, Acting Director
Special Review and
Reregistration Division

Attachments

A - Data Call-In Chemical Status Sheet
B - Data Call-In Response Form
C - Requirements Status and Registrants Response Form
D - List of Registrants Receiving This Notice
E - Cost Share and Data Compensation Forms

SPECIFIC INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM

Product Specific Data

This form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1-4 will 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.

INSTRUCTIONS FOR COMPLETING THE "DATA CALL-IN RESPONSE" FORM FOR **PRODUCT SPECIFIC DATA**

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes.**" If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)** and complete and submit the "**Generic Data Exemption" form**; you would **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.

Item 7a. 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.**" 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. See Item 6** with regard to identical products and **data exemptions.**

Items 8-11. **Self-explanatory.**

NOTE: **You may provide additional information** that does not fit **on this form** in a signed letter that accompanies this **form.** 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.

ATTACHMENT B

PRODUCT SPECIFIC DATA CALL-IN RESPONSE FORM

EPA

United States Environmental Protection Agency
Washington, D.C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
MONSANTO CHEMICAL COMPNAY **800 N. LINDBERGH BLVD.** **ST. LOUIS, MO. 63167**	**0342 Potassium Bromide** Chemical # and Name **013903** **Potassium Bromide**	**PRODUCT SPECIFIC** APR 21 1991

4. EPA Product Registration Numbers	5. I wish to cancel this product registration voluntary.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA Registration numbers listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrants' Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrants' Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrants' Response."
524-378		**N.A.**	**N.A.**		

8. Certification

I certify that the statements that I have made on this form and all attachments thereto 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 and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

EPA

United States Environmental Protection Agency
Washington, D.C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
DIVERSEY WYANDOTTE 1532 BIDDLE AVE. WYANDOTTE, MI. 48192	0342 Potassium Bromide Chemical # and Name 013903 Potassium Bromide	PRODUCT SPECIFIC APR 2 1 1991

4. EPA Product Registration Numbers	5. I wish to cancel this product registration voluntary.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA Registration numbers listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrants' Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrants' Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrants' Response."
875-42		N.A.	N.A.		

8. Certification

I certify that the statements that I have made on this form and all attachments thereto 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 and Title of Company's Authorized Representative

9. Date

10. Name of Company Contact

11. Phone Number

ATTACHMENT C

REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM

EPA

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANTS RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
DIVERSEY WYANDOTTE
1532 BIDDLE AVE.
WYANDOTTE, MI. 48192

2. Case # and Name **0342 Potassium Bromide**
Chemical # and Name
013901 Potassium Bromide
EPA Reg. No. **875-42**

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 875-RD-440
APR 21 1991

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1 yr	Progress Reports 2 yrs	Progress Reports 3 yrs	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	Product identity					ALL	EP	8 mos.	
61-2(a)	Begin. mat. & mfg. proc.					ALL	EP	8 mos.	
61-2(b)	Discussion of impurities					ALL	EP	8 mos.	
62-1	Preliminary analysis					ALL	EP	8 mos.	
62-2	Certification of limits					ALL	EP	8 mos.	
62-3	Analytical method					ALL	EP	8 mos.	
63-2	Color					ALL	EP	8 mos.	
63-3	Physical state					ALL	EP	8 mos.	
63-4	Odor					ALL	EP	8 mos.	
63-5	Melting point					ALL	EP	8 mos.	
63-6	Boiling point					ALL	EP	8 mos.	
63-7	Density, bulk density or sp. gr.					ALL	EP	8 mos.	
63-8	Solubility					ALL	EP	8 mos.	
63-9	Vapor pressure					ALL	EP	8 mos.	
63-10	Dissociation constant					ALL	EP	8 mos.	
63-11	Oct/Water partition coef.					ALL	EP	8 mos.	
63-12	pH					ALL	EP	8 mos.	
63-13	Stability					ALL	EP	8 mos.	

10. Certification
I certify that the statements that I have made on this form and all attachments thereto 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 and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

EPA

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANTS RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
DIVERSEY WYANDOTTE
1532 BIDDLE AVE.
WYANDOTTE, MI. 48192

2. Case # and Name
0342 Potassium Bromide
Chemical # and Name **013903 Potassium Bro.**
EPA Reg. No. **875-42**

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 875-RD-440
APR 21 1991

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1 yr	Progress Reports 2 yrs	Progress Reports 3 yrs	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-14	Oxidizing/Reducing Action					ALL	EP	8 mos.	
63-15	Flammability					ALL	EP	8 mos.	
63-16	Explodability					ALL	EP	8 mos.	
63-17	Storage stability					ALL	EP	8 mos.	
63-18	Viscosity					ALL	EP	8 mos.	
63-19	Miscibility					ALL	EP	8 mos.	
63-20	Corrosion characteristics					ALL	EP	8 mos.	
63-21	Dielectric breakdown voltage					ALL	EP	8 mos.	
81-1	Acute oral tox. rat					ALL	EP	8 mos.	
81-2	Acute dermal tox. rabt./rat/g.pig					ALL	EP	8 mos.	
81-3	Acute inhal. tox rat					ALL	EP	8 mos.	
81-4	Primary eye irritation-rabbit					ALL	EP	8 mos.	
81-5	Primary dermal irritation					ALL	EP	8 mos.	
81-6	Dermal sensitization					ALL	EP	8 mos.	

Initial to indicate certification as to information on this page **Date**
(full text of certification is on page one)

EPA

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANTS RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
MONSANTO CHEMICAL COMPANY
800 N. LINDBERGH BLVD.
ST. LOUIS, MO. 63167

2. Case # and Name **0342 Potassium Bromide**
Chemical # and Name
013901 Potassium Bromide
EPA Reg. No. **524-378**

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 524-RD-441 APR 21 1991

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1 yr	2 yrs	3 yrs	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	Product identity					ALL	EP	8 mos.	
61-2(a)	Begin. mat. & mfg. proc.					ALL	EP	8 mos.	
61-2(b)	Discussion of impurities					ALL	EP	8 mos.	
62-1	Preliminary analysis					ALL	EP	8 mos.	
62-2	Certification of limits					ALL	EP	8 mos.	
62-3	Analytical method					ALL	EP	8 mos.	
63-2	Color					ALL	EP	8 mos.	
63-3	Physical state					ALL	EP	8 mos.	
63-4	Odor					ALL	EP	8 mos.	
63-5	Melting point					ALL	EP	8 mos.	
63-6	Boiling point					ALL	EP	8 mos.	
63-7	Density, bulk density or sp. gr.					ALL	EP	8 mos.	
63-8	Solubility					ALL	EP	8 mos.	
63-9	Vapor pressure					ALL	EP	8 mos.	
63-10	Dissociation constant					ALL	EP	8 mos.	
63-11	Oct/Water partition coef.					ALL	EP	8 mos.	
63-12	pH					ALL	EP	8 mos.	
63-13	Stability					ALL	EP	8 mos.	

10. Certification
I certify that the statements that I have made on this form and all attachments thereto 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 and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

EPA

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANTS RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
MONSANTO CHEMICAL COMPANY
800 N. LINDBERGH BLVD.
ST. LOUIS, MO. 63167

2. Case # and Name
0342 Potassium Bromide
Chemical # and Name **013903 Potassium Bro.**
EPA Reg. No. **524-378**

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 524-RD-441
APR 21 1991

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1 yr	2 yrs	3 yrs	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-14	Oxidizing/Reducing Action					ALL	EP	8 mos.	
63-15	Flammability					ALL	EP	8 mos.	
63-16	Explodability					ALL	EP	8 mos.	
63-17	Storage stability					ALL	EP	8 mos.	
63-18	Viscosity					ALL	EP	8 mos.	
63-19	Miscibility					ALL	EP	8 mos.	
63-20	Corrosion characteristics					ALL	EP	8 mos.	
63-21	Dielectric breakdown voltage					ALL	EP	8 mos.	
81-1	Acute oral tox. rat					ALL	EP	8 mos.	
81-2	Acute dermal tox. rabt./rat/g.pig					ALL	EP	8 mos.	
81-3	Acute inhal. tox rat					ALL	EP	8 mos.	
81-4	Primary eye irritation-rabbit					ALL	EP	8 mos.	
81-5	Primary dermal irritation					ALL	EP	8 mos.	
81-6	Dermal sensitization					ALL	EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one) **Date**

ATTACHMENT D

LIST OF REGISTRANTS RECEIVING THIS NOTICE

List of all Registrants Sent this Data Call-In Notice

Case # and Name

0342 Potassium Bromide

Chemical # and Name

013903 Potassium Bromide

Company Name	Address
DIVERSEY WYANDOTTE	1532 BIDDLE AVE. WYANDOTTE, MI. 48192
MONSANTO CHEMICAL	800 N. LINDBERGH BLVD. ST.LOUIS, MO. 63167

ATTACHMENT E

COST SHARE AND DATA COMPENSATION FORMS

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
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	
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)

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistration 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)(D) 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:

_____

[ ] 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)(D) 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 sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

US Environmental Protection Agency
Washington, DC 20460

EPA

Product Specific Data Report

Registration Standard for:	EPA Registration Number	Form Approved OMB #2070-0057 Expires 11-30-89

Registration Guideline No.	Name of Test	Testing not required for my product listed above *(Check below)*	I am complying with Data Requirements by -		(For EPA Use Only) Accession numbers assigned
			Citing MR ID No.	Submitting Data *(Attached)* *(Check below)*	
Sec. 158.120 Product Chemistry					
61-1	Identity of ingredients				
61-2 (a)	Statement of composition				
61-2 (b)	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion Characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.135 Toxicology					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit /rat/g.pig				
81-3	Acute inhalation toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

Certification

I certify that the statements I have made on this form and all attachments thereto 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.

Typed Name and Title	Signature	Date