United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510C)

EPA 739-R-06-001
January 2006

Reregistration Eligibility Decision for Sodium Carbonate; Weak Mineral Bases

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (EPA) has completed its review of the available data on the antimicrobial, sodium carbonate. The Reregistration Eligibility Decision (RED) was approved and signed on January 26, 2006.

Based on the Agency's review of sodium carbonate, the RED and supporting documentation are now being published. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting documents for sodium carbonate will be available to the public in EPA's Pesticide Docket EPA-HQ-OPP-2006-0028 at http://www.regulations.gov.

Please note that the attached RED document pertains only to sodium carbonate and presents the Agency's conclusions on the dietary, occupational and ecological risks posed by exposure to sodium carbonate alone. This document also identifies product-specific data for which the Agency intends to issue Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. At this time, generic confirmatory data are required. For product-specific DCIs, the first set of required responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that sodium carbonate is eligible for reregistration. Sections IV and V of this RED document describe product-specific and generic data requirements.

If you have questions pertaining to this document, please contact the Chemical Review Manager, Rebecca Miller, at (703) 305-0012. For questions regarding product reregistration and or the product DCI that accompanies this document, please contact Marshall Swindell at (703) 308-6341.

Sincerely,

Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY DECISION

for

Weak Mineral Bases; Sodium Carbonate

List 4D

Case No. 4066

Approved By:

Frank T. Sanders
Director, Antimicrobials Division
January 26, 2006

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
AD	Antimicrobials Division
ADTC	Antimicrobials Division Toxicology Endpoint Selection Committee
a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
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
EPISUIT	Environmental Protection Agency, Estimation Program Interface Suite
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
Fl. oz.	Fluid Ounces
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FWS	United States Fish and Wildlife Services
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography
GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
HPV	High Production Volume
IDS	Incident Data System
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that

	can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NMFS	National Marine Fishery Service
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NPTN	National Pesticide Telecommunications Network
NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	Pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PCC	National Poison Control Center
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/ EXAMS	Tier II Surface Water Computer Model
Q_1^*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose

RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SAR	Structure Activity Relationship Assessment
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
μg/g	Micrograms Per Gram
μg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency (EPA or the Agency) has completed its human health and environmental review for the reregistration case 4066; Weak Mineral Bases, and is issuing its risk management decision. Case 4066 contains four active ingredients (a.i.); however, sodium carbonate is the only active ingredient in this case with active product registrations that are eligible to undergo the reregistration process since other product registrations were previously voluntarily cancelled. For that reason, this Reregistration Eligibility Decision (RED) document will focus on sodium carbonate. The Agency has decided that sodium carbonate is eligible for reregistration. This RED addresses the active use of sodium carbonate as a fungicide for use as hard surface disinfectants and sanitizers in institutional and residential settings. There are currently two registrations that contain sodium carbonate as an active ingredient. Sodium carbonate is used as an inert in 680 active product registrations. These inert uses were previously assessed by the Agency and found not be of concern. In addition, sodium carbonate is regulated by the Food and Drug Administration (FDA) as a GRAS (generally recognized as safe; 21 CFR 184.1742) substance for use as an antioxidant, curing and pickling agent, flavoring agent and adjuvant, pH control agent, and processing aid. In addition, EPA has listed sodium carbonate as a pesticide that is considered safe for all uses, active and inert as listed in 40 CFR 180.2 (68 FR 18552, Apr. 16, 2003). It has a tolerance exemption in 40 CFR 180.1234 (41 FR 4537, Jan. 30, 1976) and was recently reassessed by the Agency in 2002.

Overall Risk Summary

Hazard Profile/Human Health Risk

The Agency recently assessed the pesticidal uses of sodium carbonate as part of an evaluation of the mineral acids (hydrochloric, carbonic, phosphoric, and sulfuric; EPA July 2002). The salts of carbonic acid risk assessment, which included sodium carbonate, found that 'there is no available information on sodium carbonate indicative of a human health hazard resulting from the EPA-regulated uses as well as the FDA GRAS uses to the general public or any population subgroup. No additional information is needed to assess their safety.' The Agency has determined that sodium carbonate poses no risks of concern with respect to human exposure when used according to regulation. This risk assessment provides the basis for the sodium carbonate RED decision.

The "no risk" finding is based on various conclusions of the FAO/WHO (Food and Agriculture Organization/World Health Organization) Joint Expert Committee on Food Additives, conclusions of various FDA GRAS assessments, information previously used by the Agency as part of the reregistration process, and other information available on government websites. The 2002 Agency assessment found that there are no endpoints of concern for repeated oral, dermal, or inhalation exposure to sodium carbonate based on the available toxicity data, an understanding of the human body's ability to metabolize this chemical, and the evaluations previously conducted by FDA and WHO. There was no evidence of increased susceptibility in a developmental toxicity study. Sodium carbonate is a FDA GRAS substance (21 CFR 184.1742). Further, the Agency considers sodium carbonate to be a safe pesticide (40 CFR 180.2). Therefore a quantitative human health risk assessment was not conducted. There are no

indications of special sensitivity of infants or children resulting from exposure to sodium carbonate; therefore, the FQPA Safety Factor was removed (i.e., reduced to 1X) for sodium carbonate.

Environmental Risk

The Agency's assessment concludes that the constituents of the salts of carbonic acid, including sodium carbonate, are naturally occurring and commonly found in soil and water in the environment suggesting that releasing low levels of these chemicals would not be expected to adversely effect wildlife or water resources.

The Agency has no risk concerns for sodium carbonate with respect to non-target organisms. The Agency expects no effects to listed species or critical habitat and therefore makes a "no effect" determination for sodium carbonate.

Regulatory Decision

The Agency has determined that sodium carbonate is eligible for reregistration.

Summary of Mitigation Measures

Because no risks of concern were identified, no mitigation measures are needed for sodium carbonate.

Data Requirements

Additional product-specific data are required to complete the reregistration of sodium carbonate as described in Section V of this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks 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 or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. This document presents the Agency's human health and ecological risk assessments and the Reregistration Eligibility Decision (RED) for sodium carbonate.

Sodium carbonate is used as a fungicide in products that are hard surface disinfectants and sanitizers for use in institutional and residential settings. Sodium carbonate is also used as an inert ingredient in many pesticide products. These inert uses were previously assessed by the Agency and found not be of concern.

The Agency has concluded that the FQPA Safety Factor for sodium carbonate should be removed (equivalent to 1X) as there are no endpoints of concern for repeated oral, dermal, or inhalation exposure to sodium carbonate based on the available toxicity data, an understanding of the human body's ability to metabolize this chemical, and the evaluations previously conducted by FDA and WHO. There was no evidence of increased susceptibility in a developmental toxicity study and there are no indications of special sensitivity of infants or children resulting from exposure to sodium carbonate.

Any risks summarized in this document are those that result only from the use of the active ingredient sodium carbonate. FQPA requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for sodium

carbonate and any other substances. Sodium carbonate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that sodium carbonate has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of sodium carbonate. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for sodium carbonate referenced in this RED. The risk assessments and related addenda are not included in this document, but are available in the Public Docket at http://www.regulations.gov.

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of sodium carbonate and its regulatory history. Section III, Summary of sodium carbonate risk assessment, gives an overview of the human health and environmental assessments, based on the information available to the Agency. Section IV, Risk Management, Reregistration and Tolerance Reassessment, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

II. CHEMICAL OVERVIEW

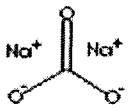
A. Regulatory History

Sodium carbonate is registered as an active ingredient fungicide that is used as a neutralizer and buffering agent in industrial and manufacturing processes. Sodium carbonate currently is an active ingredient in two products that are used as hard surface disinfectants and sanitizers in institutional and residential settings. In addition to sodium carbonate, these 2 products contain other active ingredients that are registered with the Agency as disinfectants and sanitizers. As an inert, sodium carbonate is found in 680 current registrations.

Sodium carbonate was first registered March 10, 1964 as an active ingredient. The Food and Drug Administration assessed the toxicity of carbonates and bicarbonates in 1975 and listed sodium carbonate as generally recognized as safe (GRAS).

B. Chemical Identification

Na_2CO_3



Common Name:	Washing Soda
Chemical Name:	Sodium carbonate
Other Name:	Soda ash
Chemical Family:	Inorganic carbonates
Case Number:	4066
CAS Registry Number:	497-19-8
OPP Chemical Code:	073506
Molecular weight:	105.99
Empirical Formula:	Na_2CO_3
Basic Manufacturers:	Speer Products Inc., Medical Chemical Corp., Siamons International Inc.

C. Use Profile

The following section provides information on the currently registered uses of the sodium carbonate product. Included is an overview of the use sites and application methods of sodium carbonate. Please refer to Appendix A for a comprehensive table of uses of sodium carbonate eligible for reregistration.

Type of Pesticide: Fungicide

Target Organism(s): Animal pathogenic fungi

Use Sites: Includes the following premises: household, boat, food processing plant, hospital, commercial, institutional, bathroom.

Use Classification: Sodium carbonate is categorized as a general use pesticide.

Formulation Types: The sodium carbonate products are formulated as liquid soluble concentrates.

Application Rates/Methods: In households, boats, commercial and institutional settings, hospitals and bathrooms; 2 ounces of solution per 1 gallon of water is desired. The solution can then be applied to walls, floors and other hard non-porous surfaces with a cloth or mop.

In food processing plants, 2.8 ounces per 5 gallons of water (200 ppm of active quaternary) is desired.

For hospital instruments, clean instruments thoroughly and rinse. Submerge article in solution for at least 10 minutes.

Further information and restrictions to these application rates and methods can be found in Appendix A.

III. SUMMARY OF SODIUM CARBONATE RISK ASSESMENTS

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for sodium carbonate. While the risk assessments and related addenda are not included in this document, they are available at http://www.regulations.gov. Hard copies of these documents may be found in the OPP public docket under docket number EPA-HQ-OPP-2006-0028. The OPP public docket is located in Room 119, Crystal Mall II, 1801 Bell Street, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The human health risk assessment focused on the ammonium, sodium, potassium, and magnesium salts of carbonic acid as a group due to their chemical similarities. However, these salts all contain either the bicarbonate ion (HCO_3^{-1}) or the carbonate ion (CO_3^{-2}), and thus share some common chemistries. A major focus of the assessment is the work previously performed by FDA in assessing the safety of these chemicals as food additives.

A. Human Health Risk Assessment

1. Toxicity of Sodium carbonate

A brief overview of the toxicity of sodium carbonate is presented below. Further information on the toxicity of sodium carbonate can be found in the 'Decision Document for Salts of Carbonic Acid,' issued by the Inert Ingredient Focus Group (2002), which are available at http://www.regulations.gov.

The Agency has reviewed all toxicity studies submitted for sodium carbonate and has determined that the toxicological database is sufficient for reregistration. The toxicological database for sodium carbonate is currently comprised of published and unpublished studies either submitted to the Agency or obtained directly from published open literature.

Upon reviewing the available toxicity information, the Agency has concluded that there are no endpoints of concern for oral, dermal or inhalation exposure to sodium carbonate. Sodium carbonate is a FDA GRAS substance and the Agency considers it safe for all active and inert uses (40 CFR 180.2). The FDA Assessment on which these conclusions are largely based is titled "Evaluation of the Health Aspects of Carbonates and Bicarbonates as Food Ingredients" (1975).

In the 1975 FDA Assessment acute, short-term, and developmental toxicity studies and mutagenicity studies were evaluated for potassium carbonate and bicarbonate. For sodium carbonate and bicarbonate acute, short-term, and developmental toxicity studies, and mutagenicity and metabolism studies were evaluated. No chronic studies were identified. Among the key findings of the assessment as pertains to toxicity were the following:

"The results of acute toxicity and short-term feeding experiments are not readily extrapolated in determining toxic levels for carbonate salts consumed by humans. Treatment of gastric or peptic ulcers in patients with large amounts of carbonate salts in various forms has been utilized for many years and only rarely have deleterious results of changes of acid-base balance been reported. When the human respiratory and renal functions are normal, the mechanisms for disposing of bicarbonate intake in large amounts through excretion appear to be highly efficient."

"There is no evidence in the available information on ... potassium carbonate, potassium bicarbonate, sodium carbonate, [or] sodium bicarbonate ... that demonstrates or suggests reasonable grounds to suspect a hazard to the public when used at levels that are now current or that might reasonably be expected in the future."

Below is a toxicological profile for sodium carbonate.

Table 1: Toxicological Profile

Chemical	Toxicity	Other Information
Sodium Carbonate	▪ Oral LD_{50}: rat 2880 to 4090 mg/kg; ▪ Inhalation LC_{50}: rat 2300 mg/m^3 (2 hour); ▪ Inhalation LC_{50}: mouse 1200 mg/m^3 (2 hour); ▪ Skin irritation: mild; ▪ Eye irritation : mild-moderate; ▪ Aqueous solutions are strongly alkaline; ▪ Concentrated solutions tend to produce local necrosis of mucous membranes; ▪ Sensitivity reactions may occur from repeated topical use; ▪ Ingestion of large quantities may produce corrosion of GI tract, vomiting, diarrhea, circulatory collapse, death; ▪ Dusts of vapors of sodium carbonate may cause irritation of mucous membranes with subsequent coughing and shortness of breath; ▪ A primary irritant at concentrations below 15% and caustic at concentrations above approximately 15%, depending on contact time, areas of exposure, and other factors; ▪ Developmental toxicity test on gestation days 6 to 15 in rats, mice and rabbits at levels of 3.4 to 340 mg/kg: no effects on nidation or survival of the dams or fetuses.	Common name: washing soda

The available toxicity data indicates that the human body metabolizes carbonates, ammonium, magnesium, potassium, and sodium ions through well-understood pathways. In fact, the metals are necessary human nutrients. Given the long history of safe use, the available toxicity data, and an understanding of the human body's ability to metabolize these chemicals, and the evaluations by FDA and WHO, the IIFG believes that ammonium, potassium, sodium and magnesium carbonate salts are of low oral toxicity.

Carcinogenicity Classification
Sodium carbonate is not a known carcinogen.

Mutagenicity Potential
There is no evidence that sodium carbonate has mutagenic potential.

2. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10X) to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, residential exposures, or to compensate for an incomplete database. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for sodium carbonate as there are no endpoints of concern for repeated oral, dermal, or inhalation exposure to sodium carbonate based on the available toxicity data, an understanding of the human body's ability to metabolize this chemical, and the evaluations previously conducted by FDA and WHO. There was no evidence of increased susceptibility in a developmental toxicity study and there are no indications of special sensitivity of infants or children resulting from exposure to sodium carbonate.

3. Population Adjusted Dose (PAD)

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor (SF). This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern. Since toxicological endpoints for the risk assessment were not identified based on the available data, RfDs and PADs have not been calculated for sodium carbonate.

4. Dietary and Residential Risk Assessment

Dietary and residential exposure could potentially occur from the use of sodium carbonate as an active ingredient in food-contact sanitizing solutions and hard surface disinfectants and as an inert ingredient used on agricultural crops. However, risk estimates have not been calculated for potential exposures to sodium carbonate when used as an active ingredient on food, in drinking water, or as a result of use in residential settings because there are no toxicological endpoints of concern according to a review of the available toxicity information. The inert uses were previously reviewed by the Agency and found not be of concern as well.

There are no labeled uses for sodium carbonate that would impact surface or groundwater supplies. The Agency's assessment concludes that the constituents of the salts of carbonic acid, including sodium carbonate, are commonly found in soil and water in the environment suggesting that releasing low levels of these chemicals would not normally be expected to adversely effect wildlife or water resources.

Given the widespread occurrence of these chemicals in the existing food supply, the amounts that can be applied as a disinfectant or sanitizer or as an inert to food as a result of a use in a

pesticide product would not be expected to significantly increase the existing amounts in the food supply. There is no available information on any of the chemicals considered in this document indicative of a human health hazard resulting from the EPA-regulated uses as well as the FDA GRAS uses to the general public or any population subgroup.

5. Aggregate Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information"(FFDCA, Section 408(b)(2)(A)(ii)). Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide and other non-occupational sources of exposure.

Toxicological endpoints for the sodium carbonate risk assessment were not identified based on the available data and therefore an aggregate risk assessment was not conducted for sodium carbonate.

6. Occupational Exposure

The occupational exposure assessment for sodium carbonate addresses potential exposures and risks to humans who may be exposed in "occupational settings." An occupational risk assessment is required for an active ingredient if certain toxicological criteria are triggered and there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For sodium carbonate there is potential for exposure; however, there are no toxicological endpoints of concern. The toxicity of sodium carbonate derives from the irritation and caustic effects. Labeling of products serves to protect against irritation and caustic effects.

7. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers (PCC), the Agency's Office of Pesticide Program's Incident Data System (IDS), the California Pesticide Illness Surveillance Program, and the National Pesticide Telecommunications Network (NPTN). In the data sources available to the Agency, no reports of serious illness have been associated with human exposure to sodium carbonate.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for sodium carbonate use sites and any associated uncertainties. For further information concerning all aspects about the environmental risk assessment refer to the sodium carbonate risk assessment (Decision Document for Salts of Carbonic Acid, Inert Ingredient Focus Group,2002) available http://www.regulations.gov.

1. Environmental Fate and Ecotoxicity Assessment/Characterization

In general, the constituents of the salts of carbonic acid are commonly found in soil and water in the environment suggesting that releasing low levels of these chemicals would not normally be expected to adversely effect wildlife or water resources. Large unintended releases may adversely affect wildlife and water resources either directly or indirectly. Direct effects may result from exceeding toxicity thresholds. Indirect effects may be manifested through disrupting ecosystems through altering pH or increasing availability of algal nutrients.

The magnitude of the pH changes, and thus the magnitude of effects, would depend on a number of factors including the amount of material released and the buffering capacity of the exposed soil or water. Normal aquatic pHs range from 5 to 9. EPA's Office of Water recommended water quality criteria for pH are 6.5 to 9 for freshwater and 6.5 to 8.5 for saltwater. At higher or lower pH aquatic life is expected to be adversely impacted. In addition, rapid changes in pH can also be detrimental to aquatic life.

The sodium salts of carbonic acid should dissociate in water resulting in a positively charged (cation) metal in solution. Dissociation is frequently dependent on pH, with lower (more acidic) pHs resulting in higher levels of dissociation and greater solubility. Aquatic toxicity of metals varies with the species of metal and its concentration. Metals do not degrade and thus are permanent in the environment. They are likely to dissipate by being sequestered in soil, sediment, and plants.

2. Risk to Threatened and Endangered Species

Due to the low likelihood of exposure and low toxicity of sodium carbonate, the Agency expects no effects to listed species or critical habitat and therefore the Agency makes a "No Effect" determination for sodium carbonate.

IV. RISK MANAGEMENT, REREGISTRATION AND TOLERANCE REASSESMENT DECSION

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of generic (i.e., active ingredient-specific) data to support reregistration of products containing sodium carbonate as an active ingredient. The Agency has completed its review of the generic data and has determined that the data are sufficient to support reregistration of all products containing sodium carbonate.

The Agency has completed its assessment of the dietary, residential, occupational and ecological risks associated with the use of pesticide products containing the active ingredient sodium carbonate. Based on a review of the data and other available information for the active ingredient, sodium carbonate, the Agency has sufficient information on the human health and ecological effects of sodium carbonate to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that sodium carbonate containing products are eligible for reregistration. Appendix A summarizes the uses of sodium carbonate that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of sodium carbonate and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

B. Public Comments and Responses

Risk assessments for sodium carbonate were not issued for public comment per the Agency's public participation process because no toxicological endpoints were identified, and as such, these assessments were qualitative in nature. To ensure that an opportunity is presented to the public to comment on the risk assessments and risk management decisions for sodium carbonate, the Agency will implement a public comment period on the sodium carbonate RED document.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA has concluded that there are no endpoints of concern for oral, dermal, or inhalation exposure to sodium carbonate based on a review of the available toxicity information. The Agency has concluded that the established tolerance exemption for sodium carbonate meets the FQPA safety standards and that the risk from dietary (food sources only) exposure is within the "risk cup." An aggregate assessment was not conducted for exposures through food, drinking water and residential exposure since toxicological endpoints for the risk assessment of sodium carbonate were not identified based on the available data. The Agency has determined that the aggregate exposure for food and residential uses are not of concern. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children.

b. Determination of Safety to U.S. Population

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with sodium carbonate. The Agency determined in the 2002 EPA risk assessment that the established tolerance exemption for sodium carbonate meets the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of sodium carbonate as an active ingredient. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices, exposure scenarios and environmental behavior of sodium carbonate.

Because no toxicological endpoints were identified for sodium carbonate, a qualitative risk assessment was conducted. Based on this assessment, risks are not of concern for sodium carbonate.

c. Determination of Safety to Infants and Children

The EPA has determined that the established tolerance exemption for sodium carbonate meets the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, and that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers the toxicity, use practices and environmental behavior of sodium carbonate as noted above for the general population. The safety determination for infants and children also takes into consideration the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of sodium carbonate residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of sodium carbonate, the Agency considered the completeness of the

hazard database for developmental and reproductive effects, the nature of the effects observed and other information.

The FQPA Safety Factor has been removed (i.e., reduced to 1X) as there are no endpoints of concern for repeated oral, dermal, or inhalation exposure to sodium carbonate based on the available toxicity data, an understanding of the human body's ability to metabolize this chemical, and the evaluations previously conducted by FDA and WHO. There was no evidence of increased susceptibility in a developmental toxicity study. Sodium carbonate is a FDA GRAS substance (21 CFR 184.1742). Further, the Agency considers sodium carbonate to be a safe pesticide (40 CFR 180.2). Therefore a quantitative human health risk assessment was not conducted. There are no indications of special sensitivity of infants or children resulting from exposure to sodium carbonate.

d. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, use FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and or testing protocols being considered under the EDSP have been developed, sodium carbonate may be subject to additional screening and or testing.

e. Cumulative Risks

Risks summarized in this document are those that result only from the use of sodium carbonate as an active ingredient. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residue and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which the EPA has followed a cumulative risk approach based on a common mechanism of toxicity, the EPA has not made a common mechanism of toxicity finding for sodium carbonate. For further information regarding the EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, refer to the EPA's website at: http://www.epa.gov/pesticides/cumulative/.

2. Tolerance Reassessment Summary

a. Tolerance Exemptions and Tolerance Reassessment

A tolerance exemption for residues of sodium carbonate is established under 40 CFR 180.1234 (41 FR 4537, Jan. 30, 1976). The Agency considers sodium carbonate a safe pesticide when used as an active or inert ingredient under 40 CFR 180.2 (68 FR 18552, Apr. 16, 2003) and it has been deemed a GRAS substance by the FDA (21 CFR 184.1742). The tolerance exemption for sodium carbonate was reassessed by the Agency in 2002.

b. Codex Harmonization

Currently there are no codex MRLs established for sodium carbonate.

D. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the use of sodium carbonate as an active ingredient. The Agency feels there is reasonable certainty of no harm resulting from exposure to sodium carbonate as an active ingredient to the general population and to infants and children in particular. The Agency also believes there is a low toxicity concern for ecological effects. As a result of the expected low risk for toxicity and low human and environmental exposure rates from sodium carbonate, the Agency determined that a qualitative approach to assessing human health risks and ecological risks from exposure to sodium carbonate was appropriate. Therefore, no mitigation measures are necessary at this time.

1. Listed Species Considerations

a. The Endangered Species Act

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species" (50 C.F.R. § 402.02).

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2), the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may (directly or indirectly) significantly reduce the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species

LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If it is determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (*Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations*, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment and are considered to fall under a "no effect" determination. Due to the low likelihood of exposure and the low toxicity of sodium carbonate, the Agency expects no effects to listed species or critical habitat and therefore makes a "No Effect" determination for this chemical.

b. General Risk Mitigation

Sodium carbonate end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing sodium carbonate specific to federally listed threatened and endangered species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all threatened and endangered species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting threatened and endangered species risk mitigation measures, the more stringent measure(s) should be adopted.

2. Labeling

a. Label Amendment

Currently, no label amendments are necessary in order for sodium carbonate products to be eligible for reregistration.

V. WHAT REGISTRANTS NEED TO DO

The Agency has determined that sodium carbonate is eligible for reregistration. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring product-specific data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or to request time extension and or waiver requests with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

The registrant needs to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. Completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

2. Submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. Two copies of the confidential statement of formula (EPA Form 8570-4);

2. A completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

3. Five copies of the draft label incorporating all label amendments outlined in Table 13 of this document;

4. A completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

5. If applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

6. The product-specific data responding to the PDCI.

Please contact Marshall Swindell at (703) 308-6341 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PDCI/PRB)
Marshall Swindell
US EPA (7510C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI/PRB)
Marshall Swindell
Office of Pesticide Programs (7510C)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

A. End-Use Products

1. Additional Product-Specific Data and Efficacy Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate Product-Specific Data Call-In (PDCI), outlining specific data requirements.

Efficacy data are required to ensure that the described labeled use of sodium carbonate as a disinfectant and sanitizer in end-use products is accurate and effective. The Registrant must submit as efficacy data to the Agency, Guideline No. 810.2100 (m)(2), *AOAC Germicidal and Detergent Sanitizers Method Study* (Reg. No. 875-90) for sodium carbonate.

VI. APPENDICES

Appendix A: Use Patterns Eligible for Deregistration

Use Site	Formulation	Application Rate (Range)	No. of Applications	Use Limitations
Food Handling/Storage Establishments Premises and Equipment				
Food processing equipment and food contact items	11715-34 – ready to use solution	2.8 ounces per 5 gallons of water (200 ppm of active quaternary)	Information not given on label	None given
Commercial, Institutional and Industrial Premises and Equipment				
Commercial and Institutional (Premises & Equipment)	11715-34 – ready to use solution	2 ounces per gallon of water. For best results, use Magic Guard with a cloth or mop and apply to walls, floors and other hard surfaces.	Information not given on label	None given
Residential and Public Access Premises				
Household (Premises & Contents)	11715-34 – ready to use solution	2 ounces per gallon of water. For best results, use Magic Guard with a cloth or mop and apply to walls, floors and other hard surfaces.	Information not given on label	None given

Medical premises and equipment				
Hospital (Premises and Materials)	1. 11715-34 – ready to use solution	1. 2 ounces per gallon of water. For best results, use Magic Guard with a cloth or mop and apply to walls, floors and other hard surfaces.	1. Information not given on label	1. None given

	2. 15136-10 – ready to use solution	2. Clean instruments thoroughly and rinse. Submerge article in solution for at least 10 minutes.	2. Information not given on label	2. This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. Not for sterilization of instruments contaminated with spore-bearing pathogens, viral hepatitis, tuberculosis, or rusty instruments. Contaminated instruments and hypodermic needles should always be sterilized by autoclaving. For technical use of hospitals, medical, dental and veterinary professionals only.

Appendix B: Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) CHEMISTRY				
830.1550	61-1	Product Identity and Composition	All	Open literature
830.1600 830.1620 830.1650	61-2A	Starting Materials and Manufacturing Process	All	Open literature
830.1670	61-2B	Formation of Impurities	All	Open literature
830.1700	62-1	Preliminary Analysis	All	Open literature
830.1750	62-2	Certification of Limits	All	Open literature
830.1800	62-3	Analytical Method	All	Open literature
830.6302	63-2	Color	All	Open literature
830.6303	63-3	Physical State	All	Open literature
830.6304	63-4	Odor	All	Open literature
830.7200	63-5	Melting Point	All	Open literature
830.7220	63-6	Boiling Point	All	Open literature
830.7300	63-7	Density	All	Open literature

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7840 830.7860	63-8	Solubility	All	Open literature
830.7950	63-9	Vapor Pressure	All	Open literature
830.7370	63-10	Dissociation Constant in Water	All	Open literature
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)	All	Open literature
830.7000	63-12	pH	All	Open literature
830.6313	63-13	Stability	All	Open literature
830.6314	63-14	Oxidizing/Reducing Action	All	Open literature
830.6315	63-15	Flammability	All	Open literature
830.6316	63-16	Explodability	All	Open literature
830.6317	63-17	Storage Stability	All	Open literature
830.7100	63-18	Viscosity	All	Open literature
830.6319	63-19	Miscibility	All	Open literature
830.6320	63-20	Corrosion Characteristics	All	Open literature
830.6321	63-21	Dielectric breakdown voltage	All	Open literature

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity Test - Quail/duck	All	Open literature
850.1075	72-1 C	Fish Acute Toxicity - Rainbow Trout	All	Open literature
850.1075	72-1 C	Fish Acute Toxicity - Fathead Minnow	All	Open literature
850.1010	72-2A	Acute Aquatic Invertebrate Toxicity	All	Open literature
TOXICOLOGY				
870.1100	81-1	Acute Oral - Rat	All	Open literature
870.1200	81-2	Acute Dermal - Rabbit	All	Open literature
870.1300	81-3	Acute Inhalation – Rat	All	Open literature
870.2400	81-4	Acute Eye Irritation - Rabbit	All	Open literature
870.2500	81-5	Acute Skin Irritation - Rabbit	All	Open literature
870.2600	81-6	Dermal Sensitization	All	Open literature
870.3100	82-1a	90-Day Oral Subchronic -Rat	All	Open literature
870.3250	82-3*	21-Day Subchronic Dermal	All	Open literature
870.3465	82-4*	90-Day Subchronic Inhalation	All	Open literature
870.4100	83-1a	Chronic Toxicity - rat	All	Open literature

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.4100	83-1b	Chronic Toxicity - non-rodent	All	Open literature
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity - rat	All	Open literature
870.3700	83-3a	Prenatal Developmental Toxicity - Rat	All	Open literature
870.3700	83-3b	Prenatal Developmental Toxicity - Rabbit	All	Open literature
870.3800	83-4**	Reproduction and fertility effects - Rat	All	Open literature
870.5100	84-2	Bacterial Reverse Mutation Test	All	Open literature
870.5300	84-2	In Vitro Mammalian Chromosome Aberration Test	All	Open literature
870.7485	85-1	Metabolism and Pharmocokinetics	All	Open literature
*For guidelines 82-3 and 82-4, at least one is required to be fulfilled; not both (for both food and non-food uses). **Only required for food use.				
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis of Parent and Degradates	All	Open literature

Please Note: Although the Open Literature studies do not satisfy any of the Agency's testing guideline requirements, this information is considered adequate for characterizing the potential hazard from exposure to triethylene glycol. Therefore, no additional mammalian toxicity data will be required at this time.

Appendix C: Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 South Bell Street, Arlington, VA 22202. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4:00 pm.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.regulations.gov

These documents include:

- Environmental Fate and Effects Review of Mineral Acids as Inert Ingredients in Pesticide Products. Norman Birchfield, Ph.D., Biologist. May 7, 2002. DP Barcode: D282321.

- IIFG Decision Documents on Reassessing Exemptions from the Requirement of a Tolerance for the Mineral Acids (Hydrochloric, Carbonic, Phosphoric, and Sulfuric) and their Ammonium, Calcium, Ferrous, Ferric, Magnesium, Potassium, Sodium, and/or Zinc Salts. Kathryn Boyle, CoChair IIFG and Kerry Leifer, CoChair IIFG. July 24, 2002.

- Evaluation of the Health Aspects of Carbonates and Bicarbonates as Food Ingredients. Life Sciences Research Office, Contract #FDA 223-75-2004, 1975. MRID 457727-01.

Appendix D: Bibliography Citations by Guideline

61-1 Chemical Identity

MRID	Citation Reference
7446	Hill Top Research Institute, Incorporated (1957) Germicidal Tests Comparing the Effect of a Disinfectant Containing Chlorine and a Product of a Comparable Composition Which, in Addition, Contains Potassium bromide. (Unpublished study received Nov 5, 1957 under 875-42; submitted by Diversey Chemical Co., Des Plains, Ill.; CDL:022232-A)
19359	Procter & Gamble Company (19??) Composition of Institutional Comet Cleanser with Chlorinol G. (Unpublished study received Jul 10, 1973 under 3573-30; CDL:007286-A)
19684	Sterling Drug, Incorporated (1975) Product Formula and Manufac- turing Procedure. (Unpublished study received Nov 20, 1975 under 675-41; submitted by National Laboratories, Lehn and Fink Industrial Products Div., Montvale, N.J.; CDL:225256-A)
20425	Kowalski, X. (1966) ?Efficacy of ACL Sticks vs. Tablets in the Chlorination of Swimming Pools|. (Unpublished study received Apr 4, 1969 under 4206-18; submitted by Barcolene Co., Holbrook, Mass.; CDL:025978-A)
29610	Fitzpatrick Brothers, Incorporated (19??) Ingredient Statement for Supersoft Kitchen Kelnzer ?sic|. (Unpublished study received May 5, 1977 under 6466-13; CDL:230218-B)
55634	Procter & Gamble Company (1980) ?Chemistry of Comet 3573|. (Unpub- lished study received Aug 4, 1980 under 3573-37; CDL:243063-N)
56205	Procter & Gamble Company (1963) Spic and Span with Ammonia-Plus: Data Sheet. (Unpublished study received May 2, 1963 under 3573-12; CDL:229835-C)
66661	Bullen Chemical Company (19??) Bullen Neo-mint Formulation. (Un- published study received Nov 29, 1971 under 1459-35; CDL: 228442-B)
67368	Petrocci, A. (1971) Letter sent to R. Goodell dated Apr 13, 1971: Antimicrobial testing of non-phosphate BTC 2125M based deter- gent/disinfectant Onyx NP 9.0: No. 47944. (Unpublished study received Jan 12, 1981 under 1368-26; submitted by Mellocraft Co., Toledo, Ohio; CDL:244072-A)
86138	Lonza, Incorporated (19??) ?Study of the Chemical Formulation 235 Heavy-duty Terg-o-cide|. (Unpublished study received Jun 14, 1971 under 6836-28;

CDL:233054-A)

87227 Biomarine Research Corporation (19??) Bio-san Q: Formulation. (Unpublished study received Nov 27, 1972 under 20176-1; CDL: 026333-A)

94432 Onyx Chemical Company (1979) ?Efficacy Study of CD 3.2 Detergent/Disinfectant|. (Compilation; unpublished study, including nos. LC 57669 and LC 57666, received Jan 18, 1980 under 1839- 49; CDL:241650-A)

104940 Buckman Laboratories, Inc. (1978) General Chemistry: ?Busan 101|. (Unpublished study received Aug 22, 1978 under 1448-69; CDL: 235081-A)

119351 Rohm & Haas Co. (1972) ?Chemistry of Hyamine 3500|. (Compilation; unpublished study received Apr 19, 1973 under 707-63; CDL: 008317-A)

119612 Rohm & Haas Co. (1972) ?Chemistry of Liquid Detergent-disinfectant Formulations|. (Compilation; unpublished study received Apr 7, 1972 under 707-74; CDL:024165-A)

119617 Rohm & Haas Co. (19??) Hyamine 3500-80% Formulation B (JB 1420-B). (Unpublished study received Dec 8, 1971 under 707-74; CDL: 024175-A)

120514 Pioneer Mfg. Co. (19??) ?Chemical Study: Control-35|. (Compila- tion; unpublished study received Oct 9, 1973 under 892-28; CDL:009063-A)

120917 Ohio Soap Products Co. (19??) ?Chemistry of Formula 801|. (Compi- lation; unpublished study received Sep 14, 1976 under 27872-2; CDL:226152-A)

120918 Fast Products (19??) (Power Supreme Cleaner/Disinfectant: Chemical Study). (Compilation; unpublished study received Sep 14, 1976 under 11014-1; CDL:226156-A)

120919 J.I. Holcomb Research Laboratories (19??) ?Chemistry of N-Dit II|. (Compilation; unpublished study received Oct 6, 1976 under 323- 56; CDL:226282-A)

120921 Gulf Chemicals Co. (19??) ?Conquer Disinfectant Cleaner: Chemical Study|. (Compilation; unpublished study received Oct 6, 1976 under 19605-10; CDL:226289-A)

120922 Gulf Chemicals Co. (19??) ?Mint Disinfectant: Chemical Study|. (Compilation; unpublished study received Oct 6, 1976 under 19605-12; CDL:226290-A)

120930 Rohm & Haas Co. (1977) General Product Chemistry: ?Rohm and Haas Co. DC-100B|. (Compilation; unpublished study received Aug 1, 1978 under 707-147; CDL:236692-A)

120943 Corporated Brands Sales, Inc. (19??) ?Control: Manufacturing Formu- la; Production Control Procedure; Method for Determining Quater- nary Concentration|. (Compilation; unpublished study received Sep 11, 1974 under

14943-4; CDL:239894-A)

120954 BASF Wyandotte Corp. (1970) ?Kromet: Chemical Study|. (Compila- tion; unpublished study received Jun 4, 1971 under 662-6; CDL: 240684-A)

121416 Masury-Columbia Co. (19??) ?Chemical Study: Myco-San|. (Compila- tion; unpublished study received Aug 4, 1976 under 9647-25; CDL: 224864-A)

121568 Onyx Chemical Co. (1965) ?Chemistry of BTC 2125M|. (Compilation; unpublished study received Oct 7, 1978 under 1839-50; CDL: 240905-A)

122106 Edmar Chemical Co. (19??) ?Chemical Study: Bio-Magic Rinse GPN|. (Unpublished study received May 21, 1971 under 7048-7; CDL: 050878-A)

122344 Chemifax (1965) ?Spearmint Detergent/Disinfectant Formulation: Epton Procedure|. (Compilation; unpublished study received Oct 14, 1970 under 11292-1; CDL:239260-B)

128458 Rohm & Haas Co. (1972) ?Chemistry of Hyamine 3500-50%|. (Com- pilation; unpublished study received Apr 7, 1972 under 707-63; CDL:004306-A)

137936 Paul Koss Supply Co. (19??) ?Kleen-O-Fect III: Chemical Study|. (Compilation; unpublished study received Sep 14, 1976 under 11407-2; CDL:225610-A)

137937 Nord Laboratories (19??) ?Germiplex: Chemical Study|. (Compila- tion; unpublished study received Sep 14, 1976 under 39491-1; CDL:226167-A)

141758 Premier Chemical Co. (1984) [Product/Manufacturing Chemistry and Analysis of Premquat 1532 Sanitizer Cleaner]. Unpublished com- pilation. 10 p.

157944 Tincher, C. (1978) Letter sent to R. Jente dated April 12, 1978: [Product chemistry data]: Q-128. Prepared by Vestal Labs. 6 p.

40589201 Handy, R. (1988) Bromazine S Tablets: Product Identity and Composi- tion: RFH-88-62-2. Unpublished compilation prepared by Great Lakes Chemical Corp. 10 p.

40656801 Handy, R. (1988) Bromazine S Granules: Product Chemistry Data: ...: Product Identity and Composition. Unpublished study. 10 p.

61-2 Description of Beginning Materials and Manufacturing Proces

MRID	Citation Reference

19348 Procter & Gamble Company (19??) Process for Manufacturing Comet Cleanser. (Unpublished study received Jun 20, 1972 under 3573- 30; CDL:007283-A)

19432 Coastal Industries, Incorporated (1976) A Complete Description of the Production Control Procedures Employed. Includes methods dated Mar 10, 1976. (Unpublished study received Jan 4, 1977 un- der 4829-44; CDL:230533-A)

19684 Sterling Drug, Incorporated (1975) Product Formula and Manufac- turing Procedure. (Unpublished study received Nov 20, 1975 under 675-41; submitted by National Laboratories, Lehn and Fink Industrial Products Div., Montvale, N.J.; CDL:225256-A)

29608 Fitzpatrick Brothers, Incorporated (19??) Sodium Carbonate Produc- tion. (Unpublished study received May 5, 1977 under 6466-13; CDL:230217-A)

29611 McLeod, J.E. (1975) Trona mine--soda ash production. Glass In- dustry ? (?/Aug):12-14,16. (Also~In~unpublished submission re- ceived May 5, 1977 under 6466-13; submitted by Fitzpatrick Brothers, Inc., Chicago, Ill.; CDL:230218-C)

61729 Rohm & Haas Company (19??) Manufacturing Procedure. (Unpublished study received Oct 20, 1972 under 707-74; CDL:229141-C)

66660 Bullen Chemical Company (1972) Manufacturing Procedure for Neo- mint. (Unpublished study received Jul 18, 1972 under 1459-35; CDL:228442-A)

67813 Allied Chemical Corporation (1973) Soda Ash. Morristown, N.J: Allied Chemical. (Also~In~unpublished submission received Oct 6, 1976 under 6836-27; submitted by Lonza, Inc., Fair Lawn, N.J.; CDL:228680-B)

104223 Rohm & Haas Company (19??) Sodium Carbonate Production. (Unpub- lished study received May 24, 1978 under 707-146; CDL:234002-G)

104660 Purdy Products, Inc. (1974) ?Source of Raw Material, Manufacturing Procedure and Sanitary Chemical Analysis of Trophy No-bac Disinfectant Cleaner|. (Compilation; unpublished study received Sep 26, 1974 under 10710-4; CDL:228542-C)

104940 Buckman Laboratories, Inc. (1978) General Chemistry: ?Busan 101|. (Unpublished study received Aug 22, 1978 under 1448-69; CDL: 235081-A)

109081 Maintenance Products, Inc. (1971) ?Efficacy of Mapro Hospital Deo San Disinfectant Cleaner|. (Compilation; unpublished study received Nov 20, 1972 under 7389-6; CDL:236921-A)

112498 Water Soluble Products (1971) ?Sodium Lauryl Sulfate: Analytical Procedures|. (Compilation; unpublished study received Jul 24, 1973 under 7562-9; CDL:236910-A)

112583 Lonza, Inc. (19??) Determination of Quaternary Concentration. (Un- published study received Apr 30, 1975 under 11602-2; submitted by Molar Enterprises, Minneapolis, MN; CDL:237074-A)

119351 Rohm & Haas Co. (1972) ?Chemistry of Hyamine 3500|. (Compilation; unpublished study received Apr 19, 1973 under 707-63; CDL: 008317-A)

119388 Stearns Chemical Corp. (1972) ?Chemistry of Mark 12|. (Compila- tion; unpublished study received Jan 16, 1973 under 3640-69; CDL:025872-B)

119451 Alfred Chemical Corp. (1972) ?Chemistry of Microcide Alpha|: 388- 2056. (Compilation; unpublished study received May 1, 1975 under 36837-1; CDL:235830-A)

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63-11 Oct/Water partition Coef.

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63-17 Storage stability

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MRID	Citation Reference
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81-2 Acute dermal toxicity in rabbits or rats

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81-3 Acute inhalation toxicity in rats

MRID	Citation Reference
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81-4 Primary eye irritation in rabbits

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Sanitizer: Irritation and Other Tests on Rats|: W.A.R.F. No. 3110135. (Unpublished study received Feb 9, 1972 under 5075-25; submitted by Jewel Co., Inc., Chicago, IL; CDL:222671-A)

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120474 WARF Institute, Inc. (1970) Report: ?Germ-O-Solv|: WARF No. 0070155. (Unpublished study received Sep 16, 1970 under 527-73; submitted by Rochester Midland Corp., Rochester, NY; CDL:004044-A)

120493 Molomut, N. (19??) ?Dioxcide: Toxicity to Mice and Other Subjects|: Report No. 3.1. (Unpublished study received Jan 21, 1964 under 6730-1; submitted by Bio-Cide Chemical Co., Inc., Esmond, RI; CDL:007924-D)

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120549 WARF Institute, Inc. (1972) Report: WARF No. 2032370. (Unpublished study received May 2, 1972 under 5185-91; submitted by Bio-Lab, Inc., Decatur, GA; CDL:133582-A)

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121394 WARF Institute, Inc. (1970) Report: WARF No. 0070155. (Unpublished study received Apr 1, 1971 under 527-84; submitted by Rochester Midland Corp., Rochester, NY; CDL:223429-B)

121464 De Azevedo, J.; Frances, S. (1970) Report on Primary Skin Irrita- tion Studies in Rabbits Using Aireactor DDG: Laboratory No. D-4526. (Unpublished study received Sep 7, 1971 under 6095-3; prepared by Wells Laboratories, Inc., submitted by Aireactor Corp., Southport, CT; CDL:235562-C)

121524 Wolven, A.; Levenstein, I. (1972) To Determine the Degree of Irri- tation the Material May Produce When Applied to the Clipped In- tact and Abraded Skin of Rabbits: ?Detergent/Disinfectant|: Assay No. 22888. (Unpublished study received Jun 27, 1972 under 3533-47; prepared by Leberco Laboratories, submitted by Airwick Professional Products, Carlstadt, NJ; CDL:239899-D)

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121958 Wynn, J. (1970) Oxford/Hockwald Hospital San-O-Six, Sample Un- diluted: ?Dermal Irritation--Rabbits|. (Unpublished study re- ceived Dec 4, 1970 under 3635-119; submitted by Oxford Chemi- cals, Atlanta, GA; CDL:007304-B)

122015 DeAzevedo, J.; Peterson, A. (1971) Report on Primary Skin Irrita- tion Studies in Rabbits Using Lonza Formulation SF-A-45-7: Labo- ratory No. D-9450. (Unpublished study received Dec 10, 1971 under 6836-31; prepared by Wells Laboratories, Inc., submitted Lonza, Inc., Fair Lawn, NJ; CDL:009565-C)

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122070 Moldovan, M. (1969) Primary Skin Irritation Study: ?Spearmint Disinfectant 7-131 A|: I.B.L. No. 7298. (Unpublished study received Feb 26, 1970 under 1459-28; prepared by Food and Drug Research Laboratories, Inc., submitted by Bullen Chemical Co., Folcroft, PA; CDL:024896-B)

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122143 Van Horn, E. (1972) To Study Primary Skin Irritation of Purina C & S Powder on Rabbits: S.R. Project 47. Final rept. (Unpub- lished study received May 30, 1972 under 602-61; submitted by Ralston Purina Co., St. Louis, MO; CDL:106553-B)

122150 Moldovan, M. (1972) Primary Skin Irritation Study: ?TS 1694|: I.B.L. No. 11706. (Unpublished study received Jan 16, 1975 under 3533-58; prepared by Food and Drug Research Laboratories, Inc., submitted by Airwick Professional

Products, Carlstadt, NJ; CDL:110658-B)

122163 DeAzevedo, J.; Frances, S. (1971) Report on Primary Skin Irritation Studies in Rabbits Using TOR B11-23: Laboratory No. D-5968. (Unpublished study received Sep 14, 1972 under 303-79; prepared by Wells Laboratories, Inc., submitted by Huntington Labora- tories, Inc., Huntington, IN; CDL:222687-B)

122185 WARF Institute, Inc. (1970) Report: WARF No. 0070155. (Unpublished study received Apr 1, 1971 under 527-1484; submitted by Roches- ter Midland Corp., Rochester, NY; CDL:223165-A)

127555 Procter & Gamble Co. (1972) Toxicology Data: ?Comet|. (Compila- tion; unpublished study received Jan 19, 1972 under 3573-29; CDL:103863-A)

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133906 Wynn, J. (1970) Oxford/Hockwald San-O-Six, Sample Undiluted: ?Toxi- city on Rabbit Skin|. (Unpublished study received Dec 4, 1970 under 3635-124; submitted by Oxford Chemicals, Atlanta, GA; CDL: 223149-B)

161478 Drozdowski, D. (1984) Toxicity Testing of Cut 'N' Dry: [Skin & Eye Irritation: Skin Sensitivity & Dermal Toxicity]: Test Report No. 04662-A. Unpublished study prepared by United States Testing Co., Inc. 24 p.

165206 Regel, L. (1970) Report: Germ-O-Solv: Skin Irritation: WARF No. 0070155. Unpublished study prepared by WARF Institute, Inc. 2 p.

165208 Regel, L. (1970) Report: Germ-O-Solv: Skin Irritation: WARF No. 0070155. Unpublished study prepared by WARF Institute, Inc. 2 p.

43839001 Wnorowski, G. (1995) Primary Skin Irritation (in Rabbits): Quick Tabs: Lab Project Number: 4052: P326. Unpublished study prepared by Product Safety Labs. 16 p.

81-6 Dermal sensitization

MRID	Citation Reference
120493	Molomut, N. (19??) ?Dioxcide: Toxicity to Mice and Other Subjects|: Report No. 3.1. (Unpublished study received Jan 21, 1964 under 6730-1; submitted by Bio-Cide Chemical Co., Inc., Esmond, RI; CDL:007924-D)
161478	Drozdowski, D. (1984) Toxicity Testing of Cut 'N' Dry: [Skin & Eye Irritation:

Skin Sensitivity & Dermal Toxicity]: Test Report No. 04662-A. Unpublished study prepared by United States Testing Co., Inc. 24 p.

43541001 Wnorowski, G. (1995) Dermal Sensitization Test (on Guinea Pigs)--Buehler Method: Quick Tabs: Lab Project Numbers: 3304: P328: E40922-1. Unpublished study prepared by Product Safety Labs. 27 p.

82-2 21-day dermal-rabbit/rat

MRID	Citation Reference
48953	Frances, S.; Luy, T. (1971) Report on Twenty Day Subacute Dermal Toxicity Testing on Rabbits Using Lonza Disinfectant Cleaner 30-3 Lot # 3: Laboratory No. D-6259. (Unpublished study re- ceived Jul 15, 1971 under 11602-5; prepared by Wells Labora- tories, Inc., submitted by Molar Enterprises, Minneapolis, Minn.; CDL:228896-E)
55286	Luy, T.; de Azevedo, J.P.; Frances, S. (1971) Report on Twenty Day Subacute Dermal Toxicity Testing on Rabbits Using Lonza Disin- fectant Cleaner SF-A-19-a: Laboratory No. D-6922. (Unpublished study received Sep 1, 1972 under 3636-20; prepared by Wells Laboratories, Inc., submitted by Britex Corp., Holbrook, Mass.; CDL:100346-D)
55631	Moulton, R.H.; Forbes, N.T. (1976) 28-Day Percutaneous Toxicity Study in Rabbits: S.A. No. 207509. (Unpublished study received Aug 4, 1980 under 3573-37; prepared by Scientific Associates, Inc., submitted by Procter & Gamble Co., Cincinnati, Ohio; CDL: 243063-K)
55632	Tewksbury, M.B. (1972) 28-Day Percutaneous Study (V3305-116). (Un- published study including letter dated Nov 29, 1972 from G.R. Johnson to M.B. Tewksbury and H.E. Black, received Aug 4, 1980 under 3573-37; submitted by Procter & Gamble Co., Cincinnati, Ohio; CDL:243063-L)
55633	Goldenthal, E.I.; Jessup, D.C.; Geil, R.G.; et al. (1979) 28-Day Subchronic Percutaneous Toxicity Study in Rabbits (No Rinse): IRDC No. 191-290. Final rept. (Unpublished study received Aug 4, 1980 under 3573-37; prepared by International Research and Development Corp., submitted by Procter & Gamble Co., Cincin- nati, Ohio; CDL:243063-M)
56286	Luy, T.; Frances, S.; DiRe, J.J. (1971) Report on Twenty Day Sub- acute Dermal Toxicity Testing on Rabbits Using Lonza Disinfect- ant Cleaner 30-3 Lot # 3: Laboratory No. D-6259. (Unpublished study received Sep 24, 1971 under 1459-33; prepared by Wells Laboratories, Inc., submitted by Bullen Chemical Co., Folcroft, Pa.; CDL:228445-D)
57937	Luy, T.; Frances, S. (1971) Report on Twenty Day Subacute Dermal Toxicity

Testing on Rabbits using Lonza Disinfectant Cleaner 30-3 Lot # 3: Laboratory No. D-6259. (Unpublished study re- ceived Nov 3, 1971 under 7176-9; prepared by Wells Laboratories, Inc., submitted by Butcher Polish Co., Marlborough, Mass.; CDL: 100352-D)

86144 Luy, T.; DeAzevedo, J.P.; Frances, S. (1971) Report on Twenty Day Subacute Dermal Toxicity Testing on Rabbits Using Lonza Disin- fectant Cleaner SF-A-19-a: Laboratory No. D-6922. (Unpublished study received Jun 3, 1971 under 6836-28; prepared by Wells Laboratories, Inc., submitted by Lonza, Inc., Fair Lawn, N.J.; CDL:233053-F)

107850 Luy, T.; Frances, S. (1971) Report on Twenty Day Subacute Dermal Toxicity Testing on Rabbits Using Lonza Disinfectant Cleaner 47- 5 Lot #3, 1/26/71: Laboratory No. D-6258. (Unpublished study received Jun 15, 1971 under 1685-51; prepared by Wells Labora- tories, Inc., submitted by State Chemical Mfg. Co., Cleveland, OH; CDL:100095-H)

109164 Luy, T.; DeAzevedo, J.; Frances, S. (1971) Report on Twenty Day Subacute Dermal Toxicity Testing on Rabbits Using Lonza Dis- infectant Cleaner SF-A-19-a: Laboratory No. D-6922. (Unpub- lished study received Feb 3, 1972 under 12015-1; prepared by Wells Laboratories, Inc., submitted by Robinette, Inc., Medina, OH; CDL:236932-D)

112590 Luy, T.; Frances, S. (1971) Report on Twenty Day Subacute Dermal Toxicity Testing on Rabbits Using Lonza Disinfectant Cleaner 30-3 Lot #3: Laboratory No. D-6259. (Unpublished study re- ceived May 19, 1971 under 11559-1; prepared by Wells Laborato- ries, Inc., submitted by SV Chemicals, Div. of Universal Indus- tries, Inc., Tacoma, WA; CDL:237077-E)

120475 Luy, T.; DeAzevedo, J.; Frances, S. (1971) Twenty Day Subacute Dermal Toxicity Testing on Rabbits Using Lonza Disinfectant Cleaner SF-A-19-a: Laboratory No. D-6922. (Unpublished study received Jul 12, 1971 under 783-13; prepared by Wells Labora- tories, Inc., submitted by Grace Lee Products, Inc., Minneapo- lis, MN; CDL:004444-D)

120476 Luy, T.; Frances, S. (1971) Twenty Day Subacute Dermal Toxicity Testing on Rabbits Using Lonza Disinfectant Cleaner 30-3 Lot #3: Laboratory No. D-6259. (Unpublished study received May 19, 1971 under 11559-1; prepared by Wells Laboratories, Inc., submitted by SV Chemicals, Div. of Universal Industries, Inc., Tacoma, WA; CDL:004555-E)

120483 Luy, T.; Frances, S. (1971) Twenty Day Subacute Dermal Toxicity Testing on Rabbits Using Lonza Disinfectant Cleaner 47-5: Labo- ratory No. D-6258. (Unpublished study received Dec 23, 1971 under 1275-36; prepared by Wells Laboratories, Inc., submitted by Oliver Chem Co., Inc., Cincinnati, OH; CDL:005841-E)

133768 Luy, T.; DeAzevedo, J.; Frances, S. (1971) Twenty-day Subacute Dermal Toxicity Testing on Rabbits Using Lonza Disinfectant Cleaner SF-A-19-a: Laboratory No. D-6922. (Unpublished study received Jun 15, 1971 under 1685-52; prepared by Wells Laboratories, Inc., submitted by State Chemical Mfg. Co., Cleveland, OH; CDL:100654-D)

82-3 90-day dermal-rodent

MRID	Citation Reference
63240	Harris, D.L. (1975) Report: WARF No. 5022701. (Unpublished study received May 12, 1975 under 5185-242; prepared by WARF Insti- tute, Inc., submitted by Bio-Lab, Inc., Decatur, Ga.; CDL: 234692-A)
64868	Harris, D.L. (1971) Report: W.A.R.F. No. 1062675. (Unpublished study received Feb 14, 1972 under 5185-169; prepared by WARF Institute, Inc., submitted by Bio-Lab, Inc., Decatur, Ga.; CDL: 221127-A)
75017	West, B. (1966) To Determine the Subacute Dermal Toxicity of Each of the Subject Materials: Laboratory No. PT65-162. (Unpublished study received Oct 29, 1966 under 8788-1; prepared by Rosner- Hixson Laboratories, submitted by DeSoto Chemical Coatings, Des Plaines, Ill.; CDL:106233-A)
75019	West, B. (1966) Letter sent to Robert S. Cooper dated Oct 19, 1966 ?Toxicity of Sears germicidal diaper wash|. (Unpublished study received Oct 29, 1966 under 8788-1; prepared by Rosner-Hixson Laboratories, submitted by DeSoto Chemical Coatings, Des Plaines, Ill.; CDL:106234-A)
81369	West, B. (1966) To Determine the Subacute Dermal Toxicity of Each of the Subject Materials: Laboratory No. PT65-162 (A & B). (Un- published study received Apr 19, 1966 under 8788-1; prepared by Rosner-Hixson Laboratories, submitted by DeSoto Chemical Coat- ings, Des Plaines, Ill.; CDL:106232-B)

82-4 90-day inhal.-rat

MRID	Citation Reference
29351	Nees, P.O.; Davis, D.L. (1970) Report: ?Bio-Guard Hatching Egg Spray|. (Unpublished study received Oct 20, 1970 under 5185- 156; prepared by Warf Institute, Inc., submitted by Bio-Labs, Inc., Decatur, Ga.; CDL:050631-A)
106941	Nees, P.; Harris, D. (1970) Report: ?Inhalation Toxicity Testing of Bio-guard Hatching Egg Spray--Rats|. (Unpublished study re- ceived Oct 20, 1970 under 5185-156; prepared by WARF Institute, Inc., submitted by Bio-Lab, Inc.,

Decatur, GA; CDL:222699-A)

122119 Sterner, W.; Loveless, L. (1964) Subacute Inhalation Toxicity of N-Dit to Rats: Project 2133. (Unpublished study received Jun 22, 1964 under 323-25; prepared by International Bio-Research, Inc., submitted by J.I. Holcomb Research Laboratories, Cleveland, OH; CDL:100541-A)

83-3 Teratogenicity -- 2 Species

MRID	Citation Reference
161480	Morgareidge, K. (1973) Teratologic Evaluation of FDA 71-84 in Mice: Laboratory No. FDA 71-260: Lab. No. 1765 1. Unpublished study prepared by Food and Drug Research Laboratories, Inc. 13 p.
161481	Morgareidge, K. (1973) Teratologic Evaluation of FDA 71-84 in Rats: Laboratory No. 1766 1: FDA 71-260. Unpublished study prepared by Food and Drug Research Laboratories, Inc. 13 p.
161482	Morgareidge, K. (1974) Teratologic Evaluation of FDA 71-84 in Rab- bits: Lab. No. 1767 1: FDA 71-260. Unpublished study prepared by Food and Drug Research Laboratories, Inc. 14 p.
161483	Verrett, M. (1974?) Investigations of the Toxic and Teratogenic Effects of GRAS Substances to the Developing Chicken Embryo: Sodium Carbonate. Unpublished study prepared by US Public Health Service. 7 p.
161484	Verrett, M.; Scott, W.; Reynaldo, E.; et al. (1980) Toxicity and teratogenicity of food additive chemicals in the developing chicken embryo. Toxicology and Applied Pharmacology (56):265- 273.

84-2 Intreraction with Gonadal DNA

MRID	Citation Reference
161488	Blevins, R.; Taylor, D. (1982) Mutagenicity screening of twenty- five cosmetic ingredients with the salmonella/microsome test. J. Environ. Sci. Health A17(2):217-239.

85-1 General metabolism

MRID	Citation Reference
85414	U.S. Department of Interior, Fish and Wildlife Service (1979) Haz- ards to

Domestic Animals and Humans. (Unpublished study includ- ing published data; CDL:243092-C; 243093; 243094; 243095)

112648 Oonnithan, E. (1965) Metabolism of Methylcarbamate Insecticide Chemicals by Rat Liver Enzyme Systems: ?Submitter| 17590. Doc- toral dissertation, Univ. of California--Berkeley. (Unpublished study received Sep 10, 1971 under 1G1030; submitted by Mobay Chemical Corp., Kansas City, MO; CDL:091910-AA)

86-1 Domestic animal safety

MRID	Citation Reference
79132	Frank, J.F. (1948) The toxicity of sodium chlorate herbicides. Canadian Journal of Comparative Medicine XII(8):216-218. (Also ?~In~unpublished submission received Aug 19, 1980 under 6704-84; submitted by U.S. Dept. of Interior, Fish and Wildlife Service, Washington, D.C.; CDL:243003-M)

154-8 Freshwater Fish Acute Toxicity

MRID	Citation Reference
45554901	Machado, M. (2001) GreenClean--Acute Toxicity to Rainbow Trout (Oncorhynchus mykiss) Under Static Conditions: Lab Project Number: 13780.6100. Unpublished study prepared by Springborn Laboratories. 35 p. {OPPTS 850.1075}

161-3 Photodegradation-soil

MRID	Citation Reference
124968	Abdel-Wahab, A.; Kuhr, R.; Casida, J. (1966) Fate of C14-carbonyl- labeled aryl methylcarbamate insecticide chemicals in and on bean plants. J. Agr. Food Chem. 14(3):290-297. (Submitter 18274; also In unpublished submission received Jul 15, 1976 under 3125-EX-135; submitted by Mobay Chemical Corp., Kansas City, MO; CDL:227756-E)

171-4B Residue Analytical Methods

MRID	Citation Reference
77077	Mattson, L.N. (1970) Peanuts--Analyzed for Residual of Consan 20: S.A. No. 169218. (Unpublished study received Jun 10, 1981 under 10331-9; prepared by Scientific Associates, Inc., submitted by Del Tek, Inc., Pearland, Tex.; CDL:245484-D)

171-4C Magnitude of the Residue [by commodity]

MRID	Citation Reference
5636	Babcock, S.G. (1968) Certificate of Analysis. (Unpublished study including letter dated Jul 2, 1968 from C.J. Waldapfel to Drew M. Baker, Jr., received Jul 29, 1968 under 8E0630; prepared by Edward S. Babcock & Sons, submitted by Sunkist Growers, Inc., Los Angeles, Calif.; CDL:092924-I)
120492	Bio-Cide Chemical Co., Inc. (1960) ?Chlorine Dioxide Residues in Fish and Water|. (Compilation; unpublished study received Jan 21, 1964 under 6730-1; CDL:007924-C)

171-4A2 Nature of the Residue in Plants

MRID	Citation Reference
124968	Abdel-Wahab, A.; Kuhr, R.; Casida, J. (1966) Fate of C14-carbonyl- labeled aryl methylcarbamate insecticide chemicals in and on bean plants. J. Agr. Food Chem. 14(3):290-297. (Submitter 18274; also In unpublished submission received Jul 15, 1976 under 3125-EX-135; submitted by Mobay Chemical Corp., Kansas City, MO; CDL:227756-E)

Non-Guideline Study

MRID	Citation Reference
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Appendix E: Generic Data Call-In

The Agency does not intend to issue a Generic Data Call-In at this time.

Appendix F: Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In at a later date.

Appendix G: Batching of End-Use Products

ANTIMICROBIAL DIVISION'S BATCHING OF PRODUCTS CONTAINING SODIUM CARBONATE; WEAK MINERAL BASES, AS THE ACTIVE INGREDIENT FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient Sodium Carbonate. For this RED, the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), product form (liquid, paste, solid, etc.), labeling (e.g., signal word, precautionary labeling, etc.) and acute toxicity data. The CAS Number for this active ingredient is 497-19-8.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise. If a registrant chooses to rely upon previously submitted acute toxicity data, he or she may do so provided that the data base is complete and valid by today's standards (see the attached acceptance criteria), the formulation tested is considered by EPA to be similar in terms of acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. If the registrant wishes to cite acute toxicity data conducted on another product, that cited product must first be approved via a CTT/PSB Similarity Clinic. Citing acute toxicity information on separate components of these formulations will not be acceptable.

This RED is unusual in that there are two products involved, EPA Reg. Nos. 11715-34 and 15136-10. Due to differences in their formulations, AD/PSB will not be able to place these two products into one batch. Thus, the registrants of 11715-34 and 15136-10 are being asked to submit six acute toxicity/primary irritation studies to support the data requirements for these products.

A third product, Registration Number 82552-1, was registered approximately three months prior to the writing of this appendix. Due to its recent registration, the registrant is not being asked to support the acute toxicity requirements for Registration Number 82552-1 in response to this RED.

Appendix H: List of All Registrants Sent the Data Call-In

A list of registrants sent the data call-in will be posted at a later date.

Appendix I: List of Available Forms

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf

8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

a. 83-3 Label Improvement Program--Storage and Disposal Statements
b. 84-1 Clarification of Label Improvement Program
c. 86-5 Standard Format for Data Submitted under FIFRA
d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
b. EPA Form No. 8570-4, Confidential Statement of Formula
c. EPA Form No. 8570-27, Formulator's Exemption Statement
d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

a. Registration Division Personnel Contact List
b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
c. Antimicrobials Division Organizational Structure/Contact List
d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: http://npic.orst.edu/

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

1. Date of receipt;
2. EPA identifying number; and
3. Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.