

Evaluation Report for Category B, Subcategory 1.1 and 1.3 Application

Application Number: 2012-1117
Application: B.1.1: New Source (site) By Same Registrant
 B.1.3: Change Chemistry Specifications
Product: Lonza Hyamine 1622 Crystals
Registration Number: 17011
Active ingredients (a.i.): diisobutylphenoxethoxyethyl dimethyl benzyl ammonium chloride, present as monohydrate (QAP)
PMRA Document Number: 2277102

Purpose of Application

The purpose of this application was to add two alternate sites of manufacture for Lonza Hyamine 1622 Crystals.

Chemistry Assessment

Common Name: Diisobutylphenoxethoxyethyl dimethyl benzyl ammonium chloride, present as monohydrate, or benzethonium chloride
IUPAC* Chemical Name: N-Benzyl-N,N-dimethyl-2-{2-[4-(2,4,4-trimethylpentan-2-yl)phenoxy]ethoxy}ethanaminium chloride
CAS† Chemical Name: Benzenemethanaminium, N,N-dimethyl-N-[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethyl]-, chloride (1:1)

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Lonza Hyamine 1622 Crystals has the following properties:

Property	Result
Colour and physical state	white dust
Nominal concentration	98.8%
Odour	mild aromatic
Density	0.433 g/cm ³
Vapour pressure	not provided
pH	8-10 (5% aqueous)

Property	Result
Solubility in water	soluble
n-Octanol/water partition coefficient	logP = 3.80 (estimated)

The chemistry requirements for Lonza Hyamine 1622 Crystals have been fulfilled.

Health Assessments

The toxicological profile of Lonza Hyamine 1622 Crystals produced at the new manufacturing sites is expected to be the same as that of the active ingredient produced at the originally registered site. Therefore, no new toxicology data were submitted or required for the addition of these two new manufacturing sites.

Environmental and Value Assessment

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has reviewed the information provided and has determined the two new manufacturing sites are acceptable for registration.

References

- 2171206 2011, Lonza Hyamine 1622 Product Identity and Composition, DACO:
2.11,2.11.1,2.11.2,2.11.3,2.11.4 CBI
- 2171208 2011, Hyamine 1622 Crystals Preliminary Analysis, DACO:
2.13,2.13.1,2.13.2,2.13.3,2.13.4 CBI
- 2171210 2011, Alternate Manufacturing Process for Lonza Hyamine 1622, DACO:
2.11,2.11.1,2.11.2,2.11.3,2.11.4 CBI
- 2171762 2011, Hyamine 1622 Crystals Preliminary Analysis, DACO:
2.13,2.13.1,2.13.2,2.13.3,2.13.4 CBI
- 2172320 2012, 2012-1117 Lonza Hyamine 1622 Crystals Applicant Name and Address,
DACO: 2.1
- 2172321 2012, 2012-1117 Lonza Hyamine 1622 Crystals Establishing Certified Limits,
DACO: 2.12.1 CBI
- 2172322 2012, 2012-1117 Lonza Hyamine 1622 Crystals Manuf Site Name and Address,
DACO: 2.2 CBI
- 2202394 2012, 2012-1117 Lonza Hyamine 1622 Crystals Batch Manuf Dates, DACO: 2.13.3
CBI
- 2202395 2011, 2012-1117 Lonza Hyamine 1622 Crystals Batch Manuf Dates- F2, DACO:
2.13.3 CBI
- 2202396 2011, 2012-1117 Lonza Hyamine 1622 Crystals Batch Manuf Dates- F3, DACO:
2.13.3 CBI

ISSN: 1911-8082

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