Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2020-4337
Application: Changes Technical Grade Active Ingredient (TGAI) Chemistry-New Source (site)
Product: Bromotril Technical
Registration Number: 27675
Active ingredients (a.i.): Bromoxynil
PMRA Document Number : 3281238

Purpose of Application

The purpose of this application was to add a new source of bromoxynil to Bromotril Technical.

Chemistry Assessment

Common Name: Bromoxynil octanoate
IUPAC* Chemical Name: 2,6-dibromo-4-cyanophenyl octanoate
CAS† Chemical Name: 2,6-dibromo-4-cyanophenyl octanoate

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

Bromotril Technical has the following properties:

Property	Result
Colour and physical state	slightly yellow solid
Nominal concentration	66.1 % bromoxynil (present as the octanoate ester)
Odour	faint odour
Density	1.4823 g/mL
Vapour pressure	8.6×10^{-4} Pa at 25 °C
pH	2.5 - 3
Solubility in water	0.003 g/L
n-Octanol/water partition coefficient	5.43 ± 0.07 (at pH 6.1)

The required chemistry data for Bromotril Technical have been provided, reviewed, and found to be acceptable.

Canada

Health, Environmental and Value Assessments

Health, environmental and value assessments were 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 add a new source of bromoxynil to Bromotril Technical

References

PMRA Document Number	Reference
1326098	2006, Bromoxynil Octanoate Physical and Chemical Characteristics, DACO: 2.14.1, 2.14.11,2.14.12,2.14.13,2.14.2,2.14.3,2.14.4,2.14.6,2.14.7,2.14.8
788396	2002, Accelerated Storage Stability Study, DACO: 2.14.14 CBI
1326097	2006, Bromoxynil Octanoate Vapour Pressure, DACO: 2.14.9
3154954	2019, Manufacturing Process of Bromoxynil octanoate, DACO: 2.11.1,2.11.2,2.11.3 CBI
3154955	2019, Discussion of impurities of Bromoxynil octanoate technical, DACO: 2.11.4 CBI
3154957	2019, Analysis of 5 Batches of Bromoxynil Octanoate Technical Material to Include the Determination of the relevant Manufacturing Process Impurities and Validation, DACO: 2.13.1,2.13.2,2.13.3 CBI
3278767	27675-Bromotril Technical-letter of intent-13oct2021

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2021

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.