

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2008-2681
Application: B.1.1: New / Changes TGAI or ISP Prod Chemistry-New Source(site) same registrant
B.1.3: New / Changes TGAI or ISP Prod Chemistry-Specifications
Product: Daminozide Technical Growth Regulant
Registration Number: 24490
Active ingredients (a.i.): Daminozide [DAM]
PMRA Document Number: 1812595

Purpose

Chemtura Canada Co. /CIE has submitted an application to register a new site of manufacture and change in chemistry for Daminozide Technical Growth Regulant.

Chemistry Assessment

Common name: Daminozide
Chemical name: N-(dimethylamino)succinamic acid

Daminozide Technical Growth Regulant has the following properties:

Property	Result
Colour and physical state	White to off white powder (solid)
Nominal concentration	99.4%
Odour	Faint amine like odour
Density	0.744 at 21°C
Vapour pressure	22.7 mPa at 23°C
pH	4.45
Solubility in water	18 g/100 mL
n-Octanol/water partition coefficient	$\log K_{ow} = -1.50$ at 21°C (pH 5,7,9)

The chemistry requirements for Daminozide Technical Growth Regulant are complete. The active ingredient produced at the new site was found to be chemically equivalent to Daminozide Technical Growth Regulant (PCP 24490).

Health Assessments

Daminozide Technical Growth Regulant manufactured at the new site is considered to be chemically equivalent to the product manufactured at the original manufacturing site. Therefore, the toxicity profile is not expected to be significantly different and no toxicological data are required.

Environmental Assessment

No environmental assessment is required.

Value Assessment

No value assessment is required.

Conclusion

Following the assessment of all available data, full registration of a new site of manufacture and change in chemistry for Daminozide Technical Growth Regulant is acceptable.

References

PMRA NO.	Title
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 AE F133408 (1-propanol) and AE F132339 (dipropylcarbonate) 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
1366601	1998, Propamocarb-HCl (Technical Grade Active Ingredient). Analytical Profiles of Five Production Batches from the [CBI Removed] Including Description and Validation Data for the Methods Applied., DACO: 2.13.1,2.13.2,2.13.3,2.13.4

CBI

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, DACO: 2.11.4 CBI

1620902 2008, Daminozide Technical- PCP#24490 - SPSF - F1-V1, N/A, DACO: 0.1.6003

1620905 2008, Daminozide Technical - PCP#24490 - SPSF - F2-V1, N/A, DACO: 0.1.6003

1658268 2008, Company DER - Part 2 Report 08091DC Propamocarb HCL Tech [CBI Removed], DACO: 2.1,2.12.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI

1658274 2008, Regulatory Data Compilation for Propamocarb Hydrochloride Technical Material Manufactured by [CBI Removed], DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI

1658275 2008, Product Chemistry of Banol Fungicide, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI

1782027 1999, SPECTRAL DATA (UV / VIS, IR, MS, 1H - NMR, 13C - NMR) AND MOLAR EXTINCTION COEFFICIENT Propamocarb-HCL AE B066752 00 1B97 0001, DACO: 2.14.12 CBI

1782028 1998, propamocarb hydrochloride solution 722 g/l Code: AE B066752 00 SL67 A2 (CR 18131/01/940203) Previcur N: Storage Stability up to 48months, DACO: 2.14.14 CB

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