



Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2004-1718
Application: New source by a different registrant
Product: Cambrex NaBr
Registration Number: 28480
Active ingredients (a.i.): Sodium Bromide
PMRA Document Number: 1414579

Background

The original source of sodium bromide technical grade active ingredient, “Sanibrom S Technical” (Reg. No.27209) was first registered in 2002.

Purpose of Application

The purpose of this application is to register a new technical source of sodium bromide.

Chemistry Assessment

Common Name: Sodium bromide
Chemical Name: Sodium bromide

Cambrex NaBr has the following properties:

Property	Result
Colour	White
Physical state	Solid
Nominal concentration	Sodium bromide 99.2%
Odour	None
Density	3.203 g/cm ³
Vapour pressure	Not applicable
pH	6.5
Solubility in water	121 g/100mL at 20 °C
n-Octanol/water partition coefficient	Not applicable

The chemistry requirements for Cambrex NaBr are complete.

Health and Environmental Assessment

The health and environmental risk profile of Cambrex NaBr is expected to be similar to that of the original registered source of Sanibrom S Technical. However, due to product specific registration (data protection) considerations (see Trade Memorandum T-1-249, “Product-Specific Registration and Proprietary Rights to Data”), the applicant was required to generate the following studies as a condition of registration:

Study description and organism/type	DACO
Human Toxicology	
Acute Inhalation Study	(DACO 4.2.3)
Dermal Sensitization Study	(DACO 4.2.6)

Value assessment

A value assessment is not required for technical grade active ingredient products.

Conclusions

The PMRA has completed its evaluation of the subject application and has determined that Cambrex NaBr is eligible for full registration.

References

References List

7.1.1 Studies/Information Provided by Applicant/Registrant

- 1261467 Chemistry Requirements for the registration of a TGAI, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
- 1261469 Cambrian Chemicals Inc. Cambrex NaBr Manufacturing Summary, DACO: 2.11.1
- 1261470 Cambrian Chemicals Inc. Cambrex NaBr Description of Starting material. Sodium Carbonate and Hydrobromic Acid., DACO: 2.11.2
- 1261471 Cambrian Chemicals Inc. Cambrex NaBr Detailed Production Process Description Process Flow-Chart and Description of Main Equipment, DACO: 2.11.3
- 1261472 Cambrian Chemicals Inc. Cambrex NaBr Establishing Certified Limits, DACO: 2.12.1
- 1261473 Cambrian Chemicals Inc. Cambrex NaBr Methodology/Validation and Confirmation of Identity, DACO: 2.13.1,2.13.2
- 1261474 Cambrian Chemicals Inc. Cambrex NaBr Summary of Batch Data, Certificate of Analysis, DACO: 2.13.3
- 1261475 Cambrian Chemicals Inc. Cambrex NaBr Chemical and Physical Properties and Waiver for UV/Visible Absorption Spectra, DACO: 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

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