

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

**Application Number:** 2006-7368  
**Application:** B.1.1. : Change TGAI – New source (site) same registrant  
B.1.3. : Change TGAI – New product chemistry specifications  
**Product:** Abamectin Technical  
**Registration Number:** 24484  
**Active ingredients (a.i.):** Abamectin  
**PMRA Document Number:** 1649640

### Purpose of Application

The purpose of this application is to register a new site of manufacture for Abamectin Technical (Reg. No. 24484) by the same registrant.

### 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<sup>4,8</sup>.0<sup>20,24</sup>]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- $\alpha$ -L-*arabino*-hexopyranosyl)-3-*O*-methyl- $\alpha$ -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<sup>4,8</sup>.0<sup>20,24</sup>]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- $\alpha$ -L-*arabino*-hexopyranosyl)-3-*O*-methyl- $\alpha$ -L-*arabino*-hexopyranoside (ii)

Abamectin Technical has the following properties:

Property	Result
Colour and physical state	Colorless to pale yellow solid
Nominal concentration	92%
Odour	N/A
Density @ 20°C	1.16 g/cm <sup>3</sup>
Vapour pressure @ 25°C	<3.7 x 10 <sup>-3</sup> mPa
pH	N/A
Solubility in water	Insoluble
n-Octanol/water partition coefficient (K <sub>ow</sub> )	log Kow = 4.4±0.3 (pH = 7.2)

The chemistry requirements for Abamectin Technical have been completed.

### **Health Assessments**

#### Toxicology:

The toxicological profile for Abamectin Technical remains unchanged.

#### Food Residue:

The request to add a new site of manufacture is not expected to alter the residues in food and feed crops treated with end use products containing Abamectin Technical. Therefore, no increase in dietary exposure to abamectin is anticipated.

### **Environmental and Value Assessment**

Environmental and Value assessments were not required for this application.

### **Conclusion**

The new site of manufacture of Abamectin Technical is acceptable for full registration.

## References

### Chemistry

1325313	2006, Chemistry source documents for the submission to add a new manufacturing source for Abamectin Technical, DACO: 2.1,2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.12.2,2.13.1,2.13.2,2.13.3,2.13.4,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.1
1486732	2007, MK 936 - List of By Products (Codes, Names, Formulae), DACO: 2.11.4,4.8 CBI

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