

Evaluation Report for Category B.1.1 application

Application Number: 2006-7799
Application: Cat B.1.1 (New/Changes TGAI or ISP Prod Chemistry-New Source (site) same registrant)
Product: Biobrom C-103 (DBNPA Technical)
Registration Number: 24353
Active ingredients (a.i.): 2,2-Dibromo-3-Nitrilopropionamide (BRN)
PMRA Document Number : 1479029

Background

Biobrom C-103 (DBNPA Technical) has been registered since April 12, 1996.

Purpose of Application

The purpose of this application is to add a new source to the current registered product, PCP # 24353, and to update the SPSF impurity profile. To support the application, the registrant provided a label, SPSFs dated 2007/01/16, revised SPSFs dated 2007/09/19 and Part 2 Chemistry.

Chemistry Assessment

Subcategory 1.2 (new source by different registrant)

Common Name: N/A

Chemical Name: 2,2-Dibromo-3-nitrilopropionamide

Biobrom C-103 Technical has the following properties:

<i>Property</i>	<i>Result</i>
<i>Colour and physical state</i>	white to off-white solid
Nominal concentration	98% by HPLC
Odour	mild antiseptic
Specific gravity	2.375
Vapour pressure @25°C	0.12±0.01Pa
pH	Not applicable
Solubility in water	practically insoluble
n-Octanol/water partition coefficient	log _{ow} = 0.82

Health Assessments

A health assessment was not required.

Environmental Assessment

An environmental assessment was not required.

Value Assessment

A value assessment was not required..

Conclusion

The PMRA has completed an evaluation of the subject application and has found the information sufficient to add a new source to the current registered product, PCP # 24353, and to update the SPSF impurity profile.

References

Studies/Information Provided by Applicant/Registrant

- PMRA 1340159 2006, Applicants and Manufacturers Names and Addresses, N/A, MRID: N/A, DACO: 2.1,2.2
- PMRA 1340160 2006, DACOs 2.3, 2.3.1, 2.4-2.9, 2.11.1-2.11.4, 2.12.1, 2.14.1-2.14.14, N/A, MRID: N/A, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.3,2.3.1,2.4,2.5, 2.6,2
- PMRA 1340161 2006, Analytical Profile of Batches, St 09-15A, MRID: N/A, DACO: 2.13.1,2.13.2,2.13.3,2.13.4
- PMRA 1340162 2006, Samples of Analytical Standards and ROC, N/A, MRID: N/A, DACO: 2.15
- PMRA 1470178 2007, 2.11.2 Description of Starting Materials, N/A, MRID: N/A, DACO: 2.11.2
- PMRA 1470179 2007, 2.13.1 Methodology/Validation, N/A, MRID: N/A, DACO: 2.13.1
- PMRA 1470180 2007, Method Setup for the Analysis of DBNPA, St 09-15A/Sr, MRID: N/A, DACO: 2.13.1
- PMRA 1470181 2007, Assay Determination of DBNPA, St 09-15A/Sr, MRID: N/A, DACO: 2.13.1
- PMRA 1472585 1992, Halobrom (BCDMH) - Determination of the Dissociation Constant. Amended Final Report., 91-08-3889;11192-0590-6112-795, DACO: 2.14.10
- PMRA 1472609 Halobrom - Product Identity, Chemical and Physical Properties and Storage Stability, DACO: 2.1,2.10,2.14.1,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.16,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9
- PMRA 1472780 Halobrom Manufacturing Methods for the Technical Active Ingredient, Specifications, Quality Control Method, Analytical Data and Methodology, Description of Beginning Materials, Sample Analytical Sheets, Analysis of Halobrom by HPLC, NMR and IR and Halobrom

Published Information

PMRA 1430487. Physical Properties of 2,2-Dibromo-3-nitrilopropionamide, last visited 2007/06/14.
<http://chem.sis.nlm.nih.gov/chemidplus/jsp/common/PhysicalProperties.jsp?calledFrom=lite>.

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