

Evaluation Report for Category B, Subcategory B.1.1 (New source (site of manufacture) by current registrant) and B.1.3 (New specifications)

Application Number: 2006-3850
Application: Category B, Subcategory B.1.1 and B.1.3
Product: Diafil 610 Food Grade Technical
Registration Number: 27448
Active ingredients (a.i.): Silicon Dioxide
PMRA Document Number : 1606699

Background

The product, Diafil 610 Food Grade Technical, is a registered Technical Grade Active Ingredient (TGAI) composed of silicon dioxide, present in the form of diatomaceous earth. This product is used in the manufacture of End use Products (EP) that are used as insecticidal and acaricidal agents.

Purpose of Application

The purpose of this application is to modify Diafil 610 Food Grade Technical’s specifications and to register a new manufacturing site. The application is classified as a Category B.1.1 and B.1.3.

Chemistry Assessment

1.1, 1.3 (new source by same registrant, changes to specifications)

Common Name: Diatomaceous earth, diatomite
Chemical Name: Amorphous silica

Diafil 610 Food Grade Technical has the following properties:

Property	Result
Colour and physical state	Gray fine powder
Nominal concentration	91.1%
Odour	Odourless
Specific gravity	2.2 g/cm ³ @ 25°C

Property	Result
Vapour pressure	Not applicable
pH	Not applicable
Solubility in water	Negligible
n-Octanol/water partition coefficient (K_{ow})	Not applicable

The chemistry requirements for Diafil 610 Food Grade Technical have been completed.

Health Assessments

The goal of this submission was to update the specifications of the product and change the site of manufacture. The product Diafil 610 - Food Grade Technical is composed of Diatomaceous Earth (silicon dioxide). A recent re-evaluation of this active ingredient (see RRD2004-20 and PACR2004-09) recommended that the crystalline silica content be brought below 1%. The change in specifications of the active ingredient meet this requirement and no toxicological review was required.

Silicon dioxide is one of the compounds listed on the 'SURE' list and is exempt from the adulteration of food in Division 15 of the Food and Drugs Act and Regulations (B.15.002). From food residue point of view, the revision of the specification of Diafil 610 Food Grade Technical can be supported. The dietary risk from the use of silicon dioxide is not of concern.

Environmental Assessment

An environmental assessment was not performed.

Value Assessment

A value assessment was not performed

Conclusion

The PMRA has completed an evaluation of the application and has found the information sufficient to support the new site of manufacture and changes in specifications of Diafil 610 - Food Grade Technical.

References

- PACR2004-09 (Proposed Acceptability for Continuing Registration):
Re-evaluation of Silicon Dioxide and Silica Gel. Pest Management Regulatory Agency. April 28, 2004. ISBN: 0-662-36932-7 (0-662-36933-5)
- RRD2004-20 (Re-evaluation Decision Document): Silicon Dioxide and Silica Gel. Pest Management Regulatory Agency. July 16, 2004. ISBN: 0-662-37731-1 (0-662-37732-X)
- 1273878 Three separate lots of Diafil 610 - A revised Category B submission for Diafil 610 Food Grade Technical, Registration No. 27448 has been submitted due to a discrepancy its crystalline silica content., DACO: 2.13.3 CBI
- 1295887 2006, Diafil 610 Food Grade Technical - Specifications for 3 separate lots, N/A, MRID: N/A, DACO: 2.13.3
- 1295888 2006, Silica Content Results, N/A, MRID: N/A, DACO: 2.13.3
- 1303103 2006, E-mail - address and manufacturer's name, DACO: 2.1,2.2 CBI
- 1415662 2007, Batch Data - Diafil 610 - Food grade Technical, N/A, MRID: N/A, DACO: 2.13.3
- 1421690 2007, Batch Data - Diafil 610 - Food grade Technical, N/A, MRID: N/A, DACO: 2.13.3
- 1472185 2005, Celite X-Ray Fluorescence Spectrometry, DACO: 2.13.1 CBI

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