

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2014-0704
Application: New Source of Technical Grade Active Ingredient by a New Registrant
Product: Etidot-67
Registration Number: 32257
Active ingredients (a.i.): Disodium octaborate tetrahydrate
PMRA Document Number : 2625704

Purpose of Application

The purpose of this application was to register a new source of the active ingredient, disodium octaborate tetrahydrate, by a different Registrant.

Chemistry Assessment

Common Name: Di-sodium octaborate tetrahydrate; Sodium octaborate tetrahydrate
IUPAC* Chemical Name: Disodium octaborate tetrahydrate
CAS† Chemical Name: Boron sodium oxide (B₈Na₂O₁₃), tetrahydrate

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Etidot-67 has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	99.9%
Odour	Odorless
Density	0.4-0.6 g/mL
Vapour pressure	The product is a salt
Solubility in water	9.5% at 20°C 30.1% at 50°C
n-Octanol/water partition coefficient	The product is inorganic solid

The chemistry requirements for Etidot-67 have been fulfilled.

Health and Environmental Assessments

The health risk profile of Etidot-67 is expected to be similar to that of the originally registered sources of technical disodium octaborate tetrahydrate. Therefore, no new toxicology data were required.

Use of the proposed technical, Etidot-67, is not expected to pose a risk to the environment.

Value Assessment

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

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that it can support the registration of Etidot-67.

References

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- 2396231 2014, Results of Analysis, DACO: 2.16
- 2408442 2014, Boron Specialties Analytical Testing Report, DACO: 2.13.3
- 2456734 2014, CATEGORY B 1.2 SUBMISSION - NEW SOURCE OF ACTIVE INGREDIENT BY A NEW APPLICANT ETIMINE USA INC REGISTRATION OF ETIDOT-67 (DI-SODIUM OCTABORATE TETRAHYDRATE, CAS NO. 12280-03-4; PMRA NO. 2014-0704) DATA TO SUPPORT APPLICATION September 16, 2014
- 2456735 2014, Compliance Statement, DACO: 2.13
- 2456736 2014, Test for boric acid, boric oxide, disodium tetraborates, sodium perborates and crude sodium borates for industrial use *iii* Part 3: Determination of sodium oxide and boric oxide contents and loss on ignition of disodium tetraborates, DACO: 2.13.1
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- 2456741 1995, OECD GUIDELINE FOR THE TESTING OF CHEMICALS - 105- water solubility, DACO: 2.13.1

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