

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number:	2015-3221
Application:	New Source (site) same registrant
Product:	Kasugamycin Technical Bactericide
Registration Number:	30590
Active ingredients (a.i.):	Kasugamycin
PMRA Document Number : 2651901	

Purpose of Application

The purpose of this application was to register a new source of kasugamycin by the same registrant for the technical grade active ingredient Kasugamycin Technical Bactericide.

Chemistry Assessment

Common Name: IUPAC* Chemical Name:	Kasugamycin (present as hydrochloride hydrate) 2 - $1L-1,3,4/2,5,6-1$ -deoxy-2,3,4,5,6-pentahydroxycyclohexyl 2 -amino-2,3,4,6-tetradeoxy-4-(α -iminoglycino)- α -D-arabino-hexopyranoside hydrochloride hydrate
	or [5-amino-2-methyl-6-(2,3,4,5,6-pentahydroxycyclohexyloxy) tetrahydropyran-3-yl]amino- α -iminoacetic acid hydrochloride hydrate
CAS [†] Chemical Name:	3- <i>O</i> -[2-amino-4-[(carboxyiminomethyl)amino]-2,3,4,6-tetradeoxy α - <i>D</i> -arabino-hexopyranosyl]- <i>D</i> - <i>chiro</i> -inositol monohydrochloride hydrate

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Kasugamycin Technical Bactericide has the following properties:

Property	Result
Colour and physical state	Orange solid with a tinge of brown
Nominal concentration	75.1%
Odour	Odourless
Density (25°C)	0.40 - 0.46 g/mL
Vapour pressure (25°C)	<0.013 mPa (at 25°C)



Property	Result
рН	4.35
Solubility in water (20-	207 g/L (pH 5)
25°C)	228 g/L (pH 7)
	438 g/L (pH 9)
n-Octanol/water partition coefficient	Log K _{ow} < -1.96 (pH 5)

The required chemistry data for Kasugamycin Technical Bactericide have been provided, reviewed, and found to be acceptable.

Health, Environmental and Value Assessments

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

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to add a source to the Kasugamycin Technical Bactericide.

References

Studies/Information Provided by Applicant/Registrant

PMRA	Reference
Document	
Number	
2622226	2001, [CBI removed] of Kasugamycin, DACO: 2.13.2 CBI
2552213	2014, Kasugamycin Five-Batch Analysis, DACO: 2.13.1,2.13.2,2.13.3,830.1700 CBI
2562191	2015, DACO 2: Kasugamycin Technical Bactericide (30590) Response to Deficiency
	2015-3221 Category B 1.1 Addition of New Manufacturing Source for TGAI, DACO:
	2.0,2.1,2.2
2552212	2015, Production Process of Kasugamycin Technical, DACO: 10.2.1, 2.11.1, 2.11.2,
	2.11.3, 2.11.4, 2.12.1, 2.12.2, 2.13.4, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 3.2.1, 3.2.2, 3.2.3, 3.3.1,
	3.3.2, 830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750 CBI

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