Section A6 Annex Point IIA6.6.2	In vitro cytogenicity study in mammalian cells	
	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 'Guidance for waiving' data on mutagenicity may be waived if substance is a member of a well characterised group e.g. SCLPs and the mutagenicity of that group is described. The available information on the toxicology of muscalure does not give rise to concern for the human health (see Verberk et al., 2004 and De Raat, 2006). Being a higher linear mono-alkene, there are no structural alerts for specific toxic effects. Moreover, the Ames test performed with muscalure shows negative results.	
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 A6 **Annex Point IIA6.6.3**	**In-vitro gene mutation assay in mammalian cells**	
	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 'Guidance for waiving' data on mutagenicity may be waived if substance is a member of a well characterised group e.g. SCLPs and the mutagenicity of that group is described. The available information on the toxicology of muscalure does not give rise to concern for the human health (see Verberk et al., 2004 and De Raat, 2006). Being a higher linear mono-alkene, there are no structural alerts for specific toxic effects. Moreover, the Ames test performed with muscalure shows negative results.	
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 A6 **Annex Point IIA6.6.4**	**In-vivo mutagenicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification: **I**	According to the 'Technical Notes for Guidance for data requirements' *in vivo* data are only required if there are positive results in the *in vitro* mutagenicity tests. Muscalure was negative in *in vitro* mutagenicity test, therefore no *in vivo* testing is deemed necessary.	
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 A6 **Annex Point IIA6.6.5**	**In-vivo mutagenicity, second test**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification: **I**	According to the 'Technical Notes for Guidance for data requirements' *in vivo* data are only required if there are positive results in the *in vitro* mutagenicity tests. Muscalure was negative in *in vitro* mutagenicity test, therefore no *in vivo* testing is deemed necessary.	
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 A6 **Annex Point IIA6.6.6**	**Mutagenicity, germ cells**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification: **I**	Data on germ cells are only required if there are positive results in the *in vivo* mutagenicity tests.	
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 A6 **Annex Point IIA6.6.7**	**Mutagenicity, further tests**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification: **I**	Only required if metabolites of concern are formed in mammals. This is not the case for 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)*	
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 A6 Annex Point IIA6.7	Carcinogenicity	
	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 'Guidance for waiving' data on carcinogenicity are conditionally required: triggered by adverse effects in mutagenicity or short term studies. Waiving is possible if long-term exposure above background can be excluded. Muscalure is negative in the Ames test and the available information on the toxicology of muscalure does not give rise to concern for the human health (see Verberk et al., 2004 and De Raat, 2006). Being a higher linear mono-alkene, there are no structural alerts for specific toxic effects. Moreover, the human exposure to muscalure resulting form the use of the attractant is very low (see document IIB), even much lower than the designated threshold of toxicological concern. Waiving is further justified by the fact that humans are exposed to very similar compounds via their food and otherwise at levels exceeding the estimated exposure to muscalure (see De Raat, 2006).	
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 A6 Annex Point IIA6.8.1	Teratogenicity test	
	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 'Guidance for waiving' data on teratoginicity are required in one species if there is a significant exposure potential or if a tolerance/MRL will be set. Data may be waived if the substance is a member of a well characterised group, e.g. SCLPs and the repeated dose toxicity of that group is described. The need for a teratogenicity study in the second species is triggered by adverse effects or toxicity concerns arising form other data points for health risk. The available information on the toxicology of muscalure does not give rise to concern for the human health (see Verberk et al., 2004 and De Raat, 2006). Being a higher linear mono-alkene, there are no structural alerts for specific toxic effects. Moreover, the human exposure to muscalure resulting form the use of the attractant is very low (see document IIB), even much lower than the designated threshold of toxicological concern. Waiving is further justified by the fact that humans are exposed to very similar compounds via their food and otherwise at levels exceeding the estimated exposure to muscalure (see De Raat, 2006).	
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 A6 Annex Point IIA6.8.2	Two generations reproduction study	
	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 'Guidance for waiving' data on fertility are conditionally required: triggered by adverse effects or toxicity concerns arising form other data points for health risk and depending on the level, frequency and duration of exposure. The available information on the toxicology of muscalure does not give rise to concern for the human health (see Verberk et al., 2004 and De Raat, 2006). Being a higher linear mono-alkene, there are no structural alerts for specific toxic effects. Moreover, the human exposure to muscalure resulting form the use of the attractant is very low (see document IIB), even much lower than the designated threshold of toxicological concern. Waiving is further justified by the fact that humans are exposed to very similar compounds via their food and otherwise at levels exceeding the estimated exposure to muscalure (see De Raat, 2006).	
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 A6 **Annex Point IIA6.9**	**Neurotoxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [x]**	
Detailed justification:	This toxicological endpoint is not relevant for 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)*	
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 A6.10 **Annex Point IIA6.10**	**Mechanistic studies**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**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 6.10 the following is cited: "Mechanistic study - any studies necessary to clarify effects reported in toxicity studies [Ann.IIIA, VI. 7.] · This data may be relevant on the basis of the toxicological properties of a substance. · Studies of the mechanisms of toxicity may be necessary when there are indications that active substance may have e.g. a non-genotoxic mechanism for carcinogenicity, species specific effects, adverse effects on reproduction, immunotoxicity or hormone related effects. · Scientific judgement is required to decide whether any supplementary studies are needed (see Chapter 1.2, point 4)." Muscalure does not have specific effects as meant under this section.	
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 A6.11 **Annex Point IIA6.11**	**Parenteral routes**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**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 6.11 the following is cited: "· For existing substances, data (if already existing) by alternative routes should be submitted by the applicant. · New studies will be required only in exceptional cases. · Studies on parenteral routes may supplement the information received from toxicokinetic studies and give valuable information e.g. in cases when the gastrointestinal absorption of the chemical in question is poor. · E.g. acute toxicity studies on intraperitoneal, intravenous subcutaneous and intramuscular routes, where conducted, should be submitted. · A scientific judgement is required to decide whether any supplementary studies are needed (see Chapter 1.2, point 4)." The dossier contains studies on respiratory, dermal and oral exposure.	
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 A6.12 Annex Point IIA6.12	Medical data	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification:	This statement covers 6.12.1 to 6.12.8 ! According to the 'Technical Guidance Document on data requirements' under IIIA 6.12 the following is cited: "Medical data in anonymous form *[Ann IIA, VI. 6.9.]* • Data and information on the effects of human exposure, if available, may provide valuable information for confirming the validity of extrapolations made and conclusions reached from animal data and for identifying unexpected adverse effects which are specific to humans. • Data and information following accidental or occupational exposure have to be submitted where available and of adequate quality. Practical data and information relevant to the recognition of the symptoms of poisoning, on the effectiveness of first aid and therapeutic measures must be included. • It is usually not possible to require this data for new active substances." Thus, the information under 6.12 should be provided if available; in this case no information is available.	
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 A6.13 Annex Point IIA6.13	Toxic effects on livestock and pets	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**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 6.13 the following is cited: "An estimation on toxic effects and exposure via different exposure routes (e.g. inhalation, licking, skin contact and ingestion of poisoned bait) and in relevant, but exceptional cases, toxicity testing in livestock and pets is required. Toxic effects for livestock and pets should to be estimated or studied if the substance is to be used in spaces in which animals are housed, kept or transported or exposure is possible via drinking water or feedingstuffs. Information on lethal doses for different species, symptoms of poisoning, details of the time courses in case of poisoning and antidotes should also be submitted, if available. · This data may be relevant e.g. for product type 3 (substances used for veterinary hygiene purposes), product type 4 (disinfection of surfaces and equipment), product type 5 (drinking water) product types 8 and 10 (treated materials in areas in which animals are housed, kept or transported), product types 14, 15 and 23 (ingestion of baits), product types 16 and 17 (contaminated drinking water), product types 18 and 19 (repellents to be used for veterinary hygiene purposes). An expert judgement is required to decide whether any studies are needed (see Chapter 1.2, point 4). · This data is usually not required for the product types 1, 2, 6, 7, 9, 11, 12, 13, 20, 21 and 22." The use of muscalure as attractant does not result in toxic effects for livestock and pets.	
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		

Section A6.13 **Annex Point IIA6.13**	**Toxic effects on livestock and pets**
	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 A6.14 Annex Point IIA6.14	Other tests related to the exposure of humans	
	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 6.14 the following is cited: "· Toxicity of degradation products, by-products and reaction products related to human exposure. · Information is required on the toxic effects of substances generated from an active substance, other than mammalian metabolites, in normal use of biocidal product. · The decision as to the need for this data should be made on case-by-case basis by expert judgement (see Chapter 1.2, point 4). Where human exposure is significant, toxicity testing may be needed. · This data may be relevant for many product types. As examples, product types 1 and 2 (reaction products with water when the substance is used for human hygiene purposes or reaction products with water or other materials released in water or air when the substance is used for the treatment of bathing waters), product type 5 (substances produced in a reaction with drinking water), product types 6, 7, 9 and 10 (residuals in treated materials), product type 8 (irritating and sensitising effects of chemical compounds, such as metal salts, developed on the surface of the treated wood) and product type 18 (products, which may produce harmful substances with water during gassing)." It is clear from the submitted dossier that for muscalure as attractant the above mentioned cases are not applicable and additional studies relating to human exposure are not required. All information relating to human exposure is included in B6.6	
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*	

Section A6.14 **Annex Point IIA6.14**	**Other tests related to the exposure of humans**
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 A6.15 Annex Point IIA6.15	Food and feedingstuffs	
	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:	This point covers 6.15.1 to 6.15.6 ! According to the 'Technical Guidance Document on data requirements' this is an additional data requirement and under IIIA 6.15 the following is cited: "If the active substance is to be used in preparations for use where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestock is prepared, consumed or stored, the tests and results in accordance with paragraphs A6.15.1-6.15.5. shall be required 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 Liter and by food intake), this will result in a muscalure intake via the food of 0.36 ng/day = 0.00000036 mg/day. This estimated exposure is very low, even much lower than the designated threshold of toxicological concern. Waiving is further justified by the fact that humans are exposed to very similar compounds via their food and otherwise at levels exceeding the estimated exposure to muscalure (see De Raat, 2006).	
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*	

Section A6.15 **Annex Point IIA6.15**	**Food and feedingstuffs**
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 A6 Annex Point IIA6.16	Any other test data on exposure	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [x]	**Other justification [x]**	
Detailed justification:	According to the 'Technical Guidance Document on data requirements' this is an additional data requirement and under IIIA 6.16 the following is cited: "Any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, that are considered necessary may be required. *[Ann. IIIA, VI.3.5 and XI. 2]*. • An expert judgement for suitable tests and reasoned case is needed as to decision that such additional studies are required (see Chapter 1.2, point 4). " It is clear that the dossier contains all data relevant for an appropriate exposure assessment for muscalure used in attractants. No other data on exposure 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 A6 **Annex Point IIA6.17**	**Metabolites in plants**	
	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 6.17 the following is cited: "If the active substance is to be used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required *[Ann. IIIA, VI.6]*. • Ann. IIIA VI.6. is action against plants, and therefore seen as covered sufficiently by directive 91/414/EC 867." It is clear that from the proposed uses of muscalure as attractant, no action against or on plants is meant.	
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 A6.18 Summary of mammalian toxicology and conclusions

Annex Point IIA6.18

Official use only

1 REFERENCE

1.1 Reference Cross reference to Document II-A

Section A7 Annex Point IIA7.1.1	Fate and behaviour in water, degradation, initial studies	
	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 fate and behaviour in water. This covers all headings under 7.1.1.	
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 IIA7.1.1**	**Fate and behaviour in water, degradation, initial 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 A7.1.1.2.1 Biodegradability (ready/inherent)
Section A7.1.1.2.2

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

Official use only

		1 REFERENCE
1.1	**Reference**	ENVIRON, 2006
1.2	**Data protection**	No
1.2.1	Data owner	Denka International
1.2.2		
1.2.3	Criteria for data protection	No data protection claimed
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	No, not relevant for QSAR predictions
2.2	**GLP**	No, not relevant for QSAR predictions
2.3	**Deviations**	No
		3 MATERIALS AND METHODS

Section A7.1.1.2.1 Biodegradability (ready/inherent)
Section A7.1.1.2.2

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

3.1	**Test material**	Not relevant
3.1.1	Lot/Batch number	
3.1.2	Specification	
3.1.3	Purity	
3.1.4	Further relevant properties	
3.1.5	Composition of Product	
3.1.6	TS inhibitory to microorganisms	
3.1.7	Specific chemical analysis	
3.2	**Reference substance**	
3.2.1	Initial concentration of reference substance	
3.3	**Test ing procedure**	Non-entry field
3.3.1	Inoculum / test species	QSAR prediction
3.3.2	Test system	
3.3.3	Test conditions	
3.3.4	Method of preparation of test solution	
3.3.5	Initial TS concentration	
3.3.6	Duration of test	
3.3.7	Analytical parameter	
3.3.8	Sampling	
3.3.9	Intermediates/ degradation products	
3.3.10	Nitrate/nitrite measurement	
3.3.11	Controls	
3.3.12	Statistics	

4 RESULTS

Section A7.1.1.2.1 Biodegradability (ready/inherent)
Section A7.1.1.2.2

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

4.1	**Degradation of test substance**	*Non-entry field*
4.1.1	Graph	
4.1.2	Degradation	SMILES : C(=CCCCCCCCC)CCCCCCCCCCCCC CHEM : 9-Tricosene, (Z)- CAS NUM: 027519-02-4 MOL FOR: C23 H46 MOL WT : 322.62 ---------- EPI SUMMARY (v3.12) ---------- Probability of Rapid Biodegradation (BIOWIN v4.02): Biowin1 (Linear Model) : 0.8108 Biowin2 (Non-Linear Model) : 0.8923 Expert Survey Biodegradation Results: Biowin3 (Ultimate Survey Model): 3.0829 (weeks) Biowin4 (Primary Survey Model) : 3.9204 (days) Readily Biodegradable Probability (MITI Model): Biowin5 (MITI Linear Model) : 0.7044 Biowin6 (MITI Non-Linear Model): 0.8128 Ready Biodegradability Prediction: YES
4.1.3	Other observations	
4.1.4	Degradation of TS in abiotic control	
4.1.5	Degradation of reference substance	
4.1.6	Intermediates/ degradation products	

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	BIOWIN prediction of ready biodegradability based on 6 included models
5.2	**Results and discussion**	Substance is readily biodegradable
5.3	**Conclusion**	All models indicate ready biodegradability. For substance classes that muscalure belongs to, these models are considered reliable
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A7.1.1.2.1 **Biodegradability (ready/inherent)**
Section A7.1.1.2.2

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

	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_1_1_2-1: Guidline-methods of EC and OECD for tests on ready/inherent biodegradability (according to OECD criteria); simulation test

Test	EC-method	OECD-Guideline	Test on ready/inherent biodegradability
DOC Die-Away-Test	C.4-A	301A	ready
CO_2 Evolution-Test (Modified Sturm Test)	C.4-C	301B	ready
Modified OECD-Screening-Test	C.4-B	301E	ready
Manometric Respirometry	C.4-D	301F	ready
MITI-I-Test	C.4-F	301C	ready
Closed-Bottle-Test	C.4-E	301D	ready
Zahn-Wellens-test	C.9	302B	Inherent
Modified MITI-Test (II)	-	302C	Inherent
Modified SCAS-Test	C.12	302A	Inherent
Simulation Test with activated Sewage (Coupled Units-Test)	C.10	302A	Simulation Test[1)]

[1)] Test for the determination of the ultimate degradation of test material under conditions which simulate the treatment in an activated sludge plant

Table A7_1_1_2-2: Inoculum / Test organism

Criteria	Details
Nature	*e.g. activated sludge*
Species	
Strain	
Source	*e.g. sewage treatment plant treating predominantly domestic sewage*
Sampling site	
Laboratory culture	Yes/No *(If no, specify)*
Method of cultivation	
Preparation of inoculum for exposure	*give details, e.g. on washing, centrifugation*
Pretreatment	*e.g. adaptation*
Initial cell concentration	*include data as mg suspended solids/l, mg effluent/l or approx. number of cells/l depending on test method*

Table A7_1_1_2-3: Test system

Criteria	Details
Culturing apparatus	*e.g. respirometer*
Number of culture flasks/concentration	
Aeration device	
Measuring equipment	
Test performed in closed vessels due to significant volatility of TS	Yes/No *(If yes, specify)*

Table A7_1_1_2-4: Test conditions

Criteria	Details
Composition of medium	*Give details e.g. on added mineral medium*
Additional substrate	Yes/No *(If yes, specify: e.g. peptone)*
Test temperature	*Give measurements conducted during test*
pH	*Give measurements conducted at start and end of test*
Aeration of dilution water	Yes/No *(If yes, specify: e.g. air-flow)*
Suspended solids concentration	
Other relevant citeria	*e.g. stirring of test solution*

Table A7_1_1_2-5: Pass levels and validity criteria for tests on ready biodegradability

	fulfilled	not fulfilled
Pass levels		
70% removal of DOC resp. 60% removal of ThOD or $ThCO_2$		
Pass values reached within 10-d window (within 28-d test period) - not applicable to MITI-I-Test - 14-d window acceptable for Closed-Bottle-Test		
Criteria for validity		
Difference of extremes of replicate values of TS removal at plateau (at the end of test or end of 10-d window) < 20%		
Percentage of removal of reference substance reaches pass level by day 14		

5.3.2.1 Criteria for poorly soluble test substances	5.3.2.2	5.3.2.3
5.3.2.4	**5.3.2.5**	**5.3.2.6**
5.3.2.7	**5.3.2.8**	**5.3.2.9**

Table A7_1_1_2-6: Pass levels and validity criteria for inherent biodegradability tests

	fulfilled	not fulfilled
Pass levels		
20% removal (DOC or COD);		
Pass values reached within 10-d window (within 28-d test period)		
Removal of reference substance (DOC or COD) > 70 % within 14 d		
Criteria for validity		
Percentage of DOC/COD-removal of reference compound ≥ 70 % within 14 days (OECD 302 B)		
Percentage of DOC-removal of reference compound ≥ 40 % within 7 days and ≥ 65 % within 14 days Average residual amount of test compound in blank tests ≥ 40 % (OECD 302 C)		
Removal curve of DOC or COD in the test suspension indicative for biodegradation (gradual elimination over days/weeks)		

Criteria for poorly soluble test substances	5.3.2.10	5.3.2.11
	5.3.2.12	**5.3.2.13**
	5.3.2.14	**5.3.2.15**

Section A7 **Annex Point IIA7.1.1.2.3**	**Biodegradation in seawater**	
	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. Data on biodegradation in seawater should only be submitted when a substance is to be used or released in marine environments in considerable amounts. For muscalure and its intended uses this is not the case.	
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 7.1.2.1.2 Annex Point IIIA XII 2.1	**Anaerobic biodegradation**	
	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 the Technical Notes for Guidance on Dossier Requirements, Chapter 2.5, Product type specific additional data set for active substances and biocidal products regarding ecotoxicological profile, including environmental fate and behaviour, "for products to be used in animal housing, releases to manure storage facilities are possible. An anaerobic biodegradation study is necessary." Note that muscalure is a pheromone, and therefore active at much lower airborne concentrations than standard repellents and attractants. It was estimated that average indoor air concentrations of muscalure during use are 0.14 µg/m^3. The half life of muscalure in Flylure is 159 days (see B6_6_02). Flylure is discarded after 28 days. At that point in time, it will have released 11.5% of the available muscalure. In a 600 m^3 stable, this would correspond with an amount of 28.7 mg muscalure. Most of this will remain airborne and rapidly leave the stable due to ventilation. When confined to stables, dairy cattle produce at least 50L manure per individual per day (source: http://www.nutrinorm.nl). Maximum stable density for cattle is ca. 0.5 animal m^{-2}.Assuming that the stable is only half full, this would result in a manure production of ca. 2.5 m^3 per day, and ca 70 m^3 per 28 days for a stable of 600 m^3. If we assume that 10% of the muscalure ends up in manure, this would result in an average concentration of muscalure in manure of ca is sequestered in the manure of ca 41 ng/L (41 ppt). Denka states that given the known fate and ecotox properties of muscalure, this is a totally negligible concentration. As such, Denka states that no anaerobic biodegradation study is necessary.	
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	

Section 7.1.2.1.2 **Annex Point IIIA XII 2.1**	**Anaerobic biodegradation**
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 IIA7.1.2	Rate and route of degradation in aquatic systems	
	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 fate and behaviour in water.	
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*	

Section A7 **Annex Point IIA7.1.2**	**Rate and route of degradation in aquatic systems**
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 IIA7.1.3	Adsorption/desorption screening test	
	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 fate and behaviour in soil.	
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 IIA7.1.3**	**Adsorption/desorption screening test**
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 IIA7.1.4	Further studies water/sediment	
	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 fate and behaviour in water.	
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 IIA7.1.4**	**Further studies water/sediment**
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 IIA7.2	Fate and behaviour in soil	
	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 'Technical Guidance Document on data requirements', this is an additional data requirement. As the biocidal product containing muscalure will be used indoors only and not directly on soil, this data requirement is not required. This also applies to all headings under IIA 7.2 from 7.2.1 to 7.2.3.2. 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 fate and behaviour in water.	
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*	

Section A7 **Annex Point IIA7.2**	**Fate and behaviour in soil**
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 IIA7.3	Fate and behaviour in air	
	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 'Technical Guidance Document on data requirements', this is an additional data requirement. Fate and behaviour in air may be estimated if it is necessary for the risk assessment. This applies to both 7.3.1 and 7.3.2. 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 fate and behaviour in air.	
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,*	

Section A7 **Annex Point IIA7.3**	**Fate and behaviour in air**
	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	