

Evaluation Report for Category B, Subcategory 1.1 and B.1.3 Application

Application Number: 2009-0474
Application: B.1.1 – New TGAI or ISP Prod Chemistry-New Source (site) same registrant
 B.1.3 - Changes TGAI or ISP Prod Chemistry-Specifications
Product: Abamectin Technical
Registration Number: 24484
Active ingredients (a.i.): Abamectin
PMRA Document Number: 1880775

Purpose of Application

Syngenta Crop Protection Canada Inc. has submitted an application to add a new site of manufacture of Abamectin Technical.

Chemistry Assessment

Common name: Abamectin
Chemical name: (10*E*,14*E*,16*E*,22*Z*)-(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}]pentacosa-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 (i) mixture with (10*E*,14*E*,16*E*,22*Z*)-(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}]pentacosa 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 (ii) (4:1)

Abamectin Technical has the following properties:

Property	Result
Colour and physical state	Yellowish-white solid crystals
Nominal concentration	92.1%
Odour	N/A
Density	1.16 g/cm ³
Vapour pressure	$< 3.7 \times 10^{-3}$ mPa
pH	N/A
Solubility in water	7-10 µg/L
n-Octanol/water partition coefficient	$\log K_{ow} = 4.4 \pm 0.3$ at pH 7.2

The chemistry requirements for Abamectin Technical are complete.

Health Assessments

No new residue data for Abamectin Technical were submitted in support of the registration of the new source for this active ingredient. A review of the proposed specification form was conducted in the framework of this submission. As this manufacturing concentrate will be used to formulate registered end-use products within the existing use pattern, from a food residue exposure point of view, no changes in the magnitude of the residues in food and feed crops are expected. Therefore, no increase in dietary exposure for any segment of the population is anticipated.

No change in the toxicological profile is anticipated.

Environmental Assessment

No environmental assessment was required for this application.

Value Assessment

No value assessment was required for this application.

Conclusion

Following the assessment of the submitted data, the PMRA is able to support the registration of the new source for Abamectin Technical.

References

PMRA No.	Title
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
1717438	2009, 2.2-1- Abamectin Tech_24484 - Add new source, DACO: 2.2
1717439	2008, 2.13.3 - Abamectin Tech_24484 - Add new source, DACO: 2.13.3 CBI

ISSN: 1911-8082

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