Section A1 Applicant

Annex Point IIA1

1.1 Applicant

Name: Denka International B.V.

Address: P.O. Box 337, NL-3770 AH Barneveld

Telephone: [redacted]

Fax number: [redacted]

E-mail address: [redacted]

Contact person: [redacted]

1.2 Manufacturer of Active Substance (if different)

Name: Denka International B.V.

Address: Hanzeweg 1, NL-3771 NG Barneveld

Telephone: [redacted]

Fax number: [redacted]

E-mail address: [redacted]

Location of manufacturing plant: Hanzeweg 1, NL-3771 NG Barneveld

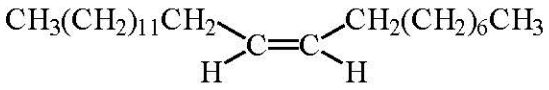
1.3 Manufacturer of Product(s) (if different)

1) Product 1

As above

2) Product n

Section A2 Identity of Active Substance

Subsection (Annex Point)			Official use only
2.1	**Common name (IIA2.1)**	Muscalure	
2.2	**Chemical name (IIA2.2)**	IUPAC: (Z)-tricos-9-ene, cis-tricos-9-ene CAS: (Z)-9-tricosene	
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	Was not assigned	
2.4	**CAS No and EC numbers (IIA2.4)**		
2.4.1	**CAS-No**	27519-02-4	
	Isomer 1	35857-62-6	
	Isomer n		
2.4.2	**EC-No**	248-505-7	
	Isomer 1	-	
	Isomer n		
2.4.3	**Other**	None assigned	
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**		
2.5.1	**Molecular formula**	$C_{23}H_{46}$	
2.5.2	**Structural formula**		
2.5.3	**Molecular mass**	322.6	
2.6	**Method of manufacture of the active substance (IIA2.1)**	*See confidential part*	
2.7	**Specification of the purity of the active substance, as appropriate (IIA2.7)**	g/kg: 84.62 (83.7 – 86.0); g/l: ; % w/w: ; % v/v:	
2.8	**Identity of impurities and additives, as appropriate (IIA2.8)**	see separate standard format	
2.8.1	**Isomeric**	*Give maximum content of active isomer and ratio*	

Section A2 Identity of Active Substance

	composition	*isomer/diastereomers if relevant*
2.9	**The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)**	The product discussed here does not originate from a natural source; it is a synthesis product. However, muscalure is secreted by houseflies (*Musca domestica*) to which it functions as an attractant/arrestant. Some other species (mainly insects but also plants) also produce muscalure. The function of muscalure to those species (if known at all) is not discussed in this dossier.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and methods	*State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of the method include appropriate reliability indicator*
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Remarks	
	COMMENTS FROM ...
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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 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

Subsection			Official use only
2.10.1	**Human exposure towards active substance**	*Guidance is given in the TNsG on Human Exposure as well as the Technical Guidance Document on Risk Assessment*	
2.10.1.1	**Production**		
	i) Description of process	Confidential information; see confidential part	
	ii) Workplace description	Confidential information; see confidential part	
	iii) Inhalation exposure	The work processes are conform the Dutch legislation (so-called 'ARBO wetgeving') for an acceptable exposure situation on the workfloor. For details see the confidential part.	
	iv) Dermal exposure	The work processes are conform the Dutch legislation (so-called 'ARBO wetgeving') for an acceptable exposure situation on the workfloor. For details see the confidential part.	
2.10.1.2	**Intended use(s)**		
	1. Professional Users		
	i) Description of application process	Muscalure granules put into traps	
	ii) Workplace description	For the use of the muscalure granules in electrocution traps and glue traps (used in stables, food processing industries and restaurants/snackbars), one standard trap is to be filled with 40 to 100 grams of granules. The application rate is 1.25 mg muscalure / m^2. After about 4 weeks the granules are removed and the trap can be filled again.	

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iii) Inhalation exposure

In the ENVIRON report of 2004, a worst-case estimate is presented for the concentration of muscalure in the air of stables based on the following assumptions:

The room in which the trap is used has a volume of 600 m^3 (height: 3 m; floor area of about 200 m^2).

The ventilation rate of the room is 300 m^3/hour (corresponding to 0.5 air changes per hour).

The muscalure in the trap evaporates completely within 28 days at a constant rate.

The release rate of muscalure into the room will then be: 250 mg / (28 x 24 hours) = 0.373 mg/hr. The clearance by (natural) ventilation of 300 m^3/hr will result in a steady state concentration of 0.373 mg/hr / (300 m^3/hr) = 0.00124 mg/m^3. It was concluded in the report that this value represents an overestimate as the evaporation would be much lower and that a value ten times lower (0.000124 mg/m^3.) could be supported.

To support this assumption on the evaporation and the lower concentration of muscalure in the air, Denka has performed measurements on the muscalure granules to determine the concentration of muscalure in air after several time periods (Denka report 2004). Based on these measurements, ENVIRON has calculated **an average concentration of muscalure in the air of 0.000142 mg/m^3** (ENVIRON report 2006). As this value corresponds with the application rate of 1.25 mg/m2 which is in all cases the same, this air concentration applies to all intended uses (i.e. in stables, in food processing industries, in residential settings).

Assuming an inhalation volume of 10 m^3 per person per day (for a professional worker / 8 hours working day) and a retention of 100%, this yields a systemic uptake of 0.00142 mg/day due to respiratory exposure.

iv) Dermal exposure

In the ENVIRON report of 2004, a worst-case estimate is presented for the possible dermal exposure from the use of the granules. The granules are poured directly from the can into the trap. Filling the traps does not require the granules to be scooped, neither does it lead to direct skin contact. The same holds for emptying the traps. Cleaning of the traps may result in some skin contact. However, any skin contact will be very local due to the physical shape of the product as no significant dusting will occur. It can safely be assumed, that any skin contact will be limited to the hands. Wearing gloves will fully eliminate skin contact with the product.

In case the granules are touched by hand, it is not expected that a significant dermal exposure to muscalure will occur. In the ENVIRON report of 2004 a calculation is presented resulting in a dermal exposure of 0.0002 mg/day, which is indeed very low.

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2. Non-professional Users including the general public	*Muscalure granules in small glue strips:* The granules containing 0.25% muscalure are poured onto the glue strips and the strips are hung up. Only the combination of the granules and the small glue strips is meant to be used by the general public. The non-professional user can put the granules on the glue strip and hang the strip in the area were they want to attract the flies with muscalure.
(i) via inhalational contact	As mentioned above, the calculated concentration of muscalure in the air of 0.000142 mg/m^3 (ENVIRON report 2006) applies to all intended uses (i.e. in stables, in food processing industries, in residential settings), thus also for the uses of the little glue strips this value can be used. In residential settings it might be possible that a person is present longer than 8 hours per day. In the TNG on human exposure 18 hours with an inhalation volume of 18 m^3 per person per day is considered. This yields a systemic uptake of 0.00256 mg/day due to respiratory exposure.
(ii) via skin contact	Dermal exposure can occur from pouring the granules onto the glue strip and from touching the strip by hand. From the above calculations it can be seen that dermal exposure from pouring the granules is very low (less than 0.0002 mg/day). Dermal exposure from touching the glue strip to which the muscalure granules are attached is not expected to be much higher. Moreover, there is no need to touch the strips by hand (sizes are prefixed and no cutting is required). As a worst-case it is assumed that the dermal exposure might be ten fold higher by touching and hanging of the strips, resulting in a dermal exposure less than 0.002 mg/day.
(iii) via drinking water (iv) via food	In addition to persons working with the granules or present in treated rooms, consumers of food products produced or stored in treated rooms may become exposed. No direct contact of food and feedstuffs with muscalure is expected due to the mode of use. Theoretically, muscalure can become absorbed from the air to the products in question. Muscalure acts by slowly vaporizing, resulting in a steady state air concentration of 0.14 µg/m^3 air. Transfer of muscalure from airborne material to food and feedstuffs resulting in relevant concentrations in said food and feedstuffs is considered highly unlikely given the Henry's law constant of . 2.95 x 10^3 Pa.m^3/mol (Kaw = 1.21), and the fact that most food and feedstuffs are predominantly water-based. A substance with a Henry's law constant of 2.95 x 10^3 Pa.m^3/mol that is present in the air at a steady state concentration of 0.14 µg/m^3 will result in an equilibrium concentration in water of 0.12 ng/L. Assuming a worst-case intake of 3 litre water per day (by drinking 2 litre and by food intake), this will result in a muscalure intake via the food of 0.36 ng/day = 0.00000036 mg/day.
(v) indirect via environment	Indirect exposure as a result of use of the active substance in biocidal product: Secondary exposure might be possible for people present in the area where muscalure granules are present. The respiratory route is the relevant exposure route. When the product is used as prescribed (hung up in the fly traps), the granules are out of reach for children and no dermal or oral contact from children with the granules will

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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

occur.

Secondary respiratory exposure resulting from professional uses:

Other people that might be present in treated areas (stables or restaurants) are also exposed to the muscalure concentration present in the air. However, normally they are not present for a full working day (8 hours), and the exposure will therefore be less than 0.00142 mg/day.

Secondary respiratory exposure resulting from residential uses:

In case the muscalure strip is hung up in the house, people might be present longer than 8 hours. However, the calculations above for non-professional use already include a longer period of presence in the room (up to 18 hours), by taking 18 m^3 as inhalation volume per day (TNG human exposure: Residence time = 18 hours/day, inhaling 18 m^3 air). Thus also for other people present for a long time in the muscalure treated area the exposure will be 0.00256 g/day maximally.

2.10.2 Environmental exposure towards active substance

[For some more detailed information see Dossier preparation relating to the exposure assessment of biocidal products and the relevant Emission scenario documents. In addition the Technical Guidance Document for the Risk Assessment should be consulted.]

2.10.2.1 Production

(i) Releases into water

All wastes from the synthesis including solvents and washing materials are collected in drums. These are collected by a certified organisation that specializes in processing wastes.

(ii) Releases into air

During the production process the air is most intensively exposed to muscalure during the transfer in open buckets

1) of raw technical muscalure from reaction vessel onto the purifying columns and

2) of purified technical muscalure from the purifying columns into the storage barrel.

(iii) Waste disposal

These are collected by a certified organisation that specializes in processing wastes.

2.10.2.2 Intended use(s)

One standard format to be used for each intended use

Affected compartment(s):

11.5 % is present in the air; the rest is waste.

water

sediment

air

soil

Muscalure is a pheromone insect attractant, falling under PT 19 as defined in the Biocidal Products Directive. Flylure, Denka's commercial product containing muscalure, is a sugar-based fly attractant intended for use in electrocution traps, glue traps and glue plate devices. None of these devices as such fall under the definition of biocidal products according to the Manual of Decisions. Therefore, the inclusion of Flylure in these devices to lure flies places these devices into PT19.

No environmental emission scenarios have been defined (yet) for

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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

	PT19. Therefore, an ad hoc emission estimation was performed (see Emission Doc). This emission estimation is based on the measured dissipation of muscalure from Flylure granules under ambient conditions. According to the Instructions for Use for Flylure products, the effective application rate is 250 mg muscalure per 200 m^2 floor area (roughly corresponding to 600 m^3 room volume. Flylure is to be renewed every 28 days. The dissipation half life of muscalure from Flylure granules is 159 days. Assuming a room ventilation rate constant of 0.5 h-1, an average indoor exposure concentration of 0.14 µg/m^3 is estimated. With these parameters it can also be shown that the emission to the outside air is 28.6 mg per 28 days for a 200 m^2 facility. This yields a worst case annual emission per hectare of 18.6 g, assuming emission takes place everywhere (i.e. all avalaible surface area is covered with emitting facilities).
Predicted concentration in the affected compartment(s)	*Give an estimation of the expected concentrations of a.s. in the affected compartments from one application of a.s. using the recommended application concentrations and techniques*
water	Not applicable according to the OECD monograph 12 and the EU Draft Guidance for Waiving of Data Requirements for Pheromones for Inclusion in Annex I/IA of Directive 98/8/EC, since the annual emission per hectare is significantly lower than the natural emission of SCLPs.
sediment	According to OECD monograph 12 and the EU Draft Guidance for Waiving of Data Requirements for Pheromones for Inclusion in Annex I/IA of Directive 98/8/EC, if outdoor exposure is comparable to natural levels, the assessment of the active substance's fate in the environment and ecotoxicity can be waived. The OECD monograph suggests that for SCLPs (straight-chained lepidopteran pheromones), the natural emission may be set at 375 g/ha/annum. Since muscalure, while not a lepidopteran pheromone but a dipteran pheromone, being Z-9-tricosene, is chemically very similar to SCLPs, and since it is used in a similar way (i.e. evaporative emission to air), it can be stated that this emission level is a relevant natural background threshold for muscalure too. Given the fact that a worst case exposure estimation results in an emission level for muscalure of 18.6 g/ha/annum, or <5% of the natural background trigger, no risk to aquatic or terrestrial wildlife is expected. Based on the ready biodegradability and photodegradation of muscalure, no persistence in the environment is expected. As such, all PEC estimations can be waived, according to the EU Draft Guidance for Waiving of Data Requirements for Pheromones for Inclusion in Annex I/IA of Directive 98/8/EC.
air	According to the TNG on data requirements, it is allowed to estimate phototransformation in air. EPIWIN was used to predict reactivity of muscalure to hydroxyl radicals and ozone (AopWin). Half lives were found of 1.6 h and 2.1 h, respectively. A level-III fugacity model resulted in a half life of 1.26 h. Concentrations in indoor air are estimated at 0.14 µg/m3. Resultant outdoor air concentrations will be several orders of magnitude lower, not taking into account the (photochemical degradation) half life of muscalure in air. As the product will be applied as attractant in a trap, no further experimental data on fate and behaviour in air are required.

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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

	Additionally, not applicable according to the OECD monograph 12 and the EU Draft Guidance for Waiving of Data Requirements for Pheromones for Inclusion in Annex I/IA of Directive 98/8/EC, since the annual emission per hectare is significantly lower than the natural emission of SCLPs.
soil	Not applicable according to the OECD monograph 12 and the EU Draft Guidance for Waiving of Data Requirements for Pheromones for Inclusion in Annex I/IA of Directive 98/8/EC, since the annual emission per hectare is significantly lower than the natural emission of SCLPs.

Evaluation by Competent Authorities	
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Reliability	*Based on the assessment of the method include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is acceptable despite a poor reliability indicator). Discuss the relevance of deficiencies.*
Remarks	
	COMMENTS FROM ...
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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*
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Remarks	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8 *fill in one form for each impurity/additive*

Subsection						Official use only
2.8.1.1	**Common name**	Included in confidential part of the dossier				
2.8.1.2	**Function**	E.g. impurity of starting material, by-product of synthesis, antifoaming agent, stabilizer				
2.8.2	**IUPAC name**					
2.8.3	**CAS-No**					
2.8.4	**EC-No**	*EINECS, ELINCS or No-longer-polymer-No.*				
2.8.5	**Other**					
	CIPAC					
2.8.6	**Molecular formula**	*use HILL or CAS system*				
2.8.7	**Structural formula**					
2.8.8	**Molecular mass**	*Give molecular mass in g/mol*				
2.8.9	**Concentration of the impurity or additive** *typical and range of concentrations*	g/kg	g/l	% w/w	% v/v	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8 *fill in one form for each impurity/additive*

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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 Melting point, boiling point, relative density (IIA3.1)								
3.1.1 Melting point								
Melting pt. 1	EEC A.1, OECD 102	96.0% Z-9-tricosene; 1.5% E-9-tricosene; 2.5% impurities (Muscalure)	Result: - 2 °C (271 K) Pressure: 1009 hPa		Y	1	Baltussen, E. (2006a) NOTOX Project 450438	
Melting pt. 2	EEC A.1, OECD 102	84.7% Z-9-tricosene; 10.5% E-9-tricosene; 4.8% impurities (Muscalure Technical)	Result: - 4 °C (269 K) Pressure: 1009 hPa		Y	1	Baltussen, E. (2006b) NOTOX Project 450585	
3.1.2 Boiling point								
Boiling pt. 1	EEC A.2, OECD 103	96.0% Z-9-tricosene; 1.5% E-9-tricosene; 2.5% impurities (Muscalure)	Result: 380 °C (653 K) Pressure: 1009 hPa		Y	1	Baltussen, E. (2006a) NOTOX Project 450438	
Boiling pt. 2	EEC A.2, OECD 103	84.7% Z-9-tricosene; 10.5% E-9-tricosene; 4.8% impurities (Muscalure Technical)	Result: 376 °C (649 K) Pressure: 1009 hPa		Y	1	Baltussen, E. (2006b) NOTOX Project 450585	

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
3.1.3 Bulk density/ relative density Bulk/rel. density 1	EEC A.3, OECD 109	98.2% Z-9-tricosene	0.803 x 10^3 kg/m^3		Y	1	Krips, H.J. (2006a) NOTOX Project 450449	
3.2 Vapour pressure (IIA3.2) Vapour pressure 1	EEC A.4	96.0% Z-9-tricosene; 1.5% E-9-tricosene; 2.5% impurities	Temperature: 20 °C Result: 6.4 x 10^{-2} Pa		Y	1	Krips, H.J. (2006b) NOTOX Project 450451	

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)	None (calculation)		Calculated result: > 2.91 x 10^{-2} atm. m^3/mol = > 2.95 x 10^3 Pa.m^3/mol		Y	1	Krips, H.J. (2006c) NOTOX Project 450462	
3.3 Appearance (IIA3.3)	US EPA Subdiv. D, §63-2,3,4	84.7% Z-9-tricosene; 10.5% E-9-tricosene; 4.8% impurities (Muscalure Technical)			Y	1	Krips, H.J. (2006d) NOTOX Project 450574	
		98.2% Z-9-tricosene (Muscalure)			Y	1	Krips, H.J. (2006e) NOTOX Project 450473	
3.3.1 Physical state			Clear liquid					

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			Muscalure Technical: colourless Muscalure: light yellow (Munsell 5Y 9/4)	The synthesis of muscalure comprises of three reaction steps which obviously don't proceed with 100% yields. The end product is usually slightly contaminated by small quantities of some by-products. Most of them are eliminated by the vacuum distillation yielding the 98% purity but a trace of one of them (lower than 0.1%) is responsible for a pale yellow colouration of the distilled product. Filtration through alumina eliminates this impurity and decolourises muscalure.				
3.3.3 Odour			No characteristic odour at 19.5 °C.					
3.4 Absorption spectra								

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
(IIA3.4)								
UV/VIS	OECD 101	98.2% Z-9-tricosene	UV spectrum in hexane: One absorbance maximum at 230 nm, molar absorption coefficient 15.0 $L.mol^{-1}.cm^{-1}$		Y	1	Krips, H.J. (2006f) NOTOX Project 450506	
IR	Working document 18th Meeting of Competent Authorities. Conception to Harmonize Requirements for Spectral Data	96.0% Z-9-tricosene; 1.5% E-9-tricosene; 2.5% impurities	C=C stretching: 3004 cm^{-1}; C-H stretching: 2920 and 2852 cm^{-1} C-H bending: 1466 cm^{-1} C-H bending: 1378 cm^{-1} CH_2 rocking: 720 cm^{-1}		Y	1	Brands, C. (2006a) NOTOX Project 450484	
NMR	Working document 18th Meeting of Competent Authorities. Conception to Harmonize Requirements for Spectral Data	98.2% Z-9-tricosene	^1H spectrum: Chemical shift: 5.4 ppm (triplet) 2.0 ppm (multiplet) 1.3 ppm (multiplet) 0.9 ppm (triplet)	The NMR spectrum is in line with the structure of the test substance	Y	1	Brands, C. (2006b) NOTOX Project 450495	
MS	In house method by GLC coupled with MS	96.0% Z-9-tricosene; 1.5% E-9-tricosene; 2.5% impurities	m/z ($C_{23}H_{46}^+$) 322	Fragmentation and m/z is in accordance with the structure and Wiley library	Y	1	Brekelmans, M.J.C. (2005a) NOTOX Project	

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
							450541	

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	EC method A.6; OECD 105 Column elution method Support materials: LiChroprep Si 100, 25-40 µm (Merck) Celite 545, 20-100 µm (Merck) Pre-treatment: samples of the effluents were collected in the extraction solvent (i.e. hexane containing internal standard) and thereby extracted. Analysis of the extracts by GC-FID	Content Z-9-Tricosene: 98.2 ± 0.72% (w/w) determined during NOTOX project 450427 Batch No. 20031118	Temperature: 20.0 ± 0.6°C Solubility pH 4 $< 7 \times 10^{-6}$ g/l pH 7 $< 7 \times 10^{-6}$ g/l pH 10 $< 7 \times 10^{-6}$ g/l	By collecting samples of the effluents in the extraction solvent, instantaneous extraction from the aqueous phase to the extraction solvent is achieved and loss due to adsorption to glass container walls is prevented. The effect of temperature was not studied. However, in view of the molecular structure and the extremely low solubility at 20° C only negligible effects of temperature on water solubility are expected. Therefore, abandonment of	Y	1	Brekelmans, M.J.C. (2006b) NOTOX Project 450517	

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
				investigating the effect of temperature is justified.				
3.6 Dissociation constant (-)	OECD 112	98.2% Z-9-tricosene	Since the water solubility of muscalure is < 7 µg/L, Perrin's calculation method was used. Result: Muscalure has no acid or basic groups and therefore no pK_a value.	Additional data requirement (see BPD, TNsG)	Y	1	Brekelmans, M.J.C. (2006c) NOTOX Project 450552	
3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1)		Muscalure technical (87.2%)	Solubility (% w/w) hexane: 70.5 toluene: 70.3 dichlormethane: 70.1 methylal: 50.2 methanol: 20.5 propyleneglycol: 20.4 acetone: 20.2 acetonitril: 20.0 DSMO dimethylsulfoxide : 20.0		N	2	Denka, 2005	
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)				Additional data requirement (see BPD, TNsG)				

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
3.9 Partition coefficient n-octanol/water (IIA3.6) log Pow 1	EEC A.8, OECD 107	98.2% Z-9-tricosene	Result: $P_{ow} > 1.51 \times 10^8$ (log $P_{ow} > 8.2$) Temperature: 20 °C pH: pH 4, 7 and 10	Because of the high solubility of muscalure in *n*-octanol experimental methods could not be used. The estimation method, based on the quotient of *n*-octanol and water solubility, was used.	Y	1	Brekelmans, M.J.C. (2006d) NOTOX Project 450528	
3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)			Thermically stable	Boils at 380°C without decomposition.			Verhaar, 2006 ENVIRON	
3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)	Pyrophoric properties: EEC A.13 Auto-ignition temperature: EEC A.15	84.7% Z-9-tricosene; 10.5% E-9-tricosene; 4.8% impurities (Muscalure Technical)	Pyrophoric properties: The molecular structures of Muscalure Technical do not contain any chemical groups that might lead to spontaneous ignition within a short time after coming into contact with air at 20 °C.		Y	1	Krips, H.J. (2006h,g) NOTOX Projects 450596 and 450607	

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
			Auto-ignition temperature: 250 °C					
3.12 Flash-point (IIA3.9) Flash-point 1	EEC A.9, ISO 2719	84.7% Z-9-tricosene; 10.5% E-9-tricosene; 4.8% impurities (Muscalure Technical)	161.5 °C		Y	1	Krips, H.J. (2006i) NOTOX Project 450618	
3.13 Surface tension (IIA3.10) Surface tension 1				Not required for poor soluble substances				
3.14 Viscosity (-)	OECD 114	84.7% Z-9-tricosene; 10.5% E-9-tricosene; 4.8% impurities (Muscalure Technical)	Result: 15 mPa.s Temperature: 20 °C Result: 10-11 mPa.s Temperature: 40 °C	Additional data requirement (see BPD, TNsG)	Y	1	Krips, H.J. (2006j) NOTOX Project 450664	
3.15 Explosive properties (IIA3.11)	EEC A.14	84.7% Z-9-tricosene; 10.5% E-9-tricosene; 4.8% impurities (Muscalure	The molecular structures of the test substances do not contain any chemical instable or highly energetic groups that	The impurities were not taken into account, but it is not expected that these substances	Y	1	Krips, H.J. (2006k) NOTOX Project	

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
		Technical)	might lead to explosions.	will make the test substance explosive.			450629	
3.16 Oxidizing properties (IIA3.12)	EC A.21	84.7% Z-9-tricosene; 10.5% E-9-tricosene; 4.8% impurities (Muscalure Technical)	Examination of the molecular structures of the test substances establish beyond reasonable doubt that the substances are incapable of showing a positive result in test EC A.21. The substances do not contain any group that might act as oxidizing agent.		Y	1	Krips, H.J. (2006l) NOTOX Project 450631	
3.17 Reactivity towards container material (IIA3.13)	ASTM G31-72	83.8% Z-9-tricosene; 10.8% E-9-tricosene; 5.4% impurities (Muscalure Technical)	No corrosive properties (7 days at 54 °C)	PE and PET bottles are used for packaging	Y	1	Krips, H.J. (2006m) NOTOX Project 450642	

Section A3 Annex Point 3.7	Solubility in organic solvents	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	A study is included and summarized in the summary table A3.	
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	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	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 A3 **Annex Point 3.8**	**Stability in organic solvents used in biocidal product**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	According to the 'Technical Guidance Document on data requirements' this is an additional data requirement. There are no organic solvents used in the biocidal product. The product exists mainly of sugar.	
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	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	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 A3 **Annex Point 3.13**	**Surface tension**	
	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 surface tension of cis-tricos-9-ene (muscalure) was not determined because the solubility in water is < 7 x 10^{-3} mg/l (20 °C). According to OECD Guideline 115 (Surface tension of aquatic solutions), § 2, substances with a water solubility lower than 1 mg/L need not to be tested.	
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	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	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 (4.1-4.3)

Annex Point IIA4.1

Analytical Methods for the Quantification of Z-9-tricosene in muscalure technical

Official use only

		1 REFERENCE
1.1	**Reference**	Brekelmans, M.J.C., 2006. Determination of the content of Z-9-tricosene in muscalure, NOTOX B.V. report # 450427, 7-2-2006.
1.2	**Data protection**	Yes
1.2.1	Data owner	Denka International
1.2.2		
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its [entry into Annex I/IA / authorisation]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Not applicable
2.2	**GLP**	Yes
2.3	**Deviations**	Not applicable
		3 MATERIALS AND METHODS
3.1	**Preliminary treatment**	
3.1.1	Enrichment	None
3.1.2	Cleanup	None
3.2	**Detection**	
3.2.1	Separation method	Gas chromatography, CP-Sil-5-B capillary column, Helium carrier gas, splitless injection into PTV injector, temperature programmed elution from 60°C to 300 °C
3.2.2	Detector	Flame ionization detector
3.2.3	Standard(s)	Internal standard: octadecane 99.7% Analytical standard: Z-9-tricosene 97%
3.2.4	Interfering substance(s)	Other tricosene isomers may interfere. Batch analysis has shown that no interfering substances elute at the retention time of Z-9-tricosene in muscalure.
3.3	**Linearity**	
3.3.1	Calibration range	0.0995 – 10.1 mg/L
3.3.2	Number of measurements	6 (in duplicate)
3.3.3	Linearity	R = 0.9995 (r2 = 0.9990)
3.4	**Specifity: interfering substances**	Blanks show no interference. Batch analysis indicates that no interfering substances are present in muscalure.
3.5	**Recovery rates at different levels**	Not relevant for this type of analytical method
3.5.1	Relative standard deviation	

Section A4 (4.1-4.3) **Analytical Methods for the Quantification of Z-9-tricosene in muscalure technical**

Annex Point IIA4.1

3.6	**Limit of determination**	0.0995 mg/L
3.7	**Precision**	
3.7.1	Repeatability	Relative standard deviation is 0.72%. Acceptability limit is 1.34% based on Horwitz equation (0.67 x 2^(1 – 0.5 log C), C = analyzed concentration)
3.7.2	Independent laboratory validation	Not required for analytical method for quantification of active substance in technical active substance
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1	**Materials and methods**	GC-FID method for the quantification of Z-9-tricosene in muscalure technical. Muscalure is dissolved in hexane to a concentration of ca 5.5 mg/L and analysed directly.
4.2	**Conclusion**	Method is valid for the quantification of Z-9-tricosene. Identification is positive and unambiguous since the batch analysis has shown that no interfering substances are present in muscalure technical. Repeatability is acceptable
4.2.1	Reliability	1
4.2.2	Deficiencies	No

Section A4 (4.1-4.3)
Annex Point IIA4.1

Analytical Methods for the Quantification of Z-9-tricosene in muscalure technical

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and methods	*State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of the method include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is acceptable despite a poor reliability indicator). Discuss the relevance of deficiencies.*
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	

Company Name	Name of A.S.	Month/Year

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1/4.2 & IIIA-IV.1

Specify where appropriate, e.g. isomer of a.s., metabolite of a.s., impurity of a.s., matrix

Official use only

1 REFERENCE

1.1	**Reference**	Ir. M.J.C. Brekelmans, 2006, Development and validation of an analytical method for the analysis of Z-9-Tricosene (active ingredient in Muscalure) in double distilled water, NOTOX B.V., NOTOX project 450539, 10-Feb-2006.
1.2	**Data protection**	Yes
1.2.1	Data owner	Denka International B.V.
1.2.2	Companies with letter of access	None
1.2.3	Criteria for data protection	Data on existing or new [a.s. / b.p.] to [maintain or vary a.s. Annex I/IA entry / vary conditions of a b.p.'s authorisation]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes European Commission: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (Part A, section 4) and Annex III (Part A, section 5) of Directive 91/414, SANCO/3029/99 rev. 4 (11/07/00).
2.2	**GLP**	Yes
2.3	**Deviations**	Yes Preparation of accuracy samples by spiking of double distilled water followed by addition of the extraction solvent (hexane containing internal standard) proved to give unreliable results. Recovery for samples prepared in this way at active ingredient (a.i.) concentrations of 0.02 and 0.8 mg/l was low (13 and 3% respectively) probably due to loss of the active ingredient on the glass wall of the containers used. Due to the very low water solubility of the test substance, this loss can only be avoided by transferring aqueous samples directly into the extraction solvent. Extraction from the aqueous phase to the extraction solvent will be instantaneously since solubility in water is very low and solubility in hexane is high (>1056 g/l). In this way, contact with the glass wall is avoided. The only way to check recovery of this approach is to prepare accuracy samples in the extraction solvent (total volume 1 ml) and to add double distilled water (10 ml) into the organic phase.

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
3.1.1	Enrichment	10 ml aqueous sample is added into 1 ml hexane containing internal standard. The mixture is vigorously shaken by hand for 30 seconds.

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1/4.2 & IIIA-IV.1 *Specify where appropriate, e.g. isomer of a.s., metabolite of a.s., impurity of a.s., matrix*

3.1.2	Cleanup	Not applicable	
3.2	**Detection**		
3.2.1	Separation method	Gas chromatography with flame ionisation detection (GC-FID)	
		Column	
		Stationary phase	CP-Sil 5-CB
		Dimensions	25 m x 250 µm, d_f = 0.12 µm
		Brand	Varian, Mulgrave, Victoria, Australia
		GC Oven Temperature program	
		Initial temperature	60°C
		Initial time	1 min
		Rate 1	20°C/min
		Temperature 1	100°C
		Rate 2	5°C/min
		Temperature 2	235°C
		Rate 3	40°C/min
		Final temperature	300°C
		Hold time	3 min
		Carrier gas	Helium
		Column flow (constant flow)	1.0 ml/min
		Injection	Programmed temperature vaporizer (PTV)
		PTV Mode	Splitless
		Splitless time	60 sec
		Injection volume	1 µl
		PTV Temperature program	
		Initial temperature	60°C
		Initial time	0.1 min
		Rate	720°C/min
		Final temperature	300°C
		Hold time	10 min
3.2.2	Detector	Flame Ionisation Detector (300°C; Hydrogen: 40 ml/min; Air: 450 ml/min) (Make-up Nitrogen: 50 ml/min)	
3.2.3	Standard(s)	Muscalure Analytical Standard, external standard	
		Octadecane, internal standard	
3.2.4	Interfering substance(s)	No interferences were found.	
3.3	**Linearity**		
3.3.1	Calibration range	0.0995 – 10.1 mg a.i./l in hexane containing internal standard	
3.3.2	Number of measurements	8	
3.3.3	Linearity	Correlation coefficient r^2 = 0.9996 (r = 0.9998)	

Company Name	Name of A.S.	Month/Year

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1/4.2 & IIIA-IV.1

Specify where appropriate, e.g. isomer of a.s., metabolite of a.s., impurity of a.s., matrix

3.4	**Specifity: interfering substances**	No interferences were found
3.5	**Recovery rates at different levels**	97% at 0.0199 mg/l (i.e. 0.0195 mg a.i./l) 98% at 0.794 mg/l (i.e. 0.780 mg a.i./l)
3.5.1	Relative standard deviation	1.1% at 0.0199 mg/l (i.e. 0.0195 mg a.i./l) 0.6% at 0.794 mg/l (i.e. 0.780 mg a.i./l)
3.6	**Limit of determination**	The Limit of Quantification (LOQ) defined as the lowest concentration level at which an accuracy in the range 70-110% and a repeatability of less than 20% is demonstrated is 0.0195 mg a.i./l double distilled water. The Limit of Detection defined as the concentration at which the response is 3 times the noise level, is 0.0018 mg a.i./l double distilled water.
3.7	**Precision**	
3.7.1	Repeatability	1.1% at 0.0199 mg/l (i.e. 0.0195 mg a.i./l) 0.6% at 0.794 mg/l (i.e. 0.780 mg a.i./l)
3.7.2	Independent laboratory validation	Not applicable

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	GC-FID analysis after extraction with hexane containing internal standard
4.2	**Conclusion**	The analytical method is applicable for analysis of samples in (double distilled) water in the concentration range of 0.0195 to 0.780 mg a.i./l if the samples are collected in the extraction solvent.
4.2.1	Reliability	1
4.2.2	Deficiencies	No

Company Name	Name of A.S.	Month/Year

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1/4.2 & IIIA-IV.1 *Specify where appropriate, e.g. isomer of a.s., metabolite of a.s., impurity of a.s., matrix*

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and methods	*State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of the method include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is acceptable despite a poor reliability indicator). Discuss the relevance of deficiencies.*
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 A4 **Annex Point IIA4.3**	**Analytical methods for residues in air**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification:	Muscalure, used as attractant in PT19, is used in fly traps. Muscalure acts by slowly vaporizing, resulting in a steady state air concentration of 0.14 µg/m^3 air, based on loss measurements. This worst case steady state air concentration does not give rise to any acute or long term risks. Therefore, air concentrations may safely be determined based on residual amounts of muscalure in flybait, and no direct air monitoring methods are needed.	
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	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	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 Annex Point IIA4.3	Analytical methods for residues in food or feedstuffs	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification:	According to the 'Technical Guidance Document on data requirements' this is an additional data requirement and under IIIA 4.3 the following is cited: "Analytical methods including recovery rates and the limits of determination for residues in/on food or feedstuffs and other products where relevant [Ann. IIIA, IV.1.] · Required if the active substance or the material treated with it is to be used in a manner which may cause contact with food or feedstuffs (e.g. when used for disinfection in food production or transportation, in the food processing industry or catering services), or intended to be placed on, in or near soils in agricultural or horticultural use. This may be the case for product types 1, 2, 3, 6, 8, 14 and 18. In addition, always required for product types 4, 5 and 20. · Required if the active substance for product type 12 is to be used for the treatment of paper pulp, paper, paperboard or any other product intended for contact with feedstuffs. Food packaging may be covered by Directive 89/109/EC which is under revision to include food-contact paper. It seems that feedstuffs are not covered by other directives. · Analytical methods for residues in fish and shellfish must be submitted for product type 21. · Reference can be made to analytical methods covered in paragraph A4.2 above where relevant." Muscalure, used as attractant in PT19, is used in fly traps in food processing and catering industry. However, muscalure acts by slowly vaporizing, resulting in a steady state air concentration of 0.14 $\mu g/m^3$ air. No direct contact of food and feedstuffs with muscalure is expected due to the mode of use. Transfer of muscalure from airborne material to food and feedstuffs resulting in relevant concentrations in said food and feedstuffs is considered highly unlikely given the Henry's law constant of . 2.95×10^3 $Pa.m^3/mol$, and the fact that most food and feedstuffs are predominantly water-based. A substance with a Henry's law constant of 2.95×10^3 $Pa.m^3/mol$ that is present in the air at a steady state concentration of 0.14 $\mu g/m^3$ will result in an equilibrium concentration in water of 0.12 ng/L.	
Undertaking of intended data submission [ ]	Not applicable	

Section A4 **Annex Point IIA4.3**	**Analytical methods for residues in food or feedstuffs**
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	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 **Annex Point IIA4.3**	**Analytical methods for residues in soil**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification:	Muscalure, used as attractant in PT19, is used in fly traps indoors. Muscalure acts by slowly vaporizing, resulting in a steady state indoor air concentration of 0.14 µg/m^3 air. Outdoor air concentrations will be much lower, due to simple dilution effects. A worst case assumption is that a steady state outdoor concentration of muscalure in an area with a high incidence of indoor muscalure use is 1/20 of the steady state indoor concentration (50% of available facilities using muscalure, dilution factor 10), or 7 ng/m^3. It is clear that at these worst case air concentrations, no relevant concentrations in soil are expected. Actual concentrations will be lower still.	
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	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	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 A5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)			Official use only
5.1	**Function (IIA5.1)**	PT 19: Attractant	Y
5.2	**Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**	Muscalure is not a killing agent. It is used to attract houseflies (*Musca domestica*) to a point where they can be controlled. The means of control may be 1) physical or 2) chemical. Ad 1) Physical means of control may be glue on a plate or band, or an electric grid for electrocution. For further detail it is referred to the dossier on the biocidal product. Ad 2) Chemical control is achieved by applying muscalure in a preparation with (a) feeding stimulant(s) (e.g. sugar) and an insecticide. For further detail it is referred to the dossier on the biocidal product. Stables in use normally attract and generate large numbers of houseflies that are a nuisance to both cattle and those who have to work in the stable. Stables are the primary target for protection by preparations that employ muscalure. Furthermore, areas where food is processed are objects to be protected.	Y, after correction by the referee
5.2.1	**Organism(s) to be controlled (IIA5.2)**	Houseflies *(Musca domestica)*	Y
5.2.2	**Products, organisms or objects to be protected (IIA5.2)**	Objects to be protected: primarily stables and areas where food is processed (restaurant kitchens, food industry, snackbars) *Organisms to be protected: cattle, pigs, poultry and humans.*	Y
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)**	Muscalure is produced by the female fly as part of the wax layer on the cuticle, together with a series of related compounds. In the laboratory, this mixture brings the sexes together (aggregation) and stimulates the male fly for mating. The influence of muscalure on male-housefly behaviour is such that, notwithstanding its low volatility and vapour pressure, it can be put to good use in housefly control	N
5.3.2	**Likely concentra-tions at which the A.S. will be used (IIA5.3)**		
	PT1	In all cases the application rate is 1.25 mg/m2	N
	PTn		
5.4	**Mode of action (including time delay) (IIA5.4)**	*If appropriate, refer to experimental studies given in the summary table in section 5.3.1 or any other studies.*	

Section A5 Effectiveness against target organisms and intended uses

5.4.1	**Mode of action**	Muscalure is produced by the female fly as part of the wax layer on the cuticle, together with a series of related compounds. In the laboratory, this mixture brings the sexes together (aggregation) and stimulates the male fly for mating	N
5.4.2	**Time delay**	Not applicable	Y
5.5	**Field of use envisaged (IIA5.5)**		
	MG03: Pest control	Product type 19	Y, see comment
	Further specification	PT 19: attractant	Y
5.6	**User (IIA5.6)**		
	Industrial	Use of granules in glue traps in food processing industry	Y
	Professional	Use of granules in electrocution traps in stables	Y
		Use of granules in glue traps in stables, restaurants etc	Y
		Use of granules in small glue strips in restaurants, snackbars etc	Y
	General public	In house use of small glue strips with muscalure granule	Y
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**	The development of resistance to muscalure is very unlikely considering that muscalure is produced by the target organism itself.	Y
5.7.2	**Management strategies**	Considering that the occurrence of resistance is very unlikely, a resistance management strategy is considered not necessary.	Y
5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**	500 – 1000 kg	Y

Section A5 Effectiveness against target organisms and intended uses

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Materials and methods	*Point 5.2.: Products, objects etc. to be controlled has been extended by the referee to those mentioned in point 5.2.2.* *Point 5.3.1/5.3.2.: Please provide data on threshold concentrations. This may affect the recommended time of use of the biocidal product. The statet dose of application seems arbitrary without justification. Threshold concentrations furthermore affect the time span, during which a lure is attractive.* *Point 5.4.1: The applicant should clearly state, whether the active substance acts as sex pheromone (emitted by one sex, attracting the other sex), as aggregation pheromone (emitted by one or either sex and attracting individuals from males and females) or both. If a function as aggregation pheromone could be ascertained and supported by data, this would evidently support the intention of the application.* *Point 5.5.: To avoid misunderstanding, the referee suggests to mention only PT19 instead of the range of product types. With MG03 it is sufficiently clear to which main group of products the active substance shall be registered.*
Conclusion	*The applicant's version should widely be adopted. However, the applicant should submit the requested information, thereby substantiating the whole application.*
Reliability	*n.a.*
Acceptability	acceptable under condition of the requested revisions
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	

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
Include respective code(s) for function type(s) given in section 5.1	*Include respective code(s) for product type(s) given in section 5.5*	*Describe specification if deviating from that given in section 2*	*Specify species, strain, sex, weight, growth stage etc. as appropriate*	*Shortly describe test system and application method used in the tests*	*Shortly describe test conditions including concentrations applied and exposure time*	*Describe relevant results; quantify the effects on target organisms; indicate the dependence on the concentrations of the A.S. and the possible existence of a threshold concentration. Also describe if results indicate the mode of action and/or the development of resistance.*	*Only author(s) and year of publication/ report; full bibliographic data in footnote*
MG 03: Pest Control	PT 19: attractant	Muscalure	*Musca domestica* (wild)	Improvement of catch of flies on glue strips or electrocution traps with and without muscalure.	Traps were hung in poultry stables under environmental conditions for 4 days. Glue strips contained 10 mg muscalure in absorbing pads with evaporation rates of 1-4 µg/hour. Electrocution traps contained 10-50 mg muscalure/trap.	Improvement of fly catch was a factor 2 in the presence of muscalure.	Oosten, A.M. van; Persoons, C.J. (1981)
MG 03: Pest Control	PT 19: attractant	Muscalure	*Musca domestica* (wild)	Improvement of catch of flies on electrocution traps with wig evaporators.	Traps were hung in poultry stables under environmental conditions for several days. Wig evaporators contained 100µL muscalure.	Improvement of fly catch was a factor 2 in the presence of muscalure.	Oosten, A.M. van; Persoons, C.J. (1983)
MG 03: Pest Control	PT 19: attractant	Muscalure	*Musca domestica* (wild)	Improvement of catch of flies on glue plates or electrocution traps.	Traps were hung in poultry stables under environmental conditions for 5 weeks. Glue plates contained 100 mg muscalure in vermiculite. Electrocution traps contained flasks with 100 µL muscalure.	Improvement of fly catch was a factor 1.5-2 in the presence of muscalure.	Oosten, A.M. van; Persoons, C.J. (1982)
MG 03: Pest	PT 19:	Muscalure	*Musca domestica*	Experiments were	Experiments were carried out	Depending on the situation in the	Oosten, A.M.