

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2015-6965
Application: Changes to TGAI Product Chemistry – New Source (site) Same Registrant
Product: MilStop Technical
Registration Number: 28094
Active ingredients (a.i.): Potassium Bicarbonate
PMRA Document Number: 2683407

Purpose of Application

The purpose of this application was to add a manufacturing site to MilStopTechnical.

Chemistry Assessment

Common Name: Potassium bicarbonate
IUPAC* Chemical Name: Potassium hydrogen carbonate
CAS† Chemical Name: Carbonic acid, potassium salt (1:1)

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

MilStop Technical has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	99.9%
Odour	Odourless
Density at 20°C	2.16-2.17 g/mL
Vapour pressure	Not applicable; product is a salt
pH	8.2-8.4
Solubility in water	224 mg/mL in cold water
n-Octanol/water partition coefficient	$K_{ow} < 0.1$ (estimated); product is an inorganic salt highly soluble in water and not soluble in 1-octanol

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

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 determined that the addition of a manufacturing site to MilStopTechnical can be supported.

References

PMRA Document Number	References
-------------------------------------	-------------------

2593324	2015, Supplemental Chemistry, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.13, 2.13.1, 2.13.2, 2.13.3 CBI
2598462	2016, Updated document 2.1 and 2.2, DACO: 2.1, 2.2 CBI
2651473	2016, Updated list of raw material suppliers, DACO: 2.11 CBI
2651474	2016, Updated manufacturing process and flow chart, DACO: 2.11 CBI
2651475	2016, Updated batch data, DACO: 2.13.3 CBI
2660091	2016, Amended manufacturing process, DACO: 2.11.3 CBI
2660092	2016, Updated certificates of analysis, DACO: 2.13.3 CBI

ISSN: 1911-8082

8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2016

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.