

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2008-2848
Application: B.1.1 (Product chemistry - New source same registrant)
Product: Copper Sulphate Technical
Registration Number: 25692
Active ingredients (a.i.): Copper (present as copper sulphate pentahydrate) (CUS)
PMRA Document Number : 1812550

Purpose of Application

The purpose of this application is to register an alternate manufacturing site by the same registrant.

Chemistry Assessment

Common Name: Copper sulfate pentahydrate
 Chemical Name: Copper sulfate pentahydrate

Copper Sulphate Technical has the following properties:

Property	Result
Colour and physical state	Blue solid
Nominal concentration	Copper 25.3% present as copper sulfate pentahydrate
Odour	none
Density (15.6°)	1200 kg/m ³
Vapour pressure	N/A as the product is a solid
pH	N/A as the product is a solid
Solubility in water (20°C)	284 g/L (pH = 2), 317 g/L (pH = 3.65)
n-Octanol/water partition coefficient	N/A as the product is practically insoluble in organic solvents

The chemistry requirements for Copper Sulphate Technical have been completed.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

The PMRA has completed the assessment of all available information and is able to support the alternate manufacturing site of Copper Sulphate Technical.

References

- 1619864 2008, 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
- 1619865 2008, DACO 2.11.1 Manufacturing Summary, DACO: 2.11.1 CBI
- 1619866 2008, DACO 2.11.2 Description of Starting Materials, DACO: 2.11.2 CBI
- 1619867 2008, DACO 2.11.3 Detailed Production Process Description, DACO: 2.11.3 CBI
- 1619868 2008, DACO 2.15, DACO: 2.15 CBI
- 1619869 2008, DACO 2.11.4 Description of Formulation of Impurities, DACO: 2.11.4 CBI
- 1619871 2008, DACO2 - Chemistry Citation to Date Previously Submitted in Support of Copper Sulphate Technical, Reg.No. 25692, DACO: 2.12.1,2.13.1,2.13.4,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9 CBI
- 1803499 20 07, [CBI REMOVED], DACO: 2.11.3 CBI
- 1803500 2006, Scope of Accreditation, DACO: 2.13.1 CBI
- 1803501 2000, Chemical Testing, DACO: 2.13.1 CBI
- 1803502 2009, [CBI REMOVED], DACO: 2.13.1 CBI
- 1803503 2000, [CBI REMOVED], DACO: 2.13.1 CBI
- 1803504 2000, [CBI REMOVED], DACO: 2.13.1 CBI
- 1803505 2006, Certificate of Analysis, DACO: 2.13.3 CBI
- 1803506 2009, Batch_Certificate of Analysis, DACO: 2.13.3 CBI
- 1804243 2007, [CBI REMOVED], DACO: 2.11.3 CBI
- 1804244 2006, Scope of Accreditation, DACO: 2.13.1 CBI
- 1804246 2000, Chemical Testing, DACO: 2.13.1 CBI
- 1804247 2009, [CBI REMOVED], DACO: 2.13.1 CBI
- 1804248 2000, [CBI REMOVED], DACO: 2.13.1 CBI
- 1804251 2000, [CBI REMOVED], DACO: 2.13.1 CBI
- 1804252 2006, Certificate of Analysis, DACO: 2.13.3 CBI
- 1804253 2009, Batch_Certificate of Analysis, DACO: 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 2010

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.