

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2020-4722

Application: New TGAI (Product Chemistry) - New Source (site), same

registrant; Specifications

Product: NEWAGCO BENTAZON TECHNICAL

Registration Number: 32996 **Active ingredient (a.i.):** Bentazone **PMRA Document Number:** 3296844

Purpose of Application

The purpose of this application was to add a new manufacturing site as a new source of technical grade active ingredient bentazone.

Chemistry Assessment

Common Name: bentazone

IUPAC* Chemical Name: 3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide

CAS† Chemical Name: 3-(1-methylethyl)-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide

NEWAGCO BENTAZON TECHNICAL has the following properties:

Property	Result
Colour and physical state	Light yellow solid
Nominal concentration	98.6%
Odour	Odourless
Density	1.412 g/mL at 20°C
Vapour pressure	1.70 x 10 ⁻⁶ Pa 25°C
pН	2.6
Solubility in water	7.880 g/L (pH 7)
n-Octanol/water partition coefficient	$\log K_{\rm ow} = 1.77$



^{*} International Union of Pure and Applied Chemistry

[†] Chemical Abstracts Service

The required chemistry data for NEWAGCO BENTAZON TECHNICAL have been provided, reviewed, and found to be acceptable.

Health Assessments

The new product is considered toxicologically equivalent to the registered product; therefore, no toxicology data were required.

Dietary and occupational/residential exposure assessments were not required for this application.

Environmental and Value Assessments

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 support the addition of a new manufacturing site for bentazone.

References

PMRA Document Number	Reference
3161457	2018, Appearance (Colour, Physical State and Odour) of Bentazone TC, DACO: 2.14.1, 2.14.2, 2.14.3 CBI
3161459	2018, Determination of Stability of Bentazone TC With and Without Metals and Metal Ions at Normal and Elevated Temperature, DACO: 2.14.13, 2.14.14 CBI
3161460	2018, UV-Visible Absorption Spectra of Bentazone TC, DACO: 2.14.12 CBI
3161461	2018, Melting Point/Melting Range of Bentazone TC, DACO: 2.14.4 CBI
3161462	2018, Specific Gravity of Bentazone TC, DACO: 2.14.6 CBI
3161463	2018, Dissociation Constant of Bentazone TC, DACO: 2.14.10 CBI
3161464	2018, Partition Coefficient (n-Octanol/Water) of Bentazone TC, DACO: 2.14.11 CBI
3161465	2018, Vapour Pressure of Bentazone TC, DACO: 2.14.9 CBI
3161466	2018, Water Solubility of Bentazone TC, DACO: 2.14.7 CBI
3161467	2018, Solubility of Bentazone TC In Organic Solvents, DACO: 2.14.8 CBI
3161471	2017, Five-Batch Analysis of Bentazone Technical Grade Active Ingredient, DACO: 2.13, 2.13.1, 2.13.2, 2.13.3 CBI
3161472	2017, Five-Batch Analysis of Bentazone Technical Grade Active Ingredient: Solvent Residue, DACO: 2.13, 2.13.1, 2.13.3, 2.13.4 CBI
3161473	2020, Manufacturing Process & Quality Control and Justification of the Presence of Impurities, DACO: 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4 CBI
3161486	2020, Statement for Study No. 0184, DACO: 2.13.3 CBI

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2022

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.