

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2008-4568

Application: B.1.1. – New Source by Same Registrant

Product: Propamocarb HCl Technical

Registration Number: 24543

Active ingredients (a.i.): Propamocarb Hydrochloride

PMRA Document Number: 1807499

Purpose of Application

The purpose of this submission is to add a new source of manufacture by the same registrant for the subject product.

Chemistry Assessment

Common name: Propamocarb hydrochloride

Chemical name: Propyl 3-(dimethylamino)propylcarbamate hydrochloride

Propamocarb HCl Technical has the following properties:

Property	Result
Colour and physical state	Colourless viscous liquid
Nominal concentration	72.1% as determined by HPLC (on a dry basis)
Odour	Odourless
Density	1.085 g/mL
Vapour pressure	$3.85 \times 10^{-2} \text{ mPa at } 20^{\circ}\text{C}$
pH	N/A
Solubility in water	100.5 g/ 100 mL at 20°C
n-Octanol/water partition coefficient	$\log K_{\text{ow}} = 2.5 \times 10^{-3} \text{ at } 22^{\circ}\text{C}$

The chemistry requirements for Propamocarb HCl Technical are complete.



Health, Environmental and Value Assessments

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

Conclusion

The Agency has completed an assessment of the subject application and has found the information to be sufficient to permit the addition of the new source of manufacture for the subject product.

References

1366594	2005, Propamocarb-HCl Technical. Material Manufacturing Process. Description of Material Used to Produce the Product and Description of Production Process.,
	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., 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),
	DACO: 2.13.1 CBI
1366599	1998, Analytical method. Determination of the solvents [CBI removed] in AE
	B066752 00 TK72 A1 (propamocarb HCl technical concentrate) by gas
	chromatography (GC), 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, DACO:
	2.13.1 CBI

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