Company Name	Muscalure	March/2006

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

Official use only

1 REFERENCE

1.1	**Reference**	Hooftman, R.N. and Van Drongelen-Sevenhuijsen, D.; 1991. The acute toxicity of muscalure to the rainbow trout *Salmo gairdneri* in a semi-static system. TNO Division of Technology of Society; TNO report R 91/087 (unpublished).
1.2	**Data protection**	Yes
1.2.1	Data owner	Denka International BV
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**	Yes EPA Pesticide Assessment Guideline no. 72-1
2.2	**GLP**	Yes
2.3	**Deviations**	No

3 MATERIALS AND METHODS

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

3.1	**Test material**	As given in section 2 (muscalure).
3.1.1	Lot/Batch number	Batch no. II/51190
3.1.2	Specification	Colourless liquid
3.1.3	Purity	> 98%
3.1.4	Composition of Product	Not applicable
3.1.5	Further relevant properties	Vapour pressure: 0.000035 mm Hg (27 °C). Poorly soluble in water.
3.1.6	Method of analysis	Gas Liquid Chromatography with FI detection after extraction with hexane at pH 6.
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Muscalure was dissolved in 15 mL of t-butyl alcohol. The concentrated t-butyl alcohol solution was dosed into 30 L of dilution water. Small droplets were seen on the surface, indicating that the solution was saturated (see also table A7_4_1_1-1).
3.3	**Reference substance**	No
3.4	**Testing procedure**	
3.5	**Dilution water**	See table A7_4_1_1-2
3.5.1	Test organisms	See table A7_4_1_1-3
3.5.2	Test system	See table A7_4_1_1-4
3.5.3	Test conditions	See table A7_4_1_1-5
3.5.4	Duration of the test	96 h
3.5.5	Test parameter	Mortality
3.5.6	Sampling	Sampling after 0 hours (after dosing), 24 hours (before replacement), 48 hours (after replacement) and 72 hours (before replacement).
3.5.7	Monitoring of TS concentration	Yes (see 4.2.5).
3.5.8	Statistics	No statistics necessary (limit test).

4 RESULTS

If appropriate, include tables. Sample tables are given below

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

4.1	**Limit Test**	Performed
4.1.1	Concentration	100 mg a.s./L
4.1.2	Number/ percentage of animals showing adverse effects	No visual deviations from the solvent control and blank control.
4.1.3	Nature of adverse effects	None
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	100 mg a.s./L (nominal).
4.2.2	Actual concentrations of test substance	0 h: 7 mg a.s./L; 24 h: 160 mg a.s./L; 48 h: 160 mg a.s./L; 72 h: 140 mg a.s./L. Due to the poor solubility the concentration of muscalure could not accurately be established.
4.2.3	Effect data (Mortality)	No mortality
4.2.4	Concentration / response curve	Not applicable
4.2.5	Other effects	None
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	No visual deviations (solvent control and blank control).
4.3.2	Nature of adverse effects	None
4.4	**Test with reference substance**	Not performed

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	A static renewal study based on Guideline EPA no. 72-1 and acceptable according to the Guidance Document on Aquatic Organisms (Sanco/3268/2001) was performed in aquaria (47 x 29 x ca. 35 cm) containing 30 L of DSWL water (groundwater amended with minerals) as dilution water. Muscalure was added as a solution in t-butyl alcohol to a final nominal concentration of 100 mg a.s./L in three replicates. The test solutions were renewed on a daily base. A blank control and a solvent control were included in the experiment. Ten fishes were assigned to each test vessel.
5.2	**Results and discussion**	No mortality or abnormal behaviour was observed in the fish exposed to muscalure (100 mg/L nominally). Due to the poor solubility of the a.s. fish were exposed to a saturated solution of muscalure.

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

5.2.1	LC_0	96-h NOEC: 100 mg a.s./L (nominally).
5.2.2	LC_{50}	96-h LC_{50}: > 100 mg a.s./L (nominally).
5.2.3	LC_{100}	> 100 mg a.s./L (nominally).
5.3	**Conclusion**	The validity criteria of OECD 203 can be considered as fulfilled. The concentration of t-butyl alcohol vehicle was ca.. 400 mg/L, which is higher than 100 mg/L indicated in the guideline. However, no mortalities or any adverse effects were observed in the solvent blank. In this limit test the 96-h LC_{50} is > 100 mg a.s./L (nominally).
5.3.1	Other Conclusions	None
5.3.2	Reliability	1
5.3.3	Deficiencies	No

Company Name	Muscalure	March/2006

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

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.*
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)*
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*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*
Results and discussion	*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	

Table A7_4_1_1-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	Yes. Tert-butyl alcohol
Concentration of vehicle	0.05%(v/v) (ca. 400 mg/L)
Vehicle control performed	No
Other procedures	No

Table A7_4_1_1-2: Dilution water

Criteria	Details
Source	Dutch Standard Water Linschoten = Groundwater amended with Na^+, K^+, Ca^{++}, Mg^{++}, Cl^-, SO_4^{--} and HCO_3^-.
Alkalinity	Not measured
Hardness	212-217 mg $CaCO_3$/L
pH	8.0-8.2
Oxygen content	8.2 mg/L
Conductance	Not measured
Holding water different from dilution water	No

Table A7_4_1_1-3: Test organisms

Criteria	Details
Species/strain	*Salmo gairdneri = Oncorhynchus mykiss*
Source	Commercial trout hatchery
Wild caught	No
Age/size	Length 4.8-5.0 cm; weight 1.9-2.2 g
Kind of food	Trouvit
Amount of food	Not reported
Feeding frequency	Not reported
Pretreatment	17 d acclimation period
Feeding of animals during test	No

Table A7_4_1_1-4: Test system

Criteria	Details
Test type	Semi-static
Renewal of test solution	Daily renewal
Volume of test vessels	30 L
Volume/animal	3 L
Number of animals/vessel	10
Number of vessels/ concentration	3 (blanks 1)
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_1_1-5: Test conditions

Criteria	Details
Test temperature	12.5-13.7 °C
Dissolved oxygen	8.2-10.7 mg/L
pH	7.5-7.9
Adjustment of pH	No
Aeration of dilution water	Yes, slightly
Intensity of irradiation	Not reported
Photoperiod	16 h photoperiod daily, with 60 min transition period

Table A7_4_1_1-6: Mortality data

Test-Substance Concentration (nominal) [mg/l]	**Mortality**							
	Number				**Percentage**			
	24 h	**48 h**	**72 h**	**96 h**	**24 h**	**48 h**	**72 h**	**96 h**
0	0	0	0	0	0	0	0	0
0 (solvent control)	0	0	0	0	0	0	0	0
100	0	0	0	0	0	0	0	0
Temperature [°C]	12.6-13.7	12.6-13.3	12.6-13.4	12.5				
pH	7.6-7.8	7.7-7.9	7.5-7.8	7.7-7.8				
Oxygen [mg/l]	8.2-10.7	9.9-10.7	9.8-10.6	9.9-10.3				

Table A7_4_1_1-7: Effect data

	48 h [mg/l][1]	95 % c.l.	96 h [mg/l][1]	95 % c.l.
LC_0	NOEC :100 (n)	-	NOEC :100 (n)	-
LC_{50}	>100 (n)	-	>100 (n)	-
LC_{100}	>100 (n)	-	>100 (n)	-

[1] indicate if effect data are based on nominal (n) or measured (m) concentrations

Table A7_4_1_1-8: Validity criteria for acute fish test according to OECD Guideline 203

	fulfilled	Not fullfilled
Mortality of control animals <10%	x	
Concentration of dissolved oxygen in all test vessels > 60% saturation	x	
Concentration of test substance ≥80% of initial concentration during test	x	
Criteria for poorly soluble test substances		x but no mortalities or any adverse effects were observed in the solvent blank (see 5.3)

Company Name	Muscalure	March/2006

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

Official use only

1 REFERENCE

1.1	**Reference**	Hooftman, R.N. and Van Drongelen-Sevenhuijsen, D.; 1991. The acute toxicity of muscalure to *Daphnia magna.* TNO Division of Technology of Society; TNO report R 91/038 (unpublished).
1.2	**Data protection**	Yes
1.2.1	Data owner	Denka International BV
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**	Yes OECD Guideline 202
2.2	**GLP**	Yes
2.3	**Deviations**	No

3 MATERIALS AND METHODS

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

3.1	**Test material**	As given in section 2 (muscalure)
3.1.1	Lot/Batch number	Batch no. I/120990
3.1.2	Specification	Colourless liquid
3.1.3	Purity	> 98%
3.1.4	Composition of Product	Not applicable
3.1.5	Further relevant properties	Vapour pressure: 0.000035 mm Hg (27 °C). Poorly soluble in water.
3.1.6	Method of analysis	Gas Liquid Chromatography with FI detection after extraction with hexane at pH 6.
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Muscalure was dissolved in 0.3 or 3 mL of t-butyl alcohol. The concentrated t-butyl alcohol solution was dosed into 3 L of dilution water. This solution was vigorously stirred for about 20 h at 20 °C and then allowed to stand for 4 h after which the Water Accommodated Fraction was drawn off.
3.3	**Reference substance**	No
3.4	**Testing procedure**	
3.4.1	Dilution water	See table A7_4_1_2-2.
3.4.2	Test organisms	*Daphnia magna*, 15 days old (see table A7_4_1_2-3).
3.4.3	Test system	The test system was a static system in glass beakers containing 250 mL of test solution (see table A7_4_1_2-4).
3.4.4	Test conditions	See table A7_4_1_2-5.
3.4.5	Duration of the test	48 h
3.4.6	Test parameter	Immobility
3.4.7	Sampling	Sampling after 0 h from the freshly prepared test solution, and after 48 h from the spent solutions. Samples were taken from the mid part of the test beakers.
3.4.8	Monitoring of TS concentration	See 3.4.7
3.4.9	Statistics	No statistics were carried out since these were not necessary.

4 RESULTS

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

4.1	**Limit Test**	Not performed		
4.2	**Results test substance**			
4.2.1	Initial concentrations of test substance	10 and 100 mg a.s./L (nominal)		
4.2.2	Actual concentrations of test substance	Nominal	0 h	48 h
		10 mg/L	2.1 mg a.s./L	0.029 mg a.s./L
		100 mg/L	8.8 mg a.s./L	0.079 mg a.s./L
		Due to the poor solubility the concentration of muscalure could not accurately be established.		
4.2.3	Effect data (Immobilisation)	The immobilisation data as absolute numbers and as percentage of exposed animals are given in table A7_4_1_1-6.		
		The 48-h NOEC based on immobilisation is 10 mg a.s./L, the 48-h LC_{50} is > 10 mg a.s./L.		
		See table A7_4_1_1-7.		
4.2.4	Concentration / response curve	Not applicable		
4.2.5	Other effects	At the 100 mg/L concentrations the animals were physically hampered by a transparent fleece of the test compound.		
4.3	**Results of controls**	There was no immobilisation in the blank control and the solvent control.		
4.4	**Test with reference substance**	Not performed		

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	A static study based on OECD Guideline 202 and acceptable according to the Guidance Document on Aquatic Organisms (Sanco/3268/2001) was performed in beakers containing DSWL water (groundwater amended with minerals) as dilution water. Muscalure was added as a solution in t-butyl alcohol to final nominal concentrations of 10 and 100 mg a.s./L in three replicates. A blank control and a solvent control were included in the experiment. Five daphnids were assigned to each test vessel.
5.2	**Results and discussion**	No immobilisation of the daphnids occurred at 10 mg a.s./L. At the 100 mg/L test level at the end of the test the animals were physically hampered by a transparent fleece; some of them were immobile. This 100 mg/L test concentration was not accounted for in the determination of the EC_{50} value. Due to the poor solubility of the a.s. daphnids were exposed to a saturated solution of muscalure.
5.2.1	EC_0	48-h NOEC = 10 mg a.s./L
5.2.2	EC_{50}	48-h EC_{50} > 10 mg a.s./L

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

5.2.3	EC_{100}	-
5.3	**Conclusion**	Validity criteria can be considered as fulfilled. The concentration of t-butyl alcohol vehicle in the highest test concentration was ca. 800 mg/L, which is higher than 100 mg/L indicated in the guideline. However, no mortalities or any adverse effect were observed in the solvent blank. No toxic effects were found up to and including the highest concentration of 100 mg a.s./L. However, at this concentration the animals were physically hampered by a transparent fleece and some were immobilised.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Company Name	Muscalure	March/2006

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

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.*
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)*
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*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*
Results and discussion	*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	

Table A7_4_1_2-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	Yes. Tert-butyl alcohol
Concentration of vehicle	Ca. 80 mg/L in the 10 mg a.s./L test level; Ca. 800 mg/L in the 100 mg a.s./L test level
Vehicle control performed	No
Other procedures	No

Table A7_4_1_2-2: Dilution water

Criteria	Details
Source	Dutch Standard Water Linschoten = Groundwater amended with Na^+, K^+, Ca^{++}, Mg^{++}, Cl^-, SO_4^{--} and HCO_3^-
Alkalinity	Not measured
Hardness	212-217 mg $CaCO_3$/L
pH	8.0-8.2
Ca / Mg ratio	2 (mol/mol)
Na / K ratio	6 (mol/mol)
Oxygen content	8.2 mg/L
Conductance	Not measured
Holding water different from dilution water	No

Table A7_4_1_2-3: Test organisms

Criteria	Details
Strain	TNO strain
Source	Own laboratory, cultured since 1967
Age	< 24 h
Breeding method	Cultures are started every week
Kind of food	Chlorella, yeast
Amount of food	Algae: 1.3 x 10^9 cells/L; yeast 0.3 g/L
Feeding frequency	Daily
Pretreatment	Not reported
Feeding of animals during test	No

Table A7_4_1_2-4: Test system

Criteria	Details
Renewal of test solution	No
Volume of test vessels	250 ml
Volume/animal	50 mL
Number of animals/vessel	5
Number of vessels/ concentration	Controls: 4; 10 mg/L: 8; 100 mg/L: 4
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_1_2-5: Test conditions

Criteria	Details
Test temperature	21 ± 1 °C
Dissolved oxygen	8.5-9.3
pH	7.8-8.0
Adjustment of pH	No
Aeration of dilution water	No
Quality/Intensity of irradiation	Not reported
Photoperiod	16 h light with transition period

Table A7_4_1_2-6: Immobilisation data

Test-Substance **Concentration (nominal)** **[mg/l]**	**Immobile *Daphnia***				**Oxygen [mg/l]**	**pH**	**Tempera-ture [°C]**
	Number		**Percentage**				
	24 h	**48 h**	**24 h**	**48 h**	**48 h**	**48 h**	**48 h**
0	0	0	0	0	9.1	7.9	21
0 (solvent control)	0	0	0	0	9.1	7.9	21
10	0	0	0	0	9.0	8.0	21
100	5*	11*	25	55	9.1	8.0	21

*Due to physical hampering

Table A7_4_1_2-7: Effect data

	EC_{50}[1]	**95 % c.l.**	**EC_0[1]**	**EC_{100}[1]**
24 h [mg/l]	> 10 (n)	-	10	-
48 h [mg/l]	> 10 (n)	-	10	-

[1] indicate if effect data are based on nominal (n) or measured (m) concentrations

Table A7_4_1_2-8: Validity criteria for acute daphnia immobilistaion test according to OECD Guideline 202

	fulfilled	**Not fullfilled**
Immobilisation of control animals <10%	**x**	
Control animals not staying at the surface	**x**	
Concentration of dissolved oxygen in all test vessels >3 mg/l	**x**	
Concentration of test substance ≥80% of initial concentration during test	**x**	
Criteria for poorly soluble test substances	**x**	**x** **(100 mg a.s./l)**

Section A7 Annex Point IIA7.4.1.3	Growth inhibition test on algae	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	According to the 'draft guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC' data are conditionally required. Only if the product is used outdoors and the exposure assessment indicates concern. 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, a waiver is claimed for the submission of information concerning the toxicity to algae. According to Verhaar, H.J.M., van Leeuwen, C.J., and Hermens, J.L.M. (1992). Classifying environmental pollutants. 1:Structure-Activity Relationships for prediction of aquatic toxicity. Chemosphere 25: 471-491, muscalure can be classified as a non-polar narcotic. The Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EECon Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances, and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, recommend the following QSAR for estimating the acute effect of nonpolar narcotics to algae: log EC50 = -1.00 logKow - 1.23. This would result in an EC50 of 120 ng/L. Note that for compounds like muscalure, the aqueous solubility is usually so low as to make the toxicity irrelevant; moreover, uptake rates will usually prevent substances reaching toxic levels before being buried in sediment or transported downstream associated with particulate matter.	

Section A7 **Annex Point IIA7.4.1.3**	**Growth inhibition test on algae**
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 A7 Annex Point IIA7.4.1.4	Inhibition to microbiological activity	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	According to the 'draft guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC' data are conditionally required. Only if the product is used outdoors and the exposure assessment indicates concern. 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, a waiver is claimed for the submission of information concerning the inhibition of microbiological activity.	
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)*	

Section A7 **Annex Point IIA7.4.1.4**	**Inhibition to microbiological activity**
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 A7 Annex Point IIA7.4.2	Bioconcentration	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [x]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [ ]	
Detailed justification:	According to the 'draft guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC' data are conditionally required. Only if the product is used outdoors and the exposure assessment indicates concern. 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, a waiver is claimed for the submission of information concerning the bioconcentration of muscalure. Several QSAR models for predicting the bioconcentration factor of organic chemicals from physicochemical parameters exist. The Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EECon Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances, and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, Part II, gives two such QSARs, viz. equations 74 and 75, that both calculate an estimated BCF based on the logKow of the substance. It should be noted here that the logKow of muscalure (Z-9-tricosene) has been estimated at >8.2, based on the solubility of muscalure in the separate phases octanol and water. The properties of muscalure are such that no significant concentrations in the aqeous phase can be reached and measured in a standard octanol/water partitioning experiment. Since ideally the quotient of solubilities and the partition coefficient are thermodynamically equivalent, this is an acceptable way of estimating the Kow. Note	

Section A7 Annex Point IIA7.4.2	Bioconcentration	
	that at the high log Kow end of the range, this approach may lead to an overestimation of the Kow as determined by an actual experimental shake flask method, since the shake flask method suffers from nonlinear effects due to the fact that after shaking the water and octanol phases are actually octanol-saturated water and water-saturated octanol phases. The so called slow-stirring method suffers less from this problem, and can readily measure octanol/water partition coefficients in the range of 6 ≤ log Kow < 9. A log Kow estimate based on the separate solubilities will resemble the slow-stirring log Kow more than it will resemble the shake-flask log Kow at the high end of the range. According to the TGD, equation 74 (the classic Veith, Defoe & Bergstedt equation) is valid for substances with a log Kow between 2 and 6. Muscalure clearly falls outside the scope of this equation. According to the TGD, for substances with a log Kow > 6 and a molecular weight of less than 700, equation 75 should be used. This implies that for muscalure, if one requires BCF to be estimated, equation 75 is the appropriate model. Using an estimated log Kow of 8.2, equation 75 would suggest that muscalure's BCF is 20000 (log BCF is 4.3).	
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 A7 Annex Point IIA7.4.3	Effects on aquatic organisms, further studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	According to the 'draft guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC' data are conditionally required. Only if the product is used outdoors and the exposure assessment indicates concern. 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, a waiver is claimed for the submission of information.	
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)*	

Section A7 **Annex Point IIA7.4.3**	**Effects on aquatic organisms, further studies**
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 A7 Annex Point IIA7.5.1.1	Inhibition to microbiological activity	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	According to the 'draft guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC' data are conditionally required. Only if the product is used outdoors and the exposure assessment indicates concern. 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, a waiver is claimed for the submission of information concerning the inhibition of microbiological activity.	
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)*	

Section A7 **Annex Point IIA7.5.1.1**	**Inhibition to microbiological activity**
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 A7 Annex Point IIA7.5.1.2	**Acute toxicity to earthworms or other soil non-target organisms**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	According to the 'draft guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC' data are conditionally required. Only if the product is used outdoors and the exposure assessment indicates concern. 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, a waiver is claimed for the submission of information concerning the toxicity to soil non-target organisms.	
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)*	

Section A7 **Annex Point IIA7.5.1.2**	**Acute toxicity to earthworms or other soil non-target organisms**
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 A7 Annex Point IIA7.5.1.3	Acute toxicity to plants	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	According to the 'draft guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC' data are conditionally required. Only if the product is used outdoors and the exposure assessment indicates concern. 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, a waiver is claimed for the submission of information concerning the toxicity to plants.	
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)*	

Section A7 **Annex Point IIA7.5.1.3**	**Acute toxicity to plants**
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 A7 Annex Point IIA7.5.2	Terrestrial tests, long-term tests	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	According to the 'draft guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC' data are conditionally required. Only if the product is used outdoors and the exposure assessment indicates concern. 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, a waiver is claimed for the submission of information.	
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)*	

Section A7 **Annex Point IIA7.5.2**	**Terrestrial tests, long-term tests**
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 A7 Annex Point IIA7.5.3	Effects on birds	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	According to the 'draft guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC' data are conditionally required. Only if the product is used outdoors and the exposure assessment indicates concern. 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, a waiver is claimed for the submission of information concerning the toxicity to birds.	
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)*	

Section A7 **Annex Point IIA7.5.3**	**Effects on birds**
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 A7 Annex Point IIA7.5.4	Effects on honeybees	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	According to the 'draft guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC' data are conditionally required. Only if the product is used outdoors and the exposure assessment indicates concern. 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, a waiver is claimed for the submission of information concerning the toxicity to honeybees.	
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)*	

Section A7 **Annex Point IIA7.5.4**	**Effects on honeybees**
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 A7 Annex Point IIA7.5.5	Bioconcentration	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	According to the 'draft guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC' data are conditionally required. Only if the product is used outdoors and the exposure assessment indicates concern. 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, a waiver is claimed for the submission of information concerning the bioconcentration behaviour of muscalure.	
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)*	

Section A7 **Annex Point IIA7.5.5**	**Bioconcentration**
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 A7 Annex Point IIA7.5.6	Effects on other terrestrial non-target organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	According to the 'draft guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC' data are conditionally required. Only if the product is used outdoors and the exposure assessment indicates concern. 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, a waiver is claimed for the submission of information concerning the toxicity to terrestrial non-target macro-organisms.	
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)*	

Section A7 **Annex Point IIA7.5.6**	**Effects on other terrestrial non-target organisms**
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 A7 Annex Point IIA7.5.7	Effects on mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	According to the 'draft guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC' data are conditionally required. Only if the product is used outdoors and the exposure assessment indicates concern. 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, a waiver is claimed for the submission of information concerning the effects on mammals.	
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)*	

Section A7 **Annex Point IIA7.5.7**	**Effects on mammals**
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 A7.6

Annex Point IIA7.6

Summary of ecotoxicological effects and fate and behaviour in the environment

Official use only

1 REFERENCE

1.1 Reference

Cross reference to Document II-A

Section A8 Measures necessary to protect man, animals and the environment

Official use only

Subsection (Annex Point)		
8.1		**Recommended methods and precautions concerning handling, use, storage, transport or fire (IIA8.1)**
8.1.0	**Methods and precautions concerning placing on the market**	Product must be packed in original containers suitable for non-corrosive hydrocarbon liquids. Product must be stored in unopened, original containers suitable for non-corrosive hydrocarbon liquids, in a dry, cool and dark place, safe from access by children.
8.1.1	**Methods and precautions concerning production, handling and use of the active substance and its formulations**	No MAC value is available. Handling precautions: Standard directives in respect of hygiene and health are to be observed. Avoid unnecessary contact with the substance. Suitable clothing and gloves are recommended. Remove contaminated clothing. Wash hands after use and before breaks. Storage: Product must be stored in unopened, original containers, in a dry, cool and dark place, safe from access by children. Keep away from food, drink and animal feeding stuffs. According to present knowledge product has no harmful effects to the environment. However, do not allow entry in streams, sewers or natural environment. Respiratory protection: Under normal circumstances respiratory protection is not regarded necessary. Hand protection: Wear suitable protective gloves. Eye protection: Use of safety glasses or goggles is not regarded necessary. Skin and body protection: Wear suitable clothing. Others: Do not eat, drink or smoke.
8.1.2	**Methods and precautions concerning storage of the active substance and its formulations**	Store in unopened, original containers in a dry, cool and dark place, safe from access by children. Ventilation is recommended.

Section A8 Measures necessary to protect man, animals and the environment

			Official use only
8.1.3	**Methods and precautions concerning transport of the active substance and its formulations**	Not classified for any mode of transportation.	
8.1.4	**Methods and precautions concerning fire of the active substance and its formulations**	**Fire fighting measures** Suited extinguishing media: Powder, foam, water spray, CO_2. Unsuited extinguishing media: Water jet. Special protective equipment for fire fighters: Self-contained respiratory apparatus and protective clothing. Exposure risks: Standard fire exposure risks.	
8.2		**In case of fire, nature of reaction products, combustion gases, etc. (IIA8.2)** Carbon dioxide	
8.3		**Emergency measures in case of an accident (IIA8.3)**	
8.3.1	**Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available**	Emergencies: In general urgent medical attention will not be necessary. Inhalation: Remove subject from exposure area to fresh air. Seek medical advice if feeling unwell. Eye contact: Flush eyes with water. Get medical attention if in any doubt. Skin contact: Wash affected skin with plenty of water and soap. Ingestion: Get medical attention if feeling unwell. Information for physician: Product contains tricosenes. Treatment is symptomatic and supportive; no specific antidote known.	
8.3.2	**Emergency measures to protect the environment**	According to present knowledge product has no harmful effects to the environment. However, do not allow entry in streams, sewers or natural environment.	
8.4		**Possibility of destruction or decontamination following release in or on the following: (a) Air; (b) Water, including drinking water; (c) Soil (IIA8.4)**	
8.4.1	**Possibility of destruction or decontamination following release in the air**	Since the vapour pressure of the product is very low, no special destruction or decontamination is needed. In buildings apply ventilation to disperse vapours.	
8.4.2	**Possibility of destruction or decontamination following release in**	Treat as contamination by fuels (kerosine). Isolation of the spill by floating barriers; suction of major spills, adsorption of minor residues onto appropriate adsorbing materials.	

Section A8 Measures necessary to protect man, animals and the environment

			Official use only
	water, including drinking water	If appropriate, the product can be dispersed by surfactants.	
8.4.3	**Possibility of destruction or decontamination following release in or on soil**	Spills on hard pavement must be wiped with absorbent and put into closed containers for later disposal. Spills in/on soil must be dug up and put into closed containers for later disposal.	
8.5		**Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration (IIA8.5)**	
8.5.1	**Possibility of re-use or recycling**	Not possible	
8.5.2	**Possibility of neutralisation of effects**	Not possible	
8.5.3	**Conditions for controlled discharge including leachate qualities on disposal**	Not possible	
8.5.4	**Conditions for controlled incineration**	The product can be safely destroyed by incineration. Incineration products are carbon dioxide and water only.	
8.6		**Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIA8.6)** None	
8.7		**Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances (IIA8.7)** Since muscalure is not a biocide *sensu stricto* in the sense of Directive 80/86/EEC (it has no potential to kill or harm organisms) it is not identified as one of the List I or List II substances.	

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	