



Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2016-6721
Application: Changes to TGAI Product Chemistry – New Source (site) Same Registrant
Product: Abamectin Technical
Registration Number: 24484
Active ingredient (a.i.): Abamectin
PMRA Document Number: 2753562

Purpose of Application

The purpose of this application was to add a manufacturing site to Abamectin Technical.

Chemistry Assessment

Common Name: Abamectin
IUPAC* Chemical Name: Mixture of $\geq 80\%$
(10*E*,14*E*,16*E*)-(1*R*,4*S*,5'*S*,6*S*,6'*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-6'-[(*S*)-*sec*-butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1^{4,8}.0^{20,24}]*pentacos*-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2'*H*-pyran)-12-yl 2,6-dideoxy-4-*O*-(2,6-dideoxy-3-*O*-methyl- α -L-*arabino*-hexopyranosyl)-3-*O*-methyl- α -L-*arabino*-hexopyranoside

And $\leq 20\%$
(10*E*,14*E*,16*E*)-(1*R*,4*S*,5'*S*,6*S*,6'*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1^{4,8}.0^{20,24}]*pentacos*-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2'*H*-pyran)-12-yl 2,6-dideoxy-4-*O*-(2,6-dideoxy-3-*O*-methyl- α -L-*arabino*-hexopyranosyl)-3-*O*-methyl- α -L-*arabino*-hexopyranoside
CAS† Chemical Name: 5-*O*-demethylavermectin A_{1a} (i) mixture with 5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl)avermectin A_{1a} (ii)

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Abamectin Technical has the following properties:

Property	Result
Colour and physical state	Yellowish white solid
Nominal concentration	92.1%
Odour	Not expected to affect efficacy.
Density	1.16 g/cm ³
Vapour pressure	< 3.7 × 10 ⁻³ mPa
pH	Not applicable, the product has low water solubility.
Solubility in water	1.21 mg/L (25°C)
n-Octanol/water partition coefficient	Log K _{ow} = 4.4 (pH 7.2)

The required chemistry data for Abamectin 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 determined that the addition of a manufacturing site to Abamectin Technical can be supported.

References

PMRA Document Number	References
1325313	2006, Chemistry source documents for the submission to add a new manufacturing source for Abamectin Technical, DACO: 2.1, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.12.2, 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
1486732	2007, MK 936 - List of By Products (Codes, Names, Formulae), DACO: 2.11.4, 4.8 CBI
2692346	2016, PC-16-002 Abamectin II [CBI Removed] OECD Document J Technical, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.12.2, 2.13.3, 2.13.4, 2.2 CBI
2692347	2016, PC-16-002 Abamectin II [CBI Removed] OECD Document J Technical, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.12.2, 2.13.3, 2.13.4, 2.2 CBI
2692348	2016, PC-16-003 Abamectin II [CBI Removed] OECD Document H (Confidential), DACO: 2.11.2 CBI
2692349	2006, ABA - Confirmation of structures of by-product, DACO: 2.13.2 CBI

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