



Proposed Registration Decision

PRD2020-11

# Silicon Dioxide (Present as 100% Diatomaceous Earth), DX13 Dust, and DX13 Industrial

*(publié aussi en français)*

**26 June 2020**

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0878 (print)  
1925-0886 (online)

Catalogue number: H113-9/2020-11E (print version)  
H113-9/2020-11E-PDF (PDF version)

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## Overview

### Proposed Registration Decision for Silicon Dioxide (present as 100% diatomaceous earth), DX13 Dust and DX13 Industrial

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the [Pest Control Products Act](#), is proposing registration for the sale and use of Celatom Food Grade Diatomaceous Earth, DX13 Dust, and DX13 Industrial, containing the active ingredient silicon dioxide (present as 100% diatomaceous earth), to control spider mites on greenhouse tomatoes, cucumbers, and peppers, cannabis produced commercially indoors and indoor ornamental plants and landscapes.

Silicon dioxide is currently registered as an insecticide and acaricide for both indoor and outdoor commercial and domestic uses. DX13 Dust and DX13 Industrial are currently registered for structural use, including bedframes and mattresses, and outdoor use to kill various insect pests. For details, see Proposed Acceptability for Continuing Registration Document, PACR2004-09, *Silicon Dioxide and Silica Gel*, and Registration Decision Document, RRD2004-20, *Silicon Dioxide and Silica Gel*.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of silicon dioxide (present as 100% diatomaceous earth), and the end-use products DX13 Dust, and DX13 Industrial.

### What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable<sup>1</sup> if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value<sup>2</sup> when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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<sup>1</sup> "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

<sup>2</sup> "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides portion of the Canada.ca website.

Before making a final registration decision on silicon dioxide (present as 100% diatomaceous earth), DX13 Dust, and DX13 Industrial, Health Canada's PMRA will consider any comments received from the public in response to this consultation document.<sup>3</sup> Health Canada will then publish a Registration Decision<sup>4</sup> on silicon dioxide (present as 100% diatomaceous earth), DX13 Dust, and DX13 Industrial, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

## **What Is Silicon Dioxide (present as 100% diatomaceous earth)?**

Silicon dioxide is a mineral substance that is found in diatomaceous earth and is the active ingredient in DX13 Dust and DX13 Industrial. It physically damages the water-proof exoskeleton of arthropods, causing them to lose water and die of dehydration.

## **Health Considerations**

**Silicon Dioxide (present as 100% diatomaceous earth) is unlikely to affect human health when it is used according to label directions.**

Potential exposure to silicon dioxide (present as 100% diatomaceous earth) may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed.

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<sup>3</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>4</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

The technical grade active ingredient, Celatom Food Grade Diatomaceous Earth containing silicon dioxide (present as 100% diatomaceous earth), is considered to be of low acute toxicity, via the oral, dermal and inhalation routes, minimally irritating to the eyes and skin and not likely to be a dermal sensitizer. Silicon dioxide has a history of use as an insecticide and is permitted as a food additive in Canada.

In laboratory animals, DX13 (Diatomaceous Earth), a toxicological equivalent to DX13 Dust, was of low acute inhalation toxicity and practically non-irritating to the eye. Considering surrogate studies and published scientific literature on the active ingredient, DX13 Dust is of low acute toxicity via the oral, dermal and inhalation routes, practically non-irritating to the eye, non-irritating to the skin, and not expected to be a dermal sensitizer. DX13 Dust is a respiratory irritant. No toxicology studies were submitted for the end-use product, DX13 Industrial, but supported rationales argued that its effects on animals would be similar to those of DX13 Dust.

### **Residues in Water and Food**

#### **Dietary risks from food and water are acceptable.**

Residues of silicon dioxide (present as 100% diatomaceous earth) on treated food crops are possible at the time of harvest. Due to its low toxicity profile and its history of use as a food additive, consumer exposure to silicon dioxide present in DX13 Dust and DX13 Industrial is not expected to pose a health risk when the end-use products are applied as directed by the label. In addition, the likelihood of silicon dioxide (present as 100% diatomaceous earth) residues in drinking water will be low. Consequently, health risks are acceptable for all segments of the population, including infants, children, adults and seniors.

### **Risks in Residential and Other Non-Occupational Environments**

#### **Estimated risk for residential and other non-occupational exposure is acceptable.**

DX13 Dust and DX13 Industrial are registered for use in commercial and residential areas. DX13 Dust and DX13 Industrial are proposed for use on greenhouse tomatoes, cucumbers and peppers, indoor plants and plantscapes and cannabis produced commercially indoors. The product labels will include measures to prevent bystander exposure such as reducing dust/spray drift, restricting access to the treated area until dusts have settled or sprays have dried and ensuring that applicators limit DX13 Dust and DX13 Industrial to target areas and remove any residues on non-target surfaces. Residential and non-occupational exposure to DX13 Dust and DX13 Industrial is therefore expected to be low when label directions are observed. Consequently, the risk to residents and the general public is acceptable.

## **Occupational Risks From Handling DX13 Dust and DX13 Industrial**

**Occupational risks are acceptable when DX13 Dust and DX13 Industrial are used according to the label directions, which include protective measures.**

Workers handling DX13 Dust and DX13 Industrial can come into direct contact with silicon dioxide (present as 100% diatomaceous earth) through inhalation and contact with eyes and skin. To protect workers from exposure to DX13 Dust and DX13 Industrial, the labels require workers to wear long-sleeved shirts, long pants, chemical-resistant gloves, socks and shoes, and protective eyewear during loading, application, clean-up and repair, as well as a dust mask during handling (including clean-up and repair) and a respirator for loading and application. A restricted-entry interval of 4 hours, or until dusts have settled or sprays have dried, is prescribed for all uses. If early entry is necessary during the restricted-entry interval, workers must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, protective eyewear (goggles or face shield) and a dust mask. For use on cannabis produced commercially indoors, greenhouse tomatoes, cucumbers and peppers, an information sheet is required for DX13 Dust or DX13 Industrial stating personal protective equipment (PPE) and re-entry requirements for post-harvest clean-up activities. Workers involved in post-harvest clean-up activities will be required to wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, protective eyewear (goggles or face shield) and a dust mask and re-entry without PPE is not permitted until dusts have settled and the area cleaned.

The occupational risks are acceptable when the precautionary statements on the label are observed.

## **Environmental Considerations**

**What Happens When Silicon Dioxide (Present as 100% Diatomaceous Earth) Is Introduced Into the Environment?**

**When Celatom Food Grade Diatomaceous Earth and its associated end-use products, DX13 Dust and DX13 Industrial, are used according to the label, the risks to the environment are acceptable.**

Silicon dioxide is a naturally occurring inert substance that is composed primarily of silica, the same major component of quartz and sand. It is an insecticide with a non-toxic mode of action, interfering with the water balance of insects by absorbing protective coatings (oils and fats) and via mechanical abrasion of the outer cuticle layer.

As an insecticide, silicon dioxide (present as 100% diatomaceous earth) may harm bees and other beneficial insects used in greenhouse production. Label instructions will include requirements to avoid application when bees or other beneficial insects are in the treatment area. Due to its non-toxic mode of action and inert nature, silicon dioxide (present as 100% diatomaceous earth) is expected to be non-toxic to other non-target organisms. When silicon dioxide (present as 100% diatomaceous earth) is used in accordance with the label and the required precautions, the resulting environmental risk is acceptable.



## **Value Considerations**

### **What Is the Value of DX13 Dust and DX13 Industrial?**

**DX13 Dust and DX13 Industrial provide a new mode of action for control of spider mites on plants grown indoors.**

Applied to provide coverage of all plant surfaces, DX13 Dust and DX13 Industrial control spider mites on greenhouse tomatoes, peppers, and cucumbers, cannabis produced commercially indoors, and indoor ornamental plants and plantscapes. For all of those uses, these products provide a new active ingredient with a new physical mode of action, to which resistance is unlikely.

### **Measures to Minimize Risk**

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of Celatom Food Grade Diatomaceous Earth, DX13 Dust and DX13 Industrial to address the potential risks identified in this assessment are as follows.

#### **Key Risk-Reduction Measures**

##### **Human Health**

The statement, 'KEEP OUT OF REACH OF CHILDREN AND PETS' is required on the principal display panel and in the PRECAUTIONS section of the secondary display panel of the DX13 Dust and DX13 Industrial labels.

Standard hazard and precautionary statements are required on the end-use product labels. Workers will be required to wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes and protective eyewear during loading, application, clean-up and repair, as well as a dust mask during handling (including clean-up and repair) and a respirator for loading and application.

There will be a restricted-entry interval of 4 hours, or until dusts have settled or sprays have dried. If early entry is necessary during the restricted-entry interval, workers must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, protective eyewear (goggles or face shield) and a dust mask.

For use on cannabis produced commercially indoors, greenhouse tomatoes, cucumbers and peppers, an information sheet is required to protect workers from dusts disturbed during post-harvest activities.

Application of DX13 Dust and DX13 Industrial will not be permitted on cannabis, or the surrounding soil, past the vegetative stage.

Additional statements have been added to the label to address post-application exposure in residential and commercial areas.

### **Environment**

Label statement indicating that the product is toxic to bees and other beneficial insects used in greenhouse production.

### **Next Steps**

Before making a final registration decision on ingredient silicon dioxide (present as 100% diatomaceous earth), DX13 Dust, and DX13 Industrial, Health Canada's PMRA will consider any comments received from the public in response to this consultation document. Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

### **Other Information**

When the Health Canada makes its registration decision, it will publish a Registration Decision on silicon dioxide (present as 100% diatomaceous earth), DX13 Dust, and DX13 Industrial (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

## Science Evaluation

### Silicon Dioxide (Present as 100% Diatomaceous Earth), DX13 Dust and DX13 Industrial

#### 1.0 The Active Ingredient, Its Properties and Uses

##### 1.1 Identity of the Active Ingredient

<b>Active substance</b>	Silicon dioxide, present as 100% 100% diatomaceous earth – fresh water fossils
<b>Function</b>	Insecticide
<b>Chemical name</b>	
<b>1. International Union of Pure and Applied Chemistry (IUPAC)</b>	Not applicable
<b>2. Chemical Abstracts Service (CAS)</b>	Diatomite
<b>CAS number</b>	61790-53-2
<b>Molecular formula</b>	SiO <sub>2</sub> (major component)
<b>Molecular weight</b>	60.1
<b>Structural formula</b>	O=Si=O (major component)
<b>Purity of the active ingredient</b>	82%

##### 1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

###### Technical Product—Celatom Food Grade Diatomaceous Earth

Property	Result
Colour and physical state	Off white to tan dry powder
Odour	Earthy when damp
Melting range	Not applicable
Boiling point or range	Not applicable
Specific gravity	2.0
Vapour pressure at 20°C	Not applicable
Ultraviolet (UV)-visible spectrum	Not applicable

Solubility in water	< 3%
Solubility in organic solvents at 20°C	Not applicable
<i>n</i> -Octanol-water partition coefficient ( $K_{ow}$ )	Not applicable
Dissociation constant ( $pK_a$ )	Not applicable
Stability (temperature, metal)	Stable

### End-Use Product — DX13 Dust

Property	Result
Colour	Off white to tan
Odour	Earthy when damp
Physical state	Dry powder
Formulation type	Dust or powder (DU)
Label concentration	82%
Container material and description	Paper bags 0.5–20 kg
Specific gravity	2.0
pH of 1% dispersion in water	6–8 (10% water slurry)
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	The product is considered to be stable in its packaging material at ambient temperatures.
Corrosion characteristics	The product is not corrosive to the packaging material.
Explosibility	Product does not contain any explosive components.

### End-Use Product—DX13 Industrial

Property	Result
Colour	Slightly buff to off-white
Odour	Mild alcohol odour
Physical state	Pressurized product, suspension of diatomaceous earth powder in liquid
Formulation type	Pressurized product (PP)
Label concentration	6.56%
Container material and description	Tin-plated steel aerosol cans with protective liner and sealed with a dispensing valve, 211 × 713, 400 g net weight
Specific gravity	0.69
pH of 1% dispersion in water	Not required for aerosol products

<b>Property</b>	<b>Result</b>
Oxidizing or reducing action	Product does not contain any oxidizing or reducing agents; product is not compatible with strong oxidizing agents
Storage stability	The product is considered to be stable at ambient temperatures.
Corrosion characteristics	The product is not corrosive to the packaging material.
Explosibility	The product will ignite in the presence of a direct flame; product is not expected to be sensitive to impact; since it is a pressurized product, there is potential for explosion – the container may burst if exposed to temperatures above 54.4°C.

### **1.3 Directions for Use**

Using a dust blower (DX13 Dust) or the aerosol can in which the product is packaged (DX13 Industrial), the products are applied in an even layer covering all plant surfaces as well as surrounding areas including the soil, pots, tables, shelving, and stem support structures, with reapplication in 7-14 days, as needed to maintain good film coverage. Label directions include recommendations for 3-7 applications per crop cycle on tomatoes and cucumbers, 3-10 applications per crop cycle on peppers, and 3-7 applications per year on indoor ornamental plants and plantscapes, but applications of DX13 Dust and DX13 Industrial will not be permitted on cannabis, or surrounding soil, past the vegetative stage.

### **1.4 Mode of Action**

Silicon dioxide in the form of diatomaceous earth has a physical mode of action, abrading the cuticle of the arthropod exoskeleton, leading to lethal dehydration.

## **2.0 Methods of Analysis**

### **2.1 Methods for Analysis of the Active Ingredient**

Food Chemicals Codex (FCC) test results were provided for this diatomaceous earth source and all requirements are attested to be met, therefore method for the analysis of the active ingredient is not required.

### **2.2 Method for Formulation Analysis**

The method for the analysis of the active ingredient in the formulation is not required since the product is considered food grade.

### **2.3 Methods for Residue Analysis**

No methods are required to quantify residues of silicon dioxide (present as 100% diatomaceous earth).

### **3.0 Impact on Human and Animal Health**

#### **3.1 Toxicology Summary**

A detailed review of submitted and published scientific literature was conducted in support of the new use of Celatom Food Grade Diatomaceous Earth. The data package for Celatom Food Grade Diatomaceous Earth, DX13 Dust and DX13 Industrial is considered acceptable to assess the toxic effects that may result from exposure to silicon dioxide (present as 100% diatomaceous earth). The data package consisted of surrogate acute toxicity studies (acute inhalation toxicity and eye irritation) for DX13 (Diatomaceous Earth) which was toxicologically equivalent to DX13 Dust, published scientific literature on silicon dioxide, and rationales supported by published scientific literature to waive acute toxicity testing for DX13 Industrial.

Celatom Food Grade Diatomaceous Earth contains less than 1% respirable crystalline silica as required by the PMRA and complies with food-grade criteria established by the FCC. Silicon dioxide is considered to be of low acute toxicity, via the oral, dermal and inhalation routes, minimally irritating to the eyes and skin, and not likely to be a dermal sensitizer. Silicon dioxide has a history of use as a food additive under Canada's Food and Drug Regulations (FDR).

An acute inhalation four-hour, nose-only aerosol study with DX13 (Diatomaceous Earth), found it to be of low acute toxicity based on an LC<sub>50</sub> of greater than 2.15 mg/L. A primary eye irritation animal study with DX13 (Diatomaceous Earth) found it to be practically non-irritating to the eyes of rabbits. There were no signs of irritation at 48 hours. Since DX13 (Diatomaceous Earth) is toxicologically equivalent to DX13 Dust, the submitted studies (Table 1, Appendix I) are acceptable as surrogate studies for DX13 Dust. Considering all sources of information (i.e., surrogate studies and published scientific literature on silicon dioxide), DX13 Dust is of low acute oral, dermal and inhalation toxicity, practically non-irritating to the eye, not irritating to the skin and not expected to be a dermal sensitizer. DX13 Dust is a respiratory irritant.

Requests were accepted to waive data requirements for DX13 Industrial based on its similarity to DX13 Dust, Celatom Food Grade Diatomaceous Earth is a food grade substance, and silicon dioxide has a history of use as a food additive in Canada.

#### **Health Incident Reports**

As of December 12, 2019, 71 human and 63 domestic animal incidents involving silicon dioxide (present as 100% diatomaceous earth) were submitted to the PMRA.

The majority of the incidents (67%) were considered to be possibly related to the reported pesticide. In almost all incidents, a domestic class silicon dioxide (present as 100% diatomaceous earth) product formulated as a dust was used indoors in residential areas. People as well as pets were affected in the reported incidents. Reported exposure scenarios in people include inhaling silicon dioxide (present as 100% diatomaceous earth) dust when applying the product or contact with product residues when living in treated areas.

The symptoms reported in people following product exposure were mainly minor in severity and include signs such as respiratory tract irritation, shortness of breath, rash or watery eyes. In pets, exposure to the product was reported to have occurred by licking the product off of treated areas. Signs reported in animals were also mainly minor in severity and include effects such as vomiting, diarrhea or loss of appetite.

The reported incidents indicate a potential for exposure of people and pets to silicon dioxide (present as 100% diatomaceous earth) when products are used indoors as per label directions. The exposure scenarios reported in incidents are relevant to the two registered commercial class products (Pest Control Product Registration Numbers 32178, 30966) when used in indoor residential sites. It is therefore recommended that the proposed product labels be improved as per Guidance Document 2020, Structural Pest Control Products: Label Updates to minimize the likelihood of human and domestic animal exposure to silicon dioxide (present as 100% diatomaceous earth) products used in indoor areas.

### **3.2 Occupational, Residential and Bystander Exposure and Risk Assessment**

#### **3.2.1 Dermal Absorption**

No information on dermal absorption of silicon dioxide (present as 100% diatomaceous earth) from DX13 Dust or DX13 Industrial was provided, however, dermal exposure is expected to be limited when the precautionary statements on the label are observed.

#### **3.2.2 Use Description**

The commercial end-use products DX13 Dust and DX13 Industrial are currently registered as insecticides (ants, bed bugs, cockroaches, crickets, earwigs, fleas and silverfish) in residential and commercial areas (including both indoor and outdoor areas). The proposed expansion of use would add greenhouse food crops (tomatoes, cucumbers and peppers), indoor plants and plantscapes and cannabis produced commercially indoors for the control of spider mites to the end-use product labels. DX13 Dust is applied with a dust blower while DX13 Industrial is an aerosol spray. DX13 Dust and DX13 Industrial is intended to be applied as an even coating directly to all plant surfaces (both sides of leaves, stems and/or fruits and vegetables) and surrounding areas to good or near drip coverage. The end-use products are applied at a rate of 6 g of active ingredient/m<sup>2</sup>, with applications at the first sign of spider mite infestation and re-application permitted every seven to 14 days as needed to maintain good film coverage. Label directions permit three to seven applications per crop cycle for greenhouse tomatoes, cucumbers and indoor ornamental plants and plantscapes, and three to 10 applications per crop cycle for greenhouse peppers. Application of DX13 Dust and DX13 Industrial will not be permitted on cannabis, or surrounding soil, past the vegetative stage.

#### **3.2.3 Mixer, Loader, and Applicator Exposure and Risk**

When DX13 Dust and DX13 Industrial are used according to label directions, occupational exposure is characterized as short- to intermediate-term in duration and is primarily by the inhalation route but dermal and ocular exposure are also possible during loading, applying and

handling (including clean up and repairs). To protect workers from exposure to DX13 Dust and DX13 Industrial, workers are required to wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes and protective eyewear during loading, application, clean-up and repair, as well as a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) during handling (including clean-up and repair) and a respirator with a NIOSH-approved cartridge with a prefilter or canister for loading and application. A label statement is also included to use adequate ventilation when handling and during application and clean-up activities.

Precautionary statements on the end-use product labels, such as the wearing of PPE, aimed at mitigating exposure are adequate to protect individuals from any risk due to occupational exposure. Overall, occupational risks to workers are acceptable when the precautionary statements on the labels are followed which include PPE.

### **3.2.4 Post-application Exposure and Risk**

There is the potential for post-application exposure to workers re-entering areas treated with DX13 Dust and DX13 Industrial. Given the nature of the post-application activities typically performed (e.g., harvesting, thinning and pruning), inhalation of the end-use products as well as dermal contact with treated plants, soil, and surfaces is possible. A restricted entry interval (REI) of 4 hours, or until dusts have settled or sprays have dried, has been established for all uses as well as instructions for individuals to remain out of the treated area until the dusts or sprays have settled or dried. If early entry is required, workers must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, protective eyewear (goggles or face shield) and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested. To minimize occupational and bystander exposure during post-harvest clean-up activities for cannabis produced commercially indoors, greenhouse tomato, cucumber and pepper crops, an information sheet is required for DX13 Dust or DX13 Industrial stating required PPE for post-harvest clean-up activities and that re-entry without PPE is only permitted after dusts have settled and the area cleaned. At the time of post-harvest clean-up activities, workers will be required to wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, protective eyewear (goggles or face shield) and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested. As there could be a significant time period between the application(s) and post-harvest clean-up activities, the information sheet is required to be posted at points of entry.

Precautionary (e.g., wearing of PPE) statements on the end-use product labels aimed at mitigating exposure are adequate to protect workers from risk due to post-application exposure.

### **3.2.5 Residential and Bystander Exposure and Risk**

DX13 Dust and DX13 Industrial are registered for use in residences, motels, hospitals and other commercial buildings and the proposed new use expands the label to greenhouse tomatoes, cucumbers, and peppers, cannabis produced commercially indoors and indoor ornamental plants and plantscapes. Due to the number of reported incidents with this active ingredient (see “Incident Reports” under Section 3.1), label updates were performed to include statements that



restrict access to the treated areas until dusts have settled or sprays have dried and ensure that applicators limit application of dusts or sprays to target areas. Adhering to label instructions will ensure that exposure to bystanders (humans and companion animals) and individuals in residential areas is low. Consequently, the health risks to individuals in residential areas and bystanders are acceptable.

### **3.3 Food Residue Exposure Assessment**

#### **3.3.1 Food**

While dietary exposure to silicon dioxide (present as 100% diatomaceous earth) may occur through consumption of treated crops, the risk from consuming food crops treated with DX13 Dust or DX13 Industrial is acceptable due to their low toxicity profiles, the history of use of silicon dioxide as a food additive, and Celatom Food Grade Diatomaceous Earth is a food grade substance.

When the end-use products are applied as directed by the label to cannabis produced commercially indoors, consumer exposure to silicon dioxide (present as 100% diatomaceous earth) is low and therefore the health risk is acceptable.

#### **3.3.2 Drinking Water**

Dietary exposure from drinking water is expected to be negligible as the label has the necessary mitigative measures to limit contamination of drinking water from the proposed uses of silicon dioxide (present as 100% diatomaceous earth). Health risks from residues of silicon dioxide (present as 100% diatomaceous earth) in drinking water are acceptable due to the low toxicity profile and limited exposure following application of DX13 Dust and DX13 Industrial.

#### **3.3.3 Acute and Chronic Dietary Risks for Sensitive Subpopulations**

Calculations of acute reference doses (ARfDs) and acceptable daily intakes (ADIs) are not required for silicon dioxide (present as 100% diatomaceous earth). Based on all the available information and hazard data, this active ingredient is considered to be of low acute toxicity by the oral route. As a result, the PMRA has not used a margin of exposure (safety) approach to account for intra- and inter-species variability or have a margin of exposure given that a threshold for potential effects is not required.

#### **3.3.4 Aggregate Exposure and Risk**

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. A major consideration is the likelihood of co-occurrence of exposures. Additionally, only exposures from routes that share common toxicological endpoints can be aggregated.

Silicon dioxide (present as 100% diatomaceous earth) is considered to be of low toxicity by the oral route and end-use products will not be applied near or to drinking water. Label statements on the DX13 Dust and DX13 Industrial have been updated to minimize non-occupational exposure (dermal and inhalation) in residential and commercial areas to the general Canadian population, including infants and children. When the end-use products are used as labelled, there is reasonable certainty that no harm will result from aggregate exposure of residues of silicon dioxide (present as 100% diatomaceous earth).

### **3.3.5 Cumulative Assessment**

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pest control products with a common mechanism of toxicity. Accordingly, an assessment of potential common mechanism of toxicity with other pesticides was undertaken. It is likely that silicon dioxide shares a common mechanism of toxicity with other silica-based pesticides relating to effects on the respiratory system, including irritation. However, the likelihood of non-occupational co-exposure via the inhalation route to multiple silica-based products is low and therefore not of concern at this time, since the use pattern and target pests in residential areas are similar across these pest control products. Given silicon dioxide is a food additive and has low oral toxicity, potential health risks from cumulative dietary and drinking water exposures from pesticide uses are also acceptable.

### **3.3.6 Maximum Residue Limits (MRLs)**

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as an MRL under the *Pest Control Products Act* (PCPA) for the purposes of adulteration provision of the *Food and Drugs Act* (FDA). Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

Dietary risk to humans from the proposed use of silicon dioxide (present as 100% diatomaceous earth) on agricultural crops is acceptable due to the low toxicity profile of silicon dioxide. Furthermore, Division 15 Section B.15.002(2) of the FDR lists silicon dioxide and other agricultural chemicals, and their components or derivatives that singly or in combination do not adulterate food. Consequently, silicon dioxide is exempt from the specification of an MRL.

## **4.0 Impact on the Environment**

The new use to control spider mites on greenhouse tomatoes, peppers and cucumbers, cannabis grown indoors, and indoor ornamental plants and plantscapes are a negligible addition to the potential environmental exposure of silicon dioxide (present as 100% diatomaceous earth).

## 4.1 Fate and Behaviour in the Environment

Silicon dioxide is a naturally occurring form of silica, formed from the fossilized siliceous frustules and fragments of various species of diatoms mined from the beds of former inland lakes. It is a white, inert powder and is practically insoluble in water. Transformation products are not expected.

## 4.2 Environmental Risk Characterization

Silicon dioxide has a non-toxic mode of action, interfering with the water balance of insects by absorbing protective coatings (oils and fats) and via mechanical abrasion of the outer cuticle layer, leading to fatal dehydration. As such, it may harm bees and other beneficial arthropods used in greenhouse production. A label statement to warn users to avoid application when bees or other beneficial insects are in the treatment area will be required.

Given its non-toxic mode of action and inert nature, silicon dioxide (present as 100% diatomaceous earth) is expected to be non-toxic to other non-target organisms. Furthermore, exposure of non-target organisms to Celatom Food Grade Diatomaceous Earth and its end-use products is expected to be limited due to the use pattern (indoor plants, plantscapes and greenhouse crops). Risks to non-target organisms are considered acceptable when the products are used according to label directions.

### 4.2.1 Environmental Incident Reports

Environmental incident reports are obtained from two main sources, the Canadian pesticide incident reporting system (including both mandatory reporting from the registrant and voluntary reporting from the public and other government departments) and the United States Environmental Protection Agency (USEPA) Ecological Incident Information System. Specific information regarding the mandatory reporting system regulations that came into force 26 April 2007 under the *Pest Control Products Act* can be found at <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/report-pesticide-incident.html>.

There are no environmental incident reports for silicon dioxide (present as 100% diatomaceous earth) in the PMRA database or the USEPA Ecological Incident Information System (last updated October 5, 2015).

## 5.0 Value

Submitted value information included three laboratory efficacy trials on twospotted spider mite, a rationale based on the mode of action to extrapolate to spider mites in general, and residue studies on leaves of four broad-leafed plants with different foliar characteristic and shoots of two different types of conifer foliage as well as filter paper. This information was sufficient to support the proposed claims for control of spider mites on greenhouse tomatoes, peppers, and cucumbers, cannabis produced commercially indoors, and indoor ornamental plants and plantscapes using either DX13 Dust or DX13 Industrial applied to cover all plant surfaces.

Proposed reapplication intervals of 7-14 days with up to 7 applications per crop cycle on tomatoes and cucumbers, 10 applications per crop cycle on peppers, and 7 applications per year on indoor ornamental plants and landscapes are acceptable; however, for health reasons, application of DX13 Dust and DX13 Industrial will not be permitted on cannabis, or surrounding soil, past the vegetative stage.

There are numerous different active ingredients, representing almost as many different modes of action, registered for spider mites on greenhouse vegetables and indoor ornamentals; however, there are only three active ingredients registered for spider mites on cannabis, all non-conventional (potassium salts of fatty acids, canola oil, and mineral oil). DX13 Dust and DX13 Industrial provide a new active ingredient with a new mode of action for all of the proposed uses and, being a physical mode of action, the development of resistance is unlikely. These products may reduce reliance on, and aid in management of resistance to, conventional chemical pest control products.

## **6.0 Pest Control Product Policy Considerations**

### **6.1 Toxic substances Management Policy Considerations**

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, i.e., those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the Canadian Environmental Protection Act. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, Celatom Food Grade Diatomaceous Earth was assessed in accordance with the PMRA Regulatory Directive DIR99-03 and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that Celatom Food Grade Diatomaceous Earth does not meet all of the TSMP Track 1 criteria.

Please refer to Table 2, Appendix I for further information on the TSMP assessment.

### **6.2 Formulants and Contaminants of Health or Environmental Concern**

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*<sup>5</sup>. The list is used as described in the PMRA Notice of Intent NOI2005-01<sup>6</sup> and is based on existing policies

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<sup>5</sup> SI/2005-114, last amended on June 25, 2008. See Justice Laws website, Consolidated Regulations, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern

<sup>6</sup> PMRA's Notice of Intent NOI2005-01, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act

and regulations, including the *Toxic Substances Management Policy*<sup>7</sup> and *Formulants Policy*<sup>8</sup>, and taking into consideration the *Ozone-depleting Substance Regulations, 1998*, of the *Canadian Environmental Protection Act* (substances designated under the *Montreal Protocol*).

The PMRA has reached the conclusion that Celatom Food Grade Diatomaceous Earth, and its end use products, are naturally contaminated with trace levels of TSMP Track 1 polychlorinated dibenzodioxins and furans. When compared to other registered sources, the use of Celatom Food Grade Diatomaceous Earth is not expected result in an increase in the release of Track 1 contaminants. These products do not contain any formulants or other contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

## **7.0 Summary**

### **7.1 Human Health and Safety**

The available information for Celatom Food Grade Diatomaceous Earth, DX13 Dust and DX13 Industrial) is adequate to qualitatively identify the toxicological hazards that may result from exposure to silicon dioxide (present as 100% diatomaceous earth). Celatom Food Grade Diatomaceous Earth complies with food-grade criteria and contains less than 1% respirable crystalline silica as required by the PMRA. Celatom Food Grade Diatomaceous Earth is of low acute toxicity, via the oral, dermal and inhalation routes, minimally irritating to the eyes and skin and not likely to be a dermal sensitizer.

DX13 Dust and DX13 Industrial are of low acute oral, dermal and inhalation toxicity, practically non-irritating to the eye, not irritating to the skin and not expected to be dermal sensitizers. However, these products are respiratory irritants.

Workers can be exposed to silicon dioxide (present as 100% diatomaceous earth) while loading, applying and handling (including clean-up and repair) DX13 Dust and DX13 Industrial. Labels will include statements to wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes and protective eyewear during loading, application, clean-up and repair, as well as a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) during handling (including clean-up and repair) and a respirator with a NIOSH-approved cartridge with a prefilter or canister for loading and application. Adequate ventilation is also required during handling and application.

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<sup>7</sup> DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

<sup>8</sup> DIR2006-02, *Formulants Policy and Implementation Guidance Document*

Post-application exposure will occur mainly by the inhalation and dermal routes. A REI of 4 hours, or until dusts have settled or sprays have dried, has been established as well as instructions for individuals and companion animals to remain out of the treated area until the dusts have settled and sprays have dried. If early entry is necessary, workers will be required to wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, protective eyewear (goggles or face shield) and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested.

To minimize occupational and bystander exposure during post-harvest clean-up activities for cannabis produced commercially indoors, greenhouse tomato, cucumber and pepper crops, an information sheet for DX13 Dust or DX13 Industrial stating PPE and re-entry requirements will be posted at points of entry.

DX13 Dust and DX13 Industrial is registered for use in residences, motels, hospitals and other commercial buildings and the proposed new use expands the label to greenhouse tomatoes, cucumbers, and peppers, cannabis produced commercially indoors and indoor ornamental plants and plantscapes. Adhering to label instructions will ensure that exposure to humans and companion animals in residential areas is low.

Precautionary statements (e.g., wearing of PPE) on the end-use product labels aimed at mitigating exposure are adequate to protect individuals from risk due to occupational, post-application, bystander, and residential exposures.

While dietary exposure to silicon dioxide (present as 100% diatomaceous earth) may occur through consumption of treated crops, the dietary risks to humans from the consumption of treated crops and cannabis are acceptable due to its low toxicity profile, its history of use as a food additive, Celatom Food Grade Diatomaceous Earth is a food grade substance and application of DX13 Dust and DX13 Industrial will not be permitted on cannabis, or surrounding soil, past the vegetative stage. Exposure to silicon dioxide (present as 100% diatomaceous earth) from drinking water will be negligible. Consequently, the dietary and consumer risk from food, cannabis and drinking water is acceptable. In addition, silicon dioxide is exempt from the specification of an MRL under FDR.

## **7.2 Environmental Risk**

Silicon dioxide is an inert substance; the formation of transformation products of environmental concern are not expected. Silicon dioxide has a non-toxic mode of action. However, silicon dioxide (present as 100% diatomaceous earth) is an insecticide and may harm bees and other beneficial arthropods used in greenhouse production. As such, a label statement to avoid application when bees or other beneficial arthropods are in the treatment area will be required for greenhouse use. Silicon dioxide is expected to be non-toxic to other non-target organisms. After a review of the available information, the environmental risks associated with the use of silicon dioxide (present as 100% diatomaceous earth) and its associated end-use products are acceptable when used according to the proposed label.

### **7.3 Value**

DX13 Dust and DX13 Industrial provide control of spider mites on greenhouse tomatoes, peppers, and cucumbers, cannabis produced commercially indoors, and indoor ornamental plants and landscapes. For all of those uses, these products provide a new active ingredient with a new physical mode of action, to which resistance is unlikely.

### **8.0 Proposed Regulatory Decision**

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of Celatom Food Grade Diatomaceous Earth, DX13 Dust, and DX13 Industrial, containing silicon dioxide (present as 100% diatomaceous earth), to control spider mites on greenhouse tomatoes, cucumbers, and peppers, cannabis produced commercially indoors and indoor ornamental plants and landscapes.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

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## List of Abbreviations

♀	female
♂	male
°C	degrees centigrade
ADI	acceptable daily intake
ARfD	acute reference dose
BAF	bioaccumulation factor
BCF	bioconcentration factor
CAS	Chemical Abstracts Service
CEPA	<i>Canadian Environmental Protection Act</i>
FCC	Food Chemicals Codex
FDA	<i>Food and Drug Act</i>
FDR	Food and Drug Regulations
g	gram
h	hour
ha	hectare(s)
IUPAC	International Union of Pure and Applied Chemistry
$K_{ow}$	<i>n</i> -octanol-water partition coefficient
L	litre
LC <sub>50</sub>	lethal concentration 50%
mg	milligram
m <sup>2</sup>	square metre
MAS	maximum average score
MIS	maximum irritation score
MMAD	mass median aerodynamic diameter
MRL	maximum residue limit
NIOSH	National Institute for Occupational Safety and Health
PCPA	<i>Pest Control Products Act</i>
pKa	dissociation constant
PMRA	Pest Management Regulatory Agency
PP	pressurized product
PPE	personal protective equipment
REI	restricted entry interval
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet



## Appendix I Tables and Figures

**Table 1 Acute Toxicity Profile of DX13 (Diatomaceous Earth)**

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type, Animal and PMRA No.	Study Results
Acute Inhalation Toxicity (Nose-only exposure)  Sprague-Dawley rats  5/sex/group  PMRA # 2959221	LC <sub>50</sub> (combined) > 2.15 mg/L  MMAD <sup>a</sup> = 3.2  No mortality or clinical signs of toxicity. At necropsy, dark spots on lungs (1 ♂ and 2 ♀) and mottled lungs (two ♂) were observed.  <b>Low acute inhalation toxicity</b>
Eye Irritation  New Zealand rabbit  1 ♂, 2 ♀  ~ 100mg  PMRA # 2959226	MAS <sup>b</sup> = 0.44/110 (at 24, 48 and 72 hours) MIS <sup>c</sup> = 5.33/110 (1 h)  All signs of irritation resolved by 48 hours.  <b>Practically non-irritating to the eye</b>

<sup>a</sup> MMAD = Mass median aerodynamic diameter

<sup>b</sup> MAS = Maximum Average Score for 24, 48, and 72 hrs

<sup>c</sup> MIS = Maximum Irritation Score

**Table 2 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria**

TSMP Track 1 Criteria	TSMP Track 1 Criterion value	Active Ingredient Endpoints
CEPA toxic or CEPA toxic equivalent <sup>1</sup>	Yes	No, non-toxic mode of action
Predominantly anthropogenic <sup>2</sup>	Yes	No
Persistence <sup>3</sup> :	Soil	Half-life ≥ 182 days
	Water	Half-life ≥ 182 days
	Sediment	Half-life ≥ 365 days
	Air	Half-life ≥ 2 days or evidence of long range transport
Bioaccumulation <sup>4</sup>	Log K <sub>ow</sub> ≥ 5	Not applicable, not soluble in water or octanol
	BCF ≥ 5000	Not available
	BAF ≥ 5000	Not available

Is the chemical a TSMP Track 1 substance (all four criteria must be met)?	No, does not meet TSMP Track 1 criteria.
<p><sup>1</sup>All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e., all other TSMP criteria are met).</p> <p><sup>2</sup>The policy considers a substance “predominantly anthropogenic” if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.</p> <p><sup>3</sup> If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.</p> <p><sup>4</sup>Field data (e.g., BAFs) are preferred over laboratory data (e.g., BCFs) which, in turn, are preferred over chemical properties (e.g., log K<sub>ow</sub>).</p>	

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## References

### A. List of Studies/Information Submitted by Registrant

#### 1.0 Chemistry

<b>PMRA Document Number</b>	<b>Reference</b>
2877306	2018, Celatom Diatomaceous Earth Products, DACO: 2.11.1 CBI
2954965	2018, Certificate of Analysis, DACO: 2.13.4 CBI
2954966	2018, Certificate of Analysis, DACO: 2.13.4 CBI
2990139	2019, Test Report – [CBI-REMOVED] Analysis of Diatomaceous Earth Samples, DACO: 2.13.3 CBI
3029279	2019, 2018-1741 Description of Starting Materials, DACO: 3.2.1 CBI
3029280	2019, 2018-1741 Discussion of the formation of impurities of toxicological concern, DACO: 3.2.3 CBI

#### 2.0 Human and Animal Health

<b>PMRA Document Number</b>	<b>Reference</b>
2877770	2018, Part 6 Metabolism DX13 Industrial, DACO: 6.1
2877787	2018, Part 4 Toxicology DX13 Industrial waiver request , DACO: 4.6.1, 4.6.2,4.6.3,4.6.4,4.6.5,4.6.6
2877789	2018, Part 6 Metabolism DX13 Industrial, DACO: 6.1
2877790	2018, Part 7 Residues DX 13 Industrial, DACO: 7.1
2954954	2019, Response to Deficiency Letter DX13 Dust, DACO: 0.8, 10.2, 10.3.2, 4.6.1, 4.6.2,4.6.3,4.6.4,4.6.5,4.6.6,5.2
2954957	2019, Comments on Potential Residues, DACO: 7.4.1
2954959	2019, Measuring DX13 aerosol and dust residues on ornamental conifers, DACO: 10.2.2
2954960	2018, Measuring DX13 aerosol residues on different leaves, DE Labs Inc. (Vancouver). Unpublished. DACO: 7.4, 10.2.2
2954961	2019, Measuring DX13 aerosol and dust residues on cannabis leaves and filter paper, DE Labs Inc. (Vancouver). Unpublished. DACO: 7.4, 10.2.2
2959220	2019, 4.6.3 Waiver Request, DACO: 4.6.3
2959221	2019, Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2959222	(Confidential Business Information removed), DACO: 4.6.3,4.6.4,4.8

2959223	(Confidential Business Information removed), DACO: 4.6.3,4.6.4,4.8
2959224	(Confidential Business Information removed), DACO: 4.6.3,4.6.4
2959225	2019, Waiver Request, DACO: 4.6.4
2959226	2019, Acute Eye Irritation in Rabbits, DACO: 4.6.4

### 3.0 Environment

None

### 4.0 Value

PMRA Document Number	Reference
2900721	2018, Part 10 Value - DX13 Industrial, DACO: 10.2.3.2
2954954	2019, Response to Deficiency Letter DX13 Dust, DACO: 0.8
2954958	2018, Mite species affected by DE, DACO: 10.2.2
2954959	2019, Measuring DX13 aerosol and dust residues on ornamental conifers, DACO: 10.2.2
2954960	2018, Measuring DX13 aerosol residues on different leaves, DACO: 10.2.2
2954961	2019, Measuring DX13 aerosol and dust residues on cannabis leaves and filter paper, DACO: 10.2.2

## B. Additional Information Considered

### i) Published Information

#### 1.0 Chemistry

None

#### 2.0 Human and Animal Health

PMRA Document Number	Reference
3058618	U.S Department of Health and Human Services Agency for Toxic Substances and Disease Registry (ATSDR), 2019, Toxicological Profile of Silica, DACO: 12.5
3058627	J.H.E. Arts, H. Muijser, E. Duistermaat, K. Junker, C.F. Kuper, 2007, Five-day inhalation toxicity study of three types of synthetic amorphous silicas in Wistar rats and post-exposure evaluations for up to 3 months, Food and

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	Chemical Toxicology 45; 1856-1867, DACO: 4.8
3058634	(Confidential Business Information removed), DACO: 4.8
3058636	World Health Organization (WHO), 2011, Evaluation of Certain Food Additives and Contaminants, Seventy-third report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Technical Report Series 960, DACO: 4.8
3058651	(Confidential Business Information removed), DACO: 4.6
3058652	(Confidential Business Information removed), DACO: 4.8
3069122	International Agency for Research on Cancer (IARC), 1997, Silica, Some Silicates, Coal Dust and para-Aramid Fibrils. IARC Monographs on the Evaluation of Carcinogenic Risks to Human, No. 68. IARC Working Group on the Evaluation of Carcinogenic Risk to Humans.

**3.0 Environment**

None

**4.0 Value**

None