

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2011-2693
Application: Changes TGAI Prod Chemistry-New Source (site) same registrant
Product: Forum Technical (Dimethomorph)
Registration Number: 24545
Active ingredients (a.i.): Dimethomorph (DME)
PMRA Document Number: **2131402**

Purpose of Application

The purpose of this application was to register a new manufacturing site for the technical grade active ingredient, Forum Technical (Dimethomorph) (Registration No. 24545).

Chemistry Assessment

Common Name: Dimethomorph
IUPAC Chemical Name: (*EZ*)-4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl]morpholine
CAS Chemical Name: 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine

Forum Technical (Dimethomorph) has the following properties:

| Property | Result |
|---------------------------------------|--|
| Colour and physical state | Colourless to grey |
| Nominal concentration | 98.98% |
| Odour | Odourless |
| Density at 20°C | 1.318 g/mL |
| Vapour pressure at 25°C | 9.7 × 10 ⁻⁷ Pa (<i>E</i> -isomer) 1.0 × 10 ⁻⁶ Pa (<i>Z</i> -isomer) |
| pH | N/A |
| Solubility in water | <u>pH</u> <u>Solubility (ppm)</u> |
| | 5 19 |
| | 7 18 |
| | 9 16 |
| n-Octanol/water partition coefficient | Log K _{ow} = 2.63 (<i>E</i> -isomer) |
| | Log K _{ow} = 2.73 (<i>Z</i> -isomer) |

The chemistry requirements for Forum Technical (Dimethomorph) have been completed.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application as there were no changes to the use pattern.

Conclusion

The PMRA has conducted a review of the available information for this application and has determined that the new manufacturing site may be approved under the condition that new batch data is submitted.

References

Studies/Information Provided by Applicant/Registrant

- | | |
|---------|--|
| 2073941 | 2011, DACO 2 Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient (TGAI) or an Integrated System Product, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI |
| 2073942 | 2010, Dimethomorph TC Announcement of an Additional Source and Documentation of Equivalency, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI |
| 2073943 | 2010, Characterization of Five Batches of BAS 550 F from [CBI Removed] DACO: 2.13.1,2.13.2,2.13.3 CBI |

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2012

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 the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.