

Evaluation Report for Category B, Subcategory B.1.1 Application

Application Number: 2012-2206
Application: New source of active from the same registrant
Product: Sani-Marc BCDMH-II
Registration Number: 31319
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 : 2380473

Purpose of Application

The purpose of this application was to register a new source 1-bromo-3-chloro-5,5-dimethylhydantoin (BCDMH) by the existing registrant.

Chemistry Assessment

Common Name: bromochlorodimethylhydantoin or BCDMH
Chemical Name: 1-bromo-3-chloro-5,5-dimethylhydantoin

Sani-Marc BCDMH-II has the following properties:

Property	Result
Colour and physical state	Bright white solid
Nominal concentration	Available bromine 64.8% and available chlorine 28.75%, present as 1-bromo-3-chloro-5,5-dimethylhydantoin and related hydantoins
Odour	Slight chlorine odour
Density	1.12 g/mL
Vapour pressure	N/A as the product is a solid
pH	Not required for a TGAI
Solubility in water	0.2 g / 100 g
n-Octanol/water partition coefficient	N/A as the product is very quickly hydrolyzed in water

The chemistry requirements for Sani-Marc BCDMH-II have been completed.

Health, Environmental, and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

The new source of 1-bromo-3-chloro-5,5-dimethylhydantoin (BCDMH) was found to be chemically equivalent to that of Sani-Marc BCDMH-I (Registration Number 30019) and has been approved.

References

PMRA.

Document

Number	Reference
2200107	2012, Applicant name and commercial address , DACO: 2.1 CBI
2200108	2012, Name and address of manufacturer , DACO: 2.2 CBI
2200109	2012, Product trade name , DACO: 2.3 CBI
2200110	2012, Common name, DACO: 2.4 CBI
2200111	2012, Chemical name , DACO: 2.5 CBI
2200112	2012, CAS number , DACO: 2.6 CBI
2200114	2012, Developed formula , DACO: 2.7 CBI
2200116	2012, Molecular weight. , DACO: 2.9 CBI
2200117	2012, Production summary , DACO: 2.11.1 CBI
2200118	2012, Description of starting material, DACO: 2.11.2 CBI
2200119	2012, Detailed production process, DACO: 2.11.3 CBI
2200121	2012, Discussion on impurities , DACO: 2.11.4 CBI
2200122	2012, Certified established limits , DACO: 2.12.1 CBI
2200123	2012, Preliminary analysis method. , DACO: 2.13.1 CBI
2200126	2012, Confirmation of identity , DACO: 2.13.2 CBI
2200127	2012, Batch data. , DACO: 2.13.3 CBI
2200128	2012, Contaminant of toxicological importance, DACO: 2.13.4 CBI
2200129	2012, [Privacy removed] COA_422869_3, DACO: 2.13.4 CBI
2200130	2012, Color , DACO: 2.14.1 CBI
2200131	2012, Physical state , DACO: 2.14.2 CBI
2200132	2012, Odor , DACO: 2.14.3 CBI
2200133	2012, Melting point , DACO: 2.14.4 CBI
2200134	2012, Boiling point , DACO: 2.14.5 CBI
2200135	2012, Density , DACO: 2.14.6 CBI
2200136	2012, Solubility in water, DACO: 2.14.7 CBI
2200137	2012, Solubility in solvent , DACO: 2.14.8 CBI
2200138	2012, Vapor pressure.doc, DACO: 2.14.9 CBI
2200139	2012, Dissolution coefficient , DACO: 2.14.10 CBI
2200140	2012, Octanol Water split coefficient , DACO: 2.14.11 CBI
2200141	2012, Absorption spectrum , DACO: 2.14.12 CBI
2200143	2012, Stability , DACO: 2.14.13 CBI
2200144	2012, Storage Stability Data, DACO: 2.14.14 CBI
2200145	2012, Product quality control , DACO: 2.16 CBI

2247303 2012, Preliminary analysis method , DACO: 2.13.1 CBI
2251421 2012, Preliminary analysis method, DACO: 2.13.1 CBI
2275023 2013, Batch data-(moiture content) , DACO: 2.13.3 CBI
2275024 2013, Preliminary analysis method rationale , DACO: 2.13.1 CBI
2317311 2013, Methodology, DACO: 2.13.1 CBI

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