

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2016-4608
Application: New/Changes TGAI Product Chemistry-New Source (site) same registrant
Product: Sani-Marc Bromine
Registration Number: 28624
Active ingredients (a.i.): available chlorine and bromine present as 1-bromo-3-chloro-5,5-dimethylhydantoin and related hydantoins
PMRA Document Number : 2780003

Purpose of Application

The purpose of this application was to add a new manufacturing site for the technical grade active ingredient, Sani-Marc Bromine.

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-

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Sani-Marc Bromine has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	66% available bromine and 29% available chlorine
Odour	Faint bromine and chlorine
Density	1.72 g/mL
Vapour pressure	N/A
pH	4.5 for a 0.1% solution
Solubility in water	Sparingly soluble in cold water
n-Octanol/water partition coefficient	0.35

The required chemistry data for Sani-Marc Bromine have been provided, reviewed, and found to be acceptable.

Health Environmental and Value Assessments

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

Conclusion

The PMRA has conducted a review of the available information and has determined that the new manufacturing site for Sani-Marc Bromine can be supported.

References

PMRA #	Reference
2668892	2016, Data, DACO: 2.1
2668893	2016, Data, DACO: 2.2 CBI
2668894	2016, Data, DACO: 2.3
2668895	2016, Data, DACO: 2.4
2668896	2016, Data, DACO: 2.5
2668897	2016, Data, DACO: 2.6
2668898	2016, Data, DACO: 2.7
2668899	2016, Data, DACO: 2.9
2668900	2016, Data, DACO: 2.11.1 CBI
2668901	2016, Data, DACO: 2.11.2 CBI
2668902	2016, Data, DACO: 2.11.3 CBI
2668903	2016, Data, DACO: 2.12.1 CBI
2668904	2016, Data, DACO: 2.13.1 CBI
2668905	2016, Data, DACO: 2.13.2 CBI
2668906	2016, Data, DACO: 2.13.3 CBI
2668907	2016, Data, DACO: 2.13.4 CBI
2713362	2017, Impurete, DACO: 2.11.4 CBI
2713363	2017, Impurete, DACO: 2.13.3 CBI

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