US Environmental Protection Agency
Office of Pesticide Programs

BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Potassium Silicate

PC Code 072606

September 7, 2007

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U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
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BIOPESTICIDES REGISTRATION ACTION DOCUMENT TEAM

Office of Pesticide Programs:

Biopesticides and Pollution Prevention Division

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I. Executive Summary

Potassium silicate is the potassium salt of silicic acid, and, in formulation, is readily absorbed by the plant. Silicon comprises 32% of the Earth's crust, and silicic acid salts (silicates) are the most common form of silicon. Consequently exposure to silicates is widespread in activities involving contact with soil and natural water. The other part of the chemical, potassium is a required element for survival of both plants and animals, as is silicon.

Potassium silicate is an active ingredient to be used as a fungicide, insecticide and miticide. Potassium silicate will be used as a broad spectrum, preventative fungicide with optimum control obtained when used under a scheduled preventative spray program. Potassium silicate also provides suppression of mites, whiteflies, and other insects. It is approved for use on agricultural crops, fruits, nuts, vines, turf and ornamentals.

Data and information addressing the mammalian and non-target toxicology data requirements were submitted and adequately satisfy data requirements to support the registration. No additional data are needed to support registration.

II. Overview

A. ACTIVE INGREDIENT OVERVIEW

Common Name: Potassium silicate

Chemical Name: Potassium salt of silicic acid

CAS Number: 1312-76-1

Chemical Formula: $K_2O \cdot 3.9SiO_2$

Molecular Weight: 328

Trade Name: AgSil®25, Kasil 1

OPP Chemical Code: 072606

Manufacturer: PQ Corporation
P.O. Box 840
Valley Forge, PA, 19482-0840

B. USE PROFILE

Proposed uses and application methods for potassium silicate include the following:

Type of Pesticide: Fungicide, miticide, insecticide

Use Sites: Agricultural crops, fruits, nuts, vines, turf and ornamentals

Formulation Types: Liquid

Method and Rates of Application: Conventional spray application equipment should be used in the field.

Use Practice Limitations: Do not allow workers into treated areas for four hours following application. Do not spray when and where bees are foraging.

Timing: Begin applications when environmental conditions are conducive to disease development. Repeat applications no sooner than every 7 days.
For mite and insect suppression, begin applications when pests first appear and repeat

applications as necessary to maintain suppression, but no sooner than every 7 days. Apply up to the day of harvest (0 day PHI).

C. ESTIMATED USAGE

This is a new product and projected usage is not available.

D. DATA REQUIREMENTS

The Biopesticides and Pollution Prevention Division (BPPD) reviewed data requirements for granting this registration under Section 3(c)(5) of FIFRA. Mammalian toxicology and ecological effects data requirements for PS were fulfilled. Product analysis data requirements were adequately satisfied.

E. REGULATORY HISTORY

On July 27, 2005, EPA published a notice of filing acknowledging receipt of an application to register a pesticide product containing an active ingredient not currently in any other pesticidal product, and a petition (5F6905) from PQ Corporation proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the biochemical pesticide potassium salt of silicic acid (potassium silicate). The exemption from the requirement for a tolerance was published June 14, 2006 (71 FR 34267), with the caveat that it not be applied at rates exceeding 1% by weight in aqueous solution. Potassium silicate is used as a non-food use inert, but does not a tolerance exemption as an inert ingredient.

F. CLASSIFICATION

Potassium silicate has not been formally classified by the Biochemical Classification Committee.

G. FOOD CLEARANCES/TOLERANCES

FDA has determined that sodium silicate and potassium silicate can be used interchangeably. Sodium silicate has been determined to be GRAS (Generally-Recognized as Safe) by FDA (21 CFR 182.90 and 21 CFR 182.1711) for limited use in canned potable water as a corrosion inhibiting agent. Potassium silicate is also used as a corrosion inhibitor for potable water, with the use rate for municipal water supplies at 8 parts per million. Sodium silicate has been is exemption from requirement of a tolerance when used as an inert ingredient in pre and post-harvest pesticide products (40 CFR 180.910). Sodium silicate can be used as an inert as a surfactant, emulsifier, wetting agent, stabilizer, inhibitor, while there is not a food use inert

tolerance exemption for potassium silicate. Silica is also approved by the FDA for use as an anti-caking agent in food.

III. Science Assessment

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for the technical grade and the end-use products are met.

1. Product Identity and Mode of Action

a. Product Identity:

The technical grade active ingredient (TGAI) consists of 99.4% potassium silicate and at this time there is one end-use product that is 29.1% potassium silicate

b. Mode of Action:

Potassium silicate is a dessicant.

2. Physical and Chemical Properties Assessment

The physical and chemical characteristics of the TGAI were submitted to support the registration. They are summarized in Table 1.

Table 1. Product chemistry data requirements:

TABLE 1. Physical and Chemical Properties for Technical Potassium Silicate[a]		
Guideline Reference No./Property	**Description of Result**	**Methods**
830.6302 Color	White	--
830.6303 Physical State	Solid @ room temperature	--
830.6304 Odor	Odorless	--
830.6313 Stability	Stable	Not provided, not required if provided for EP
830.6314 Oxidation/Reduction: Chemical Incompatibility	Based on known chemistry and prior practical experience, will oxidize metals	Not provided

830.6315	Flammability	N/A[1]	--
830.6316	Explodability	N/A	--
830.6317 830.6320	Storage Stability Corrosion Characteristics	Based on typical results from container corrosion testing of other solid products, no significant reaction is expected between the TGAI/MP and the commercial packaging	--
830.6319	Miscibility	N/A, product is a solid	--
830.6321	Dielectric Breakdown Voltage	N/A, product not for use on electrical equipment	--
830.7000	pH	N/A, product is a solid	--
830.7050	UV/Visible	N/A	--
830.7100	Viscosity	N/A, product is a solid	--
830.7200	Melting Range	1400EF (760EC)	Not provided
830.7220	Boiling Range	N/A, product is a solid	--
830.7300	Bulk Density	1.24 g/cc	Not provided
830.7370	Dissociation Constant in Water	Product is completely ionized to potassium and silicate	--
830.7550	Partition Coefficient	N/A, product is a polar chemical.	--
830.7840	Water Solubility	<0.336 g/L @ 25EC, increasing to 300 g/L @ 80EC. Once dissolved, material will not precipitate out	Not provided
830.7950	Vapor Pressure	N/A	--

[a] Data from MRID 46434702
[1] Not Applicable

B. HUMAN HEALTH ASSESSMENT

Information submitted to support the registration application of the technical grade active ingredient and the end-use product adequately satisfies the food and non-food use requirements set forth in 40 CFR 158.690 (c) for biochemical pesticides. The overall toxicological risk from human exposure to potassium silicate is negligible.

1. Toxicology Assessment

Adequate mammalian toxicology data are available and support registration of the products containing the active ingredient potassium silicate.

a. Acute Toxicity

TABLE 3a Acute Toxicity Profile - Technical Grade

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral [rat]	46434903	LD_{50} = 2000 mg/kg (80-85% potassium silicate powder)	III
870.1200	Acute dermal [rat]	46434902	Moderate to low toxicity (Silica gel)	IV
870.1300	Acute inhalation [rat]	46434906	No animal mortality (40% Silica gel), No lung damage (Silicon dioxide or silicates)	IV
870.2400	Acute eye irritation [rabbit]	46434905	An ocular irritant (Aqueous concentrated potassium silicate) Corrosive (> 80% concentration potassium silicate) Irritating (Sodium silicate powder)	III I III
870.2500	Acute dermal irritation [rabbit]	46434901	A dermal irritant (Aqueous concentrated potassium silicate), Corrosive(> 80% concentration potassium silicate), Not irritating (Sodium silicate powder)	III I IV
870.2600	Skin sensitization [guinea pig]	46434904	Not a sensitizer (Laundry product containing 6% sodium silicate and 30% sodium metasilicate)	IV

TABLE 3b Acute Toxicity Profile - End-Use Product

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral [rat]	46434903	LD_{50} > 5,000 mg/kg (29% aqueous potassium silicate end use fungicide/insecticide)	IV
870.1200	Acute dermal [rat]	46434902	LD_{50} > 5,000 mg/kg (AgSil®25, a 29% potassium silicate aqueous solution)	IV

870.1300	Acute inhalation [rat]	46434906	> 2.06 mg/L (AgSil®25, a 29% potassium silicate aqueous solution)	IV
870.2400	Acute eye irritation [rabbit]	46434905	Irritation cleared within 7 days (Kasil 1, unknown percentage of potassium silicate aqueous solution),	III
870.2500	Acute dermal irritation [rabbit]	46434901	Slightly irritating; irritation cleared within 72 hours (Kasil 1, unknown percentage of potassium silicate in aqueous solution)	IV
870.2600	Skin sensitization [guinea pig]	46434904	Not sensitizing (AgSil®25)	IV

b. Genotoxicity, Immune Response, Mutagenicity, Developmental, Oncogenicity, Subchronic and Chronic Toxicity

Waiver requests (MRID 464347-01) were submitted for 90-day oral toxicity (OPPTS 870.3100), genotoxicity (OPPTS 870.5100; 870.5300; 870.5375), teratogenicity (OPPTS 870.3700) and immunotoxicity (OPPTS 880.3550) for the active ingredient potassium silicate.

The registrant also submitted an evaluation article prepared by the Joint FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization) Expert Committee on Food Additives which met in Geneva, 25 June - 4 July 1973, World Health Organization, Geneva 1974.

In the article, the previously published monograph has been expanded and reproduced. The available data from the seventeenth report regarding silicon dioxide and certain silicates for biochemical aspects and toxicological aspects including special studies on carcinogenicity and special studies on reproduction have been summarized and discussed.

The Joint FAO/WHO Expert Committee concluded available data on orally administered silica and silicates, including flumed silicon dioxide, appear to substantiate the biological inertness of these compounds. Any silicate absorbed is excreted by the kidneys without evidence of toxic accumulation in the body, except for the reported damage to dog kidney by magnesium trisilicate and sodium silicate. Methods for estimating silica in body tissues have been greatly improved in recent years making some of the earlier data somewhat less valuable. A number of short-term studies in two species are available. Talc and magnesium silicate are specified free from asbestos-like particles. This stipulation is made while acknowledging the fact that existing methods for estimating asbestos-like particles in talc and magnesium silicate are not yet fully adequate. Excluding the silicates magnesium silicate and talc, FAO/WHO's estimate of acceptable daily intake for man for silicon dioxide and certain silicates is "Not limited."

FDA has determined that sodium silicate and potassium silicate can be used interchangeably. Sodium silicate has been determined to be GRAS (Generally-Recognized as Safe) by FDA (21 CFR 182.90 and 21 CFR 182.1711) for limited use in canned potable water as a corrosion inhibiting agent.

Sodium silicate has been registered with an exemption from the requirement for a tolerance (40 CFR 180.910) as surfactant, emulsifier, wetting agent, stabilizer, or inhibitor. Solutions of potassium silicate are used in potable water for corrosion protection. Potassium silicates are sold as fertilizer.

Comprehensive reviews of soluble silicates, including potassium silicates (HERA, 2005), potassium silicate fertilizers (NOSB/TAP, 2003), and the Silicon Dioxide and Silica Gel RED (EPA, 1991) indicate there will be no human health concerns when the end-use product is used in accordance with accepted labeling.

Therefore, BPPD concludes the submitted information in support of the requested toxicity waivers for 90-Day Oral Toxicity (OPPTS 870.3100), Genotoxicity (OPPTS 870.5100; 870.5300; 870.5375), Teratogenicity (OPPTS 870.3700) and Immunotoxicity (OPPTS 880.3550) is acceptable.

c. Effects on the Endocrine System

BPPD has considered, among other relevant factors, available information concerning whether potassium silicate may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known related chemical that acts as an endocrine disruptor. The Agency concludes that there will be no incremental adverse effects to the endocrine system.

2. Dose Response Assessment

No toxicological endpoints are identified.

3. Aggregate Exposure and Risk Characterization

a. Dietary

i. Food

In the absence of any toxicological endpoints, risk from the consumption of residues is not expected for the general population, including infants and children.

ii. Drinking Water

Treatment of crops in the fields may include run-off to surface and ground water, but the compound is ubiquitous and cannot be distinguished from natural sources.

b. Other Non-occupational Exposure

Potassium silicate is ubiquitous in the environment so there is routinely exposure to it without toxic effects.

4. Occupational, Residential, School and Day Care Exposure

Human exposure to potassium silicate is expected in residential, school and day care areas, as everyone is daily exposed to potassium silicate in dust, dirt, soil, etc. The additional amount of potassium silicate found in foodstuff as a result of the use of the subject pesticidal products is expected to be minuscule compared to these other sources.

a. Occupational Exposure

Agricultural use of potassium silicate is subject to the Worker Protection Standards (WPS), requiring Personal Protective Equipment (PPE) a long-sleeved shirt, long pants, socks, shoes and gloves, plus a 4 hour Restricted Entry Interval (REI).

b. Residential, School and Day Care Exposure and Risk Characterization

In the absence of any toxicological endpoints, risk from the consumption of residues is not expected for populations in residential, school and day care settings, including infants and children.

5. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency concludes that potassium silicate is practically non-toxic to mammals, including infants and children. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety does not apply. Further, the provisions of

consumption patterns, special susceptibility, and cumulative effects do not apply. And, as no toxic endpoints have been identified, any hazard is impossible to determine. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of potassium silicate.

6. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

Aggregate exposure to potassium silicate by field workers and applicators may occur via oral, dermal and inhalation routes. These risks are measured via the acute toxicity studies submitted to support registration. As the oral toxicity study for PS showed no toxicity at the maximum dose tested (2,000 mg/kg) (Toxicity Category III), the risks anticipated from oral exposure are considered to be minimal.

Because the inhalation toxicity studies for potassium silicate showed no toxicity either (Toxicity Category IV), the risks anticipated for this route of exposure are also considered minimal.

Results of the acute dermal toxicity study indicated moderate to low toxicity at the maximum dose tested, although dermal irritation was observed (Toxicity Category III). Based on these results, the anticipated risks from dermal exposure are also considered to be of low consequence.

Therefore, the risks from aggregate exposure via oral, dermal and inhalation exposure are a compilation of three low risk exposure scenarios and are considered negligible.

7. Cumulative Effects

Potassium silicate is not toxic and therefore cumulative effects from common mechanisms of toxicity are not possible.

8. Risk Characterization

The Agency has considered potassium silicate in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of potassium silicate when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

Comprehensive reviews have already been conducted on potassium silicate effects on the environment and non-target organisms by the Human Environmental Risk Assessment On Ingredients of European Household Cleaning Products (HERA, 2005), including the related

soluble silicates sodium silicate and sodium metasilicate, and by the National Organic Standards Board/Technical Advisory Panel (NOSB/TAP, 2003) for its use as a fertilizer. Both reviews concluded that the use of potassium silicate was unlikely to result in any adverse effects to the environment or non-target organisms for the aforementioned uses. Additionally, the Silicon Dioxide and Silica Gel RED (EPA/OPP, 1991) states that products containing silicon dioxide and silica gel, when used in accordance with accepted labeling, will not present hazards to non-target organisms or the environment. Potassium and silica are ubiquitous in terrestrial and aquatic environments and are essential nutrients in plants and animals (Anderson et al., 2005; Mengel and Kirby, 1978; Nielson, 1991; review by Savant et al., 1999). Potassium and silica respectively comprise approximately 2.59% and 32% of the Earth's crust by weight (Mengel and Kirby, 1978; review by Savant et al., 1999).

A detailed EPA review of the available public information and information submitted by the registrant in support of non-target organism waiver requests is presented below. In certain instances, information/data regarding sodium silicate was used when similar information/data for potassium silicate were unavailable. According to FDA (Chao, 1978) and HERA (2005), potassium silicate and sodium silicate have enough chemical similarity to be used interchangeably for purposes of risk assessment.

1. Ecological Effects Hazard Assessment: Tier I Non-Target Organisms

When applied according to the proposed label directions, no direct exposure of birds or aquatic organisms to the end use product is expected to occur. Many published studies were supplied to the Agency which indicates potential environmental/ecological effects from potassium silicate are likely to be negligible.

a. Avian Acute Toxicity and Avian Dietary Toxicity

No Guideline studies (OPPTS 850.2100 & 850.2200) were submitted. In lieu of Guideline studies, the registrant submitted a non-guideline avian dietary study (see Table 1) obtained from the public literature; an additional non-Guideline study was also reviewed by EPA. In both studies, no apparent toxicity resulted from short-term, sub-chronic consumption of dietary silicon. Dietary exposure of applied potassium silicate to birds is likely to be low and will not exceed exposure to potassium and silicates that are already present in the environment, particularly in many plants and in natural waters. Naturally-occurring potassium and silica are present at levels in excess of what would be applied to the environment as potassium silicate. Furthermore, no direct application of potassium silicate to birds is expected. It is concluded that when potassium silicate is applied in accordance with accepted labeling, there will be no adverse effects on birds.

Table 1. Avian Toxicity Studies

Study Protocol	Species	Effects	Toxicity Category	Reference
Studies with soluble Sodium silicate				
Non-guideline	*Meleagris gallopavo* (male turkey)	4-wk study with 270 ppm sodium silicate in diet reported no adverse effects; pH not reported	No observed toxicological effects	Kayongo-Male & Jia, 1999
Non-guideline	*Gallus domesticus* (broiler chicken)	16-day study with 250 mg/kg silica had no effect on growth or skeletal development	No observed toxicological effects	Elliot & Edwards, 1991

b. Freshwater Fish Acute Toxicity

No Guideline studies (OPPTS 850.1075) were submitted. In lieu of Guideline studies, the registrant submitted data from non-EPA guideline studies and OECD guideline studies contained in comprehensive ecological effects reviews for potassium silicates and related soluble silicates [HERA, 2005; IUCLID 1995; NOSB/TAP, 2003 (see Table 2)]. Additional publicly-available literature was reviewed by EPA. Soluble silicates were practically non-toxic to fish with 96-hr LC50s ranging from 146 mg/L for *Leciscus idus* (Golden orfe) to 3185 mg/L for *Brachydanio rerio* (zebra fish). In all studies, toxicity was assumed to have resulted from the effects of high pH rather than from any direct effects of the test substance. Even at a range of pH 7.2-10.1, the test substances were practically non-toxic for the duration of the studies. Most natural aquatic ecosystems fall within the range of pH 6-9 and due to the high buffering capacity of these ecosystems, effects on pH by applied potassium silicate is highly unlikely (HERA, 2005). The presence of soluble silicates in water has been demonstrated to be beneficial to fish by reducing the bioavailability (and toxicity) of soluble aluminum in fish-bearing waters (Birchall et al., 1989; Exley et al., 1997). Naturally-occurring potassium and silica are present at levels in excess of what would be applied to the environment as potassium silicate. Since the end-use product is not intended for use on aquatic sites, exposure to the product is mitigated. Any inadvertent exposure to aquatic sites would not be expected to affect pH because the product is unbuffered. It is concluded that when potassium silicate is applied in accordance with accepted labeling, there will be no adverse effects on fish.

Table 2. Freshwater Fish Studies

Study Protocol	Species	Data (pH)	Toxicity Category	Reference
Studies with soluble Potassium silicate				
OECD 203;	*Leuciscus idus*	48-hr LC50 > 146 mg/L	Practically	HERA (2005)

Study Protocol	Species	Data (pH)	Toxicity Category	Reference
DIN 38412/15 (Germany)]	(Golden orfe)	(pH not reported)	non-toxic	
	Leuciscus idus (Golden orfe)	48-hr LC50 > 500 mg/L (pH not reported)		IUCLID (1995)
Studies with soluble Sodium meta-silicate (ms) or soluble Sodium silicate (s)				
ISO 7346/2	Danio rerio (Zebra fish)	96-hr LC50 = 210 mg/L (ms) (pH 9.1-9.8)	Practically non-toxic	HERA (2005)
OECD 203	Danio rerio (Zebra fish)	96-hr LC50 = 1108 mg/L (s) NOEC (mortality) = 348 mg/L (pH 7.9-10.3)		HERA (2005)
	Brachydanio rerio (Zebra fish)	96-hr LC50 = 3185 mg/L (pH 8.0)		IUCLID (1995)
Non-guideline	*Oncorhynchus mykiss* (Rainbow trout)	96-hr LC50 = 260 mg/L (s) (pH 6.8-7.5) 96-hr LC50 = 310 mg/L (s) (pH 7.2-8.0)		HERA (2005)
	Gambusia affinis (Mosquito fish)	96-hr LC50 = 2320 mg/L (s) (pH 8.9-10.1)		HERA (2005)
	Lepomis macrochirus (Bluegill sunfish)	96-hr LC50 =301-478 mg/L (pH not reported)		IUCLID (1995)

c. **Aquatic Invertebrate Acute Toxicity**

No Guideline studies (OPPTS 850.1010) were submitted. In lieu of Guideline studies, the registrant submitted data from non-EPA guideline studies and OECD guideline studies contained in comprehensive ecological effects reviews for potassium silicates and related soluble silicates (HERA, 2005; IUCLID 1995; NOSB/TAP, 2003). Soluble silicates were practically non-toxic to aquatic invertebrates with 48-hr EC50s ranging from 146 mg/L for *Leciscus idus* (Golden orfe) to 3185 mg/L for *Brachydanio rerio* (zebra fish). In all studies, toxicity was assumed to have resulted from the effects of high pH rather than from any direct effects of the test substance. Although the reported pH of some of the test substances was up to pH 9.8, the test substances were practically non-toxic for the duration of the studies. Naturally-occurring soluble silicates are continuously removed from water by numerous aquatic organisms, such as diatoms, radiolarians, silicoflagellates, and certain sponges which serve as a sink for silica by incorporating it into their shells and skeletons (HERA 2005). Naturally-occurring potassium and silica are present at levels in excess of what would be applied to the environment as potassium silicate. Since the end-use product is not intended for use on aquatic sites exposure to aquatic

organisms to the product is mitigated. Any inadvertent exposure to aquatic sites would not be expected to affect pH because the product is unbuffered. It is concluded that when potassium silicate is applied in accordance with accepted labeling, there will be no adverse effects on aquatic invertebrates.

Table 3. Aquatic Invertebrate Studies.

Study Protocol	Species	Data (pH)	Toxicity Category	Reference
Studies with soluble Potassium silicate				
OECD 202; EU Guideline 92/69/EWG	*Daphnia magna* (Daphnia)	48-hr EC50 > 146 mg/L (pH not reported)	Practically non-toxic	HERA (2005)
DIN 38412/11 [Germany]	*Daphnia magna* (Daphnia)	24-hr EC50 > 500 mg/L (pH not reported)		IUCLID (1995)
Studies with soluble Sodium silicate				
ISO 7346/2	*Daphnia magna* (Daphnia)	48-hr EC50 = 1700 mg/L (pH 9.1-9.8)	Practically non-toxic	HERA (2005)
Not reported	*Daphnia magna* (Daphnia)	96-hr EC50 = 216 mg/L (pH 9.1) Note: static test in lake water		IUCLID (1995)
Not reported	*Daphnia magna* (Daphnia)	100-hr EC50 = 247 mg/L (pH not reported)		IUCLID (1995)
Not reported	*Lymnea spp.* (Snail eggs)	48-hr EC50 = 632 mg/L (egg hatching) (pH not reported)		NOSB/TAP (2003)
Not reported	*Hyallela spp.* (Amphipods)	96-hr EC50 = 160 mg/L (immobilization) (pH not reported)		NOSB/TAP (2003)

d. **Non-Target Plant Toxicity**

No Guideline studies (OPPTS 850.4100 & 850.4150) were submitted. In lieu of Guideline studies, the registrant submitted data from an OECD guideline study contained in a comprehensive ecological effects review for potassium silicates and related soluble silicates (HERA, 2005). The study demonstrated that a 72-hr EC50 was = 207 mg/L for biomass accumulation in the green algae *S. subspicatus*. Reduced biomass accumulation was attributed to the relatively high pH of the test substance, rather than to any toxicity. Potassium and silica are naturally-occurring and ubiquitous in the soil. Therefore, plants are continually exposed to

potassium and silica compounds. Potassium is present in seeds, seedlings, and mature plants and is an essential nutrient required for growth and health of plants (Mengel and Kirby, 1978). In plants, potassium has an important role in enzyme activation, the opening and closing of stomates, and the maintenance of cellular osmotic balance (Johnson, 2003).

Silica also is ubiquitous in plants and is present primarily as silica gel [hydrated amorphous silica, $(Si)O_2{\cdot}nH_2O$, or polymerized silicic acid] in the cell walls, and as monosilicic acid in the xylem sap (Mengel and Kirby, 1978). Most soils contain significant quantities of silica, although continuous cropping systems may result in significant removal of silica by plants to the point where silica fertilization is required (NOSB/TAP, 2003). For example, sugarcane may remove up to 380 kg/ha/year from the soil (review by Savant et al., 1999).

Potassium silicate has been recommended for use as a crop fertilizer for a variety of crops (NOSB/TAP, 2003; and Yao et al., 2003). Silica (applied as potassium silicate) has been demonstrated to counteract the toxic effects of excess aluminum, cadmium, and manganese in contaminated soils and hydroponic solutions (Barcelo et al., 1993; Horst and Marschner, 1978; Tredar and Ciesliski, 2005) and to suppress the effects of pathogenic fungi (Cherie et al., 1992; Kant et al., 2004). Silicate fertilizers applied to cucumbers at rates of up to 1400 kg SiO_2/A/year for three consecutive years were observed to increase growth and reduce wilt disease damage (NOSB/TAP, 2003). There are no reports available regarding any plant toxicity following treatments with potassium, silica, and/or potassium silicate. Naturally-occurring potassium and silica are present at levels in excess of what would be applied to the environment as potassium silicate. It is concluded that when potassium silicate is applied in accordance with approved labeling, there will be no adverse effects on plants.

Table 4. Plant Study

Study Protocol	**Species**	**Data (pH)**	**Toxicity Category**	**Reference**
Studies with soluble Sodium silicate				
OECD 201; DIN 38412/9 (Germany)]	*Scenedesmus subspicatus* (algae)	72-hr EC50 (biomass) = 207 mg/L (pH 8.2-9.5)	Practically non-toxic	HERA (2005)

e. Non-Target Insect Toxicity

A Guideline study (OPPTS 850.3020) conducted by the registrant (MRID 469887-01) demonstrated that the 48-hr LD50 for potassium silicate is >25.6 ug potassium silicate/bee (practically non-toxic). The pH of the test solution was reported as pH 9.99, whereas the CSF for the EP (EPA Reg. No. 82100-1) lists a pH of 11.1. However, it is noted that the EP is unbuffered and will be diluted prior to application, which will lower the pH of the solution to be applied. Therefore, there are no concerns that the pH of the applied product will have any adverse effects on honey bees or other non-target insects when the product is used in accordance with approved labeling.

Table 5. Plant Study

Study Protocol	Species	Data (pH)	Toxicity Category	Reference
Studies with Potassium silicate				
OPPTS 850.3020	*Apis mellifera* (European Honey bee)	48-hr >25.6 *u*g/L (pH 9.99)	Practically non-toxic	MRID 469887-01

2. Environmental Fate Assessment

When dissolved in water, the active ingredient potassium silicate dissociates into potassium cations, hydroxide anions, and mono- and polysilicic acids. The active ingredient does not contain any volatile organic compounds and will not degrade to any hazardous or environmentally persistent breakdown products (NOSB/TAP, 2003). Dissolved soluble silica from commercial sources will be indistinguishable from dissolved soluble silica from natural sources and any soluble silica input into aquatic or terrestrial environments will be insignificant in relation to the high flux of the natural silica cycle (IUCLID, 1995). The primary hazard to non-target organisms results from the alkaline pH of the active ingredient, potassium silicate, a soluble silicate compound (HERA, 2005; IUCLID, 1995). The end-use product (AgSil®25; EPA Reg. No. 81200-1) is approximately pH 11.1, but it is unbuffered. Therefore, when applied to terrestrial and aquatic environments, commercial potassium silicate formulations will have little effect on pH due to the high buffering capacity of the natural environments (HERA, 2005). At environmental pH [approximately pH 4.5-9; (Smith, 2001)], potassium cations are readily soluble, but soil solution concentration is dependent upon clay content and clay type (Mengel and Kirby, 1978). Below pH 9, soluble silicates are present as poorly soluble amorphous silica and monosilicic acid (HERA, 2005).

The need for environmental fate and groundwater data (Tier II, (40 CFR Section 158.690(d)(2)(vii through xv)) was not triggered because the Tier I studies were waived. Risk is minimal due to low toxicity, use pattern, and application methods.

3. Ecological Exposure and Risk Characterization

a. Environmental Exposure Assessment

Worldwide production of soluble silicates (sodium silicate, disodium metasilicate, and potassium silicate) is approximately 3-4 million metric tons per year (HERA, 2005). Soluble silicate exposure (from commercial sources) to aquatic and terrestrial environments occurs via uses in detergents, pulp and paper effluent, water/wastewater treatment, soil stabilization, and as fertilizer (HERA, 2005; NOSB/TAP, 2003; Perry & Keeling-Tucker, 2000). When used as a fertilizer, potassium silicate is used primarily as a silica amendment (NOSB/TAP, 2003). Due to their ubiquitous distribution in terrestrial and aquatic environments, non-target organisms are continually exposed to soluble silicates (including potassium silicate), potassium, silicon dioxide, and silica gel via contact and/or oral exposure.

b. Naturally-Occurring Potassium and Silicon

i. Potassium

Potassium is a common basic cation found in the environment and is an essential element in human and plant nutrition (Johnson, 2003). In plants, potassium has an important role in enzyme activation and the maintenance of cellular osmotic balance; as in plants, potassium is necessary in animals for maintaining osmotic equilibrium as well as participating in life-supporting activities such as nerve impulses, heartbeat, and enzyme activation (Johnson, 2003). Potassium is a common soil plant nutrient and fertilizer (as K_2O). Potassium comprises approximately 2.59% of the Earth's crust by weight (Merck, 1983). The primary source of naturally-occurring soluble potassium is from the weathering of potassium containing minerals [e.g. alkali feldspars; (Mengel and Kirby, 1978)]. Mobility of potassium in the soil is dependent upon the clay content, the type of clay (vermiculite, illite, montmorillonite, or kaolinite), and to a lesser extent, pH; potassium content is higher in high clay content soil and is greater with 2:1 clays (e.g. montmorillonite) than in 1:1 clays [e.g. kaolinite (Mengel and Kirby, 1978)].

ii. Silicon

Silicon also is ubiquitous in the environment, comprises approximately 32% of the soil by weight (review by Savant et al., 1999) and is present as dissolved silica, amorphous silica in the solid phase, and silica bound to organic matter (IUCLID, 1995). Silicon is the second most

abundant element in the lithosphere after oxygen (Mengel and Kirby, 1978). At less than pH 9, Si is present in soil solution primarily as monosilicic acid ($Si(OH)_4$ and as silicate ions at higher pH (Mengel and Kirby, 1978). The solubility of silica is relatively constant in a pH range between 2 to 8.5, and increases rapidly above pH 9 (review by Savant et al., 1999). The pH-dependent adsorption on sequioxides (e.g. iron oxide, aluminum oxide) controls the concentration of silicic acids in soil solution, which decreases on either side of a maximum at pH 9.5 (Mengel and Kirby, 1978); adsorption is greatest on aluminum oxides. In the normal range of soil pH, silicic acid is the major silicate in soil water (IUCLID, 1995). In natural waters most dissolved silica results from the weathering of silicate minerals. It is estimated that silica is introduced into the environment via weathering at a rate of approximately 2000 kg/square km/year and natural waters may contain 3.8-363 ppm soluble silica (IUCLID, 1995) depending on the geological materials with which the waters are in equilibrium. The high and variable flux of the natural silica cycle will cause influx of soluble silicates from commercial sources to be insignificant in relation to silica from natural sources (IUCLID, 1995). According to a review by HERA (2005), "silica is continuously removed from water by biochemical processes: diatoms, radiolarians, silicoflagellates, and certain sponges serve as a sink for silica by incorporating it into their shells and skeletons as amorphous biogenic silica, frequently referred to as opal ($SiO_2 \cdot nH_2O$)." Commercial soluble silicates rapidly degrade to molecular forms that are indistinguishable from natural dissolved silica (IUCLID, 1995). The most common form of silica, quartz, comprises approximately 12% of the Earth's crust (IARC, 1997) by volume. Beach sand is almost 100% silica (Crop Protection handbook, 2003). Silica is chemically unreactive. Silica and silica gel (a hydrated amorphous form of silica) are considered GRAS by FDA (21 CFR 182.90 and 21 CFR 182.1711).

When used as a pesticide, potassium silicate residues are low relative to naturally present concentrations and other uses in the environment. Minimal potential for additional exposure exists to insects, fish and other nontarget wildlife as a result of potassium silicate use as a pesticide.

D. EFFICACY DATA

No efficacy data are required, because no public health uses are involved.

IV. Risk Management Decision

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the

environment and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

To satisfy criterion (A) above, potassium silicate will protect agricultural commodities from fungi, insects and mites. Criterion (B) is satisfied by the current label and by the data presented in this document. It is believed this new pesticidal active ingredient will not cause any unreasonable adverse effects, satisfying Criterion (C). Criterion (D) is satisfied by the data submitted and the low exposure to the product when used according to the label's directions.

Therefore, potassium silicate is eligible for registration. The uses are listed in Table 4, Appendix A.

B. REGULATORY POSITION

1. Unconditional Registration

All data requirements have been fulfilled and/or waived by the Agency and the Biopesticides and Pollution Prevention Division approved unconditional registration of products which contain potassium silicate as their sole active ingredient.

2. Exemption from the Requirement of a Tolerance for food uses

EPA received a pesticide petition proposing, pursuant to section 408(b)(2)(D) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346, to amend 40 CFR Part 180 by establishing an exemption from the requirement of a tolerance for the pesticide ingredient, potassium silicate. This was granted June 14, 2006 (71 FR 34272), 40 CFR 180.1268 so long as potassium silicate is not applied at rates greater than 1.0% by weight in aqueous solutions.

3. CODEX Harmonization

There is no CODEX or international tolerance exemption established for the subject active ingredient at this time.

4. Nonfood Re/Registrations

There are no non-food issues at this time. The non-food uses are listed in Appendix A, Table 4.

5. Risk Mitigation

There are no significant risk issues. Risks to workers are mitigated by protective clothing requirements and a 4-hour re-entry interval restriction.

6. Endangered Species Statement

EPA concludes that potassium silicate does not pose an unreasonable risk to the environment, including non-target organisms, when used according to label directions. The primary hazard resulting from use of potassium silicate is its high pH (approximately 11.1). However, since most terrestrial and aquatic ecosystems are highly buffered in the slightly acid to slightly alkaline range (pH 5-9), and end-use products will be diluted prior to use, application of the unbuffered potassium silicate will have little effect on environmental pH and non-target organisms. Therefore, when used in accordance with accepted labeling, use of potassium silicate products will have No Effects **(NE)** on endangered species.

C. LABELING RATIONALE

It is the Agency's position that the labeling of the end use and the technical grade active ingredient products containing, respectively, 29.1% and 99.40% potassium silicate complies with current pesticide labeling requirements.

1. Human Health Hazard

a. Worker Protection Standard

This product comes under the provisions of the Worker Protection Standard (WPS).
PPE (long-sleeved shirt and long pants, socks, shoes, and gloves) and REI (4-hour) required.

b. Non-Worker Protection Standard

There are no non-WPS human health hazard issues.

c. Precautionary Labeling

The Agency has examined the toxicological data base for potassium silicate products and concluded proposed precautionary labeling (i.e., Signal Word, Statement of Practical Treatment and other label statements) adequately mitigates any risks associated with the proposed uses.

Technical Product Precautionary Labeling: For potassium silicate is "CAUTION."

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Wear: Long-sleeved shirt and long pants, socks, shoes, and gloves.

First Aid:

If swallowed:
-Call a poison control center or doctor for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to do so by a poison control center or doctor.
-Do not give anything to an unconscious person.

If on skin or clothing:
-Take off contaminated clothing.
-Rinse skin immediately with plenty of water for 15-20 minutes.
-Call a poison control center or doctor for treatment advice.

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
-Call a poison control center or doctor for treatment advice.

End-Use product Precautionary Labeling: For end use potassium silicate is "CAUTION."

Hazards to Humans and Domestic Animals:

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Wear: Long-sleeved shirt and long pants, socks, shoes, and gloves.

First Aid:
If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
-Call a poison control center or doctor for treatment advice.

2. Environmental Hazards Labeling

End-Use Product Environmental Hazards Labeling: Potassium silicate is considered non-toxic to the environment and no environmental hazard statement is required on the end-use product's label.

3. Application Rate

It is the Agency's position that the labeling for the end-use pesticide product containing potassium silicate complies with current pesticide labeling requirements.

D. LABELING

(1) Product name: **Technical Potassium Silicate**

Active Ingredient:
Potassium Silicate..... . . . . .99.4%
Other Ingredients 0.6%

Total 100.0%

(2) Product name: **AgSil®25**

Active Ingredient:
Potassium Silicate..... . . . . ..29.1%
Other Ingredients 70.9%

Total 100.0%

Signal word is "CAUTION".

The product shall contain the following information:
- Product Name
- Ingredient Statement
- Registration Number
- Signal Word (CAUTION)

V. Actions Required by Registrants

There are no data requirements, label changes or other responses necessary for the reregistration of the end-use product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. There are also no existing stocks provisions at this time.

VI. Appendix A

Table 4 lists the use sites for the product.

Table 4. Use Site Registration

Technical Potassium Silicate (99.4% potassium silicate) Use sites: Manufacturing use product	Official date registered: May 11, 2006
AgSil®25 (29.1% potassium silicate) Use Sites: agricultural crops, fruits, nuts, vines, turf and ornamentals	Official date registered: May 11, 2006

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