

## Evaluation Report for Category B, Subcategory 1.3 Application

**Application Number:** 2008-2957  
**Application:** B.1.3 – Changes to TGAI product chemistry - Specification  
**Product:** APL Diatomaceous Earth Technical Grade Active Ingredient  
**Registration Number:** 27264  
**Active ingredient (a.i.):** Silicon Dioxide (present as Diatomaceous Earth) [SIO]  
**PMRA Document Number :** 1801552

### Purpose of Application

The purpose of this application was to change the name of the registered technical grade active ingredient product (Reg. No. 27264) from Barn Fresh Technical Grade Active Ingredient to APL Diatomaceous Earth Technical Grade Active Ingredient. The applicant also requested a change to the product specifications such that the % w/w of the active ingredient (Silicon Dioxide, CAS No. 7631-86-9) is increased, the % w/w of several impurities are either increased or decreased and two additional impurities are identified and quantified in the product.

### Chemistry Assessment

Common Name: silicon dioxide  
Chemical Name: silicon dioxide

APL Diatomaceous Earth Technical Grade Active Ingredient has the following properties:

Property	Result
Colour and physical state	brown-beige solid
Nominal concentration	66.78%
Odour	earthy
Density	0.84-051 g/cm <sup>3</sup>
Vapour pressure	N/A as product is a solid
pH	5.0-6.0
Solubility in water	negligible
n-Octanol/water partition coefficient	product is not soluble in either polar or non-polar solvents

The chemistry requirements for APL Diatomaceous Earth Technical Grade Active Ingredient have been completed.

## Health Assessments

In 2004, the PMRA completed a re-evaluation of silicon dioxide and silica gel and determined that silicon dioxide and silica gel products were acceptable for continued registration provided that label amendments were made regarding mitigation measures for any potential risks associated with the presence of crystalline silica as an impurity in the silicon dioxide.

The application for APL Diatomaceous Earth Technical Grade Active Ingredient was based on changes to the specifications of the active ingredient (silicon dioxide) and impurities, and the addition of new impurities to the previously registered Barn Fresh Technical Grade Active Ingredient. Because of the small magnitude of the change to the specifications for the active ingredient and the very low concentrations of the impurities, a qualitative assessment of the potential health risks from these changes was conducted. Based on this assessment including a consideration of the precautionary statements and personal protective equipment directions on the label, the health risk profile of APL Diatomaceous Earth Technical Grade Active Ingredient is expected to be similar to that of the previously registered Barn Fresh Technical Grade Active Ingredient.

## Environmental and Value Assessments

Environmental and value assessments were not required for this application.

## Conclusion

Following the review of all available data, the PMRA can support the name change of Reg. No. 27264 from Barn Fresh Technical Grade Active Ingredient to APL Diatomaceous Technical Grade Active Ingredient. The PMRA is also able to support the changes made to the product specification for APL Diatomaceous Technical Grade Active Ingredient.

## References

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

PMRA #	Title
1622639	2008, Chemistry Requirements for TGAI or ISP, DACO: 2.0,2.1,2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.12.2,2.13,2.2,2.3 CBI
1622640	2008, Crystalline Silica, DACO: 2.13.3 CBI
1622641	2007, ALS - Chemex - Monthly Composite - March 2007, DACO: 2.13.3 CBI
1622642	2007, ALS - Chemex - Monthly Composite - April 2007, DACO: 2.13.3 CBI
1622643	2007, ALS - Chemex - Monthly Composite - May 2007, DACO: 2.13.3 CBI
1622644	2007, ALS - Chemex - Monthly Composite - June 2007, DACO: 2.13.3 CBI
1622645	2008, ALS - Chemex - Monthly Composite - March 2008, DACO: 2.13.3 CBI
1775782	2009, Limits of Detection for Diatomaceous Earth, DACO: 2.13.1
1775783	2008, Quality Assurance Overview, DACO: 2.13.1
1775786	2006, Geochemical Procedure [CBI REMOVED], DACO: 2.13.1
1775787	2006, Whole Rock Geochemistry [CBI REMOVED], DACO: 2.13.1
1775788	2006, Geochemical Procedure [CBI REMOVED], DACO: 2.13.1

B. Additional Information Considered

i) Published Information

PMRA #	Title
1780993	Environment Canada, 2001, ARSENIC (INORGANIC) 1997 Canadian Soil Quality Guidelines for the Protection of Environmental and Human Health. originally published in the working document entitled “Recommended Canadian Soil Quality Guidelines” (Canadian Council of Ministers of the Environment)
1781042	21 CFR Ch. I (4-1-02 Edition) Food and Drug Administration, HHS, DACO: 4.8
1781049	CADMIUM 1999 Canadian Soil Quality Guidelines for the Protection of Environmental and Human Health. Originally published in the working document entitled “Recommended Canadian Soil Quality Guidelines” (Canadian Council of Ministers of the Environment)
1781056	Environment Canada, LEAD 1999 Canadian Soil Quality Guidelines for the Protection of Environmental and Human Health. Originally published in the working document entitled “Recommended Canadian Soil Quality Guidelines” (Canadian Council of Ministers of the Environment)
1781061	Environment Canada, MERCURY (INORGANIC) 1999 Canadian Soil Quality Guidelines for the Protection of Environmental and Human Health. Originally published in the working document entitled “Recommended Canadian Soil Quality Guidelines” (Canadian Council of Ministers of the Environment)
1781286	Choudhury, D., Barium and Barium Compounds. Concise International Chemical Assessment Document 33, DACO: 12.5

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