

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2007-0270
Application: B.1.1: New Site of Manufacture (same registrant)
Product: Propamocarb HCL Technical
Registration Number: 24543
Active ingredients (a.i.): Propamocarb Hydrochloride
PMRA Document Number: 1532855

Purpose of Application

The purpose of this application is to register a new site of manufacture for Propamocarb HCL Technical (Reg. No. 24543) by the same registrant.

Chemistry Assessment

Common Name: Propamocarb Hydrochloride
IUPAC Chemical Name: Propyl 3-(dimethylamino)propylcarbamate hydrochloride
CAS Chemical Name: Propyl [3-(dimethylamino)propyl]carbamate monohydrochloride

Propamocarb HCL Technical has the following properties

Property	Result
Colour and physical state	Colourless to yellowish viscous liquid
Nominal concentration	72.1%
Odour	Odourless
Density	1.085 g/mL at 20°C
Vapour pressure	3.85×10^{-2} mPa at 20°C
pH	Not provided
Solubility in water	1005 g/L
<i>n</i> -Octanol–water partition coefficient	$\log K_{ow} = 0.84$ at 20°C

The chemistry requirements for the new manufacturing site for Propamocarb HCL Technical have been completed and the new site is acceptable for registration

Health, Environment and Value Assessments

As Propamocarb HCL Technical is currently registered, health, environment and value assessments are not required.

Conclusion

The new site of manufacture for Propamocarb HCL Technical is acceptable for full registration.

References

- 1366593 2006, Propamocarb Hydrochloride Technical, PART 2 Product Chemistry Requirements for the Registration of a Technical Grade Active Ingredient (TGAI) or an Integrated System Product (ISP) - DACO 2.1 - 2.9, DACO: 2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI
- 1366594 2005, Propamocarb-HCl Technical. Material Manufacturing Process. Description of Material Used to Produce the Product and Description of Production Process., AE B066752, DACO: 2.11.1,2.11.2,2.11.3 CBI
- 1366596 2006, Composition Statement Technical Material, DACO: 2.12.1 CBI
- 1366597 1998, Analytical Method, Determination of Propamocarb hydrochloride (AE B066752) in technical substance and formulations by HPLC., AL051/97-0, DACO: 2.13.1 CBI
- 1366598 1998, Analytical method. Determination of AE B018563 in AE B066752 00 TK72 A1 (propamocarb HCl technical concentrate) by gas chromatography (GC), AL018/97-1, DACO: 2.13.1 CBI
- 1366599 1998, Analytical method. Determination of the solvents AE F133408 (1-propanol) and AE F132339 (dipropylcarbonate) in AE B066752 00 TK72 A1 (propamocarb HCl technical concentrate) by gas chromatography (GC), AL096/96-2, DACO: 2.13.1 CBI
- 1366600 1999, Analytical method. Determination of water in propamocarb-hydrochloride technical concentrate (AE B066752 00 TK72 A1), using KF-titration, AL020/98-0, DACO: 2.13.1 CBI
- 1366601 1998, Propamocarb-HCl (Technical Grade Active Ingredient). Analytical Profiles of Five Production Batches from the Muskegon Plant Including Description and Validation Data for the Methods Applied., PA98/001, DACO: 2.13.1 CBI
- 1366602 2006, Material Accountability of AE B066752 (Propamocarb Hydrochloride) Technical Concentrate. Analytical Profile of Five Production Batches from Knaosack, Germany, PA05/125, DACO: 2.11.4,2.13.1,2.13.2,2.13.3 CBI
- 1399500 2007, Propamocarb Hydrochloride Technical: Part 2 Product Chemistry Requirements for the Registration of a Technical Grade Active Ingredient (TGAI) or an Integrated System Product (ISP), DACO 2.2, DACO: 2.2

1525584 1999, Discussion of the Formation of impurities in the Technical Grade Active Substance - Propamocarb HCl (Technical Grade Active Ingredient) Code: AE B066752 00 TK72 A1, OE98/065, DACO: 2.11.4 CBI

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