COMPETENT AUTHORITY REPORT

METHYL NONYL KETONE (PT 19)

Document IIIA

Active Substance

Rapporteur Member State: Spain

March 2009

Index

Section A1 Applicant

Annex Point IIA1

1.1	**Applicant**	Name: Address:	[redacted] Guaber UK Limited Chartmoor Road Leighton Buzzard LU7 4WG UK
		Telephone: Fax number: E-mail address:	[redacted]
		Contact Point	
		Name: Address:	[redacted]
		Telephone: Fax number: E-mail address:	[redacted]
1.2	**Manufacturer of Active Substance**	Name: Address:	[redacted]
		Telephone: Fax number: E-mail address:	[redacted]
1.3	**Manufacturer of Product(s)**	Name: Address:	[redacted] Guaber UK Limited Chartmoor Road Leighton Buzzard LU7 4WG UK
		Telephone: Fax number: E-mail address:	[redacted]

Section A2 Identity of Active Substance

Annex Point IIA, II 2

Subsection (Annex Point)			Official use only
2.1	**Common name (IIA2.1)**	Methyl Nonyl Ketone	
2.2	**Chemical name (IIA2.2)**	2-undecanone	
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	[redacted]	
2.4	**CAS No and EC numbers (IIA2.4)**		
2.4.1	**CAS-No**	112-12-9	
	Isomer 1	Not applicable	
	Isomer n	Not applicable	
2.4.2	**EC-No**	203-937-5	
	Isomer 1	Not applicable	
	Isomer n	Not applicable	
2.4.3	**Other**	Not applicable	
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**		
2.5.1	**Molecular formula**	$C_{11}H_{22}O$	
2.5.2	**Structural formula**	CH_3-CO-$(CH_2)_8$-CH_3	
2.5.3	**Molecular mass**	170.29 g/mol	
2.6	**Method of manufacture of the active substance (IIA2.1)**	See Document III, Appendix 2 Business Confidential Information.	
2.7	**Specification of the purity of the active substance, as appropriate (IIA2.7)**	g/kg: > 975; g/l: ; % w/w: > 97.5; % v/v:	
2.8	**Identity of impurities and additives, as appropriate (IIA2.8)**	See Document III, Appendix 2 Business Confidential Information.	
2.8.1	**Isomeric composition**	Not applicable	
2.9	**The origin of the natural active substance or the**	Not applicable as Methyl Nonyl Ketone is not a natural active substance.	

Section A2 Identity of Active Substance

Annex Point IIA, II 2

precursor(s) of the active substance (IIA2.9)

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	March 2007
Materials and methods	The applicant's version is adopted
Conclusion	The applicant's version is adopted
Reliability	Reliability indicator 0: not applicable since no studies were performed for these subsections
Acceptability	acceptable
Remarks	No further remarks

Section A2.10 Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Annex Point IIA2.10

Subsection			Official use only
2.10.1	**Human exposure towards active substance**		
2.10.1.1	**Production**		
	i) Description of process	[redacted] manufactures MNK by reacting [redacted] fatty acids in the presence of a catalyst at a high temperature. The crude product is refined using a standard distillation process.	
	ii) Workplace description	MNK is manufactured in a closed system. There is no exposure to workers. However, workers must wear a helmet, safety glasses work clothing and safety shoes on the manufacturing site.	
	iii) Inhalation exposure	Not available	
	iv) Dermal exposure	Not available	
2.10.1.2	**Intended use(s)**		
	1. Professional Users		
	i) Description of application process	No assessment for professional users is presented, as the biocidal product containing Methyl Nonyl Ketone is not intended for professional use.	
	ii) Workplace description	No assessment for professional users is presented, as the biocidal product containing Methyl Nonyl Ketone is not intended for professional use.	
	iii) Inhalation exposure	No assessment for professional users is presented, as the biocidal product containing Methyl Nonyl Ketone is not intended for professional use.	
	iv) Dermal exposure	No assessment for professional users is presented, as the biocidal product containing Methyl Nonyl Ketone is not intended for professional use.	
Users	**2. Non-professional including the general public**		

Section A2.10 Annex Point IIA2.10	Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC	
	(i) via inhalational contact	Spraying leads to inhalation exposure and to dermal exposure. An exposure model (Consumer product spraying and dusting – model 2, TNsG Part 2, p. 199) has been applied to perform the quantitative exposure assessment in humans by inhalation. Considering the worst-case scenario, the level of exposure for this product is of lower concern. In order to complete the risk assessment for the consumers, the primary and secondary exposures for non-professionals has been calculated using the model ConsExpo 4.1 (RIVM, Netherlands, 2005). The primary and secondary exposures taking into account the worst-case scenarios were determined to be very low and they could be considered to be of lower concern. The secondary exposure for children and infants is considered of low concern when the children comes into contact with wet sprayed surface, during inhalation of volatilized residues indoor or when they play on a surface that has been treated with the animal repellent. However, the risk assessment for children and infants carried out using ConsExpo 4.1 is not considered an appropriate model as it does not take into consideration the high volatility of MNK.
	(ii) via skin contact	Spraying leads to inhalation exposure and to dermal exposure. An exposure model (Consumer product spraying and dusting – model 2, TNsG Part 2, p. 199) has been applied to perform the quantitative exposure assessment in humans by dermal contact. Considering the worst-case scenario, the level of exposure for this product is of lower concern. In order to complete the risk assessment for the consumers, the primary and secondary exposures for non-professionals has been calculated using the model ConsExpo 4.1 (RIVM, Netherlands, 2005). The primary and secondary exposures taking into account the worst-case scenarios were determined to be very low and they could be considered to be of lower concern. The secondary exposure for children and infants is considered of low concern when the children comes into contact with wet sprayed surface, during inhalation of volatilized residues indoor or when they play on a surface that has been treated with the animal repellent. However, the risk assessment for children and infants carried out using ConsExpo 4.1 is not considered an appropriate model as it does not take into consideration the high volatility of MNK.
	(iii) via drinking water	As the recommended uses have no potential for water contact and since Methyl Nonyl Ketone will not persist in the environment due to its high volatility, indirect exposure via drinking water is considered negligible.
	(iv) via food	As the recommended uses have no potential for food contact and since Methyl Nonyl Ketone will not persist in the environment due to its high volatility, indirect exposure via food is considered negligible.
	(v) indirect via environment	As the recommended uses have no potential for food, feeding stuff or drinking water contact, and since Methyl Nonyl Ketone will not persist in the environment due to its high volatility, indirect exposure via environment is considered negligible.
2.10.2 Environmental		

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

exposure towards active substance	
2.10.2.1 Production	
(i) Releases into water	It is proposed that this data point is not relevant as Methyl Nonyl Ketone is produced in closed systems with appropriate control measurements in place to exclude release of the active substance to the environment. Furthermore, According to the Technical Notes for Guidance, Assessment of human exposure to biocides, (Report to DG XI from the biocides steering group, 1998), industrial processes including the manufacturing of the active substance and the biocidal product are regulated under various other Directives. It is therefore considered acceptable that the exposure during the production/formulation of MNK is not considered here.
(ii) Releases into air	It is proposed that this data point is not relevant as Methyl Nonyl Ketone is produced in closed systems with appropriate control measurements in place to exclude release of the active substance to the environment. Furthermore, According to the Technical Notes for Guidance, Assessment of human exposure to biocides, (Report to DG XI from the biocides steering group, 1998), industrial processes including the manufacturing of the active substance and the biocidal product are regulated under various other Directives. It is therefore considered acceptable that the exposure during the production/formulation of MNK is not considered here.
(iii) Waste disposal	It is proposed that this data point is not relevant as Methyl Nonyl Ketone is produced in closed systems with appropriate control measurements in place to exclude release of the active substance to the environment. Furthermore, According to the Technical Notes for Guidance, Assessment of human exposure to biocides, (Report to DG XI from the biocides steering group, 1998), industrial processes including the manufacturing of the active substance and the biocidal product are regulated under various other Directives. It is therefore considered acceptable that the exposure during the production/ formulation of MNK is not considered here.
2.10.2.2 Intended use(s)	PT 19 (repellant) Vapet® Get Off™ Spray is intended for use indoors, which is effective against cats and dogs.
Affected compartment(s):	A Level I Mackay Fugacity Model was used to assess the distribution of Methyl Nonyl Ketone in the various environmental compartments:
[redacted]	
water	0.000001%
sediment	0.0000003%
air	99.9%
soil	0.00002%
Predicted concentration in the affected compartment(s)	Predicted environmental concentration levels are provided in Document IIB
water	5.62×10^{-6}

Section A2.10 Annex Point IIA2.10	Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC
sediment	2.03×10^{-4}
air	2.07×10^{-7}
soil	3.52×10^{-4}

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	November 2007
Materials and methods	The applicant's version is acceptable
Conclusion	The applicant's version is adopted.
Reliability	
Acceptability	Acceptable
Remarks	No further 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 Melting point, boiling point, relative density (IIA3.1)								
3.1.1 Melting point								
Freezing Point 1	EC Method A1	99.5%	**Result:** 12.2° C		Y	1	Drake, R. M., 2004	
3.1.2 Boiling point	EC Method A2	99.5%	**Result:** 235.5°C		Y	1	Drake, R. M., 2004	
3.1.3 Relative density	EC Method A3	99.5%	**Result:** $D^{20}_{4} = 0.826$ **Temperature:** 20°C		Y	1	Drake, R. M., 2004	**X1**
3.2 Vapour pressure (IIA3.2)	EC Method A4 (Static Method)	99.5% Batch No: 20070274	**Result:** 11.8 Pa **Temperature**: 20° C		Y	1	Parsons, A.H., 2007	
3.2.1 Henry´s Law Constant (Pt. I-A3.2)								
Henry's law constant 1	Not documented	Not documented	**Measured/calculated:** Not indicated **Result:** 6.36×10^{-5} atm m^3/ mol **Temperature:** 25°C		N	0 Literature Reference	ChemIDplus Advanced, 2005	**X2**
Henry's law constant 2	Calculated using solubility and vapour pressure values	99.5% Batch No: 20070274	**Results:** 1395.4 Pa m^3/mol **Temperature:** 20°C		Y	1	Parsons, A.H., 2007	**X3**
3.3 Appearance (IIA3.3)								

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
3.3.1 Physical state	Visual inspection	99.5% Batch No: 20070274	**Result:** Mobile Liquid		Y	1	Parsons, A.H., 2007	
3.3.2 Colour	Visual inspection	99.5% Batch No: 20070274	**Result:** Clear (Colourless)		Y	1	Parsons, A.H., 2007	
3.3.3 Odour	Olfactory inspection	99.5% Batch No: 20070274	**Result:** Strong characteristic smell		Y	1	Parsons, A.H., 2007	
3.4 Absorption spectra (IIA3.4)								
UV/VIS	OECD 101	97.5% pure MNK, batch number: 0550604421017	**Result:** Acidic (pH 1.8) λ_{max}= 275 nm Molar absorption coefficient: 22.4 dm^3/mol/cm		Y	1	White, D.F. and Mullee, D.M., 2007	
UV/VIS	OECD 101	97.5% pure MNK, batch number: 0550604421017	**Result:** Neutral (pH 6.6) λ_{max}= 275 nm Molar absorption coefficient: 20.4 dm^3/mol/cm		Y	1	White, D.F. and Mullee, D.M., 2007	
UV/VIS	OECD 101	97.5% pure MNK, batch number: 0550604421017	**Result:** Alkaline (pH 12.2) λ_{max}= 275 nm Molar absorption coefficient: 20.7 dm^3/mol/cm		Y	1	White, D.F. and Mullee, D.M., 2007	

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	The IR spectra was determined using a Mattson Genesis Series, Fourier Transform Infra Red Spectrophotometer	99.5% Batch No: 20070274	**Result**: Peak absorbencies were CH3-1357.64-1400cm^{-1},-(^{1}C=O, CH3CH methyl), 1717.83cm^{-1} CH2-c=O, at 1717.83cm^{-1} C-O Strech and 595.90cm^{-1}C-H rock	The major absorbencies where seen	Y	1	Parsons, A.H., 2007	
NMR	The NMR spectra were determined using a Brücker DPX 300 NMR spectrometer	97.5% batch number: 0550604421017	The proton (^{1}H) and carbon (^{13}C) nuclear magnetic resonance spectra were consistent with the proposed chemical structure		Y	1	White, D.F. and Mullee, D.M., 2007	
MS	The Mass Spectrum was prepared using a Varian 3800GC equipped with a Saturn 4D, MSD.	99.5% Batch No: 20070274	**Results:** m/z 171,170,155,71,58 &43 Molecular peak at m/z:171, which confirms the identity of the test substance.		Y	1	Parsons, A.H., 2007	
3.5 Solubility in water (IIA3.5)	EC Method A6 (Flask method)	99.5% Batch No: 20070274	**Result:** 1.44 mg/L Temperature: 20° C PH: 7		Y	1	Parsons, A.H., 2007	**X4**
3.6 Dissociation constant	Not applicable as MNK does not dissociate in water							
3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1)	CIPAC Method MT181	99.5% Sample ID: 20070274	**Result:**>250 g/L soluble in n-Heptane, p-Xylene, 1,2-Dichloroethane, Methanol, Acetone and Ethyl Acetate at 20°C.		Y	1	Parsons, A.H., 2007	

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 the active substance as manufactured does not include an organic solvent							
3.9 Partition coefficient n-octanol/water (IIA3.6)	EC Method A8 (Shake Flask Method)	99.5% Sample ID: 20070274	**Results:** 4.342 **Temperature:** 21.5°C **pH**: Not documented		Y	1	Parsons, A.H., 2007	
3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)								
Storage Stability 1	OECD 113	99.8% pure Methyl Nonyl Ketone Batch No: 3352X	**Result:** No significant exothermic events over the temperature range 30 to 400°C when tested by DSC.		Y	1	Parsons, A.H., 2007	**X5**
3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)	EC Method A15	99.5% Sample ID: 20070274	**Result:** 207°C		Y	1	Parsons, A.H., 2007	
3.12 Flash-point (IIA3.9)	EC Method A9	99.5% Sample ID: 20070274	**Result:** 97°C		Y	1	Parsons, A.H., 2007	

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	EC Method A5	99.5% Sample ID: 20070274	Neat Methyl Nonyl Ketone **Result:** 29.5mN/m **Temperature:** 20°C **Result**: 26.8mN/m **Temperature:** 40°C	MNK is not a surface active material.	Y	1	Parsons, A.H. 2007	**X6**
Surface tension 2	EC Method A5	99.5% Sample ID: 20070274	90% Saturated Solution in HPLC Grade Water **Result:** 62.3mN/m **Temperature:** 20°C **Result**: 26.8mN/m **Temperature:** 40°C	MNK is not a surface active material.	Y	1	Parsons, A.H. 2007	
3.14 Viscosity (-)	OECD 114	99.5% pure Methyl Nonyl Ketone Sample ID: 20070274	**Results:** 2.3 mPa.s **Temperature**: 20°C **Result**: 1.8 mpa.s **Temperature:** 40°C	Methyl Nonyl Ketone can be said to be almost Newtonian in its behaviour.	Y	1	Parsons, A.H. 2007	
3.15 Explosive properties (IIA3.11)	The molecular structure of MNK indicates that the substance has no explosive properties							
3.16 Oxidizing properties (IIA3.12)	The molecular structure of MNK indicates that there is no potential for this material as an oxidising or reducing agent							
3.17 Reactivity towards container material (IIA3.13)	Information not available	Purity: Not documented; batch number: Not specified	**Result:** Stable at room temperature. Slight discolouration was observed over an extended period of time		N	0 Literature Reference	US EPA, 1995	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	March 2008
Comment	
Evaluation of data submitted under section A3	**3.1.1. Freezing point** Materials and Method: The applicant's version is adopted. Results: The results are acceptable Reliability: 1 Acceptability: The method and result are acceptable **3.1.2. Boiling point** Materials and Method: The applicant's version is adopted. Results: The results are acceptable Reliability: 1 Acceptability: The method and result are acceptable **3.1.3. Relative density** Materials and Method: The applicant's version is adopted. (X1): The pycnometer method was applied for the determination of this parameter. Results: The results are acceptable Reliability: 1 Acceptability: The method and result are acceptable **3.2. Vapour pressure** Materials and Method: The applicant's version is adopted. Results: The results are acceptable Reliability: 1 Acceptability: The method and result are acceptable **3.2.1. Henry's Law Constant** *Henry's Law Constant 1* (X2): The information was obtained from the literature, but no information on the purity of the test substance and or the method were provided, therefore a new test report was requested to the applicant that presented a new calculated value for this parameter. *Henry's Law Constant 2* (X3): This is the new value calculated using the water solubility and the vapour pressure experimentally determined at 20 ºC with the same test substance. Materials and Method: The applicant's version is adopted. Results: The results are acceptable Reliability: 1 Acceptability: The method and result are acceptable **3.3. Appearance** Materials and Method: The applicant's version is adopted. Results: The results are acceptable Reliability: 1 Acceptability: The method and result are acceptable **3.4. Absorption spectra, and mass spectrum** **3.4.1. UV/VIS** Materials and Method: The applicant's version is adopted. Results: The results are acceptable Reliability: 1 Acceptability: The method and result are acceptable

3.4.2. IR

Materials and Method: The applicant's version is adopted.
Results: The results are acceptable
Reliability: 1
Acceptability: The method and result are acceptable

3.4.3. NMR

Materials and Method: The applicant's version is adopted.
Results: The results are acceptable
Reliability: 1
Acceptability: The method and result are acceptable

3.4.4. MS

Materials and Method: The applicant's version is adopted.
Results: The results are acceptable
Reliability: 1
Acceptability: The method and result are acceptable

3.5. Water solubility

Materials and Method: (X4): The applicant should have used the column elution method instead of the flask method due to low solubility of the substance in water. Nevertheless, the applicant's version is adopted.
Results: The results are acceptable
Reliability: 1
Acceptability: The method and result are acceptable

3.7. Solubility in organic solvents

Materials and Method: The applicant's version is adopted.
Results: The results are acceptable
Reliability: 1
Acceptability: The method and result are acceptable

3.9 Partition coefficient

Materials and Method: The applicant's version is adopted.
Results: The results are acceptable
Reliability: 1
Acceptability: The method and result are acceptable

3.10 Thermal stability

Materials and Method: (X5): The applicant's version is adopted although the amount of test substance is lower than the range indicated in OECD Guideline 113.
Results: The results are acceptable
Reliability: 1
Acceptability: The method and result are acceptable

3.11. Flammability

Materials and Method: The applicant's version is adopted.
Results: The results are acceptable
Reliability: 1
Acceptability: The method and result are acceptable

3.12. Flash point

Materials and Method: The applicant's version is adopted.
Results: The results are acceptable
Reliability: 1
Acceptability: The method and result are acceptable

3.13 Surface tension

Materials and Method: The applicant's version is adopted. The ring method was used to determine this parameter.
Results: (X6): The results are acceptable; however the remark included by the applicant indicating that the substance is not surface active is not correct. Substances with surface tensions lower than 60 mN/m should be regarded as being surface-active materials.
Reliability: 1
Acceptability: The method and result are acceptable

3.14 Viscosity

Materials and Method: The applicant's version is adopted.
Results: The results are acceptable
Reliability: 1
Acceptability: The method and result are acceptable

3.17. Reactivity towards the container

Materials and Method: The applicant presented the EPA's Reregistration Eligibility Decision. In this document it is stated that after one year of storage at room temperature no significant changes regarding purity, colour, specific gravity, and refractive index was observed. Moreover the substance is considered non-corrosive after 12 months of storage at room temperature.
Results: The results may be considered acceptable
Reliability: 2
Acceptability: The method and result may be acceptable

Section A3 Annex Point 3.6	Dissociation constant (-)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	Not applicable as MNK does not dissociate in water.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2007	
Evaluation of applicant's justification	Justification is considered acceptable	
Conclusion		
Remarks		

Section A3 Annex Point 3.8	Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	Not required as the active substance as manufactured does not include an organic solvent.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2007	
Evaluation of applicant's justification	Justification is considered acceptable	
Conclusion		
Remarks		

Section A3 Annex Point 3.15	Explosive properties (IIA3.11)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	The molecular structure of MNK indicates that the substance has no explosive properties.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2007	
Evaluation of applicant's justification	Justification is considered acceptable	
Conclusion		
Remarks		

Section A3 Annex Point 3.16	Oxidizing properties (IIA3.12)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	The molecular structure of MNK indicates that there is no potential for this material as an oxidising or reducing agent.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2007	
Evaluation of applicant's justification	Justification is considered acceptable	
Conclusion		
Remarks		

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

Annex Point IIA, IV 4.1 Analytical method for the determination of MNK in the active substance

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted]	
		Dates of experimental work: May 1 – 15, 2008	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Spotless UK Ltd.	
1.2.2	Companies with letter of access	Not applicable	
1.2.3	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.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, the study was conducted according to SANCO 3030/99 rev. 4, PSD Guidelines for the Validation of Analytical Methods for Pesticides (PRD 2400), and Commission Directive 96/46/EC.	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	[redacted]	
3.1.2	Cleanup	Not applicable	

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

Annex Point IIA, IV 4.1 Analytical method for the determination of MNK in the active substance

3.2 Detection

3.2.1	Separation method	[redacted]
3.2.2	Detector	FID (flame ionisation detector)
3.2.3	Standard(s)	Internal standard, Methyl nonyl ketone (MNK) analytical standard 99.5% purity
3.2.4	Interfering substance(s)	None identified

3.3 Linearity

3.3.1	Calibration range	MNK: 0.0343g – 0.1222 g
3.3.2	Number of measurements	Duplicate determinations at 6 levels.
3.3.3	Linearity	Correlation coefficient (r) was determined as 0.9998 and coefficient of determination (R^2) was determined to be 0.9997. The equation of the calibration curve for MNK was y = 8.635 x – 0.0033, where y is the peak area and x the weight of the analyte in grams.

3.4 Specifity: interfering substances

The specificity was confirmed by observation of the retention time of the technical material prepared without the addition of internal standard.

Confirmation was determined by GC/MS on a sample of the technical MNK. Identity confirmation was made by retention time match and ion identity.

3.5 Recovery rates at different levels

The determination of accuracy is not required for the active substance in the technical material, however injections of a single standard solution were made and the mean percent recovery for Methyl Nonyl Ketone was 100.3%, with a range of 99.6 % - 100.8%.

3.5.1	Relative standard deviation	Not required for the active substance in technical material.

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

Annex Point IIA, IV 4.1 Analytical method for the determination of MNK in the active substance

3.6	**Limit of determination**	Not required for the active substance in technical material.
3.7	**Precision**	
3.7.1	Repeatability	Repeatability was determined as the RSD calculated from six replicate samples of MNK technical ranging ± 25% of the nominal weight specified in the method and ranging ± 50% for impurities. This value was found to be lower than the levels recommended by the Horwitz equation (1.34%) and was therefore acceptable.
3.7.2	Independent laboratory validation	Not required

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	The objective of the study was to validate a method for the determination of MNK in the active substance manufactured. Samples were dissolved and diluted in internal standard and filled to volume with dichloromethane prior to analysis by GC-FID. No deviations according to SANCO/3030/99 rev. 4 were found.
4.2	**Conclusion**	The method presented allows for the determination of MNK and in technical substance since no interferences were observed. The RSD was within the guideline requirements. The method is acceptable for the determination of MNK.
4.2.1	Reliability	1
4.2.2	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*September 2008*
Materials and methods	*The applicant's version is adopted*
Conclusion	*The applicant's version is adopted*
Reliability	*1*
Acceptability	*Acceptable*
Remarks	*No further 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
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [X]	**Other justification [ ]**	
Detailed justification:	**It is proposed that this point is not relevant for MethylNonyl Ketone because:** 1. It is a volatile substance (vapour pressure 50.8 Pa at 25ºC) and will not persist in soil (half-life 0.5 days). 2. Soil exposure to Methyl Nonyl Ketone is not expected due to the use pattern of Methyl Nonyl Ketone products. The product is for amateur use and is applied as an animal repellent in indoor use until the dog or cat is discouraged from visiting the area. Therefore, the use pattern of the product is not intended for applying directly to the soil. 3. The possibility of the active substance to enter soil as result of the animals taking the product can be considered to be negligible. In addition, there are no toxicologically, ecotoxicologically or environmentally significant metabolites of Methyl Nonyl Ketone.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2007	
Evaluation of applicant's justification	The applicant's justification is considered acceptable.	
Conclusion		
Remarks		

Section A4(4.2.b/1) Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2.b/1

Air

			Official use only
		1 REFERENCE	
1.1	**Reference**	Labows, J.N., Kenneth, J.M., Webster, G.F., Leyden, J.J., Headspace analysis of volatile metabolites of *Pseudomonas aeruginosa* and related species by gas chromatography - mass spectrometry, Journal of Clinical Microbiology, Vol. 12, No. 4, pp.521-526, October 1980. Dates of experimental work: Not documented	
1.2	**Data protection**	No	
1.2.1	Data owner	Not applicable (literature data)	
1.2.2	Companies with letter of access	Not applicable	
1.2.3	Criteria for data protection	No data protection claimed	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No	
2.2	**GLP**	No	
2.3	**Deviations**	Yes, the method deviates from the guidance SANCO/3029/99 rev. 4 and SANCO/825/00 rev.7 in the following respects: 1. No validation data was addressed. This deviation is considered to be major; however, it does not compromise the scientific validity of the study.	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	Samples were partitioned using a headspace technique. The headspace of the culture was swept with nitrogen and the collected volatiles were then back-flushed with heating onto the first 15 cm of the GC column, which was cooled with dry ice.	
3.1.2	Cleanup	Not applicable	

Section A4(4.2.b/1) Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2.b/1

Air

3.2	**Detection**	
3.2.1	Separation method	GC Column: Pyrex 20 Carbowax, 3 m x 2 mm on 80/100 Gas-Chrom Q Column temperature: 70ºC (4 min) and 70 to 220°C (4ºC per min) Ionizing voltage: 70 eV Detector temperature: 200ºC
3.2.2	Detector	MS
3.2.3	Standard(s)	External standard
3.2.4	Interfering substance(s)	None identified
3.3	**Linearity**	
3.3.1	Calibration range	Not addressed
3.3.2	Number of measurements	Not addressed
3.3.3	Linearity	Not addressed
3.4	**Specifity: interfering substances**	Any compound with identical retention times to this of MNK will potentially interfere with the analysis. The sample chromatograms provided do not show any interference on the MNK peak. No chromatograms were included in the report for control (untreated) samples. However, as GC-MS is highly specific, it provides unequivocal identification and any response at the MNK retention time should correspond to MNK. Confirmatory techniques are not required since the GC-MS method is highly specific and provides unequivocal identification and quantification.
3.5	**Recovery rates at different levels**	Not addressed
3.5.1	Relative standard deviation	Not addressed
3.6	**Limit of determination**	Not addressed
3.7	**Precision**	
3.7.1	Repeatability	Not addressed
3.7.2	Independent laboratory validation	Not required
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1	**Materials and methods**	Headspace analysis techniques involving GC have been developed to sample the volatile metabolites (including Methyl Nonyl Ketone) produced by bacterial cultures. The headspace of the culture was swept with nitrogen and the collected volatiles were then back-flushed

Section A4(4.2.b/1) Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2.b/1

Air

		with heating onto the first 15 cm of the GC column, which was cooled with dry ice. The volatiles were then separated and identified by combined GC-MS. Individual components were identified by comparison of their fatty acid ethyl ester retention indexes on a Carbowax column with those previously reported in the literature and by comparison of retention times and mass spectral data with authentic samples. The following deviations were found according to the guidances SANCO/3029/99 rev. 4 and SANCO/825/00 rev.7: 1. No validation data was addressed. This deviation is considered to be major; however, they do not compromise the scientific validity of the study.
4.2	**Conclusion**	The method presented allows for the determination of MNK in air samples. Although there are validation deviations, the method is scientifically valid.
4.2.1	Reliability	0 (Literature Data)
4.2.2	Deficiencies	Some deviations were noted and are outlined under point 3.3, 3.5, 3.6 and 3.7.1. However, they do not compromise the scientific validity of this study.

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	November 2007
Materials and methods	
Conclusion	The method may be considered acceptable although no validation was carried out. It could be useful as a screening method.
Reliability	3
Acceptability	Acceptable
Remarks	The applicant has presented a fully validated method in Section 4.2b/2

Section A4 (4.2.b/2) Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2.b/2

Air

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] Date of experimental work: July 2, 2007 – July 11, 2007	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Spotless UK	
1.2.2	Companies with letter of access	Not relevant	
1.2.3	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	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, the study was conducted according to SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 6.	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	[redacted]	
3.1.2	Cleanup	Not applicable	
3.2	**Detection**		
3.2.1	Separation method	GC: [redacted]	
3.2.2	Detector	MS	

Section A4 (4.2.b/2) Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2.b/2 **Air**

		MS acquisition range: m/z 40 to 80 Delay time: 3 min Background mass: m/z 39 Quantitative ion: m/z 58
3.2.3	Standard(s)	External standard MNK (purity: 99%)
3.2.4	Interfering substance(s)	None identified
3.3	**Linearity**	
3.3.1	Calibration range	0.1 – 2 µg/ml.
3.3.2	Number of measurements	Duplicate determinations at 5 levels.
3.3.3	Linearity	Correlation coefficient (r) was determined as equal to 0.9992. The equation of the line was determined to be y = 50257x – 594.61, where y is the peak area and x the concentration of analyte in μg/ml.
3.4	**Specifity: interfering substances**	There was no determinable signal found in the control samples at the retention time of MNK. There were no interferences at the retention time of the analyte above 30% of the LOQ. The technique was confirmed by identifying three characteristic ions at m/z = 71, 58 and 43. Due to the low molecular weight of the molecule, it was not possible to identify peak above mz>100. The mass spectrum was also compared to the Saturn library and the identity of MNK was confirmed.
3.5	**Recovery rates at different levels**	Recovery was determined at two fortification levels. Results are summarised in Table A4.2b/2-1. The mean recovery for MNK at fortification level 1 µg/tube (equivalent to 5.56 µg/m^3) was 100.4%. The mean recovery for MNK at fortification level 10 µg/tube (equivalent to 55.56 µg/m^3)was 94.4%. The overall recovery for MNK was 97.4%. The mean recovery values are within the SANCO/3029/99 rev.4 guideline requirements (70 – 110%, RSD ≤ 20%). Two control samples were analysed.
3.5.1	Relative standard deviation	Refer to Table A4.2b/2-1.
3.6	**Limit of determination**	The LOQ, defined as the lowest concentration at which a recovery of 70-110% with relative standard deviation of ≤20% is obtained, for MNK was 1 µg/tube (equivalent to 5.56 µg/m^3). An AOEL of 0.5 mg/kg bw/day was set based on a 90 day oral toxicity in rat study. Using this AOEL produced a concentration (C) of 0.15 mg/m^3. Therefore, LOQ value is within the required specification (equal or lower than C) according to SANCO/825/00 rev.7.
3.7	**Precision**	
3.7.1	Repeatability	Repeatability was determined as the RSD calculated from five determinations at each fortification level. Results are summarised in

Section A4 (4.2.b/2) Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2.b/2 **Air**

		Table A4.2b/2-1. The mean RSD for MNK was 2.02 and 5%, respectively with overall RSD of 4.78%. All of these results are within the specification (i.e. ≤ 20%).
3.7.2	Independent laboratory validation	Not required
		4 APPLICANT'S SUMMARY AND CONCLUSION
4.1	**Materials and methods**	The analytical method was validated for the determination of Methyl Nonyl Ketone. [redacted] Quantitation was performed using GC-MS. No deviations were found according to the guidance documents requirements SANCO/3029/99 rev. 4 and SANCO/825/00 rev 7.
4.2	**Conclusion**	The method appears to be specific for the determination of Methyl Nonyl Ketone in air since no interferences were observed. The mean recovery and RSD were within the guideline requirements. The method is acceptable for the determination of Methyl Nonyl Ketone in air.
4.2.1	Reliability	1
4.2.2	Deficiencies	None

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	March 2008
Materials and methods	The applicant's version is adopted
Conclusion	The method and results are acceptable
Reliability	1
Acceptability	Acceptable
Remarks	No further remarks

Table A4.2b/2-1: Validation data for the analytical determination of MNK in air

Fortification level (µg/tube)	n	Recovery		RSD (%)
		Range (%)	Mean (%)	
1.0 (equivalent to 5.56 µg/m^3)	5	97.9 – 102.7	100.4	2.02
10.0 (equivalent to 55.56 µg/m^3)	5	87.6 – 98.6	94.4	5.00
Overall	10	88 – 98	97.4	4.78

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

Annex Point IIA, IV 4.2.c/1

Water

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] Dates of experimental work: February 12, 2004 – February 14, 2003	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Pet and Garden Manufacturing Plc.Pet and Garden Manufacturing Plc is fully owned by Guaber UK Limited.	
1.2.2	Companies with letter of access	Not applicable	
1.2.3	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.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No	
2.2	**GLP**	Yes	
2.3	**Deviations**	Yes, the method deviates from the guidance SANCO/3029/99 rev. 4 and SANCO/825/00 rev.7 in the following respects: 2. No validation data was addressed. This deviation is considered to be major; however it does not compromise the scientific validity of the study.	
		3 MATERIALS AND METHODS	

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

Annex Point IIA, IV 4.2.c/1

Water

3.1	**Preliminary treatment**	
3.1.1	Enrichment	Methyl Nonyl Ketone (MNK) was partitioned using a headspace technique.
3.1.2	Cleanup	Not applicable
3.2	**Detection**	
3.2.1	Separation method	[redacted]
3.2.2	Detector	FID
3.2.3	Standard(s)	External standard
3.2.4	Interfering substance(s)	None identified
3.3	**Linearity**	
3.3.1	Calibration range	Not addressed
3.3.2	Number of measurements	Not addressed
3.3.3	Linearity	Not addressed
3.4	**Specifity: interfering substances**	This point was not addressed. Sample and control samples chromatograms were not provided. No confirmatory techniques were reported.
3.5	**Recovery rates at different levels**	Not addressed
3.5.1	Relative standard deviation	Not addressed
3.6	**Limit of determination**	Not addressed
3.7	**Precision**	
3.7.1	Repeatability	Not addressed
3.7.2	Independent laboratory validation	Not required

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	Determination of Methyl Nonyl Ketone in water samples was carried out using a headspace technique. [redacted]

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

Annex Point IIA, IV 4.2.c/1

Water

		[redacted] The following deviations were found according to the guidances SANCO/3029/99 rev. 4 and SANCO/825/00 rev.7: 2. No validation data was addressed. This deviation is considered to be major; however, they do not compromise the scientific validity of the study.
4.2	**Conclusion**	The method presented allows for the determination of MNK in water samples. Although there are validation deviations, the method is scientifically valid.
4.2.1	Reliability	2
4.2.2	Deficiencies	Some deviations were noted and are outlined under point 3.3, 3.4, 3.5, 3.6 and 3.7.1. However, they do not compromise the scientific validity of this study.

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	November 2007
Materials and methods	The method presented was included in a test report where the toxicity to *Daphnia magna* was assayed. A very short summary that included the chromatographic conditions was given
Conclusion	The method may be acceptable but no validation data was provided therefore the RMS requested a validated method for water.
Reliability	3
Acceptability	
Remarks	A validated method has been provided by the applicant in section A4.2c/2

Section A4(4.2.c/2) Analytical Methods for Detection and Identification
Annex Point IIA, IV 4.2 Water

Official use only

1 REFERENCE

4.3	**Reference**	[redacted] Date of experimental work: July 2, 2007 – July 4, 2007
	Data protection	Yes
4.4.1	Data owner	Spotless UK
4.4.2	Companies with letter of access	Not relevant
4.4.3	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

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes, the study was conducted in accordance with the SANCO/3029/99 rev. 4 and SANCO/825/00 rev 7.
	GLP	Yes
	Deviations	Yes, with the following deviations: 1. No chromatogram of matrix blank is presented. 2. Only drinking water was used as a matrix. However, these deviations do not compromise the scientific validity of the study.

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
4.6.1	Enrichment	[redacted]
4.6.2	Cleanup	Not applicable
	Detection	
4.7.1	Separation method	[redacted]

Section A4(4.2.c/2) Analytical Methods for Detection and Identification
Annex Point IIA, IV 4.2 **Water**

4.7.2	Detector	MS MS acquisition range: m/z 40 to 80 Delay time: 3 min Background mass: m/z 39 Quantitative ion: m/z 58	
4.7.3	Standard(s)	External standard MNK (purity: 99%)	
4.7.4	Interfering substance(s)	None identified	
	Linearity		
4.8.1	Calibration range	0.025 – 0.5 µg/ml	**X1**
4.8.2	Number of measurements	Duplicate determinations at 5 levels	
4.8.3	Linearity	Correlation coefficient (r) was determined as equal to 0.9997. The equation of the calibration curve was y = 50510x – 182.88, where y is the peak area and x the concentration of the analyte in µg/ml.	
4.9	**Specifity: interfering substances**	There was no determinable signal found in the control samples at the retention time of MNK. There were no interferences at the retention time of the analyte above 30% of the LOQ. The technique was confirmed by identifying three characteristic ions at m/z = 71, 58 and 43. Due to the low molecular weight of the molecule, it was not possible to identify peak above mz>100. The mass spectrum was also compared to the Saturn library and the identity of MNK was confirmed.	
4.10	**Recovery rates at different levels**	Recovery was determined at two fortification levels. Results are summarised in Table A4.2c/2-1. The mean recovery for MNK at fortification level 0.103 µg/l was 82.4% (with a range of 78.4 – 88.9%). The mean recovery for MNK at fortification level 1.03 µg/l was 100.2% (with a range of 97.9 – 102.9%). The overall recovery for MNK was 91.3%. The mean and overall mean values are within the SANCO/3029/99 rev.4 guideline requirements (70 – 110%). Two controls were used as required by SANCO/825/00 rev.7 guideline requirements.	**X2**
4.10.1	Relative standard deviation	Refer to Table A4.2c/2-1.	
4.11	**Limit of determination**	LOQ, defined as the lowest concentration at which a recovery of 70-110% with relative standard deviation of ≤20% is obtained, was 0.103 µg/l. The LOQ meets the requirements of Council Directive 80/778/EEC and SANCO/825/00 rev. 7 for drinking water, since the method can detect concentrations equal to 0.1 µg/l.	
4.12	**Precision**		
4.12.1	Repeatability	Repeatability was determined as the RSD calculated from five determinations at each fortification level. Results are summarised in Table A4.2c/2-1.	

Section A4(4.2.c/2) Analytical Methods for Detection and Identification
Annex Point IIA, IV 4.2 Water

		The mean RSD for MNK was 4.97 and 1.92%, respectively with overall RSD of 10.8%. All of these results are within the specification (i.e. ≤ 20%).
4.12.2	Independent laboratory validation	Not required

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	An analytical method was validated for the determination of MNK in water. [redacted] Analyses were conducted by GC-MS. This study was conducted in accordance with the guidelines SANCO/3029/99 rev. 4 and SANCO/825/00 rev 7 with the following deviations: 1. No chromatogram of matrix blank is presented. 2. Only drinking water was used as a matrix However, these deviations do not compromise the scientific validity of the study.
5.2	**Conclusion**	The method is specific for the determination of MNK in water. The mean recovery and RSD values were within the specified limits. The method is acceptable for the determination of MNK in water.
5.2.1	Reliability	1
5.2.2	Deficiencies	Two deviations were noted and are outlined under point 4.1. However, they do not compromise the scientific validity of the study.

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	November 2007
Materials and methods	(X1): The range of calibration solutions used is higher than the analyte concentrations used in the recovery assays. The applicant should have performed the calibration with lower analyte concentrations. (X2): The recovery results were corrected with the control samples.
Conclusion	The method and results are considered acceptable
Reliability	2
Acceptability	Acceptable
Remarks	No further remarks

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

Sample matrix	Fortification level (µg/l)	n	Recovery		RSD (%)
			Range (%)	Mean (%)	
Drinking water	0.103	5	78.4 – 88.9	82.4	4.97
Drinking water	1.03	5	97.9 – 102.9	100.2	1.92
Overall	-	10	78.4 – 102.9	91.3	10.8

Section A4(4.2.d) Annex Point IIA 4.2.d	Analytical Methods for the Detection and Identification Animal and human body fluids and tissues	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	This point is not relevant as Methyl Nonyl Ketone is not classified as toxic or very toxic to humans and there are no toxicologically, ecotoxicologically or environmentally significant metabolites of Methyl Nonyl Ketone.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2007	
Evaluation of applicant's justification	As the active substance is not classified as toxic or very toxic an analytical method for the determination of residues in animal and human fluids is not required	
Conclusion	The justification is considered acceptable	
Remarks	No further 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
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	This point is not relevant because the product is applied as an animal repellent in indoor use in no food/feed areas in homes. Therefore, the product will not be in contact with food or feedstuffs.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2007	
Evaluation of applicant's justification	As the active substance is not to be used in manner that may cause contact with food or feedstuffs. an analytical method for the determination of residues is not required	
Conclusion	The justification is considered acceptable	
Remarks	No further remarks	

Section A5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)			Official use only
5.1	**Function (IIA5.1)**	Repellent	
5.2	**Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**		
5.2.1	**Organism(s) to be controlled (IIA5.2)**	Cats and dogs.	**X1**
5.2.2	**Products, organisms or objects to be protected (IIA5.2)**	Indoor doorways, carpets and furnishings.	
5.3	**Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**		
5.3.1	**Effects on target organisms (IIA5.3)**	Methyl Nonyl Ketone is a volatile substance whose odour confuses the sense of smell of animals such as dogs and cats, hence discouraging them from visiting treated areas.	
5.3.2	**Likely concentrations at which the A.S. will be used (IIA5.3)**		
PT19		3.58 %	
5.4	**Mode of action (including time delay) (IIA5.4)**		
5.4.1	**Mode of action**	Methyl Nonyl Ketone is an aliphatic ketone repellent. Its mode of action involves volatilisation of the compound to release an odour confusing the sense of smell of animals such as dogs and cats, hence, discouraging them from visiting treated areas.	
5.4.2	**Time delay**	Animals are deterred from visiting treated areas and over a period of weeks will be trained to avoid these areas.	
5.5	**Field of use envisaged (IIA5.5)**		
MG03: Pest control		Repellent Methyl Nonyl Ketone confuses the sense of smell of dogs and cats, hence discouraging them from visiting treated areas.	
5.6	**User (IIA5.6)**		

Section A5 Effectiveness against target organisms and intended uses

General public		Product to be sprayed on doorways, carpets and furnishings.	
5.7	**Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)**		
5.7.1	**Development of resistance**	There is no available information on the development of resistance in animals to the repellent activity of Methyl Nonyl Ketone.	**X2**
5.7.2	**Management strategies**	There is no available information on the development of management strategies for the development of resistance in animals to the repellent activity of Methyl Nonyl Ketone.	
5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**	See Doc III, Appendix 2 – Business Confidential Folder	

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	December 2008
Materials and methods	Studies of efficacy with the substance were not presented. Nevertherless, efficacy data were conducted with the product in cats and dogs (see Doc IIIB).
Conclusion	**X1**: The claims of the substance against organisms were not supported by experimental data no in scientific literature. The efficacy in cats was not demonstrated with the study submitted. Basically, the applicant has shown that the metylnonylketone reduced the frequency of urination in dogs. **X2**: based on its mode of action, no development of resistance is expected.
Reliability	3
Acceptability	It has taken into account that there are not appropriate tes-guidelines for repellents. Experimental data on the effectiveness of active substance provide some evidence that methylnonylketone against dogs is acceptable.
Remarks	Further efficacy data will be required to support authorisation of the product at the Member State level.