REREGISTRATION ELIGIBILITY DOCUMENT
SILICON DIOXIDE AND SILICA GEL

LIST D

CASE 4081

SEPTEMBER 1991

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

SILICON DIOXIDE AND SILICA GEL
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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
EPA	U. S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GRAS	Generally Recognized As Safe
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose that can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the EPA.

EXECUTIVE SUMMARY

This Reregistration Eligibility Document addresses both silicon dioxide and silica gel. Silicon dioxide is essentially an inert material that contains approximately 90% silica. It is commonly used as an inert carrier in dry concentrates, dry pesticides, as an anti-caking agent, soil conditioner and turf soil supplement and occasionally used as an active ingredient. Silicon dioxide's most common insecticidal use today is for control of stored grain insects. It is also registered for use to control a variety of insects/mites in and around domestic/commercial dwellings, ornamental gardens, in kennels and on domestic pets. Silica gel is a registered insecticide and acaricide for use to control a variety of insects in and around residences/commercial dwellings, agricultural premises, institutions, warehouses, food plants, livestock, cat, dogs and in granaries. Because of their abrasive characteristics both active ingredients act on insects by removing the oily protective film covering their bodies which normally prevents the loss of water. Thus the mode of action is physical in nature causing desiccation of the insect. Both active ingredients are usually combined with other pesticides which act as a knockdown agent. All products which contain silicon dioxide and silica gel registered for these uses are eligible for reregistration.

The U. S. Environmental Protection Agency (EPA) conducted a review of the scientific data base and other relevant information supporting the reregistration of silicon dioxide and silica gel and has determined that the data base is sufficient to conduct a reasonable risk assessment. In addition, the Agency has conducted a tolerance reassessment for silicon dioxide and silica gel and its conclusions are discussed in Section IIC. The data available to the EPA support the conclusion that the currently registered uses of silicon dioxide and silica gel will not result in unreasonable public health risks or effects to the environment. No further generic data are required.

Accordingly, the EPA has determined that all products containing silicon dioxide and silica gel as the active ingredients are eligible for reregistration and will be reregistered when appropriate labeling and/or product specific data are submitted and/or cited. Before reregistering each product, the EPA is requiring product specific data to be submitted within eight months of the issuance of this document. After reviewing these data and the revised labels, the EPA will determine whether to reregister a product based on whether or not the conditions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(c)(5) have been met. End use products containing silicon dioxide and silica gel in combination with other active ingredients will not be reregistered until

those other active ingredients are determined to be eligible for reregistration. However, product specific data are being called in at this time.

I. INTRODUCTION

In l988, FIFRA was amended to accelerate the reregistration of products with active ingredients registered prior to November l, l984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by EPA of all data submitted to support reregistration.

Section 4(g)(2)(A) of FIFRA states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products, 4(g)(2)(B), and either reregistering products or taking "other appropriate regulatory action," sections 4(g)(2)(C) and (D). Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA, 3(c)(5).

This document presents the EPA's decision regarding the reregistration eligibility of the active ingredients silicon dioxide and silica gel. The document consists of five sections. Section I is this introduction. Section II describes silicon dioxide and silica gel, their uses and regulatory history. Section III discusses the human health and environmental assessments based on the data available to the EPA. Section IV discusses the reregistration eligibility decision for silicon dioxide and silica gel. Section V discusses product reregistration requirements. Additional details concerning the review of available data are available on request. *

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

II. ACTIVE INGREDIENTS COVERED BY THIS REREGISTRATION ELIGIBILITY DECISION DOCUMENT

A. IDENTIFICATION OF ACTIVE INGREDIENTS

1. Chemical Name: Silicon dioxide (diatomaceous earth)

CAS Number: 7631-86-9

Office of Pesticide Programs Chemical Code Number: 72605

Empirical Formula: $Si0_2$

Trade Name: Diatomite, Dicalite, DiaFil, Celatom,

Celite

Other Name: Infusorial Earth, Fossil Flour, Siliceous Earth

Basic Manufacturer: Produced by a number of manufacturers.

2. Chemical Name: Silica Gel

CAS Number: 63231-67-4

Office of Pesticide Programs Chemical Code Number: 72602

Empirical Formula: $Si0_2$

Trade Name: Dri-Die, Drione, Syloid

Basic Manufacturer: Fairfield American Company plus other manufacturers.

B. USE PROFILE

Type of pesticide:

Silicon Dioxide: Acaricide and/or insecticide

Silica Gel: Acaricide and/or insecticide

Registered use sites:

SILICON DIOXIDE:

Terrestrial Food/Feed Crops (including Greenhouse Crops)*:

Cranberry, pecan, peach, asparagus, broccoli, brussels sprouts, cabbage, cauliflower, celery, collards, kale, lettuce, mustard, radish, spinach, tomato, turnip, potato (Irish/white), beans, barley, corn, oats, sorghum, wheat, peanuts, peas, soybeans, and pastures

Terrestrial Non-Food Crops (including Greenhouse Crops)*:

Tobacco, ornamental herbaceous plants, ornamental woody shrubs and vines, and ornamental and/or shade trees

Outdoor Sites (including Commercial/Residential)*:

Kennels, pet sleeping quarters/veterinary and household/domestic dwelling (outdoor premises)

Indoor Food (including Commercial/Residential Sites):

Stored grains: beans, barley, grain crops, oats, rice, rye, sorghum, wheat, buckwheat, flax, corn, peas, seeds, soybeans

Grain/cereal/flour bins (empty/full), grain/cereal/flour storage areas (empty/full), food/feed storage areas (empty/full), silo, household/domestic dwelling indoor food handling areas, commercial transportation facilities, food processing plant premise/equipment, eating establishments food handling areas (food contact), eating establishment food serving areas (food contact), and food/grocery marketing/storage/distribution facility premise

Indoor Non-Food (including Commercial/Residential Sites):

Kennels, pet sleeping quarters/veterinary, cats (adult/kitten)*, dogs/canine (adult/puppies), pet living/sleeping quarters, pet bedding, domestic dwelling, household/domestic dwelling indoor premise, household/domestic dwelling content, human bedding/mattresses, refuse/solid waste containers (garbage cans)

SILICA GEL:

Aquatic Non-Food Site (Commercial):

Sewage Systems

Outdoor Sites (including Commercial/Residential):

Kennels/pet sleeping quarters/veterinary, household/domestic dwelling (outdoor), wood protection treatment to building/products (outdoor), commercial/institutional/industrial areas (outdoor)

Indoor Food (including Commercial/Agricultural/ Residential):

Grain crops, grain/cereal/flour bins (empty/ full), grain/cereal/flour elevators (empty/full), food/feed storage areas (empty/full), grain/ cereal/flour storage areas, dairy cattle, poultry, beef/range/feeder (cattle), hog/pig/swine, household/domestic dwelling food indoor establishment, food processing plants premise/equipment, feed mills/feed processing plants, flour mills, cereal plants, eating establishments food handling areas (contact), eating establishments food serving areas (contact), food/grocery marketing/storage distribution facility premise

Indoor Non-Food (including Commercial/Agricultural/ Residential):

Kennels/pet sleeping quarters/veterinary, horses, animals (lab/research), commercial transportation facility, eating establishments non-food areas, commercial/institutional/industrial premise/equipment (indoor), cats (adults/kittens), dogs/canines (adult/puppies), monkeys, ferrets, birds, pet living/ sleeping quarters, pet bedding, domestic dwellings, household/domestic dwellings (indoor), household/ domestic dwelling content, wood protection treatment to building (indoor), human bedding/mattresses

Indoor Medical:

Hospitals/medical institutions (human/veterinary)

Formulation Types Registered:

SILICON DIOXIDE: Silicon dioxide end-use products are formulated as dusts containing at least 80% diatomaceous earth as the sole active ingredient (and as a dust in combination with other active ingredients (pyrethrin, piperonyl butoxide). There are no technical or manufacturing use products registered.

SILICA GEL: Silica gel end use products are formulated as dusts (at 96% active ingredients); and as pressurized liquids at (4% active ingredient) with multi-active ingredients such as pyrethrin, piperonyl butoxide, carbaryl and as a manufacturing use product (40% a.i.)

*Registered on these sites only in combination with other active ingredients.

Methods of Application:

SILICON DIOXIDE: Silicon dioxide is applied by a hand held or power duster.

SILICA GEL: Silica gel is applied by hand held power duster, aerosol can or injection (i.e., crack and crevice treatment).

C. REGULATORY HISTORY

In 1960 and 1956 EPA first registered pesticide products containing silicon dioxide and silica gel, respectively, as active ingredients. Because of their negligible toxicity when ingested, silicon dioxide and silica gel (hydrated silica) have received exemptions from tolerances and clearances for certain use patterns associated with food commodities. These exemptions and clearances are:

-when applied as an inert ingredient, or occasionally as an active, to growing crops and raw agricultural commodities (40 CFR 180.1001(c) and (d));

-when applied as an inert, or occasionally as an active to livestock (40 CFR 180.1001(e));

-when applied as an active ingredient to growing crops, raw agricultural commodities after harvest and to livestock (40 CFR 180.1017).

Current exemptions from tolerances in 40 CFR 180.1017, 185.1700 and 186.1700 are limited to the naturally mined silicon dioxide-containing product diatomaceous earth.

The Agency intends to revise 40 CFR l80.1017 to specifically exempt silicon dioxide and silica gel from the requirements of a tolerance when used on raw agricultural commodities (growing crops and post-harvest uses) and animals. Similarly, EPA intends to revise the exemptions in 40 CFR 185.1700 and 186.1700 for diatomaceous earth to include silica gel used in food and feed handling establishments.

The use of silicon dioxide as a direct food additive (anti-caking agent) is described in 21 CFR 121.380. Silica gels with a minimum silica content of 89.5% are considered GRAS when used as anti-foaming agents in accordance with good manufacturing practice (21 CFR 172.11711). Silicon dioxides are considered GRAS as substances migrating from paper and paper-board products used in food packaging (40 CFR 182.90).

III. AGENCY ASSESSMENT OF ACTIVE INGREDIENT

The Agency has conducted a thorough review of the scientific data base for silicon dioxide and silica gel. Based on the evaluation of these data, the EPA has no reason to request additional data.

A. INGREDIENT DESCRIPTION

Anhydrous silicon dioxide has a molecular weight of 60.09. Silica gel and other amorphous forms of silicon dioxide will have a varying molecular weight, depending upon the extent of hydration. Datomaceous earth consists of siliceous frustules and fragments of various species of diatoms mined from the beds of former inland lakes. It is composed of approximately 85% silica, other oxides and organic materials. The natural grades are mined and then dried, ground, sifted and bagged. Both forms used as pesticidal active ingredients are generally white powders at room temperature which melt to a glassy consistency at high temperatures. Silicon dioxide is practically insoluble in water, but is soluble in hydrofluoric acid. Heating with concentrated phosphoric acid may slowly dissolve silicon dioxide as well. Amorphous forms of silica may be dissolved by hot concentrated alkaline solutions, but crystalline forms generally are not soluble. Silica is not soluble in any organic solvent. The bulk density is in the range of 10-20 lb/ft 3 and the true density is approximately 2.2 g/cm 3. The pH of an aqueous suspension of silica gel can range from 2.3-7. All product chemistry requirements have been satisfied.

B. HUMAN HEALTH ASSESSMENT

1. Toxicology

a. Acute Toxicity

Acute toxicity studies demonstrate that silicon dioxide and silica gel have moderate to low acute toxicities. An acute oral LD_{50} study (rat) with silicon dioxide resulted in an LD_{50} value of 3160 mg/g [1/]; this value is considered Toxicity Category III. In an acute dermal LD_{50} study [2/] silica gel produced moderate to low toxicity for a Toxicity Category of III. No test animals in an acute inhalation study [3/] died as a result of exposure to 40% silica gel. Likewise, eye and dermal irritation studies [4/] have suggested moderate and low toxicities, respectively.

b. Subchronic and Chronic Toxicity

Crystalline silicon dioxide has long been associated with silicosis, a progressive lung disease, which has been associated with the development of lung cancer in humans. Amorphous silicon dioxide has not been associated with silicosis.

1/ NIOSH (l977) Registry of Toxic Effects of Chemical Substances. U.S. Department of Health Education and Welfare, DHEW Publ. No. (NIOSH) 78-104-A. Government Printing Office, Washington, D.C.

2/ Fairfield American Corp. Acute Dermal Study No. 03240, 4/10/80. Acc. No. 242851.

3/ Fairfield American Corp. Acute Inhalation Toxicity Study,\ No. 0324E, 5/21/80, Acc. No. 242852.

4/ Fairfield American Corp. Primary Eye Irritation Study No 0324B, 4/21/80, Acc. No. 242850 and Primary Dermal Irritation Study No. 0324C, 4/17/80, Acc. No. 242849.

The International Agency for Research on Cancer (IARC) has conducted an in depth evaluation of the potential carcinogenicity of silicon dioxide. [5]/ Based on the data available, the IARC Working Group expressed its expert opinion that l) there is sufficient evidence for the carcinogenicity of crystalline silica to experimental animals; 2) there is limited evidence for the carcinogenicity of crystalline silica to humans; 3) there is inadequate evidence for carcinogenicity of amorphous silica to experimental animals; and 4) there is inadequate evidence for the carcinogenicity of amorphous silica to humans. IARC also indicated that no adequate epidemiological data were available to evaluate the carcinogenicity of amorphous silica. EPA concurs with IARC's assessment of the available data. Some of the experimental animal studies evaluated are as follows:

a. Oral Administration

Rat: A group of 30 weanling Sprague-Dawley rats was administered 20 mg/day of diatomaceous earth in cottage cheese at a concentration of 5 mg/g cheese, in addition to a basal diet ad libitum. The rats were observed for their life span (mean survival 840 days). Five malignant tumors (1 salivary gland carcinoma, 1 skin carcinoma, 2 sarcomas of the uterus, 1 peritoneal mesothelioma) and 13 benign tumors (9 mammary fibroadenomas, 1 adrenal pheochromocytoma, 3 pancreatic adenomas) were observed in treated animals. A control group of 27 rats with mean survival of 690 days had 3 carcinomas (1 each in lung, ovary and forestomach) and 5 mammary fibroadenomas. [6]/

5/ IARC (l987) IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans, Vol. 42, Silica and Some Silicates, Lyon, France, p. 39-143.

6/ Hilding, A.C., Hilding, D.A., Larson, D.M., and Aulderheide,, A. C. (l981) Biological Effects of Ingested Amosite Asbestos, Taconite Tailings, Diatomaceous Earth and Lake Superior Water in Rats. Arch. Environ. Health 36: 298-303

b. Inhalation Exposure

Mouse: Groups of 75 mice were exposed to various particulates including 0.5 g/day precipitated silica (particle size was reported to about 5 um or less in diameter) once an hour for 6 hours on 5 days/week for 1 year and observed for their lifespan. Survival at 600 days was 12/74 in the silica treated group and 17/75 in one control group and 13/73 in the second control group. The incidence of pulmonary adenomas and adenocarcinomas in mice surviving 200 days or more was 5/63 and 5/52 in the control groups at 13/61 in the silica treated group. [7]/

Rabbit: Inhalation of 40 mg/ml amorphous silica for up to to 1100 days was reported to produce "diffuse tissue reactions." [8]/

2. Occupational and Residential Exposure

Silicon dioxide end-use products are formulated as dusts and applied by a hand held or power duster to crops, stored grains, pets, and indoors. Silica gel end-use products are formulated as dusts; and as pressurized liquids and applied by a hand held power duster, aerosol can or injection (i.e., crack and crevice treatment). Current product labels for dust formulations have requirements for use of a dust mask for prolonged periods of use. EPA believes potential inhalation and dermal exposure for the applicator may be significant. However, applications and exposures are believed to be infrequent to a few times per year.

7/ Campbell, J.A. (l940) Effects of Precipitated Silica and Iron Oxide on the Incidence of Primary Lung Tumors in Mice. Br. Med. J., ii, 275-280

8/ Gartner, H. (l952) Studies on the Action of Fine Amorphous Silica on the Lung of Rabbits (Ger.) Arch. Hyg. 136: 451-467

3. **Dietary Exposure**

Dietary exposure to silicon dioxide and silica gel may occur from their application to certain crops and in and around food handling and preparation areas. The amount of ingestion has not been quantified for this assessment because they are exempt from tolerance requirements at all levels in food. They are believed to be inconsequential because of the ubiquity of forms of silicon dioxide in the environment.

4. **Human Health Risk Assessment**

EPA has considered several factors in the risk assessment for pesticidal uses of silicon dioxide. Silicon dioxide and silica gel's acute toxicity profile can be characterized as moderate to low. Dietary exposure from the direct application to food commodities or from inadvertent residues in food handling and preparation areas are not quantified here but are believed to be insignificant from a a toxicological standpoint. Ingestion of various chemical forms of silicon dioxide occurs due to their natural occurrence in the environment. FDA has classified these chemicals as Generally Recognized as Safe and has approved their use as dietary food additives at levels up to 2% by weight in food. Applicator exposure may be significant for each application, however, EPA believes based on the use patterns, the application is infrequent and therefore exposure is acute rather than chronic. In addition, the labels caution the applicator to avoid contact with eyes and skin, avoid breathing dust, and use a dust mask for prolonged periods of of use. Given these factors and assumptions, EPA concludes the human health risk is low and not unreasonable.

C. ENVIRONMENTAL ASSESSMENT

1. Environmental Fate Assessment

Silicon dioxide (diatomaceous earth) is primarily composed of silica, the same inactive ingredient as is in quartz, sand and agate. Silica gel is an amorphous (non-crystalline) form of silicon dioxide ($SiO_2 \cdot H_2O$) made by the gelation of sodium silicate and sulfuric acid. It is unlikely that silicon dioxide or silica gel would react chemically with any natural substance(s) in the environment.

The environmental fate data requirements have been waived based on the availability of public information on these compounds.

2. Ecological Effects Assessments

Based on the Environmental Fate Assessment, that both silicon dioxide and silica gel are chemically unreactive in the environment and the fact that they are practically non-toxic to non-target organisms, there is no evidence that demonstrates or suggests any grounds to suspect a hazard to the environment or to non-target organisms when these pesticides are used at the registered levels. Therefore, ecological effects studies are waived.

3. Environmental Risk Assessment

EPA concludes that silicon dioxide and silica gel do not pose unreasonable risks to the environment, including non-target organisms, when used at their registered levels. This conclusion is based on the belief that silicon dioxide and silica gel are chemically unreactive in the environment, occur naturally in various forms and are practically non-toxic to non-target organisms.

IV. REREGISTRATION DECISION FOR ACTIVE INGREDIENT

A. DETERMINATION OF ELIGIBILITY

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

The data identified in Appendix B as well as information from the open literature are sufficient to allow the Agency to conduct a reasonable risk assessment for the registered uses of silicon dioxide and silica gel. The data available to the EPA supports the conclusion that the registered uses of silicon dioxide and silica gel will not result in unreasonable adverse effects to the environment. The Agency has determined that all products containing silicon dioxide and silica gel as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in section V of this document ("Product Reregistration").

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, and the data identified in Appendix B. Although the EPA has found that products containing silicon dioxide and silica gel are eligible for reregistration, it should be understood that the EPA may take appropriate regulatory action, and/or

require the submission of additional data to support reregistration of products containing silicon dioxide and silica gel, if new information comes to the EPA's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. ADDITIONAL GENERIC DATA REQUIREMENTS

The generic data base supporting the reregistration of products containing silicon dioxide and silica gel has been reviewed and determined to be complete for reregistration. No further generic data are required.

C. LABELING REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING SILICON DIOXIDE AND SILICA GEL

The labels and labeling of all products must comply with EPA's current regulations and requirements. Follow the instructions in the Product Reregistration Handbook with respect to labels and labeling. Any product label which allows both manufacturing and end use must be amended to specify only manufacturing or end use. In this situation, if a registrant amends his/her label to specify manufacturing use only and wishes to retain end use registration, he/she must apply for a separate end/use product registration.

Although there are no technicals or MUP's for silicon dioxide (diatomaceous earth) there are MUP's for silica gel.

V. PRODUCT REREGISTRATION

A. DETERMINATION OF ELIGIBILITY

Based on the reviews of the generic data for the active ingredients, silicon dioxide and silica gel, the products containing these active ingredients are eligible for reregistration. Section 4(g)(2)(B) of FIFRA calls for the EPA to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The EPA will review these data when they have been submitted and/or cited and determine whether to reregister individual products.

B. PRODUCT SPECIFIC DATA REQUIREMENTS

The product-specific data requirements are stated

in the attached appendices.

C. LABELING REQUIREMENTS FOR END-USE PRODUCTS CONTAINING SILICON DIOXIDE AND SILICA GEL

The labels and labeling of all products must comply with EPA's current regulations and requirements. Follow the instructions in the Product Reregistration Handbook with respect to labels and labeling. Any product label which allows both manufacturing and end use must be amended to specify only manufacturing or end use. In this situation, if a registrant amends his label to specify end-use registration and wishes to retain manufacturing use registration, he must apply for a separate manufacturing use product registration.

Product labels must specify the active ingredient concentration as a percentage by weight if solid. If the product is a liquid, the ingredients statement must have a substatement giving the pounds per gallon of the product. The application rate, maximum number of applications, and minimum interval between applications must be included. All sites where application is permitted must be specifically listed.

For end-use products containing silicon dioxide as the sole active ingredient and which are used commercially, the following statement is required:

"Wear a suitable dust mask approved by NIOSH/MSHA."

APPENDIX A

USE PATTERNS SUBJECT TO REREGISTRATION

SILICON DIOXIDE AND SILICA GEL

APPENDIX B

Generic Data Requirements for Reregistration of Silicon Dioxide and Silica Gel and Data Citations Supporting Reregistration

GUIDE TO APPENDIX B

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

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

The data tables are generally organized according to the following format:

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

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

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

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

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

APPENDIX B

DATA SUPPORTING GUIDELINE REQUIREMENTS FOR REREGISTRATION OF SILICON DIOXIDE

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION

PRODUCT CHEMISTRY

Sufficient data exists to support reregistration of this chemical.

ECOLOGICAL EFFECTS

EPA waived 40 CFR Part 158 requirements as discussed in Section III.

TOXICOLOGY

EPA waived 40 CFR Part 158 requirements as discussed in Section III.

ENVIRONMENTAL FATE

EPA waived 40 CFR Part 158 requirements as discussed in Section III.

RESIDUE CHEMISTRY

EPA waived 40 CFR Part 158 requirements as discussed in Section III.

OCCUPATIONAL AND RESIDENTIAL EXPOSURE

EPA waived 40 CFR Part 158 requirements as discussed in Section III.

APPENDIX B

DATA SUPPORTING GUIDELINE REQUIREMENTS FOR REREGISTRATION OF SILICA GEL

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION

PRODUCT CHEMISTRY

Sufficient data exists to support reregistration of this chemical.

ECOLOGICAL EFFECTS

EPA waived 40 CFR Part 158 requirements as discussed in Section III.

TOXICOLOGY

EPA waived 40 CFR Part 158 requirements as discussed in Section III.

ENVIRONMENTAL FATE

EPA waived 40 CFR Part 158 requirements as discussed in Section III.

RESIDUE CHEMISTRY

EPA waived 40 CFR Part 158 requirements as discussed in Section III.

OCCUPATIONAL AND RESIDENTIAL EXPOSURE

EPA waived 40 CFR Part 158 requirements as discussed in Section III.

APPENDIX C

SILICON DIOXIDE AND SILICA GEL BIBLIOGRAPHY

Citations Considered to be Part of the
Data Base Supporting Reregistration

GUIDE TO APPENDIX C

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

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

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

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

   a. Author. Whenever the EPA could confidently identify one, the EPA has chosen to show a personal author. When no individual was identified, the EPA has shown an identifiable laboratory or testing facility as author. As a last resort, the EPA has shown the first submitter as author.

   b. Document date. When the date appears as four digits with no question marks, the EPA took it directly from the document. When a four-digit date is followed by a question mark the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the EPA was unable to determine or estimate the date of the document.

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

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

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

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

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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