



Evaluation Report for Category B, Subcategory B.1.3 Application (New/Changes to TGAI or ISP Product Chemistry-Specifications)

Application Number: 2005-1075
Application: B.1.3 - Changes to TGAI: Manufacturing Specifications
Product: Pimaricin Technical
Registration Number: 22612
Active ingredients (a.i.): Pimaricin
PMRA Document Number: 1364583

Background

The original source of Pimaricin Technical (Reg. No. 22612) was first registered in 1992.

Purpose of Application

The purpose of this submission is to convert the guarantee of Pimaricin Technical from minimal (91.5% MU) to nominal (85% NS).

Chemistry Assessment

Common Name: Natamycin
IUPAC Chemical Name: (8*E*,4*E*,16*E*,18*E*,20*E*)-(1*R*,3*S*,5*R*,7*R*,12*R*,22*R*,24*S*,25*R*,26*S*)-22-(3-amino-3,6-dideoxy- β -D-mannopyranosyloxy)-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.1.0^{5,7}]octacos-8,14,16,18,20-pentaene-25-carboxylic acid

CAS Chemical Name:
[1*R*-(1*R*,3*S*,5*R*,7*R*,8*E*,12*R*,14*E*,16*E*,18*E*,20*E*,22*R*,24*S*,25*R*,26*S*)]-22-[(3-amino-3,6-dideoxy- β -D-mannopyranosyl)oxy]-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.1.0^{5,7}]octacos-8,14,16,18,20-pentaene-25-carboxylic acid

Pimaricin Technical has the following properties:

Property	Result
Colour and physical state	white to creamy-white
Nominal concentration	85%
Odour	almost odourless
Density	not provided
Vapour pressure	not provided
pH	5.0 to 7.5 (1% suspension in demineralised water)
Solubility in water	4.1 g/L at 20 - 22 °C
n-Octanol/water partition coefficient	Log K _{OW} = -3.670

The chemistry requirements for Pimaricin Technical are complete.

Health Assessments

The health risk profile of Pimaricin Technical is expected to be similar to that of the original registered source.

Environmental Assessment

An environmental assessment was not required.

Value Assessment

A value assessment is not required for technical grade active ingredient products.

Conclusion

The Agency has completed an assessment of available information for Pimaricin Technical and has found the information sufficient to allow for registration.

References

7.1.1 Studies/Information Provided by Applicant/Registrant

- 1100488 2005, Production Process for Natamycin. AND E-mail Kujiper, A. of DSM, to Marshall, G. of cantox re: % of the ingredients in Natamycin, DACO: 2.11.1
- 1100489 JECFA Specifications, DACO: 2.14,2.16,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
- 1100490 Food Chemical Codex Specifications. Niacinamide. Page 298-299., DACO: 2.13.1
- 1100491 1996, Scientific Committee on Food Specifications. Consolidated Text produced by the CONSLEG system of the Office for Official Publications of the European Communities., DACO: 2.16

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2007

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.