



Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2017-2763
Application: Changes (TGAI Product Chemistry) - New Site, Same Registrant
Product: Polyoxin D Zinc Salt Technical
Registration Number: 32687
Active ingredient (a.i.): Polyoxin D Zinc Salt
PMRA Document Number : 2820811

Purpose of Application

The purpose of this application was to register a new manufacturing site for the technical grade active ingredient Polyoxin D Zinc Salt.

Chemistry Assessment

Common Name: Polyoxin D zinc salt
IUPAC* Chemical Name: zinc 5-(2-amino-5-*O*-carbamoyl-2-deoxy-L-xylonamido)-1-(5-carboxy-1,2,3,4-tetrahydro-2,4-dioxypyrimidin-1-yl)-1,5-dideoxy- β -D-allofuranuronate
CAS† Chemical Name: zinc 5-[[2-amino-5-*O*-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2*H*)-pyrimidinyl)-1,5-dideoxy- β -D-allofuranuronate

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Polyoxin D Zinc Salt Technical has the following properties:

Property	Result
Colour and physical state	Brown solid
Nominal concentration	23.8%
Odour	Musty
Density at 20°C	1.82 – 1.85 g/cm ³
Vapour pressure	Negligible as product is a solid
pH	7.19 (1% solution)
Solubility in water	Very soluble
n-Octanol/water partition coefficient	Not applicable as product is an ionic salt

The required chemistry data for Polyoxin D Zinc Salt Technical 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 support the registration of a new manufacturing site for the technical grade active ingredient Polyoxin D Zinc Salt.

References

PMRA Document Number	Reference
2767760	2015, Polyoxin D Zinc Salt Technical: Description of Starting Materials and Production Process, and Discussion of Formulation Impurities (Amendment 1B), DACO: 2.11.2,2.11.3
2767762	2016, Polyoxin D Zinc Salt Technical: Description of Starting Materials (2016), DACO: 2.11.2
2767764	2016, Polyoxin D Zinc Salt Technical: Description of Production Process and Discussion of Formation of Impurities (2016), DACO: 2.11.3,2.11.4
2800537	2017, Polyoxin D Zinc Salt Technical: Certified Limits (2017), DACO: 2.12.1
2800540	2017, Polyoxin D Zinc Salt Technical: 5- Batch Analysis For New Production Facility (GLP), DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI

ISSN: 1911-8082

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