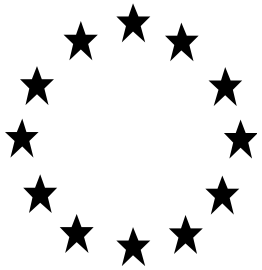
Directive 98/8/EC concerning the placing biocidal products on the market

Inclusion of active substances in Annex I or IA to Directive 98/8/EC

Assessment Report



cis-Tricos-9-ene

Product-type 19
(Repellents and attractants)

Date of SCB vote: 25 May 2012

Annex I - Austria

cis-Tricos-9-ene (PT 19)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 25 May 2012 in view of its inclusion in Annex I to Directive 98/8/EC

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of *cis*-Tricos-9-ene as product-type 19 (Repellents and attractants), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

cis-Tricos-9-ene (CAS no. 27519-02-4) was notified as an existing active substance, by Denka Registration B.V., hereafter referred to as the applicant, in product-type 19.

Commission Regulation (EC) No 1451/2007 of 4 November 2003[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, Austria was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for *cis*-Tricos-9-ene as an active substance in Product Type 19 was 2006-04-30, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 26 April 2006, Austrian competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 30 October 2006

On 11 November 2009, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 10 December 2009. The competent authority report included a recommendation for the inclusion of *cis*-Tricos-9-ene in Annex I to the Directive for product-type 19.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 10 December 2009. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

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1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

2 Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

On the basis of the final competent authority report, the Commission proposed the inclusion of *cis*-Tricos-9-ene in Annex I do Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 12 May 2012.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 25 May 2012.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include *cis*-Tricos-9-ene in Annex I to Directive 98/8/EC for product-type 19. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type 19 that contain *cis*-Tricos-9-ene. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[3], shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are products containing *cis*-Tricos-9-ene for the product-type 19, which will fulfil the requirements laid down in Article 5 of Directive 98/8/EC. This conclusion is however subject to:

i. Compliance with the particular requirements in the following sections of this assessment report,

ii. The implementation of the provisions of Article 5(1) of Directive 98/8/EC, and

iii. The common principles laid down in Annex VI to Directive 98/8/EC.

Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

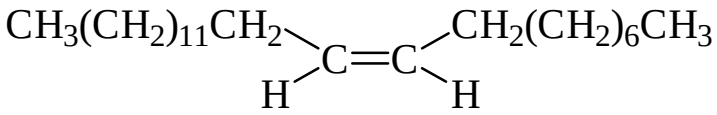
3 http://ec.europa.eu/comm/environment/biocides/index.htm

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

The active substance is listed as “Cis-tricos-9-ene” in Annex I (active substances identified as existing) and Annex II (active substances to be examined under the review programme) in Commission Regulation (EC) No 1451/2007. However, in this report, the ESA (Entomological Society of America) name “Muscalure” is used for the active substance (no ISO common name is available).

The active substance Muscalure (IUPAC names: *cis*-Tricos-9-ene; (Z)-Tricos-9-ene) is attributed the CAS-No 27519-02-4 and the EC-No 248-505-7. The molecular formula is $C_{23}H_{46}$, and the molecular weight is 322.6 g/mol. The minimum degree of purity is 80.1 %w/w Muscalure.

Structural formula:



The structure of Muscalure is confirmed by all spectra (IR, NMR, UV/VIS and MS).

The physico–chemical properties are studied for the purified active substance of stated specification (Purity: >96% Muscalure) or for the active substance as manufactured (Muscalure technical) according to the demands of the data requirements. Muscalure is a light yellow to colourless liquid; it has no characteristic odour at 19.5°C. Its melting point is -2°C and the boiling point is 380°C. The density is 0.803 kg/L at 20°C. The vapour pressure of the active substance is 6.4×10^{-2} Pa at 20°C and 0.119 Pa at 25°C; the calculated Henry’s law constant is 2.95×10^{3} Pa x m^3/mol. The water solubility is $<7 \times 10^{-6}$ g/L (at pH 4, 7 or 10; 20°C). Muscalure has no acid or basic groups and therefore no dissociation constant (pKa).

The solubility of Muscalure in different organic solvents, expressed in [%w/w], is as follows: Hexane: 70.5; Toluene: 70.3; Dichlormethan: 70.1; Methylal: 50.2; Methanol: 20.5; Propyleneglycol: 20.4; Acetone: 20.2; Acetonitril: 20.0; Dimethylsulfoxide: 20.0

The active substance as manufactured does not contain any organic solvent. The partition coefficient octanol-water is log Pow >8.2 at pH 4, 7 and 10 at 20°C. The surface tension is not required for substances with a water solubility <1 mg/L. The viscosity is 15 mPa x s at 20°C and 10^{-11} mPa x s at 40°C. The active substance Muscalure displays neither explosive nor oxidizing properties based on its structure. Its flash point is 161.5°C and its auto-ignition temperature is 250°C. The substance is thermically stable. It is not considered to be reactive to container material, because the active substance has no corrosive properties. The acceptable container material is PE and PET.

The characterisation of Muscalure is performed by using GC systems with FID detection. The methods have been validated and are considered suitable to give information on the chemical composition of the technical grade Muscalure.

According to the available guidance for waiving4 analytical methods for determination of the active substance in air, sediment and soil are not necessarily required. *Cis*-Tricos-9-ene is not classified as dangerous for the environment and the representative biocidal product Denka Flylure is intended for indoor use in fly traps. Muscalure acts by slowly vaporizing, resulting in a low steady state indoor air concentration. Outdoor concentrations will be much lower, due to simple dilution effects. Thus, it is concluded that specific studies on analytical methods for determination of the active substance in air, soil, water or sediment are not required.

However, an analytical method was developed and validated for the quantitative analysis of Muscalure from aqueous solution. The proposed Method is based on GC with FID-detection and external standard calibrations. Internal standardisation (Octadecane) is employed and allows the determination of Muscalure at concentration levels of approximately 0.002 mg a.s./L double distilled water, without complex sample preparation steps. This method is considered to be a basis for monitoring purposes. As Muscalure is not classified as toxic or very toxic, analytical methods for detection and identification of residues in animal and human body fluids and tissues were not assessed.

No analytical method for the determination of Muscalure in food/feedstuffs was provided, because no direct contact of food and feedstuffs with Muscalure is expected due to the mode of use. In addition, the applicant argued that transfer of Muscalure from airborne material to food and feedstuffs resulting in relevant concentrations in food and feedstuffs is considered highly unlikely given the low steady state air concentration, the Henry's law constant of 2.95 x 10^3 Pa x m^3/mol (K_{aw} = 1.21), and the fact that many food and feedstuffs are predominantly water-based. However, as food and feedingstuffs may also contain fat or oil or other non-polar ingredients, this justification is not accepted.

Concerning residues in exposed farm animals, the estimated external exposure of animals is above the actually proposed trigger value of 0.004 mg/kg bw, therefore analytical methods for residues in food of animal origin may appear necessary. In addition, the inhalative exposure of farm animals kept in stables / animal houses, where Denka Flylure is used as intended, has not been taken into account.

The need for data on analytic methods of food/feeding stuff should be evaluated at product authorization stage.

4 Guidance for Waiving of Data Requirements for Pheromones for Inclusion in Annex I/IA of Directive 98/8/EC, 2005, Addendum to the Technical Notes on Data Requirements, ECB, 2008. OECD Monograph 12 (OECD ENV/JM/MONO(2001)12) was taken into consideration for the development of this guidance.

2.1.2. Intended Uses and Efficacy

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

Table 1.1.3-1 Classification and labelling of the active substance according to Dir. 67/548/EC

Classification and Labelling		**Justification**
Hazard symbol		GPMT induces moderate sensitisation
Indication of danger	Irritating	
R phrases	R43 – May cause sensitisation by skin contact	
S phrases	S36/37 – Wear suitable protective clothing and gloves	Obligatory for substances which are very toxic and for which R43 has been ascribed
Classification	R43	See above
Labelling	Xi R: 43 S: 2-36/37	See above

Table 1.1.3.2 Classification and labelling of the active substance according to Reg. 1272/2008/EC

Classification and Labelling			**Justification**
GHS Pictograms		 GHS07	GPMT induces moderate sensitisation. An intradermal induction dose of 5% resulted in a 35% positive response.
Signal words		Warning	
Classification		Skin Sens. 1	
Hazard statements		H317: May cause an allergic skin reaction	
Precautionary Statements	**General**	-	
	Prevention	P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves/protective clothing/eye protection/face protection.	
	Response	P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P333 + P313: If skin irritation or rash occurs, get medical advice/attention P363 Wash contaminated clothing before reuse.	
	Storage	-	
	Disposal	P501 Dispose of contents/container to...	

Table 1.1.3-3 Classification and labelling of the biocidal product according to Directive 1999/45/EC (proposed by the RMS)

Classification and Labelling		Justification
Hazard symbol	None	
Indication of danger	None	
R phrases	None	
S phrases	S2: Keep out of reach of children S13: Keep away from food, drink and animal feeding stuffs S24: Avoid contact with skin Contains *cis*-Tricos-9-ene. May produce an allergic reaction.	As result of risk assessment: Trap contains sugar and therefore it could be attractive to children. Unacceptable risk with regard to potential sensitisation and systemic effects from acute oral exposure to the Muscalure content of one trap (100g). The applicant did neither provide a dietary risk assessment nor data on exposure of food/feeding stuff. In addition animal dietary exposure estimates result above the actually proposed trigger value of 0.004 mg/kg bw Muscalure is sensitizing and content in the biocidal product is > 0.1%
Classification	None	
Labelling	S: 2-13-24	

Table 1.5.2-2 Classification and labelling of the biocidal product according to Regulation (EC) No 1272/2008 (proposed by the RMS)

Classification and Labelling			Justification
GHS Pictograms		None	
Signal words		None	
Hazard statements		EUH208 – contains Muscalure - may produce allergic reaction	Muscalure content in biocidal product is > 0.1%.
Precautionary Statements	General	P102 Keep out of reach of children. P262 Do not get in eyes, on skin, or on clothing.	See above Muscalure is moderately sensitizing and content in the biocidal product is > 0.1%.
	Prevention	None	
	Response	None	
	Storage	None	
	Disposal	None	

Summary of the Risk Assessment

2.1.4. Risk arising from physico-chemical properties

No unacceptable risk arising from physico-chemical properties could be identified.

2.1.5. Human Health Risk Assessment

2.1.5.1. Hazard identification

The available information on the toxicology of Muscalure does not give rise to concern for the human health except for a moderate skin sensitization property estimated from the results of a Guinea Pig Maximisation Test. An intradermal induction dose of 5% resulted in a 35% positive response.

In the absence of repeated dose studies with Muscalure a short term AEL of >0.57 mg/kg bw/day was estimated based on short term human exposure to higher mono-alkenes (C17:1-C30:1) as natural food components of apples, citrus-juices, honey, olive-oil and hazelnut-oil and consideration of the results from the acute toxicity tests. A long term AEL of >0.024 mg/kg bw/day was estimated based on long term human exposure to higher mono-alkenes as natural food components. The latter estimate is also supported by the Toxicological Threshold of Concern approach that would result in long term AEL of 0.03 mg/kg bw/day for Muscalure as a substance without structural alerts for specific toxic effects (Cramer class I).

2.1.5.2. Effects assessment

The information on hazard may be summarised as follows and builds the basis for waiving5 of toxicokinetic and metabolism studies as well as repeated dose toxicity studies:

- No adverse effects in the acute oral and dermal toxicity tests with doses of 5000 and 2000 mg/kg bw, respectively
- No severe concerns from the acute inhalation toxicity test and a LC_{50} of > 5710 mg/m^3
- Within the dermal and eye irritation tests submitted no dermal irritation and only minimal eye irritation that is reversible till 24 hours
- No structural alerts for specific toxic effects - Muscalure is a higher linear mono-alkene

5 In line with the Guidance for Waiving of Data Requirements for Pheromones for Inclusion in Annex I/IA of Directive 98/8/EC, 2005, Addendum to the Technical Notes on Data Requirements, ECB, 2008. OECD Monograph 12 (OECD ENV/JM/MONO(2001)12) was taken into consideration for the development of this guidance.

- Negative bacterial mutation tests and a negative in vitro chromosomal aberration test as well as negative (Q)SAR results from the OECD toolbox

- Within the OECD/EPA SIDS HPV program a category approach was chosen grouping the higher olefins (alkenes) based on the observation that the location of the double bond or the addition of branching to the structure do not appear to affect the toxicity

- The reference to the EPA robust study summaries dossier 2005 (American Chemistry Council) for higher olefins indicating minimal oral absorption and NOAELs above 1000 mg/kg bw for 28 day studies (OECD 407), 90 day studies (OECD 408) and oral reproduction/developmental toxicity screening studies (OECD 421) as well as negative findings within the genotoxicity tests (AMES, in vitro chromosome aberration, in vitro gene mutation with *Saccharomyces cerevisiae*, in vivo micronucleus). However the original studies neither are available to the RMS nor were submitted by the applicant. Therefore these data were not evaluated by the RMS, which means that they can serve only as supplementary information within this report and cannot build up the core argument for waiving.

- The tier 1 primary exposure estimates (for application of the product) are below the short term AEL that is based on intake rate of the structurally related higher-mono-alkenes (C17:1- C30:1) as natural food component of various sources like apples, citrus-juices, honey, olive- and hazelnut-oil.

- The tier 2 secondary exposure estimates (for sojourning in in-use areas) are below the long term AEL that is based on the “Threshold of Toxicological Concern” of 1800 µg/day (as supported e.g. by ILSI 2005, International Life Sciences Institute) and below the long term intake rate of the structurally related higher-mono-alkenes (C17:1- C30:1) as natural food component.

- The moderate skin sensitizing property of muscalure (35% response in GPMT from 5% intradermal induction concentration) requires minimizing exposure in line with classification and labelling rules: Products with concentrations leading to a classification (≥1%) must not be put on the market. Furthermore with the actual representative product and intended use exposure is estimated to remain below the long term AEL (0.024 mg/kg bw/day) which is derived from natural food contents of the group of higher linear mono-alkenes. This non-standard derivation of the AEL provides some support for its scientific acceptability also as sensitization threshold.

2.1.5.3. Exposure assessment

Human exposure towards the active substance from its use in the biocidal product can take place via different "routes of exposure" (see Table 2.2.2.3-1).

Table 2.2.2.3-1: Main paths of human exposure to Muscalure contained in the biocidal product

Exposure path	**Primary (direct) exposure during application of the b.p.**		**Secondary (indirect) exposure**	**Via environment**
	Professional use	**General public**	**General Public**	
Inhalation	Yes	Yes	Yes	n.r.[1]
Dermal	Yes	Yes	Yes	n.r.[1]
Oral	n.r.[1]	n.r.[1]	Yes	n.r.[1]

[1] not relevant; inhalation exposure (exposure via air) after application is considered as secondary exposure.

Primary exposure towards Muscalure during application of the biocidal product Denka Flylure by professional users as well as the general public may occur during installation of the traps. It is summarised in table 2.2.2.3-2 below.

Table 2.2.2.3-2: Primary exposure to Muscalure contained in the biocidal product

Exposure Scenario	**Estimated Internal Exposure [mg/kg bw/day]**			
	Estimated oral uptake	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated total uptake (combined exposure)**
Application of the biocidal product by an adult (Tier 1)	n.r.[1]	0.012	0.055	0.067

[1] not relevant

Secondary exposure will mainly occur via inhalation. A scenario for dermal and oral exposure is where an unattended child finds a trap and takes up the whole content of the biocidal product (sugar granules containing Muscalure). However, this is considered as improper application (misuse). A summary is given in table 2.2.2.3-3 below.

Table 2.2.2.3-3: Secondary exposure to Muscalure contained in the biocidal product

Exposure Scenario	**Estimated Internal exposure [mg/kg bw/day]**			
	Estim. oral uptake	**Estim. inhal. uptake**	**Estim. dermal uptake**	**Estimated total uptake (combined exposure)**
Long term inhalative exposure of adult (60kg bw), tier 2[1]	-	0.0005	-	0.0005
Long term inhalative exposure of infant (10kg bw), tier 2[1]	-	0.0004	-	0.0004
Short term exposure of child (15 kg bw) to the total amount of the a.s. contained in one trap, tier 1[2]	≤ 16.7			≤ 16.7

1 due to evaporation of active substance

2 considered only to occur due to improper application (misuse).

Aggregate exposure covers exposure to a single chemical from multiple sources i.e. through primary and secondary exposure. One possible scenario is an adult applying the biocidal product at home and undergoing secondary exposure after application (see table 2.2.2.3-4).

Table 2.2.2.3-4: Aggregate exposure to Muscalure contained in the biocidal product

Exposure Scenario		**Estimated Internal Exposure [mg/kg bw/day]**		
		Estim. oral uptake	**Estim. inhal. uptake**	**Estim. dermal uptake**
Tier 1 (adult)	Adult (60 kg bw) exposed at application of b.p. (primary exposure)	Not relevant	0.012	0.055
Tier 1 (adult)	Adult (60 kg bw) exposed due to evaporation of a.s. (secondary exposure)	Not relevant	0.0005	Not relevant
Tier 1 (Total)	Aggregate exposure	0.068		

Cumulative exposure covers concurrent exposure to the same active substance from different biocidal products. This was not evaluated at present for Muscalure.

Exposure of farm animals (pigs, cattle, poultry) could occur during application in stables. Systemic intake via contaminated feed is generally considered to be the most important exposure route EC, 20016). However this was accomplished with a rough estimate for inhalation uptake. Exposure assessment is summarised in table 2.2.2.3-5 below.

Table 2.2.2.3-5: Aggregate exposure to Muscalure contained in the biocidal product

Exposure Scenario	**Estimated Internal Exposure[1] [mg/kg bw/day]**		
	oral	**inhalative**	**combined**
Exposure of pigs or cattle (maintenance) (Tier 2)	0.42	0.15	0.57
Exposure of cattle (fattening) (Tier 2)	0.29	0.02	0.31
Exposure of hens (Tier 2)	0.19	9.4	9.59
Exposure of goose (Tier 2)	0.1	2.98	3.08
Exposure of turkey (Tier 2)	0.14	2.98	3.12

[1] Disregarding oral absorption of 100%, the respective external exposure value is the same in this case.

Dietary exposure of food/feeding stuff in areas were food is prepared, like in restaurants or snack bars, or in food processing industry (e.g. through absorption of Muscalure from the air) is not assessed due to lack of data. Exposure of live stock animals in stables is described above.

6 Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC, SANCO/4145/2000 – final, 2002

2.1.5.4. Risk characterisation

The tier 1 primary exposure estimates (for application of the product) are below the short term AEL of 0.57 mg/kg bw/day that is based on intake rates of the structurally related higher-mono-alkenes (C17:1- C30:1) as natural food component of various sources like apples, citrus-juices, honey, olive- and hazelnut-oil.

The tier 2 secondary exposure estimates (for sojourning in in-use areas) are below the long term AEL of 0.024 mg/kg bw/day that is based on the "Threshold of Toxicological Concern" of 1800 µg/day (as supported e.g. by ILSI 2005, International Life Sciences Institute) and the long term intake rates of the structurally related higher-mono-alkenes (C17:1- C30:1) as natural food component.

The risk for dermal sensitization may be considered acceptable, since no product classification is necessary with contents of sensitizers below 1%. However, in order to protect already sensitized humans and in order to further reduce the risk for induction of skin sensitization dermal exposure shall be minimized. The Regulation for Classification, Labelling and Packaging (EC No 1272/2008) foresees the application of the hazard statement "EUH208 – contains Muscalure - may produce allergic reaction". Furthermore the label"P262 - Do not get in eyes, on skin, or on clothing"/"S24 - Avoid contact with skin" shall be applied. Dermal exposure is only to be expected from primary exposure during application of the product.

The health risk for pigs, cattle and poultry was estimated based on the human short term AEL and showed that risk was estimated to be acceptable for cattle and pigs, but not for poultry. A refined risk assessment for farm animals may be required at product authorisation stage.

No dietary risk assessment was submitted by the applicant. Oral exposure estimates of farm animals result above the actually proposed dietary risk assessment trigger value of 0.004 mg/kg bw. No acceptable data on analytic methods and exposure of food/feeding stuff were provided. Therefore for products containing cis-Tricos-9-ene that may lead to residues in food or feed, at product authorisation stage Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded. Respective analytic methods may also be required.

2.1.6. Environmental Risk Assessment

The evaluation was carried out under the consideration of the Guidance for waiving of data requirements for pheromones7. As stated in the Guidance sufficient information has to be provided to enable the evaluation of any risk arising to the environment from the use of this pheromone. However due to the intended indoor use and highly target specific mode of action reduced data requirements were accepted and no quantitative risk characterization for the environment was performed.

2.1.6.1. Fate and distribution in the environment

Based on model estimations on ready biodegradability and on its role in intraspecies communication it can be concluded that Muscalure will dissipate in environmental compartments due to volatilisation and biodegradation.

Abiotic degradation due to hydrolysis and photolysis in water was not investigated. From its UV/VIS absorption spectrum its susceptibility for photolytic breakdown can be considered as low.

Muscalure is decomposed in the atmosphere by photooxidation with half-lives of 4.7 hours by OH-radicals and of 2.1 hours by ozone radicals. Because of degradation and physico-chemical properties no abiotic effects on the atmospheric environment are likely.

The modelled high log Koc indicated strong adsorption to solid surfaces in soil, sediment, suspended matter and sludge. Regarding accumulation model calculations with different QSARs based on the log Kow (>8.2) results are contradictory. Based on negligible exposure Muscalure is not expected to accumulate on biota.

2.1.6.2. Effects assessment

The active substance, Muscalure is a sex pheromone, which is released by flies to attract male and female adults of the species *Musca domestica*. The pheromone itself does not have any adverse effects on the target organisms but modifies its behaviour.

Aquatic ecotoxicity studies on Muscalure were performed on fish and daphnids. No toxic effects up and above the solubility limit of the active substance were identified. The effect at the highest test concentrations on daphnids was associated with physical interactions/ impairments on the tested organisms. Acute toxicity to terrestrial mammals is considered to be low. Toxicity studies on birds suggest no acute and dietary toxicity, however indications exists for avian reproductive effects at low levels. However exposure estimates for farm animals are even lower.

The topic of parasitoid attraction to Muscalure should be systematically addressed in the future, because to date parasitoid bycatches have not been thoroughly investigated.

7 Guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC, http://ecb.jrc.ec.europa.eu/biocides/. OECD Monograph 12 (OECD ENV/JM/MONO(2001)12) was taken into consideration for the development of this guidance.

2.1.6.3. PBT assessment

Persistence:

There are no indications that Muscalure is persistent in environmental compartments. Model estimations suggest that Muscalure is degradable in environmental matrices by either abiotic or biotic processes.

The P-criterion is not met.

Bioaccumulation:

Log $BCF_{fish} \geq 2.9$

The B-criterion is probably met though it is unlikely that Muscalure will bioaccumulate in aquatic species.

Toxicity:

Based on acute toxicity data on fish and daphnids no indication exists that the chronic NOEC of Muscalure is <0.01 mg/L.

No specific tests for potential endocrine disruption and carcinogenicity were carried out.

From the available genotoxicity studies and consideration of potential effects and exposure as summarized in chapter 2.2.2.2 there is no concern for endocrine disruption or for CMR effects. The T-criterion is therefore not met.

Conclusion: Muscalure does not meet the PBT criteria.

2.1.6.4. Exposure assessment

The active substance is used in traps and small glue strips that capture flies by physical means. The application rate is 1.25 mg a.s/m^2 floor and the total amount in a single trap is up to 100 g granule corresponding to 250 mg Muscalure which is released by slow diffusion from the granule over a period of approximately 4 to 6 weeks. Exposure to all environmental compartments is considered to be insignificant. Therefore no calculation of the predicted environmental concentrations (PECs) according to the Technical Guidance Document on Risk Assessment (European Commission, 2003) is provided.

2.1.6.5. Risk characterization

According to the Guidance for waiving of data requirements for pheromones8 an environmental concentration below natural emissions is safe for non-target species. As the exposure of the aquatic and terrestrial compartment during indoor usage is negligible, for these compartments a risk characterisation is not performed. Also no predictable risk for the air compartment could be identified based on the exposure and physico-chemical properties. These are also reasons why no unacceptable effects on surface and groundwater as such and for the abstraction of drinking water are likely.

2.1.7. List of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3. DECISION

3.1. Background to the Decision

On the basis of the proposed and supported uses and the evaluation conducted as summarised in this assessment report, it can be concluded that *cis*-Tricos-9-ene (Muscalure) fulfils under the conditions listed in chapter 2.2 the requirements laid down in Article 5 (1) (b), (c), and (d) of Directive 98/8/EC. Muscalure is proposed to be included in Annex I of the Directive.

3.2. Decision regarding Inclusion in Annex I

The active substance *cis*-Tricos-9-ene shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type 19 (Repellents and attractants), subject to the following specific provisions:

Common names:	*cis*-Tricos-9-ene (Muscalure)
IUPAC name:	*cis*-Tricos-9-ene; (Z)-Tricos-9-ene
CAS No.:	27519-02-4
EC No.:	248-505-7
Minimum degree of purity of the a.s.:	80.1% w/w
Product types:	Repellents and attractants (product-type 19)

8 Guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC, http://ecb.jrc.ec.europa.eu/biocides/. OECD Monograph 12 (OECD ENV/JM/MONO(2001)12) was taken into consideration for the development of this guidance.

Specific provisions:

When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment.

For products containing *cis*-Tricos-9-ene that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.

3.3. Elements to be taken into account by Member States when authorising products

a) The analytical method for quantification of the active substance in the formulation (Denka Flylure) was not performed with the described product. A validated analytical determination for the described product should be submitted for product authorisation.

b) No comprehensive environmental risk assessment was carried out since only indoor use was considered and exposure to all environmental compartments is considered to be insignificant.

c) No dietary risk assessment was submitted by the applicant.

Oral exposure estimates of farm animals result above the actually proposed dietary risk assessment trigger value of 0.004 mg/kg bw

Inhalative exposure of farm animals kept in stables / animal houses, where Denka Flylure is used as intended, was estimated only as tier 1 without refinements and acceptable risk was only shown for cattle and pigs, not for poultry.

No acceptable data on analytic methods and exposure of food/feeding stuff were provided

Therefore for products containing cis-Tricos-9-ene that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded. In addition a refined risk assessment for farm animals and data on analytic methods of food/feeding stuff, as appropriate – may therefore be required at product authorization stage.

d) The representative product contains the active substance in a concentration of 0.25%. Products with active substance concentrations leading to classification as skin sensitising (≥1%w/w) must not be put on the market for general public use.

Justification: Classification for skin sensitization would trigger the need for the P280 phrase (Wear protective gloves/protective clothing/eye protection/face protection). General public is not expected to wear personal protective equipment.

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the inclusion of Muscalure in Annex I to Directive 98/8/EC.

3.5. Updating this Assessment Report

This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of Muscalure in Annex I to the Directive.

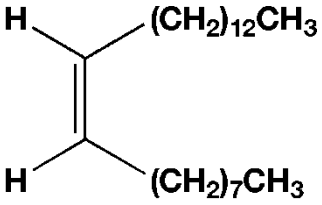
For the update of the assessment report after 10 years information concerning the parasitoid attraction to Muscalure should be provided.

APPENDIX I - LIST OF END POINTS

Chapter 1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	Muscalure (ESA name; there is no ISO common name for this substance)
Function (*e.g.* fungicide)	Fly attractant (pheromone)
Rapporteur Member State	Austria

Identity (Annex IIA, point II.)

Chemical name (IUPAC)	*cis*-Tricos-9-ene; (Z)-Tricos-9-ene
Chemical name (CA)	(9*Z*)-9-tricosene
CAS No	27519-02-4
EC No	248-505-7
Other substance No.	n.a.
Minimum purity of the active substance as manufactured (g/kg or g/l)	801 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	No relevant impurites
Molecular formula	$C_{23}H_{46}$
Molecular mass	322.6
Structural formula	

Physical and chemical properties (Annex IIA, point III., unless otherwise indicated)

Melting point (state purity)	-2°C at 1009 hPa (purity 96.0%)
Boiling point (state purity)	380°C at 1009 hPa (purity 96.0%)
Temperature of decomposition	No decomposition up to the boiling point
Appearance (state purity)	Clear colourless to light yellow liquid (Munsell 5Y 9/4) (purity 85-98%)
Relative density (state purity)	Density: 0.803 kg/L at 20°C (purity 98.2% Muscalure)
Surface tension	Not required (water solubility < 1 mg/L)
Vapour pressure (in Pa, state temperature)	6.4 x 10^{-2} Pa (20°C) 0.119 Pa (25°C)
Henry's law constant (Pa m^3 mol^{-1})	Calculated: 2.95 x 10^3 Pa x m^3/mol
Solubility in water (g/l or mg/l, state temperature)	pH 4: < 7 x 10^{-6} g/L (20°C) pH 7: < 7 x 10^{-6} g/L (20°C) pH 10: < 7 x 10^{-6} g/L (20°C) (no pH dependency expected)
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	Result: Solubility (g/L) Hexane: 465.3 g/L; Toluene: 608.8 g/L Dichlormethane: 932.3 g/L ; Methylal: 431.2 g/L Methanol: 161.3 g/L; Propyleneglycol: 212.2 g/L Acetone: 159.7 g/L; Acetonitril: 157.2 g/L Dimethylsulfoxide : 220.8 g/L
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	Not required, because the a.s. as manufactured does not contain any organic solvent.
Partition coefficient (log P_{OW}) (state temperature)	pH 4: >8.2 (20 °C) pH 7: >8.2 (20 °C) pH 10: >8.2 (20 °C) (no pH dependency expected)
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	Muscalure has no acid or basic groups and therefore no pKa value
Flammability	Pyrophoric properties: The molecular structures of Muscalure technical do not contain any chemical groups that might lead to spontaneous ignition within a short time after coming into contact with air at 20°C Auto-ignition temperature: 250°C The flashpoint of Muscalure is 161.5°C.
Explosive properties	The molecular structures of the test substance do not contain any chemical instable or highly energetic groups that might lead to explosions.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	No peak maxima at wavelengths ≥290 nm

Classification and proposed labelling (Annex IIA, point IX.)

with regard to physical/chemical data	Not applicable
with regard to toxicological data	<u>According to Dir. 67/548/EC:</u> Xi – irritant; R43 May cause sensitisation by skin contact S36/37 – Wear suitable protective clothing and gloves <u>According to Reg. 1272/2008/EC:</u> Skin sensitization, hazard category I; H317: May cause an allergic skin reaction; P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves/protective clothing/eye protection/face protection P302+P352: IF ON SKIN: Wash with plenty of soap and water. P333 + P313: If skin irritation or rash occurs, get medical advice/attention P363 Wash contaminated clothing before reuse. P501 Dispose of contents/container to...
with regard to fate and behaviour data	Not applicable
with regard to ecotoxicological data	Not applicable

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	GC/FID method
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	GC/FID method

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	Not required according to TNsG on data requirements (Guidance for Waiving of Data Requirements for Pheromones)
Air (principle of method and LOQ) (Annex IIA, point 4.2)	Not required according to TNsG on data requirements (Guidance for Waiving of Data Requirements for Pheromones)

Water (principle of method and LOQ) (Annex IIA, point 4.2)	Not required according to TNsG on data requirements (Guidance for Waiving of Data Requirements for Pheromones)
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	Not required accord. chapter 2 of TNsG on Data Requirements.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not required as long as use is restricted from food and feed arias.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not required as long as use is restricted from food and feed areas and the biocidal product has to remain out of reach of livestock animals.

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

Rate and extent of oral absorption:	100% (assumption, since no studies available)
Rate and extent of dermal absorption:	10% (no study, value based on modelling)
Distribution: Potential for accumulation: Rate and extent of excretion: Toxicologically significant metabolite	The available information on the toxicology of muscalure does not give rise to concern for human health and the human exposure to muscalure resulting form the use of the attractant is very low. Therefore no studies of metabolism and kinetics were submitted or evaluated.

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	> 5000 mg/kg bw
Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	> 5710 mg/m^3
Skin irritation	Not irritating
Eye irritation	Not irritating
Skin sensitization (test method used and result)	Sensitizing (GPMT, 7/20 animals responded positive with an intradermal induction concentration of 5%)

Repeated dose toxicity (Annex IIA, point 6.3)

Species/ target / critical effect Lowest relevant oral NOAEL / LOAEL Lowest relevant dermal NOAEL / LOAEL Lowest relevant inhalation NOAEL / LOAEL	No repeated dose toxicity tests were submitted or evaluated.

Genotoxicity (Annex IIA, point 6.6)	Ames test ± S9 mix: negative In vitro chromosomal aberration test with CHO cells ± S9 mix: negative (Q)SARs from OECD toolbox negative

Carcinogenicity (Annex IIA, point 6.4)	
Species/type of tumour lowest dose with tumours	No carcinogenicity tests were submitted and evaluated.

Reproductive toxicity (Annex IIA, point 6.8)	
Species/ Reproduction target / critical effect Lowest relevant reproductive NOAEL / LOAEL Species/Developmental target / critical effect Lowest relevant developmental NOAEL / LOAEL	No reproductive toxicity tests were submitted or evaluated.

Neurotoxicity / Delayed neurotoxicity (Annex IIIA, point VI.1)	
Species/ target/critical effect	Not applicable
Lowest relevant developmental NOAEL / LOAEL.	

Other toxicological studies (Annex IIIA, VI/XI)	
.....	Not applicable

Medical data (Annex IIA, point 6.9)	
.....	Applicable if available; not available.

Summary (Annex IIA, point 6.10)	Value	Study
AEL short term	> 0.57 mg/kg bw day	Derived from estimated short term human intake of higher Mono-Alkenes (C17:1 to C30:1) as natural food components
AEL medium term	>0.024 mg/kg bw day	No data for AEL medium term derivation available. AEL long term may be used as conservative surrogate.

AEL long term	>0.024 mg/kg bw day	Derived from estimated long term human intake of higher Mono-Alkenes (C17:1 to C30:1) as natural food components and TTC approach for substances without structural alerts.

Acceptable exposure scenarios (including method of calculation)

Professional users	**Primary exposure:** Inhalative: Assumptions: whole amount of active substance is released during 28 days, 30 min. per day for the preparation resp. replacement of several traps, uptake of the whole released amount, handling and presence of 0.4 kg biocidal product (max. package amount), 60 kg body weight, 100% inhalative absorption Dermal: Assumptions: hand's skin is totally covered with the biocidal product (840 cm^2), 100% dermal absorption, layer on the skin is 0.01cm thick, 60 kg body weight Oral: Not relevant
Non-professional users	**Primary exposure:** See Professional users
Indirect exposure as a result of use	**Secondary exposure:** Inhalative: Assumptions: whole amount of active substance is released during 28 days, residence time 18 hours per day, uptake of the whole released amount, presence of 0.1 kg biocidal product (1 trap), 100% inhalative absorption, ventilation rate of 0.6 h^{-1}, inhalation rate 1.25 m^3/h (adult) resp. 0.2 m^3/h (infant), body weight 60 kg (adult) resp. 10 kg (infant) Oral and dermal: Unattended child (15 kg bw) takes up a whole trap, however this scenario is not acceptable and is considered only to occur due to improper application (accidental). **Aggregate exposure:** Adult (60kg bw) primarily exposed at application of b.p. and secondarily exposed due to evaporation of a.s. **Exposure of farm animals:** estimated daily uptake is calculated according to ETE = (FIR / bw) * C * AV * PT * PD (mg/kg bw/day); acceptable for pigs or cattle, not acceptable for hens, goose or turkey; Refinement for poultry (average amount of a.s. available per bird) is acceptable. **Dietary exposure:** No acceptable scenario; use shall be restricted from food and feed areas and remain out of reach of livestock unless new data on dietary exposure are provided.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water (Annex IIA, point 7.6, IIIA, point XII.2.1, 2.2)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH_____: Not determined; Muscalure doesn't contain hydrolysable functional groups.
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Not determined
Readily biodegradable (yes/no)	Yes (QSAR estimation, BIOWIN v4.10)
Biodegradation in seawater	Not determined
Non-extractable residues	Not determined
Distribution in water / sediment systems (active substance)	Not determined
Distribution in water / sediment systems (metabolites)	Not determined

Route and rate of degradation in soil (Annex IIIA, point VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

Mineralization (aerobic)	Not determined
Laboratory studies (range or median, with number of measurements, with regression coefficient)	
Field studies (state location, range or median with number of measurements)	
Anaerobic degradation	
Soil photolysis	
Non-extractable residues	
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	
Soil accumulation and plateau concentration	

Adsorption/desorption (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2)

Log Koc	6.7
pH dependence (yes / no) (if yes type of dependence)	No

Fate and behaviour in air (Annex IIIA, point VII.3, VII.5)

Direct photolysis in air	Not determined
Quantum yield of direct photolysis	Not determined
Photo-oxidative degradation in air	Half-life: 4.7h by OH-radicals; 2.1h by ozone radicals
Volatilization	cf. Physical and chemical properties: vapour pressure and Henry's law constant

Monitoring data, if available (Annex VI, para. 44)

Soil (indicate location and type of study)	Not determined
Surface water (indicate location and type of study)	
Ground water (indicate location and type of study)	
Air (indicate location and type of study)	

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Species	Time-scale	Endpoint	Toxicity*
Fish			
Oncorhynchus mykiss	96 h	EC50	>100 mg/L (nominal) >119 mg/L (mean, measured)
Invertebrates			
Daphnia magna	48 h	EC50	>10 mg/L (nominal) >1.1 mg/L (mean, measured)
*Please note that the suggested values were above the solubility in water of pH 7: < 7 x 10^{-6} g/L (20°C)			
Algae, Microorganisms			
Not determined			

Effects on earthworms or other soil non-target organisms

Acute toxicity to ……..	Not determined

(Annex IIIA, point XIII.3.2)	
Reproductive toxicity to …… (Annex IIIA, point XIII.3.2)	Not determined

Effects on soil micro-organisms (Annex IIA, point 7.4)

Nitrogen mineralization	Not determined
Carbon mineralization	Not determined

Effects on terrestrial vertebrates

Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	LD50 >5000 mg/kg, oral exposure LC50 >5710 mg/m^3, inhalation exposure
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	NOEC = 2000 mg a.s./kg bw
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	NOAEL = 5000 mg a.s./kg diet
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	Not determined

Effects on honeybees (Annex IIIA, point XIII.3.1)

Acute oral toxicity	Not determined
Acute contact toxicity	Not determined

Effects on other beneficial arthropods (Annex IIIA, point XIII.3.1)

Acute oral toxicity	Not determined
Acute contact toxicity	Not determined
Acute toxicity to ……..	Not determined

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor (BCF)	Log BCF_{fish}: 4.3 (TGD estimation, "modified Connell equation") Log BCF_{fish}: 2.84 (BCFBAFWIN v3.00)
Depration time (DT_{50}) (DT_{90})	Not determined
Level of metabolites (%) in organisms accounting for > 10 % of residues	Not determined

Chapter 6: Other End Points Not relevant

APPENDIX II: LIST OF INTENDED USES

The acceptable intended use is given in table Appendix II-1.

Table Appendix II-1: Acceptable intended uses of the biocidal product "Denka Flylure"

Product Type		PT 19
Formu-lation	**Type**	Granules used in traps (electrocution traps; glue traps; glue strips)
	Conc. of a.s.	0.25%w/w a.s. in granules
Field of use envisaged, categories of users		**Electrocution traps:** use in stables[1]: professional use **Glue traps:** use in stables[1]: professional use; **Small glue strips:** in-house use: professional use and use by general public
Organisms to be controlled		Housefly (Musca domestica)
Likely amount at which the a.s. will be used (all fields of use envisaged)	**Method of application**	**Electrocution traps and glue traps:** One standard trap is to be filled with 40 to 100 grams of granules. **Granules put on small glue strips:** The granules are poured onto the glue strips and the strips are hung up.
	Applied amount of product	100 g granules per 200 m^2 floor area (roughly corresponding to 600 m^3 room volume or 0.42 mg a.s./m^3)
	Application rate	1.25 mg a.s./m^2 floor area
	Number treatments /year	~ 9 to 13 times per year. Glue strips: After 4-6 weeks the granules and the glue strips are removed and a new strip can be used (if needed). Electrocution traps and glue traps: After 4-6 weeks the granules are removed and the trap can be filled again.
	Typical size of application area	Not specified.

[1] However, the traps have to remain out of reach of livestock, see chapter 3.3 "Elements to be taken into account by Member States when authorising products" of this document.

APPENDIX III: LIST OF STUDIES

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "yes" in the "Data Protection Claimed" column of the table below. These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

Reference list A: sorted by section number

Section point/ reference number	**Year**	**Title** **Testing Facility** **Owner / Source (where different from owner)** **Report No** **GLP or GEP status (where relevant)** **Published or not**	**Data protection claimed** **yes/no**	**Owner**
A 2.10/01	2004	Decrease of muscalure in Flybait at room temperatures in course of time. Denka report. No GLP Unpublished	Y	Denka Int.
A 2.10/02	2006	Flylure granulate production process Denka report. No GLP Unpublished	Y	Denka Int.
A 2.10/03	2007	Document in response to request from Austria; ENVIRON, project no. DI-MDO-20070050 No GLP Unpublished	Y	Denka Int.
A 3.1.1/ 01 A 3.1.2/ 02	2006	Determination of the melting and boiling temperature of muscalure by differential scanning calorimetry. NOTOX B.V. Project 450438. GLP Unpublished	Y	Denka Int.
A 3.1.1/ 01 A 3.1.2/ 02	2006	Determination of the melting and boiling temperature of muscalure technical by differential scanning calorimetry. NOTOX B.V. Project 450585. GLP Unpublished	Y	Denka Int.

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 3.1.3	2006	Determination of the density (liquid) of muscalure. NOTOX B.V. Project 450449. GLP Unpublished	Y	Denka Int.
A 3.2	2006	Determination of the vapour pressure of muscalure by the static method. Project 450451. NOTOX B.V. Project 450451. GLP Unpublished	Y	Denka Int.
A 3.2.1	2006	Calculation of Henry's law constant of muscalure. NOTOX B.V. Project 450462. GLP Unpublished	Y	Denka Int.
A 3.3/01	2006	Determination of appearance of muscalure. NOTOX B.V. Project 450473. GLP Unpublished	Y	Denka Int.
A 3.3/02	2006	Determination of appearance of muscalure technical.. NOTOX B.V. Project 450574 GLP Unpublished	Y	Denka Int.
A 3.3/03	2006	Sporadic colouration of technical muscalure Denka report. No GLP Unpublished	Y	Denka Int.
A 3.4/01	2006	Determination of the UV-VIS absorption spectra of muscalure. NOTOX B.V. Project 450506. GLP Unpublished	Y	Denka Int.
A 3.4/02	2006	Determination of the IR absorption spectra of muscalure. NOTOX B.V. Project 450484. GLP Unpublished	Y	Denka Int.
A 3.4/03	2006	Determination of the 1H NMR spectrum of muscalure. NOTOX B.V. Project 450495. GLP Unpublished	Y	Denka Int.

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 3.4/04	2005	Determination of the mass spectrum of muscalure. NOTOX B.V. Project 450541. GLP Unpublished	Y	Denka Int.
A 3.5	2006	Determination of the water solubility of muscalure at 3 pH values. NOTOX B.V. Project 450517. GLP Unpublished	Y	Denka Int.
A 3.6	2006	Determination of the dissociation constant(s) of muscalure in water. NOTOX B.V. Project 450552. GLP Unpublished	Y	Denka Int.
A 3.7	2006	Solubility in organic solvents by room temperature of Muscalure Technical No GLP Unpublished	Y	Denka Int.
A 3.9	2006	Determination of the partition coefficient (n-octanol/water) of muscalure at 3 pH values. NOTOX B.V. Project 450528. GLP Unpublished	Y	Denka Int.
A 3.10	2006	The housefly pheromone muscalure as biocidal active substance. Statement on the thermal stability of cis-tricos-9-ene (muscalure), ENVIRON Nethetherlands B.V. Report no. Di-mbd-20060050 No GLP (Statement) Unpublished	Y	Denka Int.
A 3.11/01	2006	Statement on the pyrophoric properties of muscalure technical. NOTOX B.V. Project 450596. GLP Unpublished	Y	Denka Int.
A 3.11/02	2006	Determination of the auto-ignition temperature (liquid) of muscalure technical. NOTOX B.V. Project 450607. GLP Unpublished	Y	Denka Int.

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 3.12	2006	Determination of the flash-point of muscalure technical. NOTOX B.V. Project 450618. GLP Unpublished	Y	Denka Int.
A 3.14	2006	Determination of the viscosity of muscalure technical. NOTOX B.V. Project 450664. GLP Unpublished	Y	Denka Int.
A 3.15	2006	Statement on the explosive properties of muscalure technical. NOTOX B.V. Project 450629. GLP Unpublished	Y	Denka Int.
A 3.16	2006	Determination of the oxidizing properties of muscalure technical. NOTOX B.V. Project 450631. GLP Unpublished	Y	Denka Int.
A 3.17/01	2006	Determination of the corrosion characteristics of muscalure technical. NOTOX B.V. Project 450642. GLP Unpublished	Y	Denka Int.
A 3.17/02	2006	Details on packaging No GLP Unpublished	Y	Denka Int.
A 4.1/01	2011	5-Batch Analysis of Muscalure; Final Report; BioGenius, Study No. Mo4176 GLP Unpublished	Y	Denka Int.
A 4.1/02	2011	Validation of Method MV038: GC-Determination of (Z)-9-Tricosene and Corresponding Impurities in Z-9-Tricosene (Technical Material); BioGenius, Study No. Mo4066 GLP Unpublished	Y	Denka Int.

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 4.2c	2006	Development and validation of an analytical method for the analysis of Z-9-Tricosene (active ingredient in Muscalure) in double distilled water. NOTOX B.V., Project no. 450539 GLP Unpublished	Y	Denka Int.
A 5.1.1	2001	Pheromones of the housefly. Dissertation, State University Groningen, 26 June 2001. ISBN: 90-367-1440-0 No GLP Published	N	
A 5.1.2	1971	Sex attractant pheromones of the house fly: isolation, identification and synthesis. Science, vol. 174 (1971), 76-78 No GLP Published	N	
A 5.1.3	1973	Field evaluations of (Z)-9-tricosene, a sex attractant pheromone of the house fly. Environmental Entomology, vol. 2 (1973), 555-559 No GLP Published	N	
A 5.1.4	1989	Biological activity of the synthetic hydrocarbon mixtures of cuticular components of the female housefly. J. Chem. Education, vol. 15 (1989), 1475-1490 No GLP Published	N	
A 5.1.5	1980	Responses of male house flies to muscalure and to combinations of hydrocarbons with and without muscalure. Environmental Entomology, vol. 9 (1980), 605-606 No GLP Published	N	
A 5.1.6	1981	Onderzoek naar de toepasbaarheid van feromonen bij de bestrijding van de huisvlieg (Musca domestica) onder praktijkomstandigheden. (Translation: Research into the applicability of pheromones in the control of houseflies (Musca domestica) in practice). TNO Maatschappelijke Technologie. Report no. CL 81/152. No GEP Unpublished	Y	Denka Int.

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
Translation of A 5.1.6	1981	Onderzoek naar de toepasbaarheid van feromonen bij de bestrijding van de huisvlieg (Musca domestica) onder praktijkomstandigheden. (Translation: Research into the applicability of pheromones in the control of houseflies (Musca domestica) in practice). TNO Maatschappelijke Technologie. Report no. CL 81/152. No GEP Unpublished	Y	Denka Int.
A 5.1.7	1983	Onderzoek naar de toepasbaarheid van feromonen bij de bestrijding van de huisvlieg (Musca domestica) onder praktijkomstandigheden. (Translation: Research into the applicability of pheromones in the control of houseflies (Musca domestica) in practice). TNO Maatschappelijke Technologie. Report no. CL 82/207. No GEP Unpublished	Y	Denka Int.
Translation of A 5.1.7	1983	Onderzoek naar de toepasbaarheid van feromonen bij de bestrijding van de huisvlieg (Musca domestica) onder praktijkomstandigheden. (Translation: Research into the applicability of pheromones in the control of houseflies (Musca domestica) in practice). TNO Maatschappelijke Technologie. Report no. CL 82/207. No GEP Unpublished	Y	Denka Int.
A 5.1.8	1982	Onderzoek naar de toepasbaarheid van feromonen bij de bestrijding van de huisvlieg (Musca domestica) onder praktijkomstandigheden. (Translation: Research into the applicability of pheromones in the control of houseflies (Musca domestica) in practice). TNO Maatschappelijke Technologie. Report no. CL 82/115. No GEP Unpublished	Y	Denka Int.
Translation of A 5.1.8	1982	Onderzoek naar de toepasbaarheid van feromonen bij de bestrijding van de huisvlieg (Musca domestica) onder praktijkomstandigheden. (Translation: Research into the applicability of pheromones in the control of houseflies (Musca domestica) in practice). TNO Maatschappelijke Technologie. Report no. CL 82/115. No GEP Unpublished	Y	Denka Int.

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 5.1.9	1984 a	Onderzoek naar de bruikbaarheid van de combinatie elektrocutieval/UV licht/muscalure bij de bestrijding van de huisvlieg (Musca domestica) in pluimveebedrijven. (Translation: Research into the usefulness of the combination electric grid/UV light/muscalure in the control of houseflies (Musca domestica) in poultry farms). TNO Maatschappelijke Technologie. Report no. R 84/15. No GEP Unpublished	Y	Denka Int.
Translation of A 5.1.9	1984 a	Onderzoek naar de bruikbaarheid van de combinatie elektrocutieval/UV licht/muscalure bij de bestrijding van de huisvlieg (Musca domestica) in pluimveebedrijven. (Translation: Research into the usefulness of the combination electric grid/UV light/muscalure in the control of houseflies (Musca domestica) in poultry farms). TNO Maatschappelijke Technologie. Report no. R 84/15. No GEP Unpublished	Y	Denka Int.
A 5.1.10	1984 b	Een oriënterend onderzoek naar de bruikbaarheid van muscalure in aerosolvorm in combinatie met een elecrocutieval/UV-licht bij de bestrijding van de huisvlieg (Musca domestica). (Translation: A pilot research into the usefulness of muscalure as an aerosol in combination with an electric grid/UV light for the control of the house fly (Musca domestica)). TNO Maatschappelijke Technologie. Report no. R 84/177. No GEP Unpublished	Y	Denka Int.
Translation of A 5.1.10	1984 b	Een oriënterend onderzoek naar de bruikbaarheid van muscalure in aerosolvorm in combinatie met een elecrocutieval/UV-licht bij de bestrijding van de huisvlieg (Musca domestica). (Translation: A pilot research into the usefulness of muscalure as an aerosol in combination with an electric grid/UV light for the control of the house fly (Musca domestica)). TNO Maatschappelijke Technologie. Report no. R 84/177. No GEP Unpublished	Y	Denka Int.

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 5.1.11	1985	A pilot research into the usefulness of technical muscalure in combination with electric grid traps in the control of the house fly (Musca domestica). TNO Technology for Society. Report no. R85/286. No GEP Unpublished	Y	Denka Int.
A 5.1.12	1995	Evaluation of the attractant and insecticidal efficacy of various fly baits. Bayer AG. 15-16 June 1995. No GLP Unpublished	Y	Denka Int.
A 5.1.13	1995	Evaluation of the attractant and insecticidal efficacy of various fly baits. Bayer AG. 6-7 July 1995 No GLP Unpublished	Y	Denka Int.
A 5.1.14	1993	Fly-bait trials. Spain. KenoGard No GEP Unpublished	Y	Denka Int.
A 5.1.15	1993	Assai comparative en laboratoire du pouvoir attractif sur mouches de quatre specialités insecticides a base de muscamone. April-May 1993. Pitman-Moore France No GEP Unpublished	Y	Denka Int.
A 5.1.16	1990	Bekaempfung der adulten der Hausfliege im Kuhstall. Plüss-Staufer AG. Study no. IST 01 90. Unpublished	Y	Denka Int.
A 5.1.17	1989	Trial report 1989 Flybait. S.I.A.P.A. Research & Experimental Centre No GEP Unpublished	Y	Denka Int.
A 5.1.18	1990	1990 Trial report Flybait. S.I.A.P.A. Research & Experimental Centre No GEP Unpublished	Y	Denka Int.

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 5.1.19	1996	Field evaluation of triflumuron and methomyl for control of the housefly Musca domestica. Danish Pest Infestation Laboratory. Report no. 4-1996. No GLP Unpublished	Y	Denka Int.
A 5.1.20	1994	Efficacy of Lurectron-baits (original Lurectron and red experimental formulations) against the housefly (Musca domestica). Bayer BG Animal Health. Report no. 348. No GLP Unpublished	Y	Denka Int.
A 5.1.21	1990	Evaluation of insecticidal baits against Houseflies Musca domestica L. Central Science Laboratory. Report no. C/88/0646. No GLP Unpublished	Y	Denka Int.
A 5.1.22	1991	Lurectron granules. Test report 1991. Insecticidal treatment of stables (House fly - Musca domestica). English translation of: Lurectron granulés. Experimentation 1991. Traitement insecticide des bâtimants d'élevage (Mouche domestique - Musca domestica). No GEP Société Somolog-France. Unpublished	Y	Denka Int.
A 5.1.23	1992	Evaluation of methomyl bait plus Muscamone fly attractant against Musca domestica L. in a chicken farm in Malaysia. Jpn. J. Zool., vol. 43 (1992), 287-289. No GLP Published	N	
A 5.1.24	1986	Köder zur Fliegenbekämpfung – vergleichende Untersuchungen in Labor und Stall Angewandte Zoologie 1986(4), 481-510 No GLP Published	N	
A 5.1.25	1998	An evaluation of (Z)-9-tricosene and food odours for attracting house flies, Musca domestica, to baited targets in deep-pit poultry units. Entomologia Experimentalis et Applicata, vol. 89 (1998), 183-192 No GLP Published	N	

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 5.1.26	1974	Evaluation of (Z)-9-tricosene for attractancy for Musca domestica in the field The Florida Entomologist, vol. 57 (1974), 137-140 No GLP Published	N	
A 5.1.27	2008	Room test to determine the attractiveness of different concentrations of Flylure (Z-9 tricosene) to male and female adult houseflies, Musca domestica. I2LResearch Ltd. Report no. 08/19 No GLP Unpublished	Y	Denka Int.
A 5.1.28	2008	Effects of mucalure on female houseflies and housefly parasitoids. ENVIRON Netherlands BV No GLP Unpublished	Y	Denka Int.
A 5.1.29	1998	Evaluation of three (Z)-9-tricosene formulations for control of Musca domestica (Diptera: Muscidae) in caged-layer poultry units. Journal of Economic Entomology 91 (1998b) 915-922. No GLP Published	N	
A 5.1.30	2004	Evaluation of (Z)-9-tricosene baited targets for control of the housefly (Musca domestica) in outdoor situations. JEN 128 (2004) 478-482. No GLP Published	N	
A 5.1.31	2003	Effect of age and sex on the sensitivity of antennal and palpal olfactory cells of houseflies. Entomologia Experimentalis et Applicata 106 (2003) 45-51. No GLP Published	N	
A 5.1.32	1990	Attractant composition for synanthropic flies. United States Patent 5008107. 1990. No GLP Published	N	

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 5.1.33	1974	Evaluation of (Z)-9-tricosene for attractancy for Musca domestica in the field. The Florida Entomologist 57 (1974) 136-140. No GLP Published	N	
A 5.1.34	1975	Effect of muscalure on house fly traps of different color and location in poultry houses. Journal of the Georgia Entomological Society 10 (1975) 165-168. No GLP Published	N	
A 6.1.1	1990 a	Determination of the acute oral toxicity of the compound “MUSCALURE” in rats. TNO-CIVO. Report no. V 90.356. GLP Unpublished	Y	Denka Int.
A 6.1.2	1990 b	Determination of the acute dermal toxicity of the compound “MUSCALURE” in rats. TNO-CIVO. Report no. V 90.359. GLP Unpublished	Y	Denka Int.
A 6.1.3	1991	Acute (4-hour) inhalation toxicity study of Muscalure in rats. TNO Nutrition and Food Research. Report no. V 91.375. GLP Unpublished	Y	Denka Int.
A 6.1.4s	1990 a	Primary skin irritation/corrosion study with muscalure in the rabbit (4-hour semi-occlusive application). RCC NOTOX B.V. Project ID 038576. GLP Unpublished	Y	Denka Int.
A 6.1.4e	1990 b	Acute eye irritation/ corrosion study with muscalure in the rabbit. RCC NOTOX B.V. Project ID 038587. GLP Unpublished	Y	Denka Int.
A 6.1.5	1991	Contact hypersensitivity to MUSCALURE in the Albino Guinea Pig (Maximization-Test). RCC NOTOX B.V. Project ID 051637. GLP Unpublished	Y	Denka Int.

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 6.6.1	2006	Evaluation of the mutagenic activity of muscalure technical in the Salmonella typhimurium reverse mutation assay and the Escherichia coli reverse mutation assay (with independent repeat) NOTOX B.V. Project no. 456457 GLP Unpublished	Y	Denka Int.
A 6.6.2	2008	Chromosomal aberration test with Muscalure in cultured Chinese Hamster Ovary (CHO) cells. TNO Quality of Life. Project V7902/02 GLP Unpublished	Y	Denka Int.
A 7.1.1 and A 7.3.1	2006	EPIWIN calculations EPI Suite EPA-SRC 2000 No GLP Unpublished		
A 7.4.1.1	1991 a	The acute toxicity of muscalure to the rainbow trout Salmo gairdneri in a semi-static system. TNO Division of Technology for Society. Report no. R 91/087. GLP Unpublished	Y	Denka Int.
A 7.4.1.2	1991 b	The acute toxicity of muscalure to Daphnia magna. TNO Division of Technology for Society. Report no. R 91/038. GLP Unpublished	Y	Denka Int.
A 7.5.3.1.1	1990 a	Acute oral toxicity study in bobwhite quail with muscalure. Limit. RCC NOTOX B.V. Project ID 038598. GLP Unpublished	Y	Denka Int.
A 7.5.3.1.2	1990 b	5-day dietary toxicity study in bobwhite quail with muscalure. RCC NOTOX B.V. Project ID 039094. GLP Unpublished	Y	Denka Int.

Reference list B: sorted by section number

Section No / Reference No	Year	Title Source Institution; report nr GLP-, GEP-status Published or unpublished	Data Protec-tion	Owner
B 2/01 Confidential	2006	Composition of product confidential Denka BV Not GLP Unpublished	Y	Denka Int.
B 2/02 Confidential	2004	Safety Information confidential Not GLP Unpublished	Y	Denka Int.
B 2/03 Confidential	2006	Details on formulants 1 confidential Not GLP Unpublished	Y	Denka Int.
B 2/04 Confidential	2006	Details on formulants 2 confidential Not GLP Unpublished	Y	Denka Int.
B 3/01	2006	Flylure Granulate Denka BV Not GLP Unpublished	Y	Denka Int.
B 3.6	2008	Determination of bulk density of Denka Flylure Denka BV Not GLP Unpublished	Y	Denka Int.
B 3.7/01	2006	Storage stability: Flylure probe pack study Denka BV Not GLP Unpublished	Y	Denka Int.
B 3.7/02	2006	Details on packaging Not GLP Unpublished	Y	Denka Int.
B 4.1	2002	Determination of the content of muscalure in Quickbayt and Flybait Denka BV Not GLP Unpublished	Y	Denka Int.

Section No / Reference No	Year	Title Source Institution; report nr GLP-, GEP-status Published or unpublished	Data Protec-tion	Owner
B 5.10.2/01	1993a	A preliminary study with Berson electrocution traps and flybait. File no. Berson01. Denka BV Not GLP Unpublished	Y	Denka Int.
B 5.10.2/02	1993b	A trial with Berson electrocution traps and flybait. File no. Berson04. Denka BV Not GLP Unpublished	Y	Denka Int.
B 5.10.2/03	1993 c	Experiments with flyplates, horizontally and vertically placed. Denka BV Not GLP Unpublished	Y	Denka Int.
B 5.10.2/04	1992	Experiment with Denka Flylure Granulate on flyplates. Unpublished Not GLP Unpublished	Y	Denka Int.
B 6.6/01	2004	The Housefly Pheromone Muscalure as Biocidal Active Substance. Statements meant to address Requirements of Directive 98/8/EC. ENVIRON Document DI-MST-20040222 Not GLP (Statement) Unpublished	Y	Denka Int.
B 6.6/02	2006	Muscalure. Emission to indoor and outdoor air. ENVIRON. Document DI-MBD-2006044 Not GLP (Statement) Unpublished	Y	Denka Int.
B 6.6/03	2006	Muscalure as biocidal active substance. Application of the TTC concept and human exposure to muscalure-like compounds. Addendum to Report DI-MST-20040222 (Verberk et al., 2004) ENVIRON. Document 77dimbd-20060049-a.doc Not GLP (Statement) Unpublished	Y	Denka Int.
B 8	2004	Safety data sheet Flylure granules	N	Denka Int.

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Author(s)	Year	Title, Reference	Data protection claimed yes/no	Owner
Barlow S.	2005	Threshold of toxicological concern (TTC) – a tool for assessing substances of unknown toxicity present at low levels in the diet ILSI Monograph; ISBN 1-57881-188-0ILSI Monograph; ISBN 1-57881-188-0	no	
Benitez-Sanchez PL., Leon-Comacho M., Aparicio R.	2003	A comprehensive study of hazelnut oil composition with comparisons to other vegetable oils, particularly olive oil. Eur Food Res Technol 218: 13-19	no	
Bonaga G., Giumanini AG, Grazia G.	1986	Chemical composition of chestnut honey: analysis of the hydrocarbon fraction. J. Agric. Food Chem. 34(2):319-326.	no	
Bortomoleazzi R., Berneo P., izzale L., Conte LS.J	2001	Sesquiterpene, alkene and alkane hydrocarbons in virgin olive oils of different varieties and geographical origins. J. Agric Food Chem. 49(7): 3278-83	no	
Nagy S., Nordby HE.	1971	Comparative long-chain hydrocarbon profiles of orange and tangor juice sacs. Phytochemistry 10(11): 2763-2768	no	
Nagy S., Nordby HE.	1972	Long Chain hydrocarbon profiles of Duncan grapefruit, DAncy mandarin and their hybrids. Lipids 7, No 11: 722-727	no	
Nagy S., Nordby HE.	1972	Saturated and monosaturated long chain hydrocarbon profiles of lipids from orange, grapefruit, mandarin and lemon juice sacs. Lipids 7(19): 666-670	no	
Nagy S., Nordby HE.	1972	Saturated and monosaturated long-chain hydrocarbons of lime juice sacs. Phytochemistry 11 (9): 2865-2869	no	
Nagy S., Nordby HE.	1973	Saturated and mono-unsaturated long-chain hydrocarbon profiles of sweet oranges. Phytochemistry 12(4): 801-805	no	
Nagy S., Nordby HE., Lastinger JC.	1975	Variation in the long-chain hydrocarbon pattern in different tissues of Duncan greapefruit. Phytochemistry 14(11): 2443-2445	no	
Verado G., Pagani E., Geatti P., Martinuzzi P.	2003	A thorough study of the surface of wax of apple fruits. Anal. Bioanal. Chem. 376(5). 659-67.	no	-

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Berlitz, Grosch	1999	Food Chemistry Springer, ISBN 3-540-64692-2	no	
Cravo-Laureau C; Labat C; Joulian C; Matheron R; Hirschler-Réa A.	2007	Desulfatiferula olefinivorans gen. nov., sp. nov., a long-chain n-alkene-degrading, sulfate-reducing bacterium. Int J Syst Evol Microbiol. 2007, Nov; 57(Pt 11):2699-702.	no	
Fuchs, G. (Hrsg.), Schlegel H.G.	2006	Allgemeine Mikrobiologie, 8 Edition, 2006, Thieme, Germany ISBN-10: 3134446081 pp. 308-309	no	
Leahy G.J., Corwell R.R.	1990	Microbial Degradation of Hydrocarbons in the Environment. Microbiological Review, Sept. 1990, p.305-315.	no	
Grosjean E., Grosjean D.	1997	Gas phase reaction of alkenes with ozone: Formation yields of primary carbonyls and biradicals. Environmental Science & Technology; 31 (8). 1997. 2421-2427.	no	
Guoni-Berthold, Berthold HK	2002	Policosanol: clinical pharmacology and therapeutic significance of a new lipid-lowering agent. Am Heart J 143, 356-365	no	
Hargrove James L., Greenspan Phillip, Hartle Diane K.	2004	Nutritional Significance and Metabolism of Very Long Chain Fatty Alcohols and Acids from Dietary Waxes Exp Biol Med. 229/3, 215-26.	no	
Mankin, R.W., Vick, K.W., Mayer, M.S., Coffelt, J.A., Callahan, P.S.	1979	Models for Dispersal of Vapors in Open and Confined Spaces: Application to Sex Pheromone Trapping in a Warehouse Purchased by the U.S. Department of Agriculture, Forest Service, for official use. Journal of Chemical Ecology, Vol. 6, No. 5, 1980	no	
Place AR	1992	Comparative aspects of lipid digestion and absorption: physiological correlates of wax ester digestion. Am J Physiol 263, R464-R471	no	
USEPA	1994	Reregistration Egligibility Decision (RED) (Z)-9-Tricosene http://www.epa.gov/oppsrrd1/REDs/4112.pdf	no	
USEPA	1996a	Estimating Toxicity of Industrial chemicals to aquatic organisms using structure-activity relationships, Edit. Clements, http://www.epa.gov/oppt/newchems/tools/sarman.pdf	no	
William B. RizzoS, Debra A. Craft, Andrea L. Dammann, and Mary W. Phillips	1987	Fatty Alcohol Metabolism in Cultured Human Fibroblasts The Journal of biological chemistry. 262/36, 17412-17419.	no	-

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WHO	2006	GEMS/Food Consumption Cluster Diets, cluster E: http://www.who.int/foodsafety/chem/gems/en/index1.html	no	
WHO	2008	Highest reported 97.5th percentile consumption figures (eaters only) for various commodities by the general population and children ages 6 and under (Updated April 2008): http://www.who.int/foodsafety/chem/en/acute_hazard_db1.pdf	no	

APPENDIX IV-1: STANDARD TERMS AND ABBREVIATIONS

Note: The technical terms “active ingredient” and “active substance” are equivalent

Stand. Term / Abbreviation	Explanation
A	ampere
Ach	acetylcholine
AchE	acetylcholinesterase
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
ADP	adenosine diphosphate
AE	acid equivalent
AF	assessment factor
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD_{50}	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
Ann.	Annex
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BAF	bioaccumulation factor
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BP	Biocidal Product
BPD	Biocidal Products Directive
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathy
BSP	bromosulfophthalein
Bt	*Bacillus thuringiensis*

Stand. Term / Abbreviation	Explanation
Bti	*Bacillus thuringiensis israelensis*
Btk	*Bacillus thuringiensis kurstaki*
Btt	*Bacillus thuringiensis tenebrionis*
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10^{-2})
°C	degrees Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
CAS	Chemical Abstracts Service
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DANN
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
CSF	Confidential Statement of Formula
Cv	ceiling value
d	day(s)
DES	diethylstilboestrol
DIS	draft international standard *(ISO)*
DFR	Dislodgeable Foliar Residue
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon

Stand. Term / Abbreviation	Explanation
dpi	days post inoculation
DRES	Dietary Risk Evaluation System
DRP	detailed review paper *(OECD)*
DSC	Differential scanning calorimetry
$DT_{50(lab)}$	period required for 50 percent dissipation (under laboratory conditions) (define method of estimation)
$DT_{90(field)}$	period required for 90 percent dissipation (under field conditions) (define method of estimation)
dw	dry weight
DWEL	Drinking Water Equivalent Level
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
E_bC_{50}	median effective concentration, biomass
E_rC_{50}	median effective concentration, growth rate
EC_{50}	median effective concentration
ECD	electron capture detector
ED_{50}	median effective dose
EDI	estimated daily intake
EEC	Estimated Environmental Concentration
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EPMA	electron probe micro-analysis
ERL	extraneous residue limit
ESPE46/51	evaluation system for pesticides
EUSES	European Union system for the evaluation of substances

Stand. Term / Abbreviation	Explanation
F	field
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
FBS	full base set
FDA	Food and Drug Administration
FELS	fish early-life stage
FIA	fluorescence immuno-assay
FID	flame ionisation detector
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
F_{mol}	fractional equivalent of the metabolite´s molecular weight compared to the active substance
FOB	functional observation battery
f_{oc}	organic carbon factor (compartment dependent)
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram(s)
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice

Stand. Term / Abbreviation	Explanation
GM	geometric mean
GMM	genetically modified micro-organism
GMO	genetically modified organism
GPC	gel-permeation chromatography
GPS	global positioning system
GRAS	Generally Recognized As Safe as designated by FDA
GSH	glutathione
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value)
ha	hectare(s)
HA	Health Advisory
Hb	haemoglobin
HC5	concentration which will be harmless to at least 95 % of the species present with a given level of confidence (usually 95 %)
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_S	Shannon-Weaver index
Ht	haematocrit
HUSS	human and use safety standard
I	indoor

Stand. Term / Abbreviation	Explanation
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration or median inhibitory concentration 1
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
INT	2-p-iodophenyl-3-p-nitrophenyl-5-phenyltetrazoliumchloride testing method
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
IUCLID	International Uniform Chemical Information Database
iv	intravenous
IVF	*in vitro* fertilisation
k *(in combination)*	kilo
k	rate constant for biodegradation
K	Kelvin
Ka	acid dissociation constant
Kb	base dissociation constant
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
kg	kilogram
K_H	Henry´s Law constant (in atmosphere per cubic metre per mole)
K_{oc}	organic carbon adsorption coefficient
K_{om}	organic matter adsorption coefficient
K_{ow}	octanol-water partition coefficient
Kp	solid-water partition coefficient
kPa	kilopascal(s)
l, L	litre
LAN	local area network

Stand. Term / Abbreviation	Explanation
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD	Lethal Dose-low
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LEL	Lowest Effect Level
ln	natural logarithm
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOC	Level of Concern
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
log	logarithm to the base 10
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometer (micron)
MAC	maximum allowable concentration
MAK	maximum allowable concentration
MATC	Maximum Acceptable Toxicant Concentration
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCLG	Maximum Contaminant Level Goal
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
MIC	minimum inhibitory concentration
min	minute(s)
MKC	minimum killing concentration
mL	millilitre
MLD	median lethal dose
MLT	minimum lethal time
mm	millimetre
MMAD	mass median aerodynamic diameter
mo	month(s)
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
Mp	melting point
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRE	maximum residue expected
MRID	Master Record Identification (number).
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MT	material test
MW	molecular weight
n.a., N/A	not applicable
n-	normal (defining isomeric configuration)
N	number of observations

Stand. Term / Abbreviation	Explanation
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometre
NMR	nuclear magnetic resonance
no, n°	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOE_rC	no observed effect concentration, growth rate
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPDES	National Pollutant Discharge Elimination System
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OEL	occupational exposure limit
OH	hydroxide
OJ	Official Journal
OM	organic matter content
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime

Stand. Term / Abbreviation	Explanation
PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Method
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the acid dissociation constant
pKb	negative logarithm (to the base 10) of the base dissociation constant
PNEC	predicted no effect concentration (compartment to be added as subscript)
po	by mouth
POP	persistent organic pollutants
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PPP	plant protection product
ppq	parts per quadrillion ($10^{-24)}$
ppt	parts per trillion (10^{-12})
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PRN	Pesticide Registration Notice

Stand. Term / Abbreviation	Explanation
PT	product type
PT(CEN)	project team CEN
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
Q*1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
QA	quality assurance
QAU	quality assurance unit
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RA	risk assessment
RBC	red blood cell
RED	Reregistration Eligibility Decision
REI	restricted entry interval
RENI	Registry Nomenclature Information System
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	revolutions per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RS	Registration Standard
RSD	relative standard deviation
s	second
S	solubility
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange

Stand. Term / Abbreviation	Explanation
SCAS	semi-continous activated sludge
SCTER	smallest chronic toxicity exposure ratio (TER)
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
S/L	short term to long term ratio
SMEs	small and medium sized enterprises
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
ssp	subspecies
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STER	smallest toxicity exposure ratio (TER)
STMR	supervised trials median residue
STP	sewage treatment plant
t	tonne(s) (metric ton)
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
T_{25}	tumorigenic dose that causes tumours in 25 % of the test animals
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TC	Toxic Concentration
TCD	thermal conductivity detector
TD	Toxic Dose
TDR	time domain reflectrometry
TG	technical guideline, technical group
TGD	Technical guidance document

Stand. Term / Abbreviation	Explanation
TID	thermionic detector, alkali flame detector
TEP	Typical End-Use Product
TER	toxicity exposure ratio
TER_I	toxicity exposure ratio for initial exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGAI	Technical Grade Active Ingredient
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TNsG	technical notes for guidance
TOC	total organic carbon
Tremcard	transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TTC	2,3,5-triphenylterazoliumchloride testing method
TTC	Toxicological-Threshold-of-Concern
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UR	unit risk
UV	ultraviolet
UVC	unknown or variable composition, complex reaction products
UVCB	undefined or variable composition, complex reaction products in biological material
v/v	volume ratio (volume per volume)
vis	visible
WBC	white blood cell
Wk	week
WP	Wettable Powder
WPS	Worker Protection Standard
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
Yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

APPENDIX IV-2: ABBREVIATIONS OF ORGANISATION AND PUBLICATIONS

Abbreviation	Explanation
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
BBA	German Federal Agency of Agriculture and Forestry
CA(S)	Chemical Abstracts (System)
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe
CEC	Commission of the European Communities
CEFIC	European Chemical Industry Council
CEN	European Committee for Normalisation
CEPE	European Committee for Paints and Inks
CIPAC	Collaborative International Pesticides Analytical Council Ltd
CMA	Chemicals Manufacturers Association
COREPER	Comite des Representants Permanents
COST	European Co-operation in the field of Scientific and Technical Research
DG	Directorate General
DIN	German Institute for Standardisation
EC	European Commission
ECB	European Chemicals Bureau
ECCO	European Commission Co-ordination
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EEC	European Economic Community
EHC	Environmental Health Criteria
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre

Abbreviation	Explanation
EPA	Environmental Protection Agency
EPAS	European Producers of Antimicrobial Substances
EPFP	European Producers of Formulated Preservatives
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organization
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
EWMP	European Wood Preservation Manufacturers
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System
GRIN	Germplasm Resources Information Network
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
ICBP	International Council for Bird Preservation
ICCA	International Council of Chemical Associations
ICES	International Council for the Exploration of the Seas
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organization for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JECFA FAO/WHO	Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring

Abbreviation	Explanation
	Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
MITI	Ministry of International Trade and Industry, Japan
NATO	North Atlantic Treaty Organization
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Center for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Program (USA)
OECD	Organization for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
OPPTS	Office of Prevention, Pesticides and Toxic Substances (US EPA)
OSPAR	Oslo Paris Convention (Convention for the Protection of the Marine Environment of the North-East Atlantic)
PAN	Pesticide Action Network
RIVM	Netherlands National Institute of Public Health and Environmental Protection
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SETAC	Society of Environmental Toxicology and Chemistry
SI	Système International d'Unitès
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UBA	German Environmental Protection Agency
UN	United Nations
UNEP	United Nations Environment Programme
WFP	World Food Programme
WHO	World Health Organization
WPRS	West Palearctic Regional Section
WTO	World Trade Organization
WWF	World Wildlife Fund