

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2018-5640
Application: B.1.1: New Source Same Registrant
Product: Dodecylguanidine Hydrochloride (Microbiocide-Technical)
Registration Number: 23787
Active ingredients (a.i.): Dodecylguanidine Hydrochloride
PMRA Document Number : 3050005

Purpose of Application

The purpose of this application was to register two new sources of technical for Dodecylguanidine Hydrochloride (Microbiocide-Technical) Reg. No. 23787.

Chemistry Assessment

Common Name: Dodecylguanidine Hydrochloride
 IUPAC* Chemical Name: 1-dodecylguanidine hydrochloride (1:1)
 CAS† Chemical Name: Guanidine, N-dodecyl, hydrochloride (1:1)

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Dodecylguanidine Hydrochloride (Microbiocide-Technical) has the following properties:

Property	Result
Colour and physical state	Pale yellow liquid
Nominal concentration	35.0%
Odour	Mild, aromatic
Density	0.96 g/ cm ³
Vapour pressure	6000 Pa
pH	3.0-3.5
Solubility in water	347.46 g/L
n-Octanol/water partition coefficient	Log P _{ow} < 1.1

The required chemistry data for Dodecylguanidine Hydrochloride (Microbiocide-Technical) 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

PMRA has carried out a review of the data submitted to support the two new sources. Based on the results of this review, the two new sources are acceptable.

References

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- 2944467 2018, Chemical Equivalency Notice for [CBI Removed], DACO: 2.11.2
- 2944468 2018, Formulant Tradename Change, Response to Screening Deficiencies for Dodecylguanidine Hydrochloride (Microbiocide-Technical) (Reg. No. 23787), Submission Number 2018-5640, DACO: 2.11.2 CBI
- 3001095 2019, Dodecylguanidine Hydrochloride - Discussion of Formation of Impurities, DACO: 2.11.4 CBI
- 3001096 1988, Five Month Stability Data for DGH ([CBI-Removed], Registered), DACO: 2.14.14 CBI
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- 3009629 2003, DETERMINATION OF THE PARTITION COEFFICIENT (N-OCTANOL / WATER) OF Dodecylguanidine-hydrochloride (DGH), DACO: 2.14.11
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- 3009632 2019, Dodecylguanidine Hydrochloride (Microbiocide-Technical) PMRA Reg. No. 23787, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.12.1 CBI

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