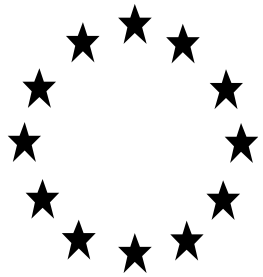
Competent Authority Report

Programme for Inclusion of Active Substances in Annex I to Council Directive 98/8/EC



S-Methoprene (PT 18)

CAS-No. 65733-16-6

DOCUMENT IIIA (A1-3)

Evaluation Report

Rapporteur: Ireland

January 2013

s-Methoprene (PT18)

Document A1-3

CONTENTS

Section A1 Applicant

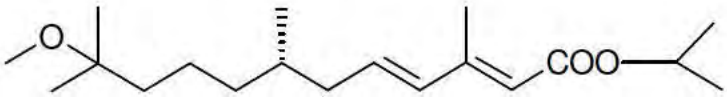
Annex Points IIA1

1.1	**Applicant**	Name: Bábolna Bioenvironmental Centre Ltd. Address: H-1107 Budapest, X. Szállás u. 6, Hungary [redacted]	
1.2	**Manufacturer of Active Substance (if different)**	Bábolna Bioenvironmental Centre Ltd., H-1107 Budapest, X. Szállás u. 6, Hungary	X
1.3	**Manufacturer of Product(s) (if different)**	Bábolna Bioenvironmental Centre Ltd., H-1107 Budapest, X. Szállás u. 6, Hungary	
	(1) Product 1	Biopren® Pharaoh's Ant Colony Eliminator (outside Hungary) Protect® Pharaoh's Ant Colony Eliminator (in Hungary)	

Section A2 Identity of Active Substance

Subsection (Annex Point)			Official use only
2.1	Common name (IIA2.1)	S-Methoprene	
2.2	Chemical name (IIA2.2)	(7*S*, 2*E*, 4*E*)-(+)-11-methoxy-3,7,11-trimethyldodeca-2,4-dienoic acid isopropyl ester Isopropyl (7*S*, 2*E*, 4*E*)-(+)-11-methoxy-3,7,11-trimethyldodeca-2,4-dienoate Isopropyl (*E*,*E*)-(7*S*)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate (*S*) Isopropyl-(2*E*, 4*E*)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate	
2.3	Manufacturer´s development code number(s) (IIA2.3)	None	
2.4	CAS No and EC numbers (IIA2.4)		
2.4.1	CAS-No	65733-16-6	
	Isomer 1	Not applicable	
	Isomer n	Not applicable	
2.4.2	EC-No	Not available	
	Isomer 1	Not applicable	
	Isomer n	Not applicable	
2.4.3	Other	Not applicable	

Section A2 Identity of Active Substance

2.5	**Molecular and structural formula, molecular mass (IIA2.5)**						
2.5.1	**Molecular formula**	$C_{19}H_{34}O_3$					
2.5.2	**Structural formula**						
2.5.3	**Molecular mass**	310.48 g/mol					
2.6	**Method of manufacture of the active substance (IIA2.1)**	See Confidential Data and Information.					
2.7	**Specification of the purity of the active substance, as appropriate (IIA2.7)**	g/kg ≥ 960	g/l	% w/w ≥ 96	% v/v	X	
2.8	**Identity of impurities and additives, as appropriate (IIA2.8)**	See Confidential Data and Information.					
2.8.1	**Isomeric**	Not applicable					

Section A2 Identity of Active Substance

	composition	
2.9	**The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)**	See confidential Data and Information

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Specification of the purity of the active substance, as appropriate (IIA2.7)**
Date	13/11/12
Materials and methods	
Conclusion	The min. specification is 95% w/w. The min. specification has been agreed with the applicant and is supported by batch data. Batches will be blended in order to achieve 95% w/w. Location of manufacturing plant - Bábolna Bioenvironmental Centre Ltd., H-1107 Budapest, X. Szállás u. 6, Hungary See Confidential Data and Information.
Reliability	1
Acceptability	Acceptable.
Remarks	No further remarks.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion. Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1 Freezing point, boiling point, relative density (IIA3.1)								
3.1.1 Freezing point	Not documented.	98.3% pure S-Methoprene technical; Batch number: 35716 / Specification given in Section 2	**Result:** < -22°C		Y	1	Laky, V., 2006a	
3.1.2 Boiling point Boiling pt. 1	EEC Method A2 OECD 103 US OPPTS 830.7220 (Differential Thermal Analysis)	98.3% pure S-Methoprene technical; Batch number: 35716 / Specification given in Section 2	**Result:** 279.9 °C **Pressure:** 97.2 kPa		Y	1	Laky, V., 2006a	
Boiling point 2	US OPPTS 830.7220	> 95% pure S-Methoprene technical (LX 125-03); Batch number: M8991 /	**Result:** >262 °C		Y	1	Anderson, W., 1999	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
		Specification given in Section 2						
3.1.3 Bulk density/ relative density								
Bulk/rel. density 1	US OPPTS 830.7300 OECD 109 (Pycnometer Method)	> 95% pure S-Methoprene technical (LX 125-03); Batch number: M8991 / Specification given in Section 2	**Result:** D^{20}_{20} = 0.924 g/ml at 20ºC		Y	1	Anderson, W., 1999	X
3.2 Vapour pressure (IIA3.2)								
Vapour pressure 1	US OPPTS 830.7950	> 95% pure S-Methoprene technical (LX 125-03); Batch number: M8991 / Specification given	**Result:** 3.15 mPa (2.37 x 10^{-5} mmHg)	The vapour pressure study is not considered acceptable because the temperature at	Y	1	Anderson, W., 1999	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
		in Section 2		which the vapour pressure was determined was not reported. Therefore, this study was not considered acceptable and a new study was commissioned (Bates, 2007).				
Vapour pressure 2	EEC Method A4 OECD 104 (Effusion Method)	98.1% pure S-Methoprene technical; Batch number: 41711 / Specification given in Section 2	**Result:** 0.623 mPa at 20°C 1.08 mPa at 25°C		Y	1	Bates, M., 2007	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.2.1 Henry´s Law Constant (Pt. I-A3.2)	Calculated using solubility and vapour pressure values.		**Result:** 0.0306 Pa x m^3/mol **Temperature:** 20°C					X
3.3 Appearance (IIA3.3)								
3.3.1 Physical state	US OPPTS 830.6303	> 95% pure S-Methoprene technical (LX 125-03); Batch number: M8991 / Specification given in Section 2	**Result:** Liquid **Temperature:** 24 °C		Y	1	Anderson, W., 1999	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.3.2 Colour	US OPPTS 830.6302	> 95% pure S-Methoprene technical (LX 125-03); Batch number: M8991 / Specification given in Section 2	**Result:** Transparent, pale yellow **Temperature:** 24 °C		Y	1	Anderson, W., 1999	
3.3.3 Odour	US OPPTS 830.63024	> 95% pure S-Methoprene technical (LX 125-03); Batch number: M8991 / Specification given in Section 2	**Result:** 5-inch description: faint waxy and fruity **Temperature:** 24 °C		Y	1	Anderson, W., 1999	

Section A3 **Physical and Chemical Properties of Active Substance**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.4 Absorption spectra (IIA3.4) **UV/VIS**	US OPPTS 830.7050	> 95% pure S-Methoprene technical (LX 125-03); Batch number: M8991 / Specification given in Section 2	**Result:** 90% Neutral Methanol: λ_{max} = 264 nm; ε = 26,700 90% Acidified Methanol: λ_{max} = 264 nm; ε = 26,600 90% Alkalinized Methanol: λ_{max} = 266 nm; ε = 27,450		Y	1	Anderson, W., 1999	X
IR 1		> 96% pure S-Methoprene technical; Batch number: 18825 / Specification given in Section 2	3040 – 2800 cm^{-1}: alken, alkyl and CH 1720 cm^{-1}: C=O ester 1640 and 1615 cm^{-1}: C=C 1380 and 1470 cm^{-1}: flexion CH_2 and CH_3 1240, 1160 and 1110 cm^{-1}: C-O-C	The IR spectrum is consistent with the chemical structure of S-Methoprene	N	1	Balbona Bio, 2002a	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
IR 2	Directive 98/8/EC, Annex IIA, 3.4	97.6% pure S-Methoprene technical; Batch number: 41711 / Specification given in Section 2	2972-2822 cm^{-1}: C-H stretch 1706 cm^{-1}: C=0 stretch 1636 - 1611 cm^{-1}: C=C stretch 1465 - 1361 cm^{-1}: C-H deformation 1237 cm^{-1}: C-O stretch (ester) 1115 - 1107 cm^{-1}: C-O stretch (saturated aliphatic ether) 965 cm^{-1}: C-H out of plane deformation (unsaturated)	The IR spectrum is consistent with the chemical structure of S-Methoprene	Y	1	Woolley, S.M. and Mullee, D.M. 2006	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
NMR 1		> 97% pure S-Methoprene technical; Batch number: 9812042 / Specification given in Section 2	^{1}H NMR Spectrum: 0.89 (d, J=6.5 Hz, 3H, CH_3), 1.14 (s, 7H, 2 CH_3, C_8-H), 1.25 (d, J=6.3 Hz, 6H, 2 CH_3), 1.30 (m, 2H, C_8-H and C_9-H), 1.38 (m, 1H, C_9-H), 1.43 (m, 2H, C_{10}-H´s), 1.57 (m, 1H, C_7-H), 2.00 (m, 1H, C_6-H), 2.17 (m, 1H, C_6-H), 2.27 (s, 3H, C_3-CH_3), 3.17 (s, 3H, OCH_3), 5.04 (M, 1H, OCH), 5.67 (S, 1H, C_2-H), 6.08 (M, 2H, C_4-H and C_5-H) ^{13}C NMR Spectrum: 13.88 (C_3-CH_3), 19.60 (C_7-CH_3), 21.29 (C-9), 21.99 ($2CH_3$), 24.99 ($2CH_3$), 33.18 (C-7), 37.21 (C-8), 40.09 (C-10), 40.56 (C-6), 49.08 (CH_3-O), 66.69 (O-CH), 74.55 (C-11), 118.22 (C-2), 134.88 (C-4), 135.85 (C-5), 152.14 (C-3), 166.82 (COO)	The NMR spectrum is consistent with the chemical structure of S-Methoprene.	N	1	Balbona Bio, 1998	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
NMR 2	Directive 98/8/EC, Annex IIA, 3.4	97.6% pure S-Methoprene technical; Batch number: 41711 / Specification given in Section 2	^{1}H NMR Spectrum: 0.9 - 1.3 ppm: 18 H from 5 –CH_3 with the exception of the methyl ether group 1.4 - 2.4 ppm: 10H –CH2 (C_6-H, C_8-H, C_9-H,C_{10}-H and O-C-H) 1.51 ppm: -CH (C_7-H) 3.2 ppm: singlet, 3H from –CH3 on the methyl ether group (-O-CH_3) 5.0 - 5.1 ppm: septant multiplet, 1H (O–CH-$(CH_3)_2$) 5.68 ppm: singlet, 1H, no splitting –CH (C_3-C_2H-C_1O(O-$(CH_3)_2$) 6.1 - 6.2 ppm: 1H, -CH (C_4H-C_5H- and 1H, -C_5H-C_6H) ^{13}C NMR Spectrum	The NMR spectrum is consistent with the chemical structure of S-Methoprene.	Y	1	Woolley, S.M. and Mullee, D.M., 2006	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
			13.83 ppm: C_9H_3 19.55 ppm: $C_{14}H_3$ 21.95 ppm: C_3H_3 and C_4H_3 24.94 ppm: $C_{18}H_3$ and $C_{19}H_3$ 21.24 ppm: C_6H_2 37.16 ppm: $C_{10}H_2$ 40.03 and 40.52 ppm:, , C_5H_2 and C_7H_2 49.04 ppm: C_1H_3 66.65 ppm: $C_{17}H$ 118.7 ppm: $C_{15}H$ 135.82 ppm: $C_{11}H$ 134.84 ppm: $C_{12}H$ 74.50, 152.10 and 166.77 ppm: C_2, C_{13} and C_{16}					

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
MS 1		> 96% pure S-Methoprene technical; Batch number: 18825 / Specification given in Section 2	Molecular ion at: m/z 311: $C_{19}H_{35}O_3$ m/z 279: $C_{18}H_{31}O_2$ m/z 310: $C_{19}H_{34}O_3$	The MS spectrum is consistent with the chemical structure of S-Methoprene.	N	1	Babolna Bio, 2002	X
MS 2		97.6% pure S-Methoprene technical; Batch number: 41711 / Specification given in Section 2	Molecular ion at: m/z 311: $C_{19}H_{35}O_3$ $(M+H)^+$ m/z 328: $C_{19}H_{36}O_4$ $(M+H+OH^-)^+$ m/z 279: $C_{18}H_{31}O_2$ $(M - CH_3OH)$	The MS spectrum is consistent with the chemical structure of S-Methoprene.	Y	1	Laky, V.,2006b	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.5 Solubility in water (IIA3.5) Water solubility 1	US OPPTS 830.7840 OECD 105	> 95% pure S-Methoprene technical (LX 125-03); Batch number: M8991 / Specification given in Section 2	**Result:** 6.85 ppm **Temperature:** 20 °C		Y	2	Anderson, W., 1999	X
3.6 Dissociation constant (-)				Not required as S-Methoprene does not dissociate in water.				X
3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1)	SOP of LAB International Research Centre Hungary Ltd.; ANE 176, "Solubility Testing"	98.1% pure S-Methoprene technical; Batch number: 41711 / Specification given in Section 2	**Result:** Hexane: > 5 10^5 mg/l Methanol:> 4.5 10^5 mg/l Acetone: > 5 10^5 mg/l **Temperature:** 20 ± 1 °C		Y	1	Laky, V., 2006c	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)				Not required as no organic solvents are present in the technical.				
3.9 Partition coefficient n-octanol/water (IIA3.6) log Pow 1	US OPPTS 830.7570 OECD 117	> 95% pure S-Methoprene technical (LX 125-03); Batch number: M8991 / Specification given in Section 2	**Result:** 9.5	The pH could not be determined as S-methoprene does not dissociate in water.	Y	2	Anderson, W., 1999	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.10 Thermal stability, identity of relevant breakdown products (IIA3.7) Thermal stability 1	CIPAC Method MT 39, 41, 46	> 95% pure S-Methoprene technical (LX 125-03); Batch number: M8991 / Specification given in Section 2	**Result:** Stable at 54 ± 1°C for 14 days Stable when exposed to simulated sunlight and darkness in alternating cycles of 12 hours over a 72-hour period. Stable when exposed to iron filings, ferric phosphate, aluminium leaf and aluminium phosphate at 20 ± 2°C and 37 ± 1°C for 14 days.		Y	3	Anderson, W., 1999	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
Thermal stability 2	MSZ 08 0208 1988	95% S-Methoprene technical; Batch number: Not specified / Specification given in Section 2	**Result:** Stable for 2 years. **Temperature:** 20 – 25 °C. **Result:** Stable for 14 days. **Temperature:** 54 ± 2 °C.		N	3	Szabó, E., 2005	X
3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)								
Auto-flammability	EEC Method A15	98.3% pure S-Methoprene technical; Batch number: 35716 / Specification given in Section 2	**Result:** 263 °C		Y	1	Laky, V., 2006d	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
Flammability				The preparation is not flammable since the flash point is higher than 55°C				
3.12 Flash-point (IIA3.9) Flash-point 1	EEC Method A9	98.3% pure S-Methoprene technical; Batch number: 35716 / Specification given in Section 2	**Result:** 143 °C		Y	1	Laky, V., 2006e	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.13 Surface tension (IIA3.10) Surface tension 1	EEC Method A5	98.3% pure S-Methoprene technical; Batch number: 35716 / Specification given in Section 2	**Result:** 50.1 mN/m **Temperature:** 20 °C. The active substance is surface active.		Y	1	Laky, V., 2006f	X
3.14 Viscosity (-)	OECD 114	98.3% pureS-Methoprene technical; Batch number: 35716 / Specification given in Section 2	**Result:** Dynamic: 51.3 mPa/sec Kinematic: 55.3 mm^2/sec **Temperature:** 20 °C **Result:** Dynamic: 17.8 mPa/sec Kinematic: 19.2 mm^2/sec **Temperature:** 40 °C		Y	1	Laky, V., 2006g	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.15 Explosive properties (IIA3.11)				The molecular structure of S-Methoprene indicates that the substance has little or no explosive properties.				X
3.16 Oxidizing properties (IIA3.12)				The molecular structure of S-Methoprene indicates that there is little or no potential for this material as an oxidising or reducing agent.				X
3.17 Reactivity towards container material								

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
(IIA3.13)								
Reactivity towards container material 1	CIPAC Method MT 39, 41, 46	> 95% pure S-Methoprene technical (LX 125-03); Batch number: M8991 / Specification given in Section 2	**Result:** S-Methoprene is stable when stored in glass and with metal.		Y	2	Anderson, W., 1999	X
Reactivity towards container material 2	US OPPTS 830.6317 US OPPTS 830.6320	0.5% pure S-Methoprene technical (LX 125-10); Batch number: 7/98 / Specification given in Section 2	**Result:** S-Methoprene is stable with no evidence of corrosion or other signs of deterioration when stored in polyethylene plastic at 20ºC for 1 year.		Y	3	Anderson, W., 2003	X

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Relative Density**
Date	19.9.2008
Materials and methods	Study has been conducted on 97.2% a.s..
Conclusion	Bulk/relative density = 0.924
Reliability	1
Acceptability	Acceptable.
Remarks	No further data required
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X Vapour Pressure IIA 3.2**
Date	18/09/08
Materials and methods	X: Test conducted using 94% pure technical grade active substance, Lot no. 80601. Not as specified under point 3.2. X: Test conducted using >98% pure a.s. to GLP. V.P. = 6.23 x 10^{-4} Pa at 20°C (0.623mPa) V.P. = 1.08 x 10^{-3} Pa at 25°C (1.08mPa)
Conclusion	Test substance is not volatile
Reliability	1
Acceptability	Acceptable
Remarks	No further data required
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Henrys Law Constant Pt.A. 3.2**
Date	30/07/08
Materials and methods	Results derived using water solubility value and vapour pressure value at 20°C.
Conclusion	Henrys Law Constant = 0.0306Pa m^3/mol at 20°C
Reliability	1
Acceptability	Acceptable.
Remarks	No further data required
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Spectral data, UV IIA 3.4**
Date	17/12/12
Materials and methods	Test performed using TGAI. The test should have been performed purified active substance, however the min. purity of the test material is reasonably high (>95% w/w), and the overall aim of the study has been achieved.
Conclusion	The study is acceptable. No further data required.
Reliability	2
Acceptability	Acceptable.
Remarks	No further data required.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Spectral data, IR, IIA 3.4**
Date	19/09/08
Materials and methods	X: Spectral data should be submitted for purified active substance. X: Test conducted using 97.6% a.s. Company have claimed that 98% purity is the maximum that can be achieved.
Conclusion	Spectrum in accordance with molecular structure
Reliability	1
Acceptability	Acceptable
Remarks	No further data required
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Spectral data, NMR IIA 3.4**
Date	19/09/08
Materials and methods	Test conducted using 97.6% a.s. Company have claimed that 98% purity is the maximum that can be achieved.
Conclusion	Spectrum in accordance with molecular structure
Reliability	1
Acceptability	Acceptable
Remarks	No further data required
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Spectral data, MS IIA 3.4**
Date	14/11/12
Materials and methods	The study is acceptable.
Conclusion	The study is acceptable.
Reliability	1
Acceptability	Acceptable
Remarks	No further data required.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Solubility in water IIA 3.5**
Date	09/09/08
Materials and methods	Concentration of a.s. was given as 97.2%. The company have claimed that the active substance is unstable under both acid and alkaline conditions. At acidic pH the ester bond will cleave and under alkaline conditions a sodium salt is formed
Conclusion	Solubility of Technical active substance is 6.85mg/kg at 20°C.
Reliability	2
Acceptability	Acceptable
Remarks	The solubility of the active substance in water is very low. It is highly unlikely that an increase in temperature will affect the solubility of the test substance significantly. No further data required
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Dissociation constant, Point 3.6**
Date	13/07/07
Conclusion	Accept that S-Methoprene is not likely to dissociate The purified active substance has low solubility in water (6.8mg/L) making it difficult to determine a dissociation constant. The chemical structure of S-Methoprene indicates that the molecule is unlikely to dissociate in water. This was confirmed by the UV spectrophotometric method which found little or no change in absorbance as a function of pH.
Remarks	No further data required
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Partition coefficient IIA 3.6**
Date	11/11/12
Materials and methods	The experimentally determined LogKow value is unusually high. The test substance is surface active, therefore the experimentally determined LogKow value is not reliable according to OECD Test Guidelines. The OECD Test Method for LogKow recommends using a calculation method for surface active materials. The applicant has provided a calculated LogKow value of 6.34. The applicant used EPA EIPWIN software using KOWWIN algorithms to determine the calculated LogKow value.
Conclusion	The calculated LogKow is acceptable.
Reliability	1 (calculated value).
Acceptability	The calculated value is considered acceptable.
Remarks	No further information is required.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Thermal stability, identity of relevant breakdown products (IIA3.7** 1)
Date	07/08/07
Materials and methods	Test substance (LX 125-03) is stated to be Technical Grade a.s., purity >95%. After storage for 14 days at 54°C there was no change in the physical state, colour or consistency of the compound. The % weight change of test substance was reported to be 0.35% (mean of two replicates). There was no data supplied to indicate that the active substance content was analysed either before or after storage or if this value of 0.35% change relates to a.s. content After exposure to simulated sunlight for a 72 hr. period (alternate 12 hr. of "sunlight" from a xenon lamp, 280nm and 300nm filters) and 12 hr. darkness, there was no change in the physical state, foaming characteristics, colour or consistency of the compound. The odour was fainter than prior to storage. The % weight change of test substance was reported to be 0.39 % (mean of two replicates). There was no data supplied to indicate that the active substance content was analysed either before or after storage or if this value of 0.39% change relates to a.s. content. After storage with either (a) iron filings, (b) ferric phosphate, (c) aluminium leaf and (d) aluminium phosphate, for 14 days at both 20°C and 37°C there was no change in the physical state, colour, odour or consistency of the compound. The active substance content was not analysed either before or after storage.
Conclusion	No change in physical state or characteristics when stored for: 14 days at 54°C when exposed to sunlight for 72hr. when stored with (a) iron filings, (b) ferric phosphate, (c) aluminium leaf and (d) aluminium phosphate, for 14 days at both 20°C and 37°C. If the analysis of active substance is presented and accepted then it can be concluded that the test substance is thermally stable. This method is not acceptable because no data was provided.
Reliability	3
Acceptability	Not acceptable
Remarks	No further data required. The applicant has another study to cover this Annex point.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*

Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Thermal stability, identity of relevant breakdown products (IIA3.7 2)**
Date	19/09/08
Materials and methods	S-Methoprene was analysed before and after storage at 54°C for 14 days and after 1 year at ambient temperature (20-25°C) by GLC. Initial content Methoprene, (cis/trans = 1.5: 97.2) = 98.7% total After 14days at 54°C (cis/trans = 2 : 97.0) = 99% total After 1 year ambient temperature (cis/trans = 2.7 : 96.2) = 98.9% The results are only for 1 year at ambient temperature and not 2 years as stated. A further study has been conducted, two different batches were stored for 6 months at 40°C. The active substance and certain impurity content were determined both before and after storage. After storage 99.0% S-methoprene was present, 98.5% of R/S methoprene was present ["Accelerated storage stability test of S-methoprene technical". Marosfi, J. & Mattyasovszky-Geisz, 2007]
Conclusion	Test substance is stable when stored for up to 6 months at 40°C.
Reliability	1
Acceptability	Acceptable
Remarks	No further data required
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Autoignition**
Date	08/07/07
Materials and methods	Purified active substance was used. Test conducted to GLP. The applicant should have used technical material as manufactured for this test, however the difference in content of flammable solvents between a 98.3% preparation and the 95.0% would not be significant.
Conclusion	Auto-ignition temperature for s-Methoprene is 263°C at 99.1 k Pa.
Reliability	1
Acceptability	Acceptable
Remarks	No further data required
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Flash Point**
Date	08/07/07
Materials and methods	Closed cup method used. Purified active substance was used. Test conducted to GLP. The applicant should have used technical material as manufactured for this test, however the difference in content of flammable solvents between a 98.3% preparation and the 95.0% would not be significant.
Conclusion	Flash point of s-Methoprene is 143°C at 99.1 k Pa.
Reliability	1
Acceptability	Acceptable
Remarks	No further data required
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Surface Tension**
Date	08/07/07
Materials and methods	Ring method used, purified active substance. Test conducted to GLP.
Conclusion	Surface tension of s-Methoprene is 50.1mN/m (1mg/l) at 20°C S-Methoprene is considered to be surface active on the basis of this result.
Reliability	1
Acceptability	Acceptable
Remarks	No further data required
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Viscosity**
Date	08/07/07
Materials and methods	Rolling ball viscometer method used, purified active substance. Test conducted to GLP.
Conclusion	Dynamic: 51.3 mPa/sec Kinematic: 55.3 mm^2/sec at 20°C Dynamic: 17.8 mPa/sec Kinematic: 19.2 mm^2/sec at 40°C.
Reliability	1
Acceptability	Acceptable
Remarks	No further data required
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Explosive/Oxidising properties**
Date	14/08/07
Materials and methods	The remarks/justification presented for S-Methoprene in 3.15 & 3.16 as regards explosive and oxidising properties are acceptable.
Conclusion	Based on the structure of S-Methoprene it is concluded that there is little likelihood of the molecule being either explosive or oxidising
Reliability	2
Acceptability	Acceptable
Remarks	No further data required
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Reactivity towards container material 3.17 -1**
Date	08/07/07
Materials and methods	Five different lots of technical material (LX 125-03) were analysed by HPLC/ Detection UV at 254nm Results for the five lots: 102.68%, 102.7%, 104.66%, 103.68% and 104.92% (mean = 103.7%, std = 1.056%, RSD = 1.018%) Analytical standard, Methoprene 98% pure (This appears to be a racemic mixture) Calibration curve established with 117, 58.5 and 11.7ppm methoprene R^2= 0.999888. (Appears to be single analysis at each concentration) No validation data.
Conclusion	Results supplied do not indicate the reactivity of active substance to container material.
Reliability	4
Acceptability	Not acceptable
Remarks	No further data required. Data point is satisfied by another study.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Reactivity towards container material 3.17 -2**
Date	08/07/07
Materials and methods	Samples of LX 125-10 a formulation containing 0.5% active substance were stored in clear, pliable polyethylene plastic bags (Ziploc® freezer type) for 3, 6 and 12 months at 20ºC. A.S. content was reported as follows: Time 0 - 0.683% Month 3 - 0.735% Month 6 - 0.640% Month 12 - 0.591% Details of GC/FID analysis were given, no validation data was presented. The product was a brownish orange granular heterogeneous mixture, exhibited small amount of clumping, had a smell similar to hamster feed at time 0, month 6 and 12, respectively. More clumping was observed at baseline at month 3. No change in container material was observed over the storage period
Conclusion	Results indicate that polyethylene plastic bags were unchanged after 12 months at 20ºC when a formulation containing 0.5% s-Methoprene was stored in them.
Reliability	1
Acceptability	Acceptable
Remarks	No further data required
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 3 Physical and Chemical Properties

References by section number

Section No./Reference No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
IIIA, 3.1.1	Laky, V.	2006a	Determination of the Boiling Point of S-Methoprene. LAB International Research Centre Hungary Ltd., Report no. 05/112-324AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.1.2/1	Laky, V.	2006a	Determination of the Boiling Point of S-Methoprene. LAB International Research Centre Hungary Ltd., Report no. 05/112-324AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.1.2/2	Anderson, W.	1999	Product Chemistry: Technical Grade Product. Stillmeadow, Inc., Report no. 4755-98, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.1.3	Anderson, W.	1999	Product Chemistry: Technical Grade Product. Stillmeadow, Inc., Report no. 4755-98, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.2/1	Anderson, W.	1999	Product Chemistry: Technical Grade Product. Stillmeadow, Inc., Report no. 4755-98, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.

Section No./Reference No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
IIIA, 3.2/2	Bates, M.	2007	S-methoprene: Evaluation of Vapour Pressure. Covance Laboratories Ltd, Report no. 2694/001-D2149, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.3	Anderson, W.	1999	Product Chemistry: Technical Grade Product. Stillmeadow, Inc., Report no. 4755-98, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.4/1	Anderson, W.	1999	Product Chemistry: Technical Grade Product Stillmeadow, Inc., Report no. 4755-98, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.4/2	-	2002a	Infrared Spectra of S-Methoprene IR Laboratory of the Institute for Organic Chemistry, Report no. not documented, non GLP (unpublished).	No	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.4/3	Woolley, S.M. and Mullee, D.M.	2006	S-methoprene: Nuclear Magnetic Resonance Spectra and Infrared Spectrum Safepharm Laboratories Limited, Report no. 2073/0004, GLP (unpublished)	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.4/4	-	1998	NMR Spectra of S-Methoprene NMR Laboratory of the Faculty of Chemical Engineering, Report no. not documented, non GLP (unpublished).	No	Bábolna Bioenvironmental Centre Ltd.

Section No./Reference No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
IIIA, 3.4/5	Woolley, S.M. and Mullee, D.M.	2006	S-methoprene: Nuclear Magnetic Resonance Spectra and Infrared Spectrum Safepharm Laboratories Limited, Report no. 2073/0004, GLP (unpublished)	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.4/6	-	2002b	MS Spectra of S-Methoprene MS Laboratory of the Department of Physical Chemistry, Report no. not documented, non GLP (unpublished).	No	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.4/7	Laky, V.	2006b	Determination of the Mass Spectrum of S-Methoprene. LAB International Research Centre Hungary Ltd., Report no. 06/227-362AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.5	Anderson, W.	1999	Product Chemistry: Technical Grade Product Stillmeadow, Inc., Report no. 4755-98, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.7	Laky, V.	2006c	Determination of the Solubility of S-Methoprene in Organic Solvents. LAB International Research Centre Hungary Ltd., Report no. 05/112-358AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.9	Rivendell International	2012	Calculating the n-octanol/water partition coefficient of S-Methoprene following OECD guidance No. 117, Ireland. Unpublished report no: RIV-IE-2012-11-29-01.	Yes	Bábolna Bioenvironmental Centre Ltd.

Section No./Reference No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
IIIA, 3.9	Anderson, W.	1999	Product Chemistry: Technical Grade Product Stillmeadow, Inc., Report no. 4755-98, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.10/1	Anderson, W.	1999	Product Chemistry: Technical Grade Product Stillmeadow, Inc., Report no. 4755-98, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.10/2	Szabó, E.,	2005	Storage Stability Tests of S-Methoprene Technical Bábolna Környezetbiológiai Központ Kft., Report no. Edition 1, Non-GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.11	Laky, V.	2006d	Determination of the Auto-ignition Temperature of S-Methoprene. LAB International Research Centre Hungary Ltd., Report no. 05/112-355AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.12	Laky, V.	2006e	Determination of the Flash Point of S-Methoprene. LAB International Research Centre Hungary Ltd., Report no. 05/112-352AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.

Section No./Reference No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
IIIA, 3.13	Laky, V.	2006f	Determination of the Surface Tension of S-Methoprene. LAB International Research Centre Hungary Ltd., Report no. 05/112-326AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.14	Laky, V.	2006g	Determination of the Viscosity of S-Methoprene. LAB International Research Centre Hungary Ltd., Report no. 05/112-359AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.17/1	Anderson, W.	1999	Product Chemistry: Technical Grade Product. Stillmeadow, Inc., Report no. 4755-98, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 3.17/2	Anderson, W.	2003	Storage Stability with Corrosion Characteristics (OPPTS Series 830 Sections 6317 and 6320). Stillmeadow, Inc., Report no. 4817-98, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.

References by author

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
-	IIIA, 3.4/2	2002a	Infrared Spectra of S-Methoprene IR Laboratory of the Institute for Organic Chemistry, Report no. not documented, non GLP (unpublished).	No	Bábolna Bioenvironmental Centre Ltd.
-	IIIA, 3.4/4	1998	NMR Spectra of S-Methoprene NMR Laboratory of the Faculty of Chemical Engineering, Report no. not documented, non GLP (unpublished).	No	Bábolna Bioenvironmental Centre Ltd.
-	IIIA, 3.4/6	2002b	MS Spectra of S-Methoprene MS Laboratory of the Department of Physical Chemistry, Report no. not documented, non GLP (unpublished).	No	Bábolna Bioenvironmental Centre Ltd.
Anderson, W.	IIIA, 3.1.2/2 IIIA, 3.1.3 IIIA, 3.2/1 IIIA, 3.3 IIIA, 3.4/1 IIIA, 3.5 IIIA, 3.9 IIIA, 3.10/1 IIIA, 3.17/1 IIIA, 3.17/2	1999	Product Chemistry: Technical Grade Product. Stillmeadow, Inc., Report no. 4755-98, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
Bates, M.	IIIA, 3.2/2	2007	S-methoprene: Evaluation of Vapour Pressure. Covance Laboratories Ltd, Report no. 2694/001-D2149, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
Laky, V.	IIIA, 3.1.1 IIIA, 3.1.2/1	2006a	Determination of the Boiling Point of S-Methoprene. LAB International Research Centre Hungary Ltd., Report no. 05/112-324AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Laky, V.	IIIA, 3.4/7	2006b	Determination of the Mass Spectrum of S-Methoprene. LAB International Research Centre Hungary Ltd., Report no. 06/227-362AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
Laky, V.	IIIA, 3.7	2006c	Determination of the Solubility of S-Methoprene in Organic Solvents. LAB International Research Centre Hungary Ltd., Report no. 05/112-358AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
Laky, V.	IIIA, 3.11	2006d	Determination of the Auto-ignition Temperature of S-Methoprene. LAB International Research Centre Hungary Ltd., Report no. 05/112-355AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
Laky, V.	IIIA, 3.12	2006e	Determination of the Flash Point of S-Methoprene. LAB International Research Centre Hungary Ltd., Report no. 05/112-352AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
Laky, V.	IIIA, 3.13	2006f	Determination of the Surface Tension of S-Methoprene. LAB International Research Centre Hungary Ltd., Report no. 05/112-326AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
Laky, V.	IIIA, 3.14	2006g	Determination of the Viscosity of S-Methoprene. LAB International Research Centre Hungary Ltd., Report no. 05/112-359AN, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Szabó, E.,	IIIA, 3.10/2	2005	Storage Stability Tests of S-Methoprene Technical Bábolna Környezetbiológiai Központ Kft., Report no. Edition 1, non-GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
Woolley, S.M. and Mullee, D.M.	IIIA, 3.4/3 IIIA, 3.4/5	2006	S-methoprene: Nuclear Magnetic Resonance Spectra and Infrared Spectrum Safepharm Laboratories Limited, Report no. 2073/0004, GLP (unpublished)	Yes	Bábolna Bioenvironmental Centre Ltd.