

## Evaluation Report for Category B, Subcategory 3.11, 3.12 Application

**Application Number:** 2016-1981  
**Application:** Changes to Product Label –New pests and New Site  
**Product:** DE-cide  
**Registration Number:** 27265  
**Active ingredients (a.i.):** Silicon Dioxide (present as 100% Diatomaceous Earth)  
**PMRA Document Number:** 2701948

### Purpose of Application

The purpose of this application was to amend the end-use product (EP), DE-cide, containing silicon dioxide, to add treatment of empty storage areas and to stored grain (wheat, barley and grain), and to add new pests (Rusty Grain Beetle, Red Flour Beetle, Rice Weevil, Lesser Grain Borer, Sawtoothed Grain Beetle).

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

A toxicology assessment was not required for this application.

Workers applying the EP to empty storage areas could be exposed to silicon dioxide via the dermal and inhalation routes of exposure. These types of exposures are mitigated by precautionary and personal protective equipment (PPE) statements on the label including recommendations to avoid inhaling dusts and contact with eyes and skin, a requirement for the use of a NIOSH approved dust mask/respirator when handling, and a requirement for the use of a NIOSH approved full-face respirator when using a dust blower during mixing, loading, and application. Additional mitigating measures on the existing label include the use of appropriate eye-wear when handling, during application, and in clean-up activities, and the washing of hands with plenty of soap and water after treatments. Consequently the application of the EP to empty grain storage areas is not expected to increase occupational exposures or risks compared to existing registered uses provided that label precautionary measures are followed.

Similar to applications to empty storage areas, there is a potential for occupational dermal and inhalation exposures to silicon dioxide during mixing, loading, and application to stored grain. The precautionary/PPE statements on the label discussed above have been modified to include the use of a full-face respirator for applications to stored grain as per the PMRA proposed acceptability for continuing registration document, PACR2004-09 *Re-evaluation of Silicon*

*Dioxide and Silica Gel*, for products using sources of silicon dioxide containing less than 1% crystalline silica. Because of these precautionary/PPE measures, the use of DE-cide to treat stored grain is not expected to increase occupational exposures or risk compared to existing registered uses.

There is also a potential for dermal and inhalation exposures for personnel not involved in mixing, loading, application or clean-ups and repairs, or bystanders when they are in the vicinity of either empty grain storage sites or stored grain being treated with the EP. In order to limit potential exposures and risks to these personnel and bystanders, a precautionary statement has been added to the label advising unprotected personnel to not enter treatment areas during application or clean-up when empty storage areas and stored grain are being treated with the EP or whenever airborne dust is present. This is consistent with label precautionary statements for other products registered for use on empty storage areas and stored grain. The label for DE-cide advises that empty grain storage areas be left undisturbed for 7–10 days after treatment. In the event that any activities are required in the storage areas during this period, a statement has been added to the label for DE-cide indicating that all dust should be settled before entry into the storage areas and a NIOSH-approved dust mask and respirator should be worn.

As noted, diatomaceous earth/silicon dioxide products are already registered for use on stored grain for food and feed. Also, silicon dioxide is permitted for use as a food additive in higher concentrations than those for stored grain for the current application and inert dusts such as diatomaceous earth/silicon dioxide appear to be readily removed by methods of food preparation and industrial processes for cleaning grain. Furthermore, silicon dioxide is naturally occurring in food crops, is used in medicinal products, and occurs naturally in the human body. Consequently, there are no dietary concerns with respect to the use of DE-cide on empty grain storage areas and stored grain for food and feed.

Because the uses of DE-cide do not include applications to drinking water supplies or sources and the label contains precautionary statements on avoiding the contamination of water supplies, there are not expected to be any exposures or risks from the a.i. in drinking water.

### **Maximum Residue Limit**

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 a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure that the food Canadians eat is safe.

According to paragraph 4(1)(d) of the *Food and Drugs Act*, “No person shall sell an article of food that is adulterated;” and Division 15, Section B.15.002(2)(d) of the *Food and Drug Regulations* further states that a food is exempt from paragraph 4(1)(d) of the *Act* if it contains silicon dioxide. Consequently, food crops (i.e., grains) treated with diatomaceous earth (100% silicon dioxide) according to the use for the end-use product are not considered to be adulterated and the specification of an MRL for silicon dioxide is not required.

### **Environmental Assessment**

The additional pests and uses on stored grain and in empty storage areas are acceptable from an environmental perspective. Environmental concerns have been mitigated through adequate statements on the product label.

### **Value Assessment**

Laboratory efficacy trials with rusty grain beetle, rice weevil, red flour beetle, and lesser grain borer and a rationale extrapolating results to sawtoothed grain beetle supported control of those pests in stored grain and empty storage areas.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided and is able to support the use in empty storage areas and on stored grain and the addition of new pests to the DE-cide label.

## References

PMRA Document Number	Reference
2631076	2016, Use Site Scenarios, DACO: 5.2
2680020	2016, Clarification for Use Site Scenarios, DACO : 5.2
2631077	2016, DACO 6 & 7 Food & Feed Exposure & Toxicological Rationale, DACO: 6.1, 7.1
2631078	Bertke Eldridge M., 1963, The Effect of Ingestion of Diatomaceous Earth in White Rats: A Subacute Toxicology Test, Toxicology and Applied Pharmacology 6, 284-291, DACO: 7.8
2631079	Aldryhim, Yousif N., 1990, Efficacy of Amorphous Silica Dust, Dryacide Against <i>Tribolium Confusum</i> DUV & <i>Sitophilus Granarius</i> , J. Stored Prod. Res. 26, No. 4, 207-210, DACO: 7.8
2631080	Desmarchelier, J.M. & Allen, S.E., 1998, Diatomaceous Earths: Health, Safety, Environment Residues and Regulatory Issues, Proceedings of the 7th International Working Conference on Stored-product Protection, Volume 1, DACO: 7.8
2631072	2016, DACO 10.1 Value Summary, DACO: 10.1
2631073	2016, Efficacy of DE-cide Diatomaceous Earth against Stored-Grain Insects on Wheat, Corn, Oats and Barley, DACO: 10.2, 10.2.3.1
2631074	2016, DACO 10.2.2 Description of Pest Problem, DACO: 10.2.2
2631075	2016, DACO 10.3 Adverse Effects on Use Site, DACO: 10.3.1, 10.3.2
2631092	Zlatko Korunic and Paul Fields, 1998, The Effect of Grain Moisture Content and Temperature on The Efficacy of Six Diatomaceous Earths Against Three Stored Product Beetles, DACO: M10.5
2631093	Pinto Jr, A.R., Lazzari, F.A., Lazzari, S.M.N., Ceruti, F.C., 2008, Response of <i>Sitophilus oryzae</i> (L.), <i>Cryptolestes ferrugineus</i> (Stephens) and <i>Oryzaephilus surinamensis</i> (L.) to Different Concentrations of Diatomaceous Earth in Bulk Stored Wheat, Ciência Rural, Santa Maria, 38, No. 8, 2103-2108, DACO: M10.5
2631094	Subramanyam, B., Roesli, R., 2000, Inert dusts, DACO: M10.5

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