Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2017-4257
Application: Changes TGAI or ISP Prod Chemistry-New Source(site) same registrant, Changes TGAI or ISP Prod Chemistry-Specifications
Product: Liquibrom 4000T
Registration Number: 33408
Active ingredient (a.i.): Sodium bromide
PMRA Document Number : 2955691

Purpose of Application

The purpose of this application was to register a new source of sodium bromide by an existing registrant.

Chemistry Assessment

Common Name: Sodium bromide
IUPAC* Chemical Name: Sodium bromide
CAS† Chemical Name: Sodium bromide (NaBr)

* International Union of Pure and Applied Chemistry
† Chemical Abstracts Service

Liquibrom 4000T has the following properties:

Property	Result
Colour and physical state	Clear to pale yellow liquid
Nominal concentration	40 %
Odour	Faint, characteristic
Density	1.4044
Vapour pressure	133 kPa (806°C) (for pure NaBr)
pH	6.0 – 8.0
Solubility in water	94.32 g/100 mL (for pure NaBr)
n-Octanol/water partition coefficient	Log K_{ow} estimation -0.37 (for pure NaBr)

The required chemistry data for Liquibrom 4000T have been provided, reviewed, and found to be acceptable, except for five-batch data representing commercial-scale production, which will be

required after registration.

Health Assessments

No additional risk to human health is expected from the use of this new source of sodium bromide for Liquidbrom 4000T.

Food and exposure assessments were not required for this application.

Environmental Assessment

No additional risk to the environment is expected from the use of this new source of sodium bromide for Liquibrom 4000T.

Value Assessment

A value assessment was not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of the new source of sodium bromide.

References

Studies/Information Provided by Applicant/Registrant

2795689	2002, Methodology/Validation, DACO: 2.13.1 CBI
2795690	2017, Confirmation Of Identity, DACO: 2.13.2,2.13.3 CBI
2795691	2017, (pH), DACO: 2.14.1,2.14.15,2.14.2,2.14.3,2.14.6,830.7000 CBI
2795692	2017, Octanol/Water Partition Coefficient, DACO: 2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.4,2.14.5,2.14.7,2.14.8,2.14.9 CBI
2825717	1990, Storage Stability Data, DACO: 2.14.14 CBI
2825720	2017, Manufacturing Summary, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
2872860	2018, LiquiBrom 4000 Impurity Analysis (5 Batch Analysis), DACO: 2.13.4
2872861	2018, Impurities Of Toxicological Concern, DACO: 2.13.4 CBI
2945440	2018, Confirmation Of Identity, DACO: 2.13.1,2.13.2,2.13.3 CBI
2951904	2019, Batch Data, DACO: 2.13.3 CBI
2951905	2018, Batch Data, DACO: 2.13.3 CBI
2951906	2018, Impurities Of Toxicological Concern, DACO: 2.13.4 CBI

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