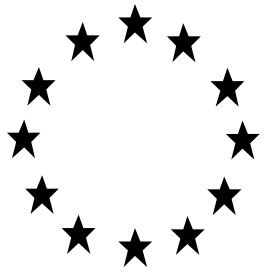
Competent Authority Report

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 (A4)

Evaluation Report

Rapporteur: Ireland

January 2013

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DOC III-A4

Please note:

- **The dossier on s-methoprene submitted under Directive 98/8/EC contained studies and information prepared originally for the dossier submitted under Directive 91/414/EEC. This was accepted by the RMS since the compilation of the dossier was made at an early stage, i.e. prior to the finalisation of the guidance document on how to utilize PPP dossiers for the preparation of BP dossiers.**

- **As a consequence, in many studies submitted by the applicant, the numbering system and format adopted under Directive 91/414/EEC and used for Plant Protection Products have been used. Several cross-references done by the applicant in the text of the studies, as well as in the text within justifications for non-submission of data, also refer to the dossier submitted under Directive 91/414/EEC (e.g., "PPP IIA 2.1.2/01"). A guide to the numbering system of 'BP vs. PPP' can be found in the last appendix of Doc I.**

- **In the reference list, however, the studies submitted are sorted also by reference number to facilitate the location of a study after its generic reference number (which is the same regardless of which directive it was submitted under).**

- **The CA's evaluations and in those cases where new study summaries have been submitted by the applicant, the numbering system of the TNsG on Preparation of Dossiers and Study Evaluation, adopted under Directive 98/8/EC, has been used.**

Section A4(4.1/1) Methods for Detection and Identification

Annex Point IIA, IV 4.1 Analytical methods for the determination of S-Methoprene in the active substance as manufactured

			Official use only
		1 REFERENCE	
1.1	**Reference**	Anderson, W. (1999), Chemical characterisation of a test substance to determine the amount of active ingredient, Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, Texas 77478-2521, USA, unpublished report no.: 4756-98. Date of experimental work: January 13, 1999 – April 27, 1999	X
1.2	**Data protection**	Yes	
Data owner		Bábolna Bioenvironmental Centre Ltd.	
Companies with letter of access		Not applicable	
Criteria for data protection		Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its entry into Annex I/IA.	
		2 GUIDELINES AND QUALITY ASSURANCE	
1.1	**Guideline study**	Not documented, test method is comparable to SANCO/3030/99 rev.4.	
1.2	**GLP**	Yes (self-certified)	
1.3	**Deviations**	Yes, this study deviates from SANCO 3030/99 rev 4 in the following respects: [redacted] These deviations are not considered to have affected the scientific validity of the study.	
		3 MATERIALS AND METHODS	
1.1	**Preliminary treatment**		
	Enrichment	Samples were placed on flasks with about 5 washes of methanol. The active substance was extracted by sonication.	

Section A4(4.1/1) Methods for Detection and Identification

Annex Point IIA, IV 4.1 Analytical methods for the determination of S-Methoprene in the active substance as manufactured

	Cleanup	Not applicable
1.2	**Detection**	
	Separation method	HPLC Column: Phenomenex C18 3µm Mobile phase: 100% Methanol Flow rate: 1 ml/min
	Detector	Ultraviolet (UV) at 254 nm
	Standard(s)	External standard
	Interfering substance(s)	Not documented
1.3	**Linearity**	
	Calibration range	[redacted]
	Number of measurements	[redacted]
	Linearity	[redacted]
1.4	**Specifity: interfering substances**	Not addressed
1.5	**Recovery rates at different levels**	Not required
	Relative standard deviation	Not required
1.6	**Limit of determination**	Not required
1.7	**Precision**	
	Repeatability	Not addressed
	Independent laboratory validation	Not required

4 Applicant's Summary and conclusion

Section A4(4.1/1)
Annex Point IIA, IV 4.1

Methods for Detection and Identification

Analytical methods for the determination of S-Methoprene in the active substance as manufactured

1.8 Materials and methods

The objective of the study was to validate a method for the determination of S-Methoprene in the active substance as manufactured.

S-Methoprene was extracted from the technical material by extraction with methanol and sonication. S-Methoprene content in the technical was determined by HPLC-UV at 254 nm. Quantification of the active substance was done by comparison with the peak area of reference analytical standard and sample.

The study deviates from SANCO 3030/99 rev 4 in the following respects:

[redacted]

These deviations are not considered to have affected the scientific validity of the study.

1.9 Conclusion

The method presented is not fully validated, however, it allows for the determination of S-Methoprene in manufactured batches.

Reliability 3

Deficiencies Some deviations were noted and are outlined under points 3.3, 3.4 and 3.7.1. However, they do not compromise the scientific validity of the study.

Section A4(4.1/1) Methods for Detection and Identification

Annex Point IIA, IV 4.1 Analytical methods for the determination of S-Methoprene in the active substance as manufactured

	EVALUATION BY COMPETENT AUTHORITIES
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X Analytical methods for the determination of S-Methoprene in the active substance as manufactured**
Date	01/08/07
Materials and methods	X - A summary of the method was presented. A three point calibration curve was used for quantitation. No details of the linearity data were given. No data was provided to demonstrate recovery, repeatability or specificity of the method.
Conclusion	The method as presented is not acceptable for determination of active substance s-methoprene in technical active substance
Reliability	3
Acceptability	Not acceptable
Remarks	Validated method for determination of active substance s-methoprene in technical active substance is not addressed by the method The data point has been addressed by the method of Mc Gowan, 2004. No further data required. It should be noted that the technical specification is being supported by 24 batches of technical material. The methods of analysis that were used during the analysis of the 24 batches of technical material have been evaluated in Section A4.1/7 of the CAR (Confidential Section). The validation data for these methods of analysis are acceptable and no further data is required.
	5 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 A4(4.1/2)
Annex Point IIA, IV 4.1

Analytical Methods for Detection and Identification
Analytical method for the determination of S-Methoprene in the active substance as manufactured

			Official use only
		REFERENCE	
1.1	**Reference**	McGowan, P. (2004), Five batch analysis of S-Methoprene, Chemex Environmental International Ltd, Bar Hill Business Park, 37 Saxon Way, Bar Hill, Cambridge CB3 8EL, UK, unpublished report no.: ENV 6947 Date of experimental: June 2004 – August 2004.	
1.2	**Data protection**	Yes	
	Data owner	Bábolna Bioenvironmental Centre Ltd	
	Companies with letter of access	Not applicable	
	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
		GUIDELINES AND QUALITY ASSURANCE	
1.3	**Guideline study**	No, test method is comparable to SANCO/3030/99 rev.4.	
1.4	**GLP**	Yes	
1.5	**Deviations**	Yes, with the following deviations: [redacted] These deviations are not considered to have affected the scientific validity of the study or the interpretation of the results.	X
		6 MATERIALS AND METHODS	
1.1	**Preliminary treatment**		
	Enrichment	Not applicable as samples were only diluted in n-hexane before analysis.	
	Cleanup	Not applicable as samples were only diluted in n-hexane before analysis.	

Section A4(4.1/2) Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.1

Analytical method for the determination of S-Methoprene in the active substance as manufactured

1.2 Detection

Separation method	HPLC Column: Phenomenex Chiracel, 5 μm, OD-H, 250 by 4.6 mm Mobile phase: Hexane with 0.5% butanol
Detector	UV at 240 nm
Standard(s)	External standard
Interfering substance(s)	None identified

1.3 Linearity

Calibration range	**Method linearity:** Linear response for S-Methoprene was obtained in the range 0.75 to 1.25 mg/ml. **Instrument calibration:** Linear calibration for S-Methoprene was obtained in the range 0.5 to 1.25 mg/ml.
Number of measurements	**Method linearity:** Duplicate determinations at three concentrations were carried out. **Instrument calibration:** Duplicate determinations at four concentrations were carried out.
Linearity	**Method linearity:** Excellent correlation coefficient for S –Methoprene was obtained (1.0). The equation of the calibration line was y = 13898.209x +275205.321 (where y is the peak area and x the concentration in μg/ml). **Instrument calibration:** Good correlation coefficient for S –Methoprene was obtained (0.9999). The equation of the calibration line was y = 13898x – 275205 (where y is the peak area and x the concentration in μg/ml).

Section A4(4.1/2)
Annex Point IIA, IV 4.1

Analytical Methods for Detection and Identification
Analytical method for the determination of S-Methoprene in the active substance as manufactured

1.4	**Specifity: interfering substances**	The method can be used to identify, and with suitable calibration standards, quantify the enantiomers R and S-Methoprene. The use of a 50:50 racemic reference standard ensures the correct peaks are readily identifiable in the UV chromatogram. Any compound with identical retention times to this of S-Methoprene will potentially interfere with the analysis. The sample chromatograms provided do not show any interference on the S-Methoprene peak. No confirmatory techniques were used.
1.5	**Recovery rates at different levels**	Method accuracy was not assessed for S-Methoprene since the product is greater than 95% pure. The determination of accuracy for the active substance in the technical material is not required.
	Relative standard deviation	Not required
1.6	**Limit of determination**	Not required.
1.7	**Precision**	
	Repeatability	Repeatability was determined as the relative standard deviation (%RSD) calculated from five determinations for each sample. %RSD was found to be 2.26%, 0.38%, 0.39%, 0.22% and 0.51%, respectively. Calculation of the modified Horwitz value was 1.34 and therefore, the %RSD met the criteria for four samples.
	Independent laboratory validation	Not required

Section A4(4.1/2)
Annex Point IIA, IV 4.1

Analytical Methods for Detection and Identification
Analytical method for the determination of S-Methoprene in the active substance as manufactured

7 APPLICANT'S SUMMARY AND CONCLUSION

1.1 Materials and methods

The objective of the study was to validate a method for the determination of S-Methoprene in the active substance as manufactured.

Samples were dissolved in hexane and stored at 4±2 °C. S-Methoprene content was determined in the samples by HPLC-UV at 240 nm. Quantification of the active substance was done by comparison with the peak area of reference analytical standard and sample.

The study was conducted according to a test method which is comparable to guideline SANCO/3030/99 rev. 4 as described under point 3 with the following deviations:

[redacted]

These deviations are not considered to have affected the scientific validity of the study or the interpretation of the results.

1.2 Conclusion

The method presented allows for the determination of S-Methoprene in manufactured batches. Although there are some deviations, the method is considered acceptable.

Reliability 2

Deficiencies *Some deviations were noted and are outlined under points 3.4 and 3.7.1. However, they do not compromise the scientific validity of the study.*

Section A4(4.1/2)
Annex Point IIA, IV 4.1

Analytical Methods for Detection and Identification
Analytical method for the determination of S-Methoprene in the active substance as manufactured

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Five batch analysis of s-methoprene**
Date	19/09/08
Materials and methods	S-methoprene and R-methoprene were analysed in the active substance using HPLC Chiral chromatography with UV detection. The molecules were quantified by comparison with an external standard of Methoprene.
Conclusion	The method is acceptable for analysis of S-methoprene and for R-methoprene. The LOQ achieved for R-methoprene was 0.21µg/ml
Reliability	2
Acceptability	Acceptable
Remarks	CIPAC /4427 Method is available for determination of methoprene in TC and EC. No further data required.
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 A4(4.2.a) Annex Point IIA, IV A4.2 (a)	Analytical Methods for Detection and Identification Soil	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only X
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [X]	**Other justification** [ ]	
Detailed justification:	It is proposed that this point is not relevant to S-Methoprene because: 1. The product is intended for indoor use as an ant bait consisting of granule, containing 0.5% w/w S-Methoprene presented in a sealed plastic container with tiny holes to allow ants to have access to the product. Furthermore, the product is not intended for applying directly to the soil and is not expected to migrate through the plastic barrier. Therefore, the product will not be in contact with soil. The possibility of the active substance entering soil as a result of the ants taking the bait back to their nest can be considered to be negligible.	
Undertaking of intended data submission [ ]	Not applicable	
	EVALUATION BY COMPETENT AUTHORITIES	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Analytical method for detection of residues in soil**	
Date	02/08/07	
Evaluation of applicant's justification	Accept that the product is for use indoors and that residues are unlikely to occur in soil with this usage	
Conclusion	Accept justification for non-submission.	
Remarks	No further data required	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A4(4.2.b) **Annex Point IIA, IV 4.2.(b)**	**Analytical Methods for the Detection and Identification** **Air**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only X
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	It is proposed that this study may not be relevant based on results from the vapour pressure study. This study is currently being undertaken and results are likely to be available in the next months. In the case where the vapour pressure is below 0.01Pa, an analytical method in air will not be required. S-Methoprene is not expected to be volatile. Furthermore, the biocidal product containing 0.5% w/w S-Methoprene is not sprayed but contained in sealed plastic bait station. However, if S-Methoprene is volatile enough to enter the air, an analytical method in air will be commissioned.	
Undertaking of intended data submission [ ]	Not applicable	
	EVALUATION BY COMPETENT AUTHORITIES	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Analytical method for detection of residues in air**	
Date	12/08/08	
Evaluation of applicant's justification	Results of Vapour pressure study indicate that the molecule is non volatile	
Conclusion		
Remarks	No further data required	
	COMMENTS FROM OTHER MEMBER STATE	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A4(4.2.c) Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 *4.2(c) Water*

			Official use only
		8 REFERENCE	
1.1	**Reference**	Geffke, T. (2007), S-Methoprene technical residue analytical method for determination in tap water, surface water and ground water, Dr. U. Noack-Laboratorien, Käthe-Paulus-Str. 1, D-31157 Sarstedt, unpublished report no: CRA119111 Date of experimental work: September 25, 2007 – October 17, 2007	
1.2	**Data protection**	Yes	
2.4.1	Data owner	Bábolna Bioenvironmental Centre Ltd.	
2.4.2	Companies with letter of access	Not applicable	
2.4.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
		9 GUIDELINES AND QUALITY ASSURANCE	
1.1	**Guideline study**	Yes, the study was conducted in accordance with SANCO/3029/99 rev.4 and SANCO/825/00 rev.7.	
1.2	**GLP**	Yes	
1.3	**Deviations**	No	
		10 MATERIALS AND METHODS	
1.1	**Preliminary treatment**		
2.4.1	Enrichment	Not applicable	

Section A4(4.2.c) Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 *4.2(c) Water*

2.4.2	Cleanup	Not applicable

1.2 Detection

2.4.1	Separation method	GC
2.4.2	Detector	MS
2.4.3	Standard(s)	External standard: S-methoprene 96.95% (trans-methoprene) and 0.98% (cis-methoprene); Batch no. 49306.
2.4.4	Interfering substance(s)	None identified

1.3 Linearity

Section A4(4.2.c) Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 *4.2(c) Water*

2.4.1	Calibration range	0.07 – 1.2 µg/L
2.4.2	Number of measurements	Single determination at 8 levels.
2.4.3	Linearity	Correlation coefficient (r) was determined as > 0.996. The equation of the line was y = 21227x + 169.82, where y is the peak area and x the concentration of analyte in µg/ml and providing that three fragment ions with an m/z ratio of >100 were used for identification.
1.4	**Specificity: interfering substances**	No significant response in the retention time and no significant matrix effects. No confirmatory techniques are necessary due to the high specificity of GC-MS.
1.5	**Recovery rates at different levels**	Recovery was determined at two fortification levels. Two controls were used as required by SANCO/825/00 rev. 7 guideline requirements. The results are summarised in Table A4.2c-1. The mean recovery at fortification level 0.1 µg/L was 75 ± 6.1% in surface water. The mean recovery at fortification level 1.0 µg/L was 96 ± 17.3% in surface water. The mean recovery at fortification level 0.1 µg/L was 95 ± 13.3% in tap water. The mean recovery at fortification level 1.0 µg/L was 105 ± 5.15% in tap water. The mean recovery at fortification level 0.1 µg/L was 82 ± 10.6% in ground water. The mean recovery at fortification level 1.0 µg/L was 99 ± 8.5% in ground water. All of these are within the SANCO/3029/99 rev.4 guideline requirements (70 – 110%, RSD ≤ 20%).
2.4.1	Relative standard deviation	Refer to Table IIA 4.2c-1.
1.6	**Limit of determination**	The LOQ was 0.100 µg/L. **The LOQ meet the requirements of Council Directive 80/778/EEC and SANCO/825/00 rev. 7, since the method can detect concentrations equal to 0.1 µg/l.** **The LOQ meets the requirements of SANCO/825/00 rev. 7, since it can detect concentrations lower than 0.38mg/l, which is the endpoint**

Section A4(4.2.c) **Analytical Methods for Detection and Identification**

Annex Point IIA, IV 4.2 *4.2(c) Water*

		for the most sensitive aquatic species.
		Two controls were used as required by SANCO/825/00 rev.7 guideline requirements.
1.7	**Precision**	
2.4.1	Repeatability	Repeatability was determined as the RSD calculated from five determinations at each fortification level.
		The mean RSD was 6.1 and 17.3% with overall RSD of 18.8% in surface water.
		The mean RSD was 13.3 and 5.15% with overall RSD of 10.6% in tap water.
		The mean RSD for 10.6 and 8.5% with overall RSD of 13.3% in ground water.
		All of these were within the specification (i.e. ≤ 20%).
2.4.2	Independent laboratory validation	Not required
		11 APPLICANT'S SUMMARY AND CONCLUSION
1.1	**Materials and methods**	An analytical method was validated for the determination S-Methoprene in three water types (surface water, ground water and drinking water).
		A GC-MS method using Headspace-SPME technique was used.
		This study was conducted according to SANCO/3029/99 rev.4 and SANCO/825/00 rev.7 with no deviations.
1.2	**Conclusion**	The method appears to be specific for the determination of S-Methoprene in water since no interferences were observed. The mean recovery and RSD were within the guideline requirements. The method is acceptable for the determination of S-Methoprene in water.
2.4.1	Reliability	1
2.4.2	Deficiencies	No

Section A4(4.2.c) Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 *4.2(c) Water*

Evaluation by Competent Authorities	
	12 EVALUATION BY RAPPORTEUR MEMBER STATE
Date	20/10/2010
Materials and methods	The residue definition for monitoring in water is parent only. The method employed GC with MSD detection over the range 100-350m/z. Quantification was performed using the ions 175 + 191 + 219m/z.
Conclusion	Acceptable method supplied for analysis of residues of parent s-Methoprene in surface (pond), ground (garden well) and drinking (tap) water to an LOQ of 0.1µgL.
Reliability	1
Acceptability	Acceptable
Remarks	No further data required
	13 COMMENTS FROM ...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A4.2c-1: Validation data for the analytical determination of S-Methoprene in water

Sample matrix	Test substance	Fortification level (μg/L)	n	Recovery		RSD (%)
				Range (%)	Mean (%)	
Surface water	S-Methoprene	0.1	5	70 – 82	75	6.1
Surface water	S-Methoprene	1.0	5	77 – 110	96	17.3
Tap water	S-Methoprene	0.1	5	74 – 107	95	13.3
Tap water	S-Methoprene	1.0	5	97 – 110	105	5.15
Ground water	S-Methoprene	0.1	5	74 – 96	82	10.6
Ground water	S-Methoprene	1.0	5	89 - 110	99	8.5

Section A4(4.2.d) Annex Point IIA, IV 4.2 (d)	Analytical Methods for Detection and Identification Animal and human body fluids and tissues	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only X
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X] **Other justification** [ ]	
Detailed justification:	S-Methoprene is not classified as being toxic or highly toxic. It is, therefore, proposed that analytical methods in animal and human body fluids and tissues are not required.	
Undertaking of intended data submission [ ]	Not relevant	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Analytical method for detection of residues in body fluids and tissue**
Date	02/08/07
Evaluation of applicant's justification	Accept justification
Conclusion	
Remarks	No further data required
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4(4.3) Annex Point IIA, IV 4.3	**Analytical Methods for Detection and Identification** in/on food or feedstuffs and other products where relevant	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only X
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [X]	**Other justification** [ ]	
Detailed justification:	It is proposed that this point is not relevant to S-Methoprene because: 2. The product is intended for indoor use as an ant bait consisting of granule, containing 0.5% w/w S-Methoprene presented in a sealed plastic container with tiny holes to allow ants access to the product. Furthermore, the product is not intended for spraying, aerosol use, etc. around food or feedstuffs. Therefore, the product will not be in contact with food or feedstuffs. 3. The exposure of food and feedingstuffs to the active substance as a result of the ants taking the bait back to their nest can be considered to be negligible.	
Undertaking of intended data submission [ ]	Not applicable	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE **X: Analytical method for detection of residues in foods and feedstuffs**
Date	02/08/07
Evaluation of applicant's justification	Accept that the use will not contribute to residues in food
Conclusion	Accept justification for non submission
Remarks	No further data required
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4(4.1/3) Analytical Methods for Detection and Identification

Reference list by section number Reference list 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, 4.1/1	Anderson, W.	1999	Chemical Characterisation of a Test Substance to Determine the Amount of Active Ingredient. Stillmeadow, Inc., Report no.: 4756-98, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 4.1/2	McGowan, P.	2004	Five Batch Analysis of S-Methoprene. Chemex Environmental International Ltd, Report no.: ENV 6947, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 4.1/3	Hegedűs, E.	2011	Analysis of S-(+) Methoprene. Bábolna Bio Ltd. Development & Regulatory Division, Head. H-1107- Budapest, Szallas u. 6. - Hungary - Unpublished report.	Yes	Bábolna Bioenvironmental Centre Ltd.
IIIA, 4.2	Geffke, T	2007	S-Methoprene technical residue analytical method for determination in tap water, surface water and ground water, Dr. U. Noack-Laboratorien, Käthe-Paulus-Str. 1, D-31157 Sarstedt, unpublished report no: CRA119111	Yes	Bábolna Bioenvironmental Centre Ltd.

Reference list 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
Anderson, W.	IIA, 1.4.1/1 (IIIA, 4.1/1)	1999	Chemical Characterisation of a Test Substance to Determine the Amount of Active Ingredient. Stillmeadow, Inc., Report no.: 4756-98, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
Hegedűs, E.	IIIA, 4.1/3	2011	Analysis of S-(+) Methoprene. Bábolna Bio Ltd. Development & Regulatory Division, Head. H-1107-Budapest, Szallas u. 6. - Hungary - Unpublished report.	Yes	Bábolna Bioenvironmental Centre Ltd.
McGowan, P.	IIA, 1.4.1/2 (IIIA, 4.1/2, 4.1/3, 4.1/4 and 4.1/5)	2004	Five Batch Analysis of S-Methoprene. Chemex Environmental International Ltd, Report no.: ENV 6947, GLP (unpublished).	Yes	Bábolna Bioenvironmental Centre Ltd.
Geffke, T	IIIA, 4.2	2007	S-Methoprene technical residue analytical method for determination in tap water, surface water and ground water, Dr. U. Noack-Laboratorien, Käthe-Paulus-Str. 1, D-31157 Sarstedt, unpublished report no: CRA119111	Yes	Bábolna Bioenvironmental Centre Ltd.