

Evaluation Report for Category B, Subcategory 1.2, 3.13 Application

Application Number: 2012-0777
Application: B.1.2 – New Source (site) with New Registrant
 B.3.13 – New Label Precautions
Product: BCDMH Technical
Registration Number: 30863
Active ingredients (a.i.): Available bromine present as 1-bromo-3-chloro-5,5-dimethylhydantoin and related hydantoins.
 Available chlorine present as 1-bromo-3-chloro-5,5-dimethylhydantoin and related hydantoins.
PMRA Document Number: **2291701**

Purpose of Application

The purpose of this application was to register a new source (site) of manufacture for BCDMH Technical by a new registrant.

Chemistry Assessment

Common Name: 1-bromo-3-chloro-5,5-dimethylhydantoin and related hydantoins.
IUPAC Chemical Name: 1-bromo-3-chloro-5,5-dimethylpyrrolidine-2,4-dione
CAS Chemical Name: 2,4-imidazolidinedione, 1-bromo-3-chloro-5,5-dimethyl-

BCDHM Technical has the following properties:

Property	Result
Colour and physical state	White granular solid
Nominal guarantee	Available bromine present as 1-bromo-3-chloro-5,5-dimethylhydantoin and related hydantoins at 65% AND Available chlorine present as 1-bromo-3-chloro-5,5-dimethylhydantoin and related hydantoins at 28.6%
Odour	Chlorine/bromine odour
Density	0.9 g/mL
Vapour pressure at 25°C	0.881 mPa (estimated)
Solubility in water	1.5 g/L
n-Octanol/water partition coefficient	Log Kow = -0.94 (estimated)

The chemistry requirements for BCDHM Technical have been completed.

Health Assessments

The new source of technical grade active ingredient is considered to be toxicologically equivalent to the currently registered source.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

PMRA has reviewed the information provided and has determined the new source (site) of manufacture of BCDHM Technical is acceptable.

References

- PMRA # 2163857 2012, Chemistry Requirements, DACO: 2.1, 2.2, 2.3, 2.3.1, 2.4 ,2.5, 2.6, 2.7, 2.8, 2.9 CBI
- PMRA # 2163858 2012, Manufacturing Methods for the TGAI, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4 CBI
- PMRA # 2163859 Certified Limits, DACO: 2.12.1 CBI
- PMRA # 2163861 1995, Analytical method - BROMOCHLORO-5,5-DIMETHYLHYDANTOIN, DACO: 2.13.1 CBI
- PMRA # 2163864 2010, Determination of the Content of BCDMH and [CBI REMOVED] in Five Batches of BCDMH Granules, DACO: 2.13.2, 2.13.3 CBI
- PMRA # 2163865 Discussion of formation of Impurities, DACO: 2.13.4 CBI
- PMRA # 2163866 Chemical and Physical Properties, DACO: 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9 CBI
- PMRA # 2163867 1991, BCDMH Formulated End-Use Product Registration, DACO: 2.14.14 CBI
- PMRA # 2225772 Batch Data, DACO: 2.13.3 CBI

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