Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report

Decanoic acid

Product-type 18 & 19
(Insecticides; Repellents and attractants)

December 2013

Austria

Decanoic acid (PT 18, 19)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 13 December 2013

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1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Principle of evaluation

This assessment report has been established as a result of the evaluation of Decanoic acid as product-type 18 & 19 (Insecticide, 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 market1, with the original view to the possible inclusion of this substance into Annex I or IA to that Directive.

The evaluation has therefore been conducted in the view to determine whether it may be expected, in light of the common principles laid down in Annex VI to Directive 98/8/EC, that there are products in product-type 18 & 19 containing Decanoic acid that will fulfil the requirements laid down in Article 5(1) b), c) and d) of that Directive.

1.2. Purpose of the assessment

The aim of the assessment report is to support a decision on the approval of Decanoic acid for product-type 6, and should it be approved, to facilitate the authorisation of individual biocidal products in product-type 18 & 19 that contain Decanoic acid. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

The conclusions of this report 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 Regulation (EU) No 528/2012.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Procedure followed

This assessment report has been established as a result of the evaluation of Decanoic acid as product-type 18 & 19 (Insecticide, 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 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

Decanoic acid (CAS no. 334-48-5) was notified as an existing active substance, by FATTY ACIDS Consortium, p.a. SOPURA N.V., hereafter referred to as the applicant, in product-type PT 18 & 19.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[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, AT 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 Decanoic acid as an active substance in Product Type 18 & 19 was 30 April 2006, in accordance with Article 9 (c) of Regulation (EC) No 1451/2007.

On 3 May 2006, AT 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. Due to data gaps the evaluation was suspended between 29 October 2007 and 29 July 2008. On 19 March 2008, the applicant submitted additional data as requested. With respect to still remaining data gaps, on 12 August 2008 the Austrian CA decided to prolong the suspension of the evaluation until 31st May 2009, to allow sufficient time for the applicant to finally close all data gaps.

On 7 December 2010, 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 4 February 2011. The competent authority report included a recommendation for the inclusion of Decanoic acid in Annex I to the Directive for product-type PT18 & 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 4 February 2011. 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.

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 13 December 2013.

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

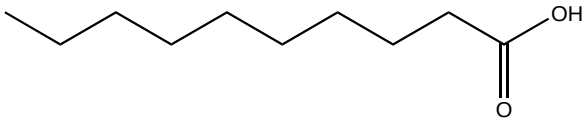
2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

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

The active substance Decanoic acid is attributed the CAS-No 334-48-5 and the EC-No 206-376-4. The molecular formula is $C_{10}H_{20}O_2$, and the molecular weight is 172.27 g/mol. The minimum degree of purity is 98.5%w/w.

Structural formula:



The structure of Decanoic acid 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 (min. 99%w/w Decanoic acid) according to the demands of the data requirements.

Decanoic acid is a white crystal solid and has a rancid smell. Its melting point is in a range of 29.8 – 31.6°C, and the boiling point range is 146.8 – 147.8°C (10 mm Hg). The relative density is $\rho^{20}_{4.0}$= 0.674 at 20°C. The vapour pressure of the active substance is 2.17 x 10^{-4} Pa at 25°C and 2.096 x 10^{-4} Pa at 20°C. The calculated Henry's law constant is 0.472 Pa x m^3 x mol^{-1} at 25°C.

The water solubility of the water test item is 43 mg/L (20°C, unpuffered), 31 mg/L (20°C, pH 4), and 1843 mg/L (20°C, pH 7) and 2882 mg/L (20°C, pH 9). The water solubility at 35°C and at 50°C is not measurable.

The dissociation constant of Decanoic acid in water is extrapolated to be in the range from 4.89 to 5.03.The solubility of Decanoic acid is >1kg/L Hexane at 22°C in g/L at > 1kg/L Ethanol 22°C. The active substance as manufactured does not include any organic solvent. The calculated partition coefficient octanol-water is 4.02 for the undissociated acid. Due to the similar molecular structure to Octanoic acid which is surface active, it is expected that Decanoic acid may also be surface active. The viscosity is 6.5 mPa s at 45°C.

The active substance does not contain structural elements such as peroxide, nitro-group known to cause explosions. It is unlikely that Decanoic acid shows oxidizing properties under the condition of the test as described in the EU method A.14. Its flash point is 178°C. The heat of combustion is -6107.7 kJ/mol, therefore auto flammability is not expected. The substance is stable up to the boiling point (146.8°C). Decanoic acid starts to decompose at 264.5°C. Uncoated metal containers should be avoided. Plastic containers made of polyethylene or polypropylene and certified for use with acid are recommended.

The identification and quantification of Decanoic acid in the active substance as well as in the biocidal products Insect shocker FL (PT18) and Repellent FS (PT19) is performed by using a GC system with FID detection. The method has been validated and shown to be sufficiently specific, accurate and sensitive.

Due to the natural occurrence of Decanoic acid in the environment and its rapid metabolism and degradation in soil an analytical method for the determination of residues of Decanoic acid in soil is not required according to the TNsG on Data Requirements, Addendum to Chapter 2, Point 4 “Analytical Methods for Detection and Identification”.

Due to the low vapour pressure of Decanoic acid no significant concentrations of Decanoic acid in air will occur. In accordance with the provisions given in the TNsG on Data requirements no analytical method for Decanoic acid in air has been submitted.

Deacnoic acid has been found to occur naturally in low concentrations in water. Although the degradation of Decanoic acid applied to water happens rapidly a GC/MS method has been developed to analyse residues in water with a limit of quantification of 0.1 µg/L.

As Decanoic acid 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.

An analytical method for the determination of residues of Decanoic acid in/on food or feedstuffs is not required because the active substance is not used in a manner that may cause contact with food or feedstuffs.

2.1.2. Intended Uses and Efficacy

This dossier is to support the use of Decanoic acid as insecticide (PT18) as well as repellent (PT 19)

In PT 18 (Insecticide) the active substance is to be used exclusively indoors by the non-professional general public to control crawling insects and isopods within private homes. Despite several methodological deficiencies which have to be clarified at product authorisation stage the studies submitted could show that the active substance has innate efficacy against crawling insects and isopods, i.e. Ants (*Lasius niger*),Cockroaches (*Blaptica dubia, Blatella germanica, Blatella orientalis, Periplaneta Americana*), Isopods (*Trichorhina tormentosa*) and Crickets (*Acheta domesticus*).The intended uses of the substance, as identified during the evaluation process, are listed in Appendix II of this document.

Upon contact with an appropriate dose insects are killed with a delay of a few hours to up to 7 days depending on the species and the individual. The mode of action is unknown. It is speculated that the active substance damages the chitin cuticle of arthropods leading to desiccation.

In the past resistance has been bread into previously susceptible pest insect species. Some insects are known to use fatty acids either for intra-specific communication or as cue to locate resources containing these acids. Given the general use patterns of the active substance by the general public, there is a high probability that resistance remained overlooked in the past. A strategy to monitor and manage resistance development should be submitted at product authorisation stage.

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In PT 19 (Repellent) the active substance is exclusevly used by the non-professional general public as a biocide to repel insects of the mosquito species of the family of *culicidae*

(Product-type 19) Applied as a repellent, Decanoic acid unfolds its effect through the vapour phase saturating the highly sensitive gas receptors of the targets. The insects do not land on the human skin and therefore do not bite (arm in cage test provided). Decanoic acid does not kill the insects.. The representative product is a ready to use lotion to be spread over exposed skin.
A strategy to monitor and manage resistance development should be submitted at product authorisation stage.

The intended uses of the substance, as identified during the evaluation process, are listed in Appendix II of this document.

2.1.3. Classification and Labelling of the active substance

Current classification according to Annex VI of Reg. (EU) No 1272/2008

This substance is not classified in the Annex VI of Reg. (EU) No 1272/2008.

Proposed classification and labelling

Table 2.1.3-1: Proposed classification and labelling according to Reg. (EU) No 1272/2008, Annex VI, Table 3.2 (proposed by RMS)

Hazard symbol	
Indication of danger	Xi Irritating N Dangerous for the environment
R phrases	R38 Irritating to skin R36 irritating to eyes R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S phrases	S26 In case of contact with eyes rinse immediately with plenty of water and seek medical advice S36/37/39 Wear suitable protective clothing, gloves and eye/face protection S61 Avoid release to the environment. Refer to special instructions/safety data sheets.
Classification	Xi; R38-R36, N; R51/53
Labelling	Xi; N; R: 38-36-51/53 S: 26-36/37/39-61

Table 2.1.3-2: Proposed classification and labelling according to Reg. (EU) No 1272/2008, Annex VI, Table 3.1 and Reg. (EU) No 286/2011 (proposed by RMS)

Classification and Labelling			Justification
GHS Pictograms		 GHS07	Weight of evidence evaluation supporting skin and eye irritation including an in vitro BCOP test from 2012*. Specification of Prevention Phrases according to Regulation (EC) No 1272/2008 Rapidly degradable substance for which adequate chronic toxicity data are available for algae (NOE_rC =0.57 mg/L). And $L(E)C_{50}$ fish and daphnia 10 – 100 mg/L and log P_{ow} 4.09.
Signal words		Danger	
Classification		Serious eye irritation – Hazard Category 2* Skin irritation- Hazard Category 2 Aquatic Chronic 3	
Hazard statements		H319: Causes serious eye irritation* H315: Causes skin irritation H412: Harmful to aquatic life with long lasting effects	
Precautionary Statements	**General**	-	
	Prevention	P264: Wash thoroughly after handling P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection.	
	Response	P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+ P313: IF EYE IRRITATION PERSISTS: Get medical advice/attention P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P332 + P313: If skin irritation occurs, get medical advice/attention P362: Take off contaminated clothing and wash before reuse.	
	Storage	-	
	Disposal	P501: Dispose of contents/container in accordance with local/regional/national/international regulation (to be specified).	

* Recently a RAC opinion was published confirming this proposal.

2.1.4. Classification and Labelling of the biocidal product for PT 18

Proposed classification and labelling

According to Directive 1999/45/EC no classification and labelling is required. However with the new Regulation (EC) No 1272/2008, Annex VI, Table 3.1 and Regulation (EU) No 286/2011 the trigger concentration for C&L for skin corrosion/irritation and for serious eye damage/irritation is reduced, which makes respective classification and labelling of the product necessary. For environmental effects C&L according to Regulation (EC) No 1272/2008, Annex VI, Table 3.1 and Regulation (EU) No 286/2011 is not necessary

Tab. 2.1.4.-1: Proposed classification and labelling of the b.p. by RMS according to Reg. (EC) No 1272/2008, Annex VI, Table 3.1 and Reg. (EU) No 286/2011

		Classification and Labelling	Justification
GHS Pictograms		 GHS07	
Signal words		Warning	
Classification*		Serious eye irritation – Hazard Category 2**	Calculation method: product contains 1.5% Octanoic acid (cat 1, H314), classification limit = 1-3% Decanoic acid (cat 2) content is 1.5%. In addition: BCOP test (2012) with product supporting non-cat 1.
		Skin irritant – Hazard Category 2**	Calculation method: product contains 1.5% Octanoic acid (cat 1, H314), classification limit = 1-5% Decanoic acid (cat 2) content is 1.5%
Hazard statements		H319: Causes serious eye irritation H315: Causes skin irritation	
Precautionary	**General**	P102: Keep out of reach of children	Protection of children from potentially serious eye and skin irritating products.

	Prevention	P264: Wash thoroughly after handling	
		P260: Do not breath the spray	Accidental direct respiratory exposure to INSECT SHOCKER FL of adults or children could lead to reversible local respiratory effects
	Response	P302: IF ON SKIN: Wash with plenty of water and soap. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: Get medical advice/attention. P362: Take off contaminated clothing and wash before reuse.	
	Storage	-	
	Disposal	-	

* The representative product contains a preservative that represents a sensitizing mixture with a specific classification limit and another component that is not sensitizing. The concentration of the preservative in the product is given, however the proportion of the 3 components in the mixture was not given, so it is unclear if the preservative mixture is present in the product above or below the specific classification limit. The exact composition of the product allowing the clarification of potential sensitizing properties has to be provided with product authorisation

** At product authorisation the need for new in vitro experimental data with the product shall be considered. New in vitro tests and testing strategies are in development. The calculation method is problematic due to differences between the active substances and the product in terms of pH and solvent.

2.1.5. Classification and Labelling of the biocidal product for PT 19

Proposed classification and labelling

For environmental hazards C&L according to Regulation (EC) No 1272/2008, Annex VI, Table 3.1 and Regulation (EU) No 286/2011 is not required.

Table 2.1.5-1: Proposed C&L of PT 19 biocidal product according to Directive 1999/45/EC

Hazard symbol	
Indication of danger	Irritant
R phrases*	R10 Flammable[1] R36 Irritating to eyes R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S phrases	S2 Keep out of reach of children S25 Avoid contact with eyes S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S61: Avoid release to the environment. Refer to special instructions/Safety data sheets.
Classification	R10 Xi:R36 R52/53
Labelling	Xi R:10-36-R52/53 S: 2/25/26-61

[1]The flash point of the product Repellent FS was determined to be 30°C. A preparation with a flash point between 21°C and 55°C needs not be classified as flammable if the preparation could not in any way support combustion. However, this was not shown in the studies (Study B 3.4/01a and Study B 3.4/01b).

Table 2.1.5-2: Proposed C&L of PT19 product according to Regulation (EC) No 1272/2008, Annex VI, Table 3.1 and Reg. (EU) No 286/2011

		Justification

GHS Pictograms		 GHS02  GHS07	
Signal words		Warning	
Classification*		Flammable liquids and vapours - Hazard Category 3	
		Serious eye irritation – Hazard Category 2, **	Calculation method: product contains 9.8% decanoic acid (cat 2, H319), classification limit ≥ 10%; BCOP test (from 2012) with Repellent FL supporting non-cat 1.**
Hazard statements		H226 Flammable liquid and vapour H319 Causes serious eye irritation**	
Precautionary statement	**General**	P102 Keep out of reach of children.	Protection of children from potentially serious eye and skin irritating products.
	Prevention	-	
	Response	P305 +P351 +P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: Get medical advice/attention.	
	Storage	None	
	Disposal	-	

* Non classification for skin irritation is based on the calculation method. With product authorisation the need for new experimental product in vitro data for skin irritation shall be considered. The calculation method is problematic due to differences between the active substances and the product in terms of pH and solvent. The intended use as repellent is application to skin.

** The data-package for the active substance and the biocidal product shall be re-evaluated at product authorisation stage. New in vitro tests and testing strategies for eye irritation are in development.

2.2. Summary of the Risk Assessment

2.2.1. Risk arising from physico-chemical properties

In conclusion, no physico-chemical hazards could be identified for the active substance. Hence no classification is required on the base of physico-chemical properties (see also chapter 2.1.1 of this document).

2.2.2. Human Health Risk Assessment

2.2.2.1. Hazard identification

The only toxicological concern evident is the severely irritating property of the medium chain fatty acids. The overall evidence including a positive in vitro TER test with rat skin (for skin corrosion) for octanoic acid and a negative in vitro TER test with human skin for decanoic acid support the classification of octanoic acid for skin corrosion (Cat 1C, H314) and the classification of decanoic acid for skin irritation (Cat 2, H315).

According to OECD guideline 405 the severe skin irritation of Octanoic acid and Decanoic acid excludes further eye irritation testing with animals and should result in considering the substances as severely eye damaging. Furthermore two publications were identified (Smyth et al. 1962, Briggs et al 1976) attributing score 9 from 10 for corneal necrosis or indicating corneal opacity and no reversibility up to 72 hours for Decanoic acid as well as Octanoic acid. However for Decanoic acid new in vitro data (BCOP, TG 437) were submitted, supporting classification for Cat 2, H319, serious eye irritation. Recently a RAC opinion was published supporting this conclusion on the basis of a total Weight of Evidence evaluation. Due to classification of Octanoic acid for severe skin burns and eye damage (cat 1C, H314) no further classification specific for eye damage is necessary.

2.2.2.2. Effects assessment

The evaluation of the toxicological hazard assessment for Decanoic acid and Octanoic acid is presented in a common chapter in this AR and it is largely based on literature data for the free fatty acids and for triglycerids.

Decanoic acid and Octanoic acid are linear saturated fatty acids and they are ubiquitous in nature. The metabolic pathways are well established, they are similar for all fatty acids: complete catabolism for energy supply or conversion to fat suitable for storage. Octanoic acid and Decanoic acid are structurally very similar and differ only by 2 C-atoms. The log Kow values are 3.03 for octanoic acid and 4.09 for decanoic acid molecular weights are 144 and 172 g/mol, respectively and the available toxicological data for both substances correspond well with each other. The OECD toolbox profiles indicate for both substances “no binding” to DNA, estrogen receptor and protein and it classifies both substances into Cramer class I (lowest toxic hazard group). Complete and rapid oral absorption can be expected for both substances. Due to this knowledge the evaluation the toxicological hazard assessment for Decanoic acid and Octanoic acid is presented in a common chapter and it is largely based on literature data for the free fatty acids and for triglycerids. The latter are esters of glycerine and

fatty acids of various chain lengths including C8 and C10. Triglyceride studies were not carried out in the context of toxicology but in the context of nutritional science, however the results are still applicable for the purpose of this AR. It is acknowledged that triglyderids (fat) need to be split into fatty acids and glycerine in order to allow absorption from the gastrointestinal tract, which means that after oral uptake the free fatty acids are available to the human or animal body.

Neither the available data for Decanoic acid and Octanoic acid on acute oral, dermal and inhalation toxicity, nor the publications with Medium Chain triglycerides and free fatty acids on subchronic rat dietary exposure or on developmental and reproductive toxicity give rise to concern for systemic toxicity, in spite of the high dose levels tested (all ≥ 1000 mg/kg bw day). These findings are in line with the acute, subacute and developmental toxicity data evaluated for Nonanoic acid in the context of the BPD 98/8/EC Annex I inclusion, which are owned by the respective applicant W.Neudorff GmbH KG (see respective Biocides CAR).

The Local Lymph Node Assay (LLNA) with Decanoic acid is borderline positive, but the weight of evidence evaluation for skin-sensitisation resulted negative with regard to Decanoic and Octanoic acid. The absence of genotoxicity is supported by the evaluation of bacterial mutation tests, in vitro chromosomal aberration tests with the CHO cell line and in vitro gene mutation tests with mouse lymphoma cells and a respective total weight of evidence discussion. Each of the three assays are available for Decanoic acid as well as Octanoic acid.

Clearly long term irritation is stimulating cell replication and can present as such a promoting effect that is increasing cancer risk. But such tumour promoting effects without tumour inducing (genotoxic) effects should not trigger classification. The conduct of a carcinogenicity study was considered not to be necessary; no new toxicological information is expected.

The available publications with regard to reproductive toxicity do not indicate any toxicologically relevant maternal or foetal effects.

Considering the ubiquitous nature of carbonic acids, natural uptake levels and detailed knowledge of metabolism as well as the description of the purity and all available data for systemic effects no further studies were required for genotoxicity, (sub)chronic or reproductive toxicity.

The publications from Webb 1993, Harkins 1968, Traul et al 2000 for medium chain triglycerides (MCTs) as well as the publications from Mori 1953 and WHO/IPCS 1998 for the free fatty acids do not indicate any adverse systemic effect and support NOAELs above 1000 mg/kg bw/d. Daily human uptake of fatty acids as food contents is, e.g. according to Henderson et al 2003 about 900 mg/kg bw day and the metabolic pathways are similar for all fatty acids, that is complete catabolism for energy supply or conversion to fat suitable for storage. Therefore the derivation of a systemic AEL is considered unnecessary. Risk assessment is focused on risk for local effects.

The available data for the active substances are insufficient for the derivation of local oral, local dermal and local inhalation acceptable exposure concentrations (AEC)s. In any case the data for the active substances would be inadequate for the assessment of the biocidal products that are different with regard to pH, solvents and other ingredients. Therefore a qualitative risk assessment for local effects of the product was preferred.

2.2.2.3. Exposure assessment PT 18

The data for medium chain triglycerides (MCTs) as well as for the free fatty acids do not indicate any adverse systemic effect and support NOAELs above 1000 mg/kg bw/d. Daily human uptake of fatty acids as food contents is, e.g. according to Henderson et al 2003 about 900 mg/kg bw day and the metabolic pathways are similar for all fatty acids, that is complete catabolism for energy supply or conversion to fat suitable for storage. Therefore the derivation of a systemic AEL is considered unnecessary. Risk assessment is focused on risk for local effects.

The available data for the active substances are insufficient for the derivation of local oral, local dermal and local inhalation acceptable exposure concentrations (AEC)s. In any case the data for the active substances would be inadequate for the assessment of the biocidal products that are different with regard to pH, solvents and other ingredients. Therefore a qualitative risk assessment for local effects of the product was preferred.

Human exposure towards the active substance from its use in the biocidal product can take place via different "routes of exposure", i.e. via inhalation, dermal contact and/or ingestion (see table 2.2.2.3-1).

Table 2.2.2.3-1: Main paths of human exposure to Decanoic acid as INSECT SHOCKER FL

Exposure path	**Primary (direct) exposure, during use of b.p.**		**Secondary (indirect) exposure Incidental contact after application**	**Via the environment**
	Professional use	**General public**	**General Public**	**General Public**
Inhalation	No	Yes	Yes	Not relevant[1]
Dermal	No	Yes	Yes	Not relevant[1]
Oral	No	Not relevant	Yes	Not relevant[1]

[1] From TNsG on Human Exposure, 2007: "Exposure via the environment is an element of secondary exposure. It includes bystanders and consumers, including children, who are inadvertently exposed to biocides by inhalation of plumes drifting off-site and ingesting contaminated food." Those scenarios are not considered relevant in this case.

The biocidal product is intended to be applied by the general public as spray. (For details on the intended use, please see Appendix II of this document.) Thereby dermal and inhalative exposure may occur. Oral exposure is considered to be not relevant.

Subsequent to the use of the biocidal product, release into air of active substance deposited on treated surfaces may occur. It is expected that this does not produce a higher concentration in air than the saturation concentration. Inhalation exposure for adults, children and infants are likely. Furthermore, dermal exposure of the general public is conceivable assuming touching contaminated surfaces. Considering the mouthing behaviour of infants, oral exposures are also regarded to be possible under these circumstances.

Exposure of pets like dogs and cats to Decanoic acid via spray application is considered to be not relevant, as the biocidal product is intended for spot treatment and not for the treatment of

big areas. Therefore, significant dermal contact with residues on the floor is unlikely as the maximum conceivable level of exposure is also limited to the applied amount of active substance in the living area.

Dietary exposure is not considered to be relevant.

2.2.2.4. Risk characterisation PT 18

INSECT SHOCKER FL is applied with a spray can directly onto the pest or into their hiding holes for up to 10 minutes resulting in about 6 g/m2. A default maximum model value of 49.5 mg/m3 may be assumed. It may be necessary to repeat the treatment after 1 to 2 days. A daily use for more than a couple of days is not likely. This intended use does not lead to a long lasting exposure, especially with the recommended normal hygienic measures as hand washing after use.

INSECT SHOCKER FL contains a preservative that represents a sensitizing mixture with a specific classification limit and another component that is not sensitizing. The concentration of the preservative in the product is given, however the proportion of the 3 components in the mixture was not given, therefore it is unclear if the preservative mixture is present in the product above or below the specific classification limit. The exact composition of the product allowing the clarification of potential sensitizing properties has to be provided with product authorisation. Substitution of skin sensitizing co-formulants should be considered. Otherwise a qualitative risk assessment of potential sensitizing effects has to be provided with product authorisation in order to decide on acceptability of risk for local effects.

INSECT SHOCKER FL is classified for skin irritation (cat 2, H315) based on the calculation method according to Reg. EC No 1272/2008 (1.5% Octanoic acid as skin cat 1, H314, is within cat 2 classification limit of 1 to 5%). No classification would result from old rules according to Dir. 1999/45/EC (classification limit 5 to 10%) A human local dermal NOAEC of 1% was considered as limit value for local dermal effects of Decanoic acid, but the uncertainty attached to this estimate is rather high (see doc IIA 3.3). However the intended use does not lead to a long lasting dermal exposure if recommend normal hygienic measures as hand washing after use are applied. Therefore severe local dermal irritation is not expected from intended use of adults. However it cannot be excluded that reversible skin irritation may result from the intended use for most sensitive humans or from accidental long lasting exposure of adults not washing their hands after use or with co-exposure to mechanical or physical stress. Reversible skin irritation might also occur with adults or children touching treated areas or infants crawling on treated areas, though this scenario is unlikely given the intended use of small spot treatment.

INSECT SHOCKER FL would need to be classified for eye irritation (cat 2) based on the calculation method (it contains 1.5% Octanoic acid (cat 1, H314), classification limit for category 2 = 1-3%; Decanoic acid (cat 2) content is 1.5%). Furthermore INSECT SHOCKER FL was tested with the bovine cornea opacity test (BCOP, TG437) to estimate potential local eye effects. The results indicate that this product is not likely to be classified for category 1, serious eye damage. At this stage it is preliminarily concluded that the product may cause eye irritation. (As soon as a new approach for full replacement of in vivo data is available at OECD or EU level, further clarifying in vitro data may be submitted. The data-package shall be re-evaluated at product authorisation stage.). However this means so far that accidental spraying into the eye or hand to eye transfer, especially without normal hygienic measures as

hand washing after use may lead to eye irritation for adults. Accidental exposure to children and infants crawling on treated area may lead in the worst case to similar effects. Therefore in summary it cannot be excluded that eye irritation may result from the intended use, but reversible local effects from accidents, i.e. non-frequent situations, may be considered as acceptable risk.

Neither Decanoic acid nor Octanoic acid are classified for acute oral toxicity consequently by application of the calculation rules also INSECT SHOCKER FL is not classified. However the potential for eye irritation indicates also some potential for local oral irritation. However since daily repeated oral exposure to the product is impossible as a result of intended use, the probability of local oral effects is very low. Accidental oral exposure to unattended children or infants could lead to reversible local oral effects from direct uptake or hand –mouth transfer.

From the available data no threshold for local respiratory effects can be derived. However the overall database for Octanoic, Nonanoic and Decanoic acid indicates a respiratory LC50 > 5 mg/L. (see Doc II-3.2). This would correspond to a product LC50 > 166 g/m3.The data are insufficient for classification for respiratory irritation (STOT –SE). Accidental direct respiratory exposure to INSECT SHOCKER FL of adults or children could lead to reversible local respiratory effects. However it is concluded that the probability for severe adverse local respiratory effects is very low with the intended use described. The precautionary statement "P260: Do not breathe spray" is proposed as additional measure.

In summary due to the lack of some detail of product composition the risk for sensitizing effects cannot be assessed now, but will be required for product authorisation. However with regard to irritation no irreversible adverse local dermal, eye, oral or respiratory effects are to be expected from use of INSECT SHOCKER FL. Reversible local dermal irritation effects may result from intended use exposure of sensitive adults or accidentally long lasting exposure of adults or children or infants. Reversible irritation to the eye may result from accidental eye exposure of adults or children or infants. However reversible local effects from non-frequent exposure may be considered as acceptable risk.

With product authorisation the available data package may need to be amended in line with new in vitro tests and testing strategies for eye and skin irritation that are actually in development. .

2.2.2.5. Exposure assessment PT 19

The data for medium chain triglycerides (MCTs) as well as for the free fatty acids do not indicate any adverse systemic effect and support NOAELs above 1000 mg/kg bw/d. Daily human uptake of fatty acids as food contents is, e.g. according to Henderson et al 2003 about 900 mg/kg bw day and the metabolic pathways are similar for all fatty acids, that is complete catabolism for energy supply or conversion to fat suitable for storage. Therefore the derivation of a systemic AEL is considered unnecessary. Risk assessment is focused on risk for local effects.

The available data for the active substances are insufficient for the derivation of local oral, local dermal and local inhalation acceptable exposure concentrations (AEC)s. In any case the data for the active substances would be inadequate for the assessment of the biocidal products that are different with regard to pH, solvents and other ingredients. Therefore a qualitative risk assessment for local effects of the product was preferred.

Human exposure towards the active substance from its use in the biocidal product can take place via different "routes of exposure", i.e. via inhalation, dermal contact and/or ingestion (see table 2.2.2.3-1).

Table 2.2.2.5-1: Main paths of human exposure to Decanoic acid as Repellent FS

Exposure path	**Primary (direct) exposure, during use of b.p.**		**Secondary (indirect) exposure Incidental contact after application**	**Via the environment**
	Professional use	General public	General Public	General Public
Inhalation	No	Yes	Not relevant	Not relevant[1]
Dermal	No	Yes	Not relevant	Not relevant[1]
Oral	No	Not relevant	Not relevant	Not relevant[1]

[1] From TNsG on Human Exposure, 2007: "Exposure via the environment is an element of secondary exposure. It includes bystanders and consumers, including children, who are inadvertently exposed to biocides by inhalation of plumes drifting off-site and ingesting contaminated food." Those scenarios are not considered relevant in this case.

The biocidal product is a repellent which is intended to be applied by the general public onto skin. (For details on the intended use, please see Appendix II of this document.) Exposure occurs via dermal absorption of the applied repellent on skin and via inhalation of gaseous releases of the active substance. Oral exposure of users is considered not relevant, if the biocidal product is used and handled appropriately.

Secondary inhalation exposure is assumed to be significantly lower than the saturation concentration in air at 25°C (0.015 mg a.s./m^3) (see chap. 4.3.3).

Secondary dermal exposure is conceivable e.g. persons, if persons, who have applied Repellent FS touch other persons. Possible secondary scenarios result in much lower exposure in comparison to exposure to users (adults, children, infants).

As Repellent FS is not intended for animals and contamination of animals is unlikely referring to the intended use, this scenario is not relevant.

Dietary exposure is not considered relevant due to the intended use.

2.2.2.6. Risk characterisation PT 19

Decanoic acid is not classified for acute oral toxicity, consequently by application of the calculation method also REPELLENT FS is not classified. Given the skin and eye irritant properties it can be assumed that oral exposure would also lead to local oral effects. However since daily repeated oral exposure to the product is impossible as a result of intended use, the probability of local oral effects is very low. Accidental oral exposure to unattended children or infants could lead to reversible local oral effects from direct uptake or hand –mouth transfer.

From the available data no threshold for local respiratory effects can be derived. However the overall database for Octanoic, Nonanoic and Decanoic acid indicates a respiratory LC50 > 5 mg/L. (see Doc II-3.2). This would correspond to a product LC50 > 50 g/m3.The data are insufficient for classification for respiratory irritation (STOT –SE). It is concluded that also the probability for severe adverse local respiratory effects is very low with the intended use described. However accidental direct respiratory exposure to liquid aerosols of REPELLENT FS of adults or children could lead to reversible local respiratory effects.

REPELLENT FS is not classified for skin irritation based on the calculation method (classification limit according to Dir. 1999/45/EC < 20% or Reg. EC No 1272/2008 < 10%). A human local dermal NOAEC of 1% was considered as limit value for local dermal effects of Decanoic acid, but the uncertainty attached to this estimate is rather high (see doc IIA 3.3). In summary it cannot be excluded that reversible skin irritation may result from the intended use for most sensitive humans or with co-exposure to mechanical or physical stress including intensive sun-light.

REPELLENT FS would not need to be classified for eye irritation (cat 2) based on the calculation method (it contains 9.8% Decanoic acid (cat 2, H319), classification limit for category 2 ≥ 10%.) Furthermore REPELLENT FS was tested with the bovine cornea opacity test (BCOP, TG437) to estimate potential local eye effects. The results indicate that this product is not likely to be classified for category 1, serious eye damage. At this stage it is preliminarily concluded that the product may cause eye irritation. (As soon as a new approach for full replacement of in vivo data is available at OECD or EU level, further clarifying in vitro data may be submitted. The data-package shall be re-evaluated at product authorisation stage.). However this means so far that accidental hand to eye transfer and accidental direct eye exposure from splashes may lead to eye irritation of adults or children or infants. Therefore in summary it cannot be excluded that eye irritation may result from the intended use. However the acceptability of this eye irritation risk depends on the efficacy of REPELLENT FS as mosquito repellent, and on the human health benefit from mosquito control by this product. Authorisation may depend on comparative evaluation with other products of identical use including toxicological considerations with regard to pregnant

women, children and infants, eco-toxicology and efficacy. However the representative product evaluated for Annex I inclusion may not be the final product submitted for product authorisation.. Consequently the available data and risk characterisation is considered acceptable for Annex I inclusion. In summary no irreversible local dermal, oral or respiratory effects are to be expected from the intended use of REPELLENT FS. Reversible skin irritation may result from the intended use for most sensitive humans or with co-exposure to mechanical or physical stress. With the data available so far it is not likely that REPELLENT FS may cause eye damage, but rather eye irritation. Irritating properties may be considered as acceptable depending on the efficacy of REPELLENT FS and the expected human health benefit from mosquito control.

With product authorisation the available data package will need to be reviewed and eventually amended in line with new in vitro tests and testing strategies for eye and skin irritation that are actually in development..

Hazard			Exposure							Risk
Hazard Category	effects in terms of C&L	additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Likelihood, frequency, duration of potential exposure	Product exposure intensity	Relevant RMM	Conclusion on risk
medium	Eye irrit. Cat 2, H319	-	19	General public: adults, children infants	Poured into hands and spread over skin of arms and legs	skin Eye (splashes, hand to eye transfer)	up to more than 1 / day for weeks	6 g / person	labelling for eye irritation, child prove closure instructions for use packaging reducing risk for eye exposure by splashes washing of hands after use	Acceptable for Annex I inclusion stage: +reversible effects +RMM applicable (see column on the left) +potentially important human health benefit from mosquito control (efficacy of final product to be clarified) but data package will be reviewed with product authorisation, due to +frequent use +high amount per event +high probability for eye exposure +children and infant exposure + representative product is likely not the final product submitted for authorisation

2.2.3. Environmental Risk Assessment

2.2.3.1. Fate and distribution in the environment

Decanoic acid is readily biodegradable (91-92% mineralisation based on ThOD at day 28; pass level reached at day 5). The principal way of degradation of fatty acids under aerobic conditions is the microbial shortening by C2 pieces (β-oxidation of fatty acids).

Hydrolysis can be excluded by its structure, since Decanoic acid does not contain any functional group or reactive centre, which can be hydrolysed by nucleophilic OH^- ions (at high pH values) or by electrophilic H_2O^+ ions (at low pH values).

Photolytic degradation in water is excluded for Decanoic acid, as it does not contain any functional group or reactive centre which displays chromophore properties at wavelengths above 290 nm.

An estimation of photochemical degradation of Decanoic acid in air according to TGD resulted in a half-life of 34.5h ($k_{deg, air}$ = 1.448 d^{-1}; $c(OH)_{air}$ = 5x10^5 molecules/cm^3). Based on this result an accumulation of Decanoic acid in air is not expected.

No adsorption equilibrium could be reached and no K_{oc} values could be calculated, since Decanoic acid rapidly degraded in the test soils despite soil sterilisation. Therefore there is negligible likelihood for leakage of Decanoic acid to groundwater due to rapid degradation. EUSES calculations resulted in a K_{oc} value of 264 L/kg, which was used for risk characterisation.

Accumulation:

The log P_{ow} of Decanoic acid is 4.09.

Due to the similar molecular structure to Octanoic acid which is surface active, it could be expected that Decanoic acid may also be surface active. As surface active molecules could have a potential for bioaccumulation, the testing of the bioaccumulation in an appropriate species of fish might be necessary.

For Decanoic acid, bioaccumulation is not an important issue, because

- Decanoic acid is rapidly biodegradable
- Decanoic acid is a fatty acid. Fatty acids are ubiquitous available in the environment and important naturally occurring biological molecules, found in all living organisms. They may be regarded as having fundamental roles (i.e. they are the building blocks of structurally important molecules in cellular membranes and also serve as sources of energy for biological systems).
- Decanoic acid is metabolized via ß-oxidation. This is quantitatively the most significant pathway for catabolism of fatty acids and results in the final products CO_2 and acetyl-CoA which as such are further metabolized to CO_2 and water (for details of the degradation steps see Doc. II-A, 3.1.2).

The calculated BCF_{fish} for Decanoic acid is 597.72L/kg and the BCF in earthworms is 148 L/kg. In addition to the facts and arguments given above, together with the knowledge on metabolism and biological properties of fatty acids, sufficient evidence is given of the non-bioaccumulating properties of Decanoic acid.

Surface water used for drinking water

For PT 18 the concentration for Decanoic acid in surface water is 0.122 µg/L and therefore it exceeds the parametric value of 0.1 µg/L, according to Directive 98/83/EC slightly (see Table 2.1.2-1).

For PT 19 Scenario 1B (ESD, consumption based) represents a concentration for Decanoic acid in surface water of 1.82 µg/L and exceeds the parametric value of 0.1 µg/L, according to Directive 98/83/EC (see Table 2.1.2-1). The remaining scenarios show no unacceptable risk regarding this threshold.

In Directive 98/8/EC, Annex VI, article 83, third note, also included in regulation (EU) No 528/2012 (Annex VI, article 69), reference is made to drinking water Directive 98/83/EC (previously 80/778), which states that the maximum concentration of organic pesticides in surface water should not exceed the threshold for the abstraction of drinking water. This threshold is 0.1 µg/L for organic pesticides.

On the other hand the PECsurface water does not correspond with the PEC for the concentration at the water abstraction point. The calculations do not take into account the degradation of Decanoic acid in water and dilution in surface water. At present there are no tools available to calculate such a PEC, taking into account these processes that may occur during the water flow from the STP to the water abstraction point.

For product authorisation additional information is required, concerning the degradation rates of the active substance during pre-treatment and/or in a waste water treatment plant (e.g. by means of simulations tests, or preferably monitoring of STP influent and effluent concentrations).

2.2.3.2. Effects assessment

Aquatic compartment (fish, daphnids, algae, micro-organisms):

The acute toxicity was investigated in zebra fish (*Brachydanio Rerio*) in a semi-static study for 96 hours conducted with Octanoic acid. The NOEC was 22 mg/L (which corresponds to 26.3 mg/L Decanoic acid), the LC_0 46 (which corresponds to 55 mg/L Decanoic acid). The calculated LC_{50} is 68 mg/L (corresponding to 81.2 mg/L Decanoic acid).

The acute toxicity study in fish is read across from Octanoic acid.

Decanoic acid and Octanoic acids are linear saturated fatty acids differing only in the chain length (10 or 8 C-atoms). Fatty acids like Octanoic and Decanoic acid are ubiquitously present in all living species and are part of the fatty acid metabolism. It is therefore possible to predict that species-specific behaviour is unlikely and substances of the even numbered carbon acids follow the rule of physical or structural properties. This results in decreasing corrosive and irritating properties as the chain length increases. For aqueous toxicity it is

expected that the higher lipophilicity of the longer fatty acid could cause an increase in toxicity. A non-GLP study of Decanoic acid conducted with Golden orfe (*Leuciscus idus*) show similar toxicity, therefore read across is justified.

Acute toxicity of Decanoic acid to daphnids (*Daphnia magna*) was investigated in a semi-static study. The highest tested nominal concentration causing no mortality after 48 hours was 10 mg/L. The EC_{50} was 16 mg/L.

A static study was conducted to estimate the toxicity of Decanoic acid to the algae *Scenedesmus subspicatus*. The highest initial concentration tested at which the measured parameters do not show a significant inhibition of cell growth rate relative to control values is 0.57 mg/L (NOE_rC). The E_rC_{50} was 2 mg/L. As the test item decreases during the test period, the results are given in mean measured concentrations. (For details of the discussion if the NOEC of the study should be given in nominal or measured concentrations, please see Doc. II-A, chapter 4.2.1).

No inhibitory effects against aquatic micro-organisms were found up to a nominal concentration of 1000 mg/L Decanoic acid. The respiration rates were enhanced up to the highest concentration. The NOEC was determined with ≥1000 mg/L (nominal).

Air compartment:

The half-life of Decanoic acid is estimated to be 34.5h. Based on this result an accumulation of Decanoic acid in air is not expected.

On the basis of its physical and chemical properties, as e.g. absence of absorption bands in the so-called atmospheric window (800-1200 nm), short atmospheric lifetime and absence of Cl, F, N or S substituents in the molecule, Decanoic acid is not expected to display adverse abiotic effects on the atmospheric environment.

Therefore, no adverse biotic effects of Decanoic acid in atmosphere are expected.

Terrestrial compartment:

No initial terrestrial toxicity tests were submitted. According to the intended uses of the biocidal products only indirect exposure of the active substance to the terrestrial compartment is expected. Therefore, according to the TNsG on data requirements no initial terrestrial toxicity tests are needed. However, a PNEC for the terrestrial compartment was calculated according to the equilibrium partitioning method (TGD 2003).

2.2.3.3. PBT assessment

Persistence:

Decanoic acid is readily biodegradable (91-92% mineralization after 28 days). At the end of the 10 days window at day 11 the mineralization rate was already 79-80%.

The P-criterion is not met: Not P

Bioaccumulation:

BCF_{fish} = 598 (calculated)

The B-criterion is not met: Not B

Toxicity:

Chronic toxicity is only available for algae, the NOEC is 0.57 mg/L.

Endocrine disrupting effects and CMR effects:

No specific test for potential endocrine disruption was carried out. From the available CMR studies and the repeated dose studies there is no evidence for endocrine disruption or for CMR effects (see Doc. II-A sections 3.5, 3.6, 3.7 and 3.8).

The T-criterion is not met: Not T

Conclusion:

Decanoic acid is neither a PBT nor a vBvP substance.

Decanoic acid is a fatty acid. There is no indication of an endocrine potential of Decanoic acid.

2.2.3.4. Exposure assessment PT 18

The environmental exposure assessment has been performed in accordance with the Emission Scenario Document for insecticides, acaricides and products to control arthropods (PT 18) for household and professional use (OECD, 2008)[3] as well as the results of the Workshop on ESD for PT 18[4], the Technical Guidance Document (TGD II, European Commission 2003)[5] and the EUSES Background report (EC 2004)[6] and is based on information relating to the Intended Use of INSECT SHOCKER FL (Appendix II of this document). Although Decanoic acid and INSECT SHOCKER FL are produced in Europe, these stages have not been addressed here. The modeling of exposure and risk assessment/risk characterization during production of Decanoic acid and the formulation of the biocidal product should be addressed under other EU legislation and not repeated under Directive 98/8/EC (agreed at the Biocides Technical Meeting TMI06).

In the ESD for PT 18 it is assumed that insecticides used indoor will generally not directly reach the environmental compartments, but it is concluded that the cleaning step after application will lead the releases to waste water through wet cleaning methods. The environmental exposure assessment was conducted for the local scale only.

Subsequent to the use of the biocidal product secondary poisoning may occur. Therefore, the concentration of contaminated food (e.g. earthworms or fish) via ingestion by birds and/or mammals is calculated according to the TGD II (EC 2003).

The exposure values relevant for risk characterization are presented in the following chapter.

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3 OECD (2008) Series on Emission Scenario documents, Number 18, Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses ENV/JM/MONO(2008)14, 30-Jun-2008 .

4 Workshop on ESD for PT18 (Brussels, Belgium, 11th of December 2007). Available via http://ecb.jrc.ec.europa.eu/documents/Biocides/EMISSION_SCENARIO_DOCUMENTS/ESD_PER_PRODUCT_TYPE/PT_18/PT18_Workshop_Environmental_Risk_Assessment_2007.pdf.

5 EC (2003)Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Part II.

6 EC (2004) European Union System for the Evaluation of Substances 2.0 (EUSES 2.0). Prepared for the European Chemicals Bureau by the National Institute of Public Health and the Environment (RIVM), Bilthoven, The Netherlands (RIVM Report no. 601900005). Available via http://ecb.jrc.ec.europa.eu/euses/.

2.2.3.5. Risk characterisation PT 18

Air compartment:

The PEC of Decanoic acid in air from its use may be considered negligible (see Doc. II-B, chapter 5.2.1). Moreover, Decanoic acid is not expected to have adverse biotic or abiotic effects on the atmosphere (see Doc. II-A, chapters 4.1.1.2 and 4.2.2).

Conclusion:

Decanoic acid poses an acceptable risk for the air compartment.

Aquatic compartment (including sediment):

STP:

Decanoic acid will generally not directly reach the sewage system. Hence, wet cleaning methods will be applied to most surfaces after application. This will lead to releases to sewage treatment plants, which are considered as the main receiving compartment for insecticides used indoors Doc. II-B, chapter 5.2.2 PEC in STP).

The PNEC for aquatic micro-organisms was determined with 100 mg/L (nominal) (see Doc. II-A, chapter 4.2.1 Aquatic compartment).

The PEC/PNEC ratio for STP is calculated by dividing the PEC_{STP} by the $PNEC_{aquatic\ micro-organisms}$ (see table 2.2.3.5-1).

Table 2.2.3.5-1: PEC/PNEC ratios for STP

PEC_{STP}	**PEC/PNEC**
Sewage treatment plant ($_{PNECaquatic\ micro-organisms:}$ 100 mg/L)	
0.00123 mg/L	$1.23x10^{-5}$

Conclusion:

Decanoic acid poses an acceptable risk to aquatic micro-organisms in sewage treatment plants.

Surface water incl. sediment:

According to the Intended Use (Doc. II-B), no direct exposure to surface water, only indirect exposure via STP is possible assuming that the effluent of the sewage treatment plant is diluted into the surface water (see Doc. II-B, chapter 5.2.3 PEC in surface water). The

concentrations in the solid phase of the sediment can be derived from the concentrations in surface water (see Doc. II-B, chapter 5.2.4).

The PEC/PNEC ratios for the aquatic ecosystem are derived by dividing the local PEC in surface water by the PNEC for aquatic organisms. For the estimation of the PNECs for aquatic organisms see Doc. II-A.

The sediment risk assessment essentially is equal to the aquatic risk assessment as both $PEC_{sediment}$ and the $PNEC_{sediment}$ have been calculated by EqP from the $PEC_{local,water}$ and the $PNEC_{aquatic}$, respectively.

Table 2.2.3.5-2: Local PEC/PNEC ratios for aquatic compartment

Exposure scenario	**PEC in mg/L or mg/kg$_{wwt}$**	**PEC/PNEC**
	Water/local (PNEC$_{water}$: 0.0057 mg/kg)	
Local PEC in surface water during emission episode (dissolved):	$1.22x10^{-4}$	$2.14x10^{-2}$
Annual average local PEC in surface water (dissolved), 1 emission day:	$3.35x10^{-7}$	$5.88x10^{-5}$
Annual average local PEC in surface water (dissolved), 270 emission days:	$9x10^{-5}$	$1.58x10^{-2}$
	Sediment/local (PNEC$_{sediment}$: 0.0372 mg/kg$_{wwt}$)	
Local PEC in fresh-water sediment during emission episode:	$7.98x10^{-4}$	$2.14x10^{-2}$

Conclusion:

Decanoic acid poses an acceptable risk to aquatic and sediment dwelling organisms.

Groundwater:

According to the TDG II (EC 2003) the concentration in pore water of soil is taken as an indication for potential groundwater levels. The calculation of the predicted environmental concentration of Decanoic acid in groundwater after continuous sludge application over 10 years gives a value of 0.042 µg/L (see Doc. II-B, section 5.2.6). This meets the parametric value of 0.1 µg/L according to Directive 98/83/EC.

In addition, potential groundwater concentrations were calculated using FOCUS Pearl groundwater model. The calculated values for all different scenarios are well below the threshold value of 0.1 µg/L as well (closest to the 80th percentile of 0.000000 µg/L).

Conclusion:

Decanoic acid is not likely to have unacceptable effects on groundwater and the requirements of Directive 98/83/EC and 2006/118/EC are complied with.

Persistence in sediment:

Decanoic acid is readily biodegradable (91-92% in 28 days). Furthermore it is known that fatty acids are nutrients for micro-organisms and are mineralised to CO_2 and water through β-oxidation (see Doc. II-A, chapter 4.1.1.1 Biodegradation).

Neither laboratory nor field sediment degradation studies are available for Decanoic acid.

In the adsorption/desorption test (OECD 106) no K_{oc} value could be determined due to rapid degradation. Therefore the formation of not extractable residues is not expected (see Doc. II-A, chapter 4.1.1.3 Distribution).

The consequences or effects on non-target organisms have been assessed in the risk assessment above and are acceptable.

Conclusion:

Decanoic acid is not persistent in sediment.

Terrestrial compartment:

Indirect exposure of agricultural soil:

According to the intended use direct emissions to the soil compartment are considered not relevant for indoor application. However, indirect exposure of agricultural soils through fertilization with sludge from a STP is considered relevant.

The PECs were calculated according to TGD (2003) for arable soil and grassland as the average concentrations over certain time-periods in agricultural soil fertilized with sludge from a STP (see Doc. II-B, chapter 5.2.5 PEC in soil).

The PNEC for soil organisms with 0.027 mg/kg_{wwt} was calculated according to the equilibrium partitioning method on the basis of the $PNEC_{water}$ (see Doc. II-A, chapter 4.2.3 Terrestrial compartment).

The PEC/PNEC ratio for soil was calculated by dividing the PEC_{soil} by the $PNEC_{soil}$ (see table 2.2.3.5-3).

Table 2.2.3.5-3: Local PEC/PNEC ratios for the terrestrial compartment

	PEC_{soil} (mg/kg_{wwt})	**PEC/PNEC**
	$PNEC_{soil}$: 0.027 mg/kg_{wwt}	
Arable soil (30 days)	$6.31x10^{-4}$	$2.34x10^{-2}$
Arable soil (180 days)	$2.00x10^{-4}$	$7.40x10^{-3}$
Grassland (180 days)	$7.64x10^{-5}$	$2.83x10^{-3}$

Conclusion:

Decanoic acid poses an acceptable risk to soil organisms.

Persistence in soil:

Decanoic acid is readily biodegradable (91-92% in 28 days). Furthermore it is known that fatty acids are nutrients for micro-organisms and are mineralised to CO_2 and water through β-oxidation by microbial activity (see Doc. II-A, chapter 4.1.1.1 Biodegradation).

Neither laboratory nor field soil degradation studies were submitted for Decanoic acid.

In the adsorption/desorption test (OECD 106) no K_{oc} value could be determined due to rapid degradation. Therefore the formation of not extractable residues is not expected (see Doc. II-A, chapter 4.1.1.3 Distribution).

The consequences or effects on non-target organisms have been assessed in the risk assessment above and are acceptable.

Conclusion:

Decanoic acid is not persistent in soil.

Secondary poisoning (Non compartment specific effects relevant to the food chain):

As the calculated octanol-water partition coefficient for Decanoic acid indicates a potential for bioaccumulation, a standard assessment for secondary poisoning was conducted.

Risk for fish eating and worm eating predators:

No toxicity tests in birds were submitted for Decanoic acid. However, data from tests conducted with Nonanoic acid are available for read across. (Doc I, chapter 2.2.3.2 Effects assessment of the Draft-CAR Nonanoic acid, PT 19, 2008).

For secondary poisoning, an initial standard assessment according to the TGD on risk assessment Part II (2003) was conducted. The risk to the fish- and worm eating predators is calculated in Table 2.4.1-1 as the ratio between the concentration in their food (fish or earthworms) (see Doc. II-B, chapter 5.2.7) and the predicted no-effect concentration for long term oral intake ($PNEC_{oral\ chron}$) (see Doc II-A, chapter 4.2.4).

Table 2.2.3.5-4: PEC/PNEC ratios for non-compartment specific effects (secondary poisoning)

Exposure scenario	**PEC**	**PEC/PNEC**
	$PNEC_{oral\ chron}$ 0.331 a.s. mg/kg diet	
Aquatic food chain, 1 emission day	$1x10^{-4}$ mg a.s./$kg_{wet\ fish}$	$3.02x10^{-4}$
Aquatic food chain, 270 emission days	$2.7x10^{-2}$ mg a.s./$kg_{wet\ fish}$	$8.16x10^{-2}$
Terrestrial food chain	$2.8x10^{-3}$ mg a.s./$kg_{wet\ earthworm}$	$8.46x10^{-3}$

Conclusion:

The PEC/PNEC ratios for secondary poisoning calculated for the aquatic and terrestrial food chain indicate an acceptable risk.

2.2.3.6. Exposure assessment PT 19

The estimation of environmental exposure during the use of the biocidal product is made by calculating the emissions and then the concentrations for each environmental compartment on basis of the intended use (see Appendix II of this document). Since there is not yet a specified ESD (Emission Scenario Document) available for PT 19 the local Predicted Environmental Concentrations (PECs) were calculated in two different approaches:

In the first approach PECs are calculated with EUSES 2.1.1 in accordance with the Emission Scenario Document for PT 1 (Human hygiene products)7 and EUSES Background report (EC 2004)[8]. The estimation can be based on a tonnage or a consumption approach. The environmental exposure assessment was conducted for the local scale only

In the second approach PECs are calculated with EUSES 2.1.1 in accordance with the Technical Guidance Document (TGD II, European Commission 2003)[9] for Industrial Category 5 (Personal/Domestic) and EUSES Background report (EC 2004). Within this Industrial Category, the use of the repellent is covered by Use Category UC36 (cosmetic/ odor agents). The estimation is tonnage based. In this scenario the regional scale is automatically included in the EUSES calculations.

Subsequent to the use of the biocidal product secondary poisoning may occur. Therefore, the concentration of contaminated food (e.g. earthworms or fish) via ingestion by birds and/or mammals is calculated according to the TGD II (EC 2003).

The exposure values relevant for risk characterization are presented in the following chapter.

7 Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1). European Commission DG ENV/RIVM. Jan 2004. (TMI 04-env-item4-PT1.doc)

8 EC (2004) European Union System for the Evaluation of Substances 2.0 (EUSES 2.0). Prepared for the European Chemicals Bureau by the National Institute of Public Health and the Environment (RIVM), Bilthoven, The Netherlands (RIVM Report no. 601900005). Available via http://ecb.jrc.ec.europa.eu/euses/.

9 EC (2003)Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Part II.

2.2.3.7. Risk characterisation PT 19

Air compartment:

The PEC of Decanoic acid in air from its use may be considered negligible (see Doc. II-B, chapter 5.2.1). Moreover, Decanoic acid is not expected to have adverse biotic or abiotic effects on the atmosphere (see Doc. II-A, chapters 4.1.1.2 and 4.2.2).

Conclusion:

Decanoic acid poses an acceptable risk for the air compartment.

Aquatic compartment (including sediment):

STP:

Decanoic acid will generally not directly reach the sewage system. Hence, bathing or taking a shower after application, will lead to releases to sewage treatment plants, which are considered as the main receiving compartment for repellents directly used on human skin.

The PECs for the STP were calculated for scenarios 1A/1B and 2. In addition for scenario 1A and 2 the PECs were calculated for 90 days (peak bug season) and 365 days of emission (see Doc. II-B, chapters 5.1 Fate and distribution in the environment and 5.2.2 PEC in STP).

The PNEC for aquatic micro-organisms was determined with 100 mg/L (nominal) (see Doc. II-A, chapter 4.2.1 Aquatic compartment).

The PEC/PNEC ratio for STP is calculated by dividing the PEC_{STP} by the $PNEC_{aquatic\ micro-organisms}$ (see table 2.2.3.7-1).

Table 2.2.3.7-1: PEC/PNEC ratios for STP

Exposure scenario	**PEC_{STP} (mg/L)**	**PEC/PNEC**
	Sewage treatment plant ($PNEC_{aquatic\ micro-organisms}$ 100 mg/L)	
Scenario 1A (90 days)	$6.86x10^{-4}$	$6.86x10^{-6}$
Scenario 1A (365 days)	$1.69x10^{-4}$	$1.69x10^{-6}$
Scenario 1B	$1.82x10^{-2}$	$1.82x10^{-4}$
Scenario 2 (90 days)	$5.5x10^{-4}$	$5.5x10^{-6}$
Scenario 2 (365 days)	$1.35x10^{-4}$	$1.35x10^{-6}$

Conclusion:

Decanoic acid poses an acceptable risk to aquatic micro-organisms in sewage treatment plants.

Surface water incl. Sediment:

According to the Intended Use (Doc. II-B), no direct exposure to surface water, only indirect exposure via STP is possible assuming that the effluent of the sewage treatment plant is diluted into the surface water (see Doc. II-B, chapter 5.2.3 PEC in surface water). The concentrations in the solid phase of the sediment can be derived from the concentrations in surface water (see Doc. II-B, chapter 5.2.4).

The PEC/PNEC ratios for the aquatic ecosystem are derived by dividing the local PEC in surface water by the PNEC for aquatic organisms. For the estimation of the PNECs for aquatic organisms see Doc. II-A.

The sediment risk assessment essentially is equal to the aquatic risk assessment as both $PEC_{sediment}$ and the $PNEC_{sediment}$ have been calculated by EqP from the $PEC_{local,water}$ and the $PNEC_{aquatic}$, respectively.

Table 2.2.3.7-2: Local PEC/PNEC ratios for aquatic compartment

	PEC (mg/L or mg/kg_{wwt})	**PEC/PNEC**
Water/local ($PNEC_{water}$: 0.0057 mg/L)		
Scenario 1A: ESD, tonnage based, 90 d peak bug season	$7.03x10^{-5}$	$1.23x10^{-2}$
Scenario 1A: ESD, tonnage based , 365 d	$1.86x10^{-5}$	$3.26x10^{-3}$
Scenario 1B: ESD, consumption based	$1.82x10^{-3}$	0.319
Scenario 1B: ESD, consumption based, annual average	$1.86x10^{-5}$	$3.26x10^{-3}$
Scenario 2: TGD, tonnage based, 90 d peak bug season	$5.64x10^{-5}$	$9.89x10^{-3}$
Scenario 2: TGD, tonnage based, 365 d	$1.49x10^{-5}$	$2.61x10^{-3}$
Sediment/local ($PNEC_{sediment}$: 0.0372 mg/kg)		
Scenario 1A: ESD, tonnage based, 90 d peak bug season	$4.59x10^{-4}$	$1.23x10^{-2}$
Scenario 1A: ESD, tonnage based , 365 d	$1.21x10^{-4}$	$3.25x10^{-3}$
Scenario 1B: ESD consumption based	$1.18x10^{-2}$	0.317
Scenario 2: TGD tonnage based, 90 d peak bug season	$3.67x10^{-4}$	$9.87x10^{-3}$
Scenario 2: TGD, tonnage based, 365 d	$9.72x10^{-5}$	$2.61x10^{-3}$

Conclusion:

Decanoic acid poses an acceptable risk to aquatic and sediment dwelling organisms.

Groundwater:

According to the TDG II (EC 2003) the concentration in pore water of soil is taken as an indication for potential groundwater levels. The calculation of the predicted environmental concentration of Decanoic acid in groundwater after continuous sludge application over 10 years gives values of 0.005 µg/L up to 0.6 µg/L, depending on the scenario (see Doc. II-B, section 5.2.6). Only the value calculated according to the ESD scenario for PT 1 (Human hygiene products) when the estimation is based on a consumption approach (1B), is slightly above the parametric value of 0.1 µg/L. This scenario represents a very worst case. If the estimations are based on the ESD for PT 1 (Human hygiene products) using a tonnage scenario (1A) and the TGD for Industrial Category 5 (Personal/Domestic) and Use Category UC 36 (Cosmetic/Odour agents) (2), the parametric value of 0.1 µg/L according to Directive 98/83/EC is met.

In addition, potential groundwater concentrations for the scenario 1B were calculated using FOCUS Pearl groundwater model. All FOCUS Pearl scenarios calculated a potential groundwater concentration for Decanoic acid below the threshold value of 0.1 µg/L (closest to the 80th percentile of 0.000000 µg/L).

Conclusion:

Decanoic acid is not likely to have unacceptable effects on groundwater and the requirements of Directive 98/83/EC and 2006/118/EC are complied with.

Terrestrial compartment:

According to the intended use as a repellent, which is directly spread onto human skin, direct emissions to the soil compartment are diffuse and are therefore considered not relevant. However indirect exposure of agricultural soils through fertilization with sludge from a STP is considered relevant.

The PECs were calculated for scenarios 1A/1B and 2 for arable soil and grassland as the average concentrations over certain time-periods in agricultural soil fertilized with sludge from a STP. In addition for scenario 1A and 2 the PECs were calculated for 90 days (peak bug season) and 365 days of emission to STP (see Doc. II-B, chapters 5.1 Fate and distribution in the environment and 5.2.5 PEC in soil).

The PNEC for soil organisms with 0.027 mg/kg$_{wwt}$ was calculated according to the equilibrium partitioning method on the basis of the PNEC$_{water}$ (see Doc. II-A, chapter 4.2.3 Terrestrial compartment).

The PEC/PNEC ratio for soil was calculated by dividing the PEC$_{soil}$ by the PNEC$_{soil}$ (see table 2.2.3.7-3).

Table 2.2.3.7-3: Local PEC/PNEC ratios for the terrestrial compartment exposed via sewage sludge

Exposure scenario	PEC_{soil} (mg/kg_{wwt})	PEC/PNEC
	$PNEC_{soil}$: 0.027 mg/kg_{wwt}	
Arable soil (averaged over 30 days)		
Scenario 1A (90 days of emission to STP)	$3.54x10^{-4}$	$1.31x10^{-2}$
Scenario 1A (365 days of emission to STP)	$8.73x10^{-5}$	$3.23x10^{-3}$
Scenario 1B	$9.36x10^{-3}$	0.35
Scenario 2 (90 days of emission to STP)	$2.84x10^{-4}$	$1.05x10^{-2}$
Scenario 2 (365 days of emission to STP)	$7.06x10^{-5}$	$2.61x10^{-3}$
Arable soil (averaged over 180 days)		
Scenario 1A (90 days of emission to STP)	$1.12x10^{-4}$	$4.15x10^{-3}$
Scenario 1A (365 days of emission to STP)	$2.77x10^{-5}$	$1.03x10^{-3}$
Scenario 1B	$2.97x10^{-3}$	0.11
Scenario 2 (90 days of emission to STP)	$9.07x10^{-5}$	$3.36x10^{-3}$
Scenario 2 (365 days of emission to STP)	$2.30x10^{-5}$	$8.52x10^{-4}$
Grassland (averaged over 180 days)		
Scenario 1A (90 days of emission to STP)	$4.29x10^{-5}$	$1.59x10^{-3}$
Scenario 1A (365 days of emission to STP)	$1.06x10^{-5}$	$3.93x10^{-4}$
Scenario 1B	$1.30x10^{-3}$	$4.81x10^{-2}$
Scenario 2 (90 days of emission to STP)	$3.51x10^{-5}$	$1.30x10^{-3}$
Scenario 2 (365 days of emission to STP)	$9.25x10^{-6}$	$3.43x10^{-4}$

Conclusion:

Decanoic acid poses an acceptable risk to soil organisms in all calculated scenarios even in scenario 1B, which is based on several worst case assumptions.

Secondary poisoning (Non compartment specific effects relevant to the food chain):

As the calculated octanol-water partition coefficient for Decanoic acid indicates a potential for bioaccumulation, a standard assessment for secondary poisoning was conducted.

Risk for fish eating and worm eating predators

For secondary poisoning, an initial standard assessment according to the TGD on risk assessment Part II (2003) was conducted. The risk to the fish- and worm eating predators is calculated in Table 2.4.1-1 as the ratio between the concentration in their food (fish or earthworms) (see Doc. II-B, chapter 5.2.7) and the predicted no-effect concentration for long term oral intake ($PNEC_{oral\ chron}$) (see Doc II-A, chapter 4.2.4).

Long term $PNEC_{oral\ chron}$: 0.331 mg a.s./kg diet

Table 2.2.3.7-4: PEC/PNEC ratios for non-compartment specific effects (secondary poisoning)

Exposure scenario	**PEC mg a.s./kg$_{wet\ fish}$ /$_{wet\ earthworm}$**	**PEC/PNEC**
	$PNEC_{oral\ chron}$ 0.331 a.s. mg/kg diet	
Aquatic food chain:		
Scenario 1A, 365 d	$6.06x10^{-3}$	$1.83x10^{-2}$
Scenario 1B, annual average	0.134	0.405
Scenario 2, 365 d	$4.86\ x10^{-3}$	$1.47x10^{-2}$
Terrestrial food chain:		
Scenario 1A, 90 d	$1.58\ x10^{-3}$	$4.77x10^{-3}$
Scenario 1A, 365 d	$3.9\ x10^{-4}$	$1.18x10^{-3}$
Scenario 1B, annual average	$4.16\ x10^{-2}$	0.135
Scenario 2, 90 d	$1.27\ x10^{-3}$	$3.84x10^{-3}$
Scenario 2, 365 d	$3.26\ x10^{-4}$	$9.85x10^{-4}$

Conclusion:

The PEC/PNEC ratios for secondary poisoning calculated for the aquatic and terrestrial food chain indicate no risk.

2.2.4. List of endpoints

In order to facilitate the work in granting or reviewing authorisations, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3. PROPOSED DECISION

3.1. Background to the proposed Decision

Decanoic acid can either be used as insecticide (PT18) or as repellent (PT19) depending on the type of product formulation.

Used as an insecticide in appropriate formulations Decanoic acid kills insects upon contact with a sufficient dose with a delay of a few hours up to 7 days depending on the species and the individual. The mode of action is unknown. It is speculated that the active substance damages the chitin cuticle of arthropods leading to desiccation.

Decanoic acid used in appropriate formulations as repellent (PT19) unfolds its effect through the vapour phase saturating the highly sensitive gas receptors of the targets. The insects do not land on the human skin and therefore do not bite. Applied as a repellent, Decanoic acid does not kill the insects.

The active substance has no hazardous physico-chemical properties.

Decanoic acid is a linear saturated fatty acid, is ubiquitous in nature and is part of the natural diet in the free form and as triglycerid. It is very unlikely that Decanoic acid poses CMR or other human health hazards except for its local skin and eye effect. Human health risk assessment is focused on local effects and considered acceptable.

The PBT assessment, based on the available data, shows that none of the three criteria are fulfilled. Therefore Decanoic acid is neither a vPvB, nor a PBT substance and it is no candidate for substitution.

In the environmental risk assessments for both product types no risk was identified for the air compartment, for the aquatic compartment including sediment, for the soil compartment including groundwater and for secondary poisoning.

Decanoic acid is a fatty acid. There is no indication of an endocrine potential of Decanoic acid.

3.2. Proposed Decision

The overall conclusion from the evaluation of Decanoic acid for use in product type 18 (insecticides, acaricides and products to control other arthropods) and product type 19 (repellent), is that it may be possible to issue authorisations of products containing Decanoic acid in accordance with the conditions laid down in Article 5(1) b), c) and d) of Dir. 98/8/EC.

It is therefore appropriate to approve Decanoic acid for use in biocidal products for product-type 18 (insecticides, acaricides and products to control other arthropods) and 19,(repellents and attractants) and subject to the following specific conditions:

For product-type 18 :

The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

Authorisations are subject to the following conditions:

1) Authorisations of products for non-professional use are subject to the packaging being designed to minimise user exposure, unless it can be demonstrated in the application for product authorisation that risks for human health can be reduced to acceptable levels by other means.

2) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council or Regulation (EC) No 396/2005 of the European Parliament and of the Council shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

For product-type 19 :

The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

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

3.3.1. PT 18:

1) In case the biocidal product is the same as the representative biocidal product, in addition to the information presented in the active substance CAR, further data might be requested, i.a. on storage stability and shelf life and persistence of foaming.

2) A minimum efficacy of the a.s. against certain target species under specific application conditions was shown. However, at the product authorisation stage, efficacy of the actual products must be demonstrated according to the requirements of this dossier.

3) General outlines of strategies to monitor and manage resistance development are required for product authorisation. Behavioural resistance, i.e. avoidance of the active substance or products containing the active substance needs consideration as well.

4) Based on the calculation method and in addition considering the negative bovine cornea opacity test results (BCOP, TG437) with the representative product, the product is classified as eye irritating (category 2). Re-evaluation of the data-package at product authorisation stage shall be considered, since (1) in vitro tests and testing strategies allowing full replacement of the in vivo tests for eye irritation are in development at OECD, (2) the actual representative product may not be the final formulation for the market; improvements of efficacy and final formulation are necessary, (3) in vivo testing should be reduced according to the 3R principle.

5) In case evaluation of the PT18 products at product authorisation stage indicates risk for eye irritation and if supported by comparative eco/toxicological and efficacy

evaluation with other products of identical use and following as far as available new guidance on risk assessment for local effects, the following risk mitigation measures may be considered: labelling with "Do not use in presence of children".

6) The representative product contains a preservative that represents a sensitizing mixture with a specific classification limit and another component that is not sensitizing. The concentration of the preservative in the product is given, however the proportion of the 3 components in the mixture was not given, so it is unclear if the preservative mixture is present in the product above or below the specific classification limit. The exact composition of the product allowing the clarification of potential sensitizing properties has to be provided with product authorisation.

7) Only indoor use including environmental exposition caused by the cleaning steps has been assessed. Outdoor use would request an altered environmental risk assessment.

8) Dermal absorption values used in the applications for product authorisation should be justified, if available by the submission of specific dermal absorption data on the product, or by read-across to existing data if scientifically justified, or by using default values.

9) A strategy to monitor and manage resistance development should be submitted at product authorisation stage.

10) For product authorisation additional information is required, concerning the degradation rates of the active substance during pre-treatment and/or in a waste water treatment plant (e.g. preferably monitoring of STP influent and effluent concentrations, or by means of simulations tests).

3.3.2. PT 19:

1) At product authorisation stage reliable efficacy testing of the product and a blank formulation (i.e. same product composition, but without active substance) against typical European mosquito species should be submitted.

2) The potential repellent property of fragrances used in the formulation has to be assessed.

3) Sound estimates on average and maximum application rates per user are required to base risk assessments upon.

4) In case the biocidal product is the same as the representative biocidal product, in addition to the information presented in the active substance CAR, further data might be requested, i.a. on storage stability and shelf life and persistence of foaming, more detailed information on the dose and frequency and of application.

5) General outlines of strategies to monitor and manage resistance development are required for product authorisation. Behavioural resistance, i.e. avoidance of the active substance or products containing the active substance needs consideration as well.

6) The representative product would not need to be classified for eye irritation (cat 2) based on the calculation method. Furthermore the representative product was tested with the bovine cornea opacity test (BCOP, TG437) to estimate potential local eye effects. The results indicate that this product is not likely to be classified for category 1, serious eye damage. At this stage it is preliminarily concluded that the product is unlikely to cause serious eye damage but it may cause eye irritation. Re-evaluation of the data-package is recommended at product authorisation stage, since (1) in vitro tests and testing strategies allowing full replacement of the in vivo tests for eye irritation are in development at OECD, (2) the actual representative product may not be the final formulation for the market; improvements of efficacy and final formulation may be necessary, (3) in vivo testing should be reduced according to the 3R principle.

7) In case evaluation of the PT19 products at product authorisation stage indicates risk for eye irritation and if supported by comparative eco/toxicological and efficacy evaluation with other products of identical use and following as far as available new guidance on risk assessment for local effects, the following risk mitigation measures may be considered: (1) no formulation/packaging for spray application; (2) labelling with "not for use on children"

8) Any potential for direct exposure to surface water as a consequence of swimming etc. has not been assessed at the European level.

9) Dermal absorption values used in the applications for product authorisation should be justified, if available by the submission of specific dermal absorption data on the product, or by read-across to existing data if scientifically justified, or by using default values.

10) At product authorisation stage refined analytical methods have to be submitted addressing the deficiencies and ambiguities identified during evaluation

11) A strategy to monitor and manage resistance development should be submitted at product authorisation stage.

12) For product authorisation additional information is required, concerning the degradation rates of the active substance during pre-treatment and/or in a waste water treatment plant (e.g. preferably monitoring of STP influent and effluent concentrations, or by means of simulations tests).

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 approval of Decanoic acid

3.5. Updating this Assessment Report

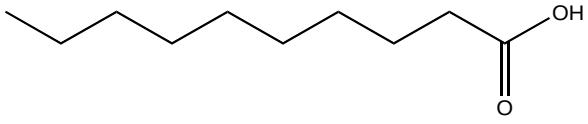
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information submitted in relation with Regulation (EU) No 528/2012. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the approval of Decanoic acid.

APPENDIX I: LIST OF ENDPOINTS

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance	Decanoic acid
Product-type	PT 18 and PT 19

Identity

Chemical name (IUPAC)	n-Decanoic acid
Common name, synonyma	Capric acid
CAS No	334-48-5
EC No	206-376-4
Other substance No.	n.a.
Minimum purity of the active substance as manufactured (g/kg or g/l)	98.5%w/w
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	There are no constituents in the substance which are classified as „toxic“, „highly toxic“ or „dangerous for the environment“.
Molecular formula	$C_{10}H_{20}O_2$
Molecular mass	172.27 g/mol
Structural formula	

Physical and chemical properties

Melting point (state purity)	29.8 -31.6°C
Boiling point (state purity)	146.8-147.8°C
Temperature of decomposition	Normal pressure Decanoic acid starts to decompose at 264.5°C
Appearance (state purity)	Solid; White crystal; Rancid
Relative density (state purity)	density ρ= 0.674 kg/L
Surface tension	Octanoic acid is surface active. Due to the similar molecular structure, it is expected that Decanoic acid may also be surface active.
Vapour pressure (in Pa, state temperature)	2.17×10^{-4} Pa (25°C) 2.096×10^{-4} Pa (20°C)
Henry’s law constant (Pa m^3 mol^{-1})	0.472 Pa x m^3 x mol^{-1}(calculated) at 25°C
Solubility in water (g/l or mg/l, state temperature)	Water: 43 mg/L; at 20°C

pH 4: 31 mg/L; at 20°C pH 7: 1843 mg/L; at 20°C pH 9: 2882 mg/L. at 20°C Solubility at 35°C and 50°C not measurable

Solubility in organic solvents (in g/l or mg/l, state temperature)	Solubility in organic solvents of Decanoic acid is >1kg/L Hexane at 22°C and > 1kg/L Ethanol at 22°C
Stability in organic solvents used in biocidal products including relevant breakdown products	Expert Statement; Not relevant. The active substance as manufactured does not include any organic solvent
Partition coefficient (log P_{OW}) (state temperature)	Calculated with KOWWIN: Log Kow = 4.02 Reference in the Program KOWWIN: Log Kow = 4.09 for the undissociated acid
Dissociation constant	The reported dissociation constant (pK. value at 25°C) of n-Octanoic acid is 4.89 (Handbook of Chemistry and Physics, 79' edition 1998- 1999, pp. 8-46/56). The dissociation constant (pK value at 25'C) of Decanoic acid in water is extrapolated from known pK values of other alkyl homologues and is expected to be in the range from 4.89 to 5.03.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	The test substance shows an absorption maximum at 208.4 nm and an minimum at 201.9 nm in methanol, a maximum at 208.0 nm and an minimum at 201.9 nm In 1N HCl/methanol (90/10 v/v/) ad no absorption maximum or minimum in 1 N NaOH/methanol (10/90 v/v/)
Flammability	The heat of combustion is -6107.7 kJ/mol (Kirk-Othmer Encyclopedia of Chemical Technology, 4th ed. Volumes 1: 1991), therefore auto flammability is not expected
Explosive properties	Decanoic Acid does not contain structural elements such as peroxide, nitro-group known to cause explosions.

Classification and proposed labelling

with regard to physical/chemical data	None
with regard to toxicological data	<u>Directive 67/548/EEC</u> Xi; R38 - Irritating to skin, R36 - Irritating to eyes S26 In case of contact with eyes rinse immediately with plenty of water and seek medical advice S36/37/39 Wear suitable protective clothing, gloves and eye/face protection <u>Reg. 1272/2008/EC</u> Serious eye irritation – Hazard Category 2 Skin irritation- Hazard Category 2 H319: Causes serious eye irritation H315: Causes skin irritation P264 Wash thoroughly after handling P280 Wear protective gloves/protective clothing/eye protection/face protection.

	P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.P337+ P313: IF EYE IRRITATION PERSISTS: Get medical advice/attention P302+P352: IF ON SKIN: Wash with plenty of soap and water. P332 + P313: If skin irritation occurs, get medical advice/attention P362 Take off contaminated clothing and wash before reuse.
with regard to fate and behaviour data and ecotoxicological data	Reg. (EU) 1272/2008, Annex VI, Table 3.2 N; R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. S61 Avoid release to the environment. Refer to special instructions/safety data sheets. Reg. (EU) 1272/2008, Annex VI, Table 3.1 and 286/2011 Aquatic Chronic 3 H412: Harmful to aquatic life with long lasting effects P273 Avoid release to the environment. P391 Collect spillage P501 Dispose of contents/container to …

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	GC/FID method
Impurities in technical active substance (principle of method)	GC/FID method, Karl Fischer titration method

Analytical methods for residues

Soil (principle of method and LOQ)	Not required
Air (principle of method and LOQ)	Not required
Water (principle of method and LOQ)	GC/MS method with a LOD of 0.1 µg/l for Decanoic acid
Body fluids and tissues (principle of method and LOQ)	Not required
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Fast and complete (no primary data, expected from textbook knowledge)
Rate and extent of dermal absorption:	Fast and complete (no primary data, expected from physchem and irritation)
Rate and extent of inhalative absorption:	Fast and complete (no primary data, expected from information on oral and dermal absorption)
Distribution:	After absorption from the gut C8 and C10 fatty acids are extensively metabolised in the liver. Only a minor fraction bypasses the liver and becomes distributed to peripheral tissues via the general circulation C8 and C10 fatty acids are catabolised predominantly in the liver to C2 fragments, which are further converted to CO2 or used to synthesize longer-chain fatty acids.
Potential for accumulation:	No
Rate and extent of excretion:	No specific data are available; but it is assumed that Octanoic and Decanoic acid become part of the natural triglyceride pathway without overloading the capacity.
Toxicologically significant metabolite(s)	None

Acute toxicity

Rat LD_{50} oral	> 2000 mg/kg bw (total WoE evaluation)
Rat LD_{50} dermal	> 2000 mg/kg bw (total WoE evaluation)
Rat LC_{50} inhalation	> 5mg a.s./L (total WoE evaluation)
Skin irritation	Skin irritation- Hazard Category 2 (total WoE evaluation)
Eye irritation	Serious eye irritation – Hazard Category 2 (total WoE evaluation)
Skin sensitization (test method used and result)	Non sensitizing (total WoE evaluation)

Repeated dose toxicity

Species/ target / critical effect	Rat and human
Lowest relevant oral NOAEL / LOAEL	Medium chain triglycerids and free fatty acids within dietary studies (total WoE evaluation) Sub-acute systemic NOAEL > 1000 mg/kg bw/day
Lowest relevant dermal NOAEL / LOAEL	Not available
Lowest relevant inhalation NOAEL / LOAEL	Not available

Genotoxicity	No genotoxicity within the following tests: Bacterial mutation test (OECD 471), in vitro chromosomal aberration test (OECD 473), in vitro gene mutation test (OECD 476) and a respective total WoE evaluation.

Carcinogenicity

	No study available; waiving accepted based primarily on consideration of the nature of Octanoic and Decanoic acid (linear saturated fatty acid), the high purity and the knowledge about kinetics and metabolism of fatty acids and the negative genotoxicity tests.

Reproductive toxicity

Species/ Reproduction target / critical effect	No study available; waiving accepted based primarily on consideration of the nature of nonanoic acid (linear saturated fatty acid), the high purity, the knowledge about kinetics and metabolism of fatty acids and the published rat developmental and fertility data for octanoic acid and medium chain triglycerids.

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	No study available; waiving was accepted based on the fact that neither the available studies and publications nor general considerations of structure and metabolism indicate a concern for neurotoxicity of Decanoic acid or Octanoic acid with oral, dermal or inhalation exposure.

Other toxicological studies

.....	no

Medical data

.....	No medical reports are available on Octanic acid or Decanoic acid. However in the public literature skin irritation and skin sensitisation tests performed on human volunteers are available. Also repeated dose human dietary studies and estimates of fatty acid uptake as natural component of food fat are referenced

Summary	Value	Study	Safety factor
Systemic short medium and long term AEL (acceptable exposure level)	Not relevant, since local effects dominant	-	-

Acceptable exposure scenarios (including method of calculation) PT 18

Production of active substance (user: /)	Not assessed
Formulation of biocidal product (user: /)	Not assessed
Application of biocidal product (user: General public)	Dermal and inhalative exposure during spraying onto the pests or into their hiding places.
Indirect exposure as a result of use	Inhalation exposure (adults, children, infants); Dermal exposure (infant crawling over treated floor)

	Oral exposure (infant crawling over treated floor)
Exposure of pets	Not considered relevant
Dietary Exposure	Not applicable

Acceptable exposure scenarios (including method of calculation) PT 19

Production of active substance (user: /)	Not assessed
Formulation of biocidal product (user: /)	Not assessed
Application of biocidal product (user: General public)	Dermal and inhalative exposure during application of the repellent on skin. (Scenario covers also oral exposure of infants or children)
Indirect exposure as a result of use	Covered by the primary exposure estimates
Exposure of pets	Not applicable
Dietary Exposure	Not applicable

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	Hydrolysis of the active substance can be excluded by its structure, as free carbon acids cannot be hydrolysed in the absence of further functional chemical groups.
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Decanoic acid does not display UV/VIS maxima at wavelengths above 290 nm. Therefore, photolytic degradation in water is excluded.
Readily biodegradable (yes/no)	Yes; 91-92% in 28 days;
Biodegradation in seawater	-----
Non-extractable residues	-----
Distribution in water / sediment systems (active substance)	-----
Distribution in water / sediment systems (metabolites)	-----

Route and rate of degradation in soil

Mineralization (aerobic)	-----
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): -----
	DT_{90lab} (20°C, aerobic): -----
	DT_{50lab} (10°C, aerobic): -----
	DT_{50lab} (20°C, anaerobic): -----
	degradation in the saturated zone: -----

Field studies (state location, range or median with number of measurements)	DT_{50f}: -----
	DT_{90f}: -----
Anaerobic degradation	-----
Soil photolysis	-----
Non-extractable residues	-----
Relevant metabolites - name and/or code, % of applied active ingredient (range and maximum)	-----
Soil accumulation and plateau concentration	-----

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	According to OECD test guideline 106 no adsorption equilibrium and no K_{oc} value could be established despite sterilisation, due to rapid degradation. For risk characterisation a default K_{oc} value for the non-ionised form of Decanoic acid of 264 L/kg (EUSES model calculation) was used.

Fate and behaviour in air

Direct photolysis in air	Not determined
Quantum yield of direct photolysis	Not determined
Photo-oxidative degradation in air	$T_{1/2}$ = 34.5 h (by OH radicals)
Volatilization	cf. Physical and chemical properties: vapour pressure and Henry's law constant

Monitoring data, if available

Soil (indicate location and type of study)	-----
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)

Species	Time-scale	Endpoint	Toxicity
Fish			
Brachydanio Rerio	96 h, semi-static	Mortality, LC_{50}	81.2 mg/L
Invertebrates			

Daphnia magna	48 h, semi-static	Immobilisation, EC_{50}	16 mg/L
Algae			
Scenedesmus subspicatus	72 h, static	Growth and biomass inhibition, NOE_rC, E_bC_{50}, E_rC_{50}	0.57 mg/L 1.16 mg/L 2 mg/L
Microorganisms			
Activated sludge	3h	Respiration inhibition NOEC	≥ 1000 mg/L, nominal

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms and plants	-----
Reproductive toxicity to ……	-----

Effects on soil micro-organisms

Nitrogen mineralization	-----
Carbon mineralization	-----

Effects on terrestrial vertebrates

Acute toxicity to mammals	Rat: LD_{50} 3.8 g/kg bw
Acute toxicity to birds	-----
Dietary toxicity to birds	-----
Reproductive toxicity to birds	-----

Effects on honeybees

Acute oral toxicity	-----
Acute contact toxicity	-----

Effects on other beneficial arthropods

Acute oral toxicity	-----
Acute contact toxicity	-----
Acute toxicity to ……..	-----

Bioconcentration

Bioconcentration factor (BCF)	598 (calculated according to TGD)
Depration time (DT_{50}) (DT_{90})	
Level of metabolites (%) in organisms accounting for > 10 % of residues	

Chapter 6: Other End Points

APPENDIX II: LIST OF INTENDED USES

Product type 18

The intended use considered in the risk assessment is given in Table II-1. As efficacy of the active substance as well as of the representative biocidal product (including choice of target organisms) was not satisfactorily proven, more information is needed at product authorisation stage (see Doc. I, chapter 3.3)

Table II-1:: Intended uses of INSECT SHOCKER FL considered in the risk assessment

PT		PT 18
Formu -lation	**Type**	Liquid applied by spraying (manual pump spray)
	Conc. of a.s.	1.5% w/w a.s. in aqueous solution
Field of use envisaged		Manual pump spray for non professional use (i.e private households) to control crawling and flying insects indoors.
User		General public (non professional use)
Target Organisms[1]		– Ants (*Lasius niger*) – Cockroaches (*Blaptica dubia, Blatella germanica, Blatella orientalis, Periplaneta Americana*) – Isopods (*Trichorhina tormentosa*) – Crickets (*Acheta domesticus*)
Likely amount at which the a.s. will be used (all fields of use envisaged)	**Method of application[1]**	The ready to use product (manual pump spray) is sprayed undiluted directly onto the pests or into their hiding places with a manual pump spray (trigger sprayer).
	Applied amount of product[1]	To cover an area of 1m^2 10 sprays are approximately applied (5-6 g of product/m^2), for smaller areas the number of sprays is reduced appropriately.
	Application rate[1]	90 mg a.s./m^2 area referring to 6 g b.p./m^2
	Number of treatments per year[1]	Number of treatments per year is not specified. The application is repeated after 1 to 2 days (if needed).
	Limitations	-Not for use outdoors. -Not for use as space spray. -Not for use on plants or pets. -Not for use on food/feeding stuff. -Not for surfaces in direct contact with food/feeding stuff.

[1]to be affirmed/precised at product authorisation stage, see Doc. I, chapter 3.3.

Product Type 19

The intended use considered in the risk assessment is given in Table II-2. As efficacy of the active substance as well as of the representative biocidal product (including choice of target organisms) was not satisfactorily proven, more information is needed at product authorisation stage (see Doc. I, chapter 3.3)

Table II-1:: Intended uses of Repellent FS considered in the risk assessment

PT		PT 19
Formu -lation	**Type**	Ready to use lotion applied by spreading over exposed skin.
	Conc. of a.s.	9.8%
Field of use envisaged		Ready to use lotion intended for general public to spread over skin to repel insects and prevent them from biting.
User		General public (non professional use), adults
Target Organisms1		Mosquitos of the family of *Culicidae*
Likely amount at which the a.s. will be used (all fields of use envisaged)	**Method of application**	The lotion is poured into the hands and spread evenly over the exposed skin, in particular arms and legs.
	Applied amount of product1	5 to 6 g of biocidal product is applied to protect exposed skin of an adult human (arms and legs). If smaller areas are protected the amount solution should be reduced appropriately.
	Application rate1	0.588 g a.s./person referring to 6 g b.p./person (applier: adult)
	Number of treatments per year1	not specified
	Typical size of application area	Arms and legs

[1]to be affirmed/precised at product authorisation stage, see Doc. I, chapter 3.3.

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 "Y" 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.

LIST OF STUDIES FOR THE ACTIVE SUBSTANCE – SORTED BY SECTION NUMBER

Section No / Reference No	Year	Title Source Institution; report nr GLP-, GEP-status Published or unpublished	Data Protection	Date of 1st submission	Owner
A2/01	2009	Decanoic Acid: Complete Analysis of Four Batch Samples ChemService S.r.l. Study Number CH-632/2008 Unpublished	Y		SOPURA
A2.10/01a	2006	Declaration Regarding Production Quantities of Insect Shocker FL Unpublished	Y		SolNova
A2.10/01c	2006	Schema der Produktionsanlage Unpublished	Y		SolNova
A2.10/01d	2006	Rezeptur Unpublished	Y		SolNova
A2.10/02a	2009	INSECT SHOCKER FL - Exposure assessment	Y		MCF-Consultancy GmbH
A2.10/02b	2009	Repellent FS - Exposure assessment	Y		MCF-Consultancy GmbH
A3/01D	1999	Determination of some physico-chemical properties of Decanoic acid TNO Prins Maurits Laboratory PML 1999-C110 Unpublished	Y		SOPURA
A3/02D	1999	Expert statement: hydrolysis and dissociation constants of n-octanoic acid and n-decanoic acid TNO Voeding, report number V99.846 Unpublished	Y		SOPURA
A3/03rev09	2008	Decanoic Acid Determination of the bulk density Sopura,	Y		SOPURA

		Study nr 5474-DECA- 5 Unpublished			
A3/03a	2008	Analysis report: Surface tension of Decanoic acid SOPURA, Unpublished	Y		SOPURA
A3/03b	2008	Decanoic Acid Determination of the Viscosity Sopura Study nr 5474-DECA-2 Unpublished	Y		SOPURA
A3/04	2006	Calculation of the Henry Law Constant and Log Kow for decanoic acid with the Program HENRYWIN v3.10 Unpublished	Y		MCF-Consultancy GmbH
A3/05rev09	2008	Decanoic Acid Determination of some Physico-Chemical Properties Study nr 5474-DECA-4 Sopura Unpublished	Y		SOPURA
A3/06	2006	Expert statement Stability of decanoic acid in organic solvents Unpublished	Y		MCF-Consultancy GmbH
A3/07_rev	2008	Expert statement Thermal stability of decanoic acid Unpublished	Y		MCF-Consultancy GmbH
A3/08	2006	Expert statement Flammability , including auto flammability and identity of combustion product of decanoic acid Unpublished	Y		MCF-Consultancy GmbH
A3/12	2006	Expert statement Explosive properties of decanoic acid Unpublished	Y		MCF-Consultancy GmbH
A3/13	2006	Expert statement Oxidizing properties of decanoic acid Unpublished	Y		MCF-Consultancy GmbH
A3/14	2006	Expert statement Reactivity of decanoic acid towards container material Unpublished	Y		MCF-Consultancy GmbH
A3/15	2006	Expert statement Approval certificates Unpublished	Y		SOPURA
A3/16	2006	Edenor C 10 98-100 (decanoic acid): Determination of the water solubility considering also the effects of temperature and pH value ChemService S r.l. Study nr CH-334/2006	Y		SOPURA

		Unpublished			
A3/17	2009	Decanoic Acid: Determination of the Solubility in organic Solvents considering also the Effect of Temperature ChemService S.r.l. Study nr CH-629/2008 Unpublished	Y		SOPURA
A3/18	2009	Decanoic Acid: Determination of the Flash Point ChemService S.r.l. Study nr CH-628/2008 Unpublished	Y		SOPURA
A3/18a	2009	Amendment Decanoic Acid: Determination of the Flash Point ChemService S.r.l. Study nr CH-628/2008 Unpublished	Y		SOPURA
A4.1/01	2009	Decanoic Acid: Validation of the Analytical Method for the Determination of the Active Ingredient Content ChemService S.r.l. Study nr CH-630/2008 GLP Unpublished	Y		SOPURA
A4.1/02	2008	Decanoic Acid: Validation of the Analytical Method for the Determination of the Significant Impurity Content ChemService S.r.l. Study nr CH-631/2008 GLP Unpublished	Y		SOPURA
A4.2/01a	1998	In-situ methylation of strongly polar organic acids in natural waters supported by ion-pairing agents for headspace GC-MSD analysis; Dresden University of technology Peter L. Neitzel , et al Fresenius J Anal Chem (1998) 361:318-323 no GLP Published	N		SOPURA
A4.2/01b	2006	Methodenvalidierung 0,1 µg/L for decanoic acid and octanoic acid Böhler Analytik Ges.m.b.H no GLP Unpublished.	Y		SOPURA
A4.3/01	2006	Food occurrence / Risk assessments Gubler-Coaching, Pfäffikon, Switzerland no GLP Unpublished	Y		MCF-Consultancy GmbH .

A4.3/02	2006	Method to calculate the unavoidable residue SOPURA, Unpublished	Y		SOPURA
A4.3/03	2006	Quantitative evaluation decanoic acid quantity likely to be found back in the environment after application SOPURA Unpublished	Y		SOPURA
A4.3/04	1990	Method for the Quantitative Analysis of Volatile Free and Total Branched-Chain Fatty Acids in Cheese and Milk Fat Kim J.H.A. and Lindsay R.C. J. Dairy Sci 73:1988-1999 Published	N		Published
A4.3/05	1990	Determination of Free Fatty Acids in Wort and Beer De Vries K ASBC Journal Published	N		Published
A4.3/06	1994	Analysis of Free Fatty Acids, Fusel Alcohols, and Esters in Beer: An Alternative to CS2 Extraction Alvarez P. and Malcorps P J. Am. Soc. Brew. Chem. 52(3):127-134 Published	N		Published
A4.3/07	1985	The Semi-Routine Use of Capillary Gas Chromatography for Analysis of Aroma Volatiles in Beer Stenroos L.E. et.al ASBC Journal:203-208 Published	N		Published
A4.3/08	1990	Extraction and Analysis of Volatile Compounds in White Wines Using Amberlite XAD-2 Resin and Capillary Gas Chromatography Edwards C.G. and Beelman R.B J. Agric. Food. Chem. 38:216-220 Published	N		Published
	Efficacy PT 18				
A5.3/01 B5.10/01	2006	Effect of the biocidal product Insect shocker FL, the active substances caprylic acid and carpric acid on crawling and flying insects including cockroaches. Institute of Zoology, Neuchatel, Switzerland. Unpublished	Y		SolNova
A5.3/02	2009	Effect of the biocidal product Insect Shocker FS, the active substances octanoic acid and decanoic acid on crawling insects by indirect exposure.	Y		SolNova

		Laboratories Engelhardt, Grandfontaine, Switzerland Unpublished			
A5.3/02a	. 2011	Amendment to Study A5.3/02: Report internal Study: Distribution of cockroaches between aluminium and plastic surface trated with Insect Shocker FS		Y	SolNova
A5.3/03	2009	Declaration Regarding Concentration Levels and Dose-Efficacy Data of Active Substances in Insect Shocker FS Unpublished	Y		SolNova
	Efficacy PT 19				
A5/01	2009	Declaration Regarding Production Quantities of Repellent FS Unpublished	Y		SolNova
A5.3/01	2006	Efficacy Tests with Decanoic Acid as Active Substance in Formulations as Biocidal Product Swiss Tropical Institute Unpublished of the University of Basel	Y		SolNova
A5.3/02a and A5.3/02b	2009	Final Report: Efficacy Test of N-Decanoic Acid Based Personal Insect Repellent with Mosquitoes under laboratory Conditions, Carroll-Loye Biological Research, USA Project ID: SNV-001	Y		SolNova
A6/ 01	1976	Safety studies on a series of fatty acids. Briggs G.B; Doyler L.; Young J. A. American Industrial Hygiene Association Journal; April, 1976 Published	N		-
A6/02	1962	Range-finding toxicity data: List IV Smyth Jr.H.F., Carpenter C.P., Weil C.S., Pozzani U.C. and Striegel J.A. American Industrial Hygiene Association Journal (AIHAJ), 23, 95-107 Published	N		-
A6/03	1979	Capric acid, Opdyke D.L.J. Fd Cosmet. Toxicol. 17 735 (review article) Published	N		published
A6/04a	1996	Toxicity Profile , n-Decanoic acid (and its sodium and potassium salts) BIBRA TNO BIBRA --- Published	N		published
A6/04b	1988	Toxicity Profile , n-Octanoic acid (and its sodium and potassium salts)	N		published

		BIBRA TNO BIBRA --- Published			
A6/05	2006	Riskassessments Gubler-Coaching, Pfäffikon, Switzerland Unpublished	Y		MCF-Consultancy GmbH
A6/07	1998	Safety evaluation of certain food additives and contaminants, saturated aliphatic acyclic linear primary alcohols, aldehydes, and acids the forty-ninth meeting of the JECFA, Joint FAO/WHO Expert Committee on Food Additives WHO/IPCS	N		Published
A6/08	2004	19,71 kg Käse ass Herr Schweizer im 2004 Anonymus Internet	N		Published
A6/09	2004	Sojaöl Spychiger Oil Trading AG,CH-6045 Meggen	N		Published
A6/10	2002	Fettsäurezusammensetzung wichtiger pflanzlicher und tierischer Speisefette und –öle Deutsche Gesellschaft für Fettwissenschaft	N		Published
A6/11	1999	Review of the Toxicologic Properties of Medium-chain Triglycerides Food and Chemical Toxicology 38 (2000) Traul K.A., Driedger A., Ingle D.L., Nakhasi D. Published	N		Published
A6/12	1982	Medium-chain triglycerides: an update The American Journal of Nutrition 36 pages 950 – 962 Bach A.C., Babayan V.K. Published	N		Published
A6/13	2005	Evaluation of certain food additives 63 report of the Joint FAO/WHO Expert Committee on Food Additives	N		Published
A6/14	2000	IUCLID entry http://ecb.jrc.ec.europa.eu/esis/index.php	Y		Not reported add. info.
A6/15	2004	A chemical dataset for evaluation of alternative approaches to skin-sensitization testing Gerberick G.F. et al. Contact Dermatitis, Vol 50, No 5, 2004 Published	N		Published

A6/16	1976	SAFETY STUDIES ON A SERIES OF FATTY ACIDS. Briggs G.B., Doyle R. L., Young J. A. American Industrial Hygiene Association Journal; April 1976	N		published
A6/17	1953	Production of gastric lesions in the rat by the diet containing fatty acids Mori K. GANN, Vol. 44; December Published	N		Published
A6/18	2007	ALTERNATIVE APPROACHES TO IMMUNOTOXICITY AND ALLERGY TESTING Presentation at EUROTOX Congress 2007 unpublished	N		
A6.1.1/01	1981	Prüfung der akuten oralen Toxizität Henkel, Düsseldorf	Y		Cognis (LoA available)
A6.1.2/01	2006	Decanoic acid: Acute Dermal Toxicity Study in Rats; RCC Ltd, Itingen Switzerland Study Number A86556 Unpublished	Y		SOPURA
A6.1.3/02	1998	THE BIOPESTICIDE MANUAL Copping L.G. British Crop Protection Council, 1st edition, p. 25 Report-No. not applicable Not GLP, Published	N		-
A6.1.3/03	--	TOXICOLOGICAL SIMILARITY OF STRAIGHT CHAIN SATURATED FATTY ACIDS OF GREATER THAN 8 CARBON CHAIN LENGTH BY VARIOUS ROUTES OF EXPOSURE Anonymous Safer Inc, Eden Prairie MN 55334-3585, USA Report-No. not applicable Not GLP, Published	N		-
A6.1.4.s/02	1999	A two-center study of the development of acute irritation responses to fatty acids. Robinson M.K., Whittle E. and Basketter D.A. American Journal of Contact Dermatitis, Vol. 10, No 3 1999 Published	N		-
A6.1.5/2	2006	Skin Sensitisation Study (Local Lymph Node Assay); Austrian Research Centers GmbH – ARC Life	Y		SOPURA

		Sciences Toxicology, Seibersdorf, Austria; Report Nr: ARC-L2241; Unpublished			
A6.1.5/1	2004	A chemical dataset for evaluation of alternative approaches to skin-sensitization testing Gerberick G.F. et al Contact Dermatitis, Vol 50, No 5, 2004 Published	N		published
A6.4.1.1/01	1993	A 91-day feeding study in rats with caprenin Webb D.R., Wood F.E., Bertram T.A. and Fortier N.E. Fd Chem. Tox. Vol 31, No 12 The Proctor & Gamble Company Published	N		published
A6.4.1.1/02 A6.8.2	1968	Nutritional Evaluation of Medium-Chain Triglycerides in the Rat Harkins R.W. and Sarett H.P. The Journal of the American Oil Chemists' Society Department of Nutritional Research, Mead Johnson Research Center, Evansville, Indiana Published	N		published
A6.6.1/1	1999a	Bacterial reverse mutation test with decanoic acid Netherlands Organisation for applied scientific research (TNO), Zeist, The Netherlands TNO-report V99.668 Ref nr A6.6.1/01	Y		SOPURA
A6.6.1/2	1999b	Bacterial reverse mutation test with octanoic acid Netherlands Organisation for applied scientific research (TNO) Zeist, Netherlands TNO-Report V99.668	Y		SOPURA
A6.6.2/1	1999a	Chromosomal aberration test with decanoic acid in cultured Chinese hamster ovary cells Netherlands Organisation for applied scientific research (TNO), Zeist, The Netherlands TNO-report V99.661 Ref nr A6.6.2/01	Y		SOPURA
A6.6.2/2	1999b	Chromosomal aberration test with octanoic acid in cultured Chinese hamster ovary cells Netherlands Organisation for applied scientific research (TNO) Zeist, Netherlands TNO-Report V99.660.	Y		SOPURA
A6.6.3/1	1999a	Gene mutation test at the TK-locus of L5178Y cells with Decanoic acid; Netherlands Organisation for applied scientific research (TNO), Zeist, The Netherlands TNO-report V99.715	Y		SOPURA

		Ref nr A6.6.3/01			
A6.6.3/2	1999b	Gene mutation test at the TK-locus of L5178Y cells with Octanoic acid Netherlands Organisation for applied scientific research (TNO) Zeist, Netherlands TNO-Report V99.715	Y		SOPURA
A6.8.1/01	1994	Pharmacokinetic Determinats of Embryotoxicity in Rats Associated with Organic Acids Scott et al. Environmental Health Perspectives 102 (suppl 11) Published	N		Published
A6.8.1/02	1993	Pharmacokinetics and pharmacodynamics of valproate analogs in rats. II. Pharmacokinetics of octanoic acid, cyclohexanecarboxylic acid, and 1-methyl-1-cyclohexanecarboxylic acid Mei-JenLiu and Pollack G. M. Biopharmaceutics & Drug Disposition, vol. 14 Published	N		Published
A6.8.2 A6.4.1.1/ 02	1968	Nutritional Evaluation of Medium-Chain Triglycerides in the Rat Harkins R. W. and Sarett H. P. The Journal of the American Oil Chemists' Society Department of Nutritional Research, Mead Johnson Research Center, Evansville, Indiana Published	N		published
A7.1.1.2.1/01	2005	Fragrances and Biodegradation Göteborgs Stad Miljö Anonymus ISSN 1401-2448 ISRN GBG-M-R—05/05—SE Published	N		Published
A7.1.1.2.1/02	2006	DECANOIC ACID: READY BIODEGRADABILITY IN A MANOMETRIC RESPIROMETRY TEST; RCC LTD, Itingen, Switzerland; RCC Study Number: A86567 Unpublished	Y		SOPURA N.V.
A7.1.3/01	2008	ADSORPTION/DESORPTION OF DECANOIC ACID ON SOILS; RCC Ltd, Itingen; RCC Report No. A86466 Unpublished	Y		SOPURA N.V.
A7.4.1.1/01	2001	Decanoic acid – fish, Acute Toxicity, Final Report R-0100702 Henkel KgaA Department of Ecology Unpublished	Y		COGNIS Deutschland GmbH (LoA

					available)
A7.4.1.1/02 O	2006	Octanoic Acid: Acute Toxicity to Zebra Fish (Brachydanio Rerio) in a 96-hour semi-static Test RCC Ltd; Itingen, Switzerland RCC Study Number A86501	Y		SOPURA
A7.4.1.1/03 O	2006	First Amendment to Study Plan Octanoic Acid: Acute Toxicity to Zebra Fish (Brachydanio Rerio) in a 96-hour semi-static Test RCC Ltd; Itingen, Switzerland RCC Study Number A86501	Y		SOPURA
A.7.4.1.2/01	2006	DECANOIC ACID: ACUTE TOXICITY TO DAPHNIA MAGNA IN A 48-HOUR IMMOBILIZATION TEST; RCC Ltd, Itingen, Switzerland; RCC Study Number: A86488 Unpublished	Y		SOPURA
A7.4.1.3/01	2008	DECANOIC ACID: TOXICITY TO SCENEDESMUS SUBSPICATUS IN A 72-HOUR ALGAL GROWTH INHIBITION TEST; RCC Ltd, Itingen, Switzerland RCC Study Number: A86523 (inclusive A86534) Unpublished	Y		SOPURA
A7.4.1.4/01	2006	DECANOIC ACID: TOXICITY TO ACTIVATED SLUDGE IN A RESPIRATION INHIBITION TEST; RCC Ltd, Itingen Switzerland; RCC Study Number A86545 Unpublished	Y		SOPURA N.V.
A7.4.2/01	2006	Calculation of the BCF for decanoic acid with the US-EPA program BCF Program	Y		MCF-Consultancy GmbH

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT – SUBMITTED ADDITIONAL LITERATURE

Section No / Reference No	**Year**	**Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published**	**Data Protection Claimed (Yes/No)**	**Date of 1st submission**	**Owner**
B5 (PT19)	2013	Declaration on Composition Perfume oil: Cleopatra 505171 LUZI AG, Switzerland unpublished	Y	March 2013	LUZI AG
B5 (PT19)	2013	Assessment of Mosquito Repellency of the	Y	April 2013	SolNova

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Fragrance "Cleopatra" SolNova srl unpublished			

LIST OF STUDIES FOR THE ACTIVE SUBSTANCE – ADDITIONAL REFERENCES INTEGRATED BY RMS

Year	Title Source Institution; report nr GLP-, GEP-status Published or unpublished	Data Protection	Date of 1st submission	Owner
2010	Agreement regarding the transfer of test reports between Octanoic and Decanoic acid Fatty acids consortium No GLP unpublished	Y		Fatty acids consortium
2010	Agreement regarding the transfer of documents between the product types Fatty acids consortium No GLP unpublished	Y		Fatty acids consortium
2008	THE COLIPA STRATEGY FOR THE DEVELOPMENT OF IN VITRO ALTERNATIVES: SKIN SENSITISATION AATEX 14, Special Issue, 375-379 http://altweb.jhsph.edu/wc6/	N		published
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2007b	THE LOCAL LYMPH NODE ASSAY: CURRENT POSITION IN THE REGULATORY CLASSIFICATION OF SKIN SENSITIZING CHEMICALS Basketter DA., Gerberick GF., Kimber I. Cutaneous and Ocular Toxicology 26:4, 293 - 301	N		published
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2005	LONG-TERM REPETITIVE SODIUM LAURYL SULFATE-INDUCED IRRITATION OF THE SKIN: AN IN VIVO STUDY. Branco N, Lee I, Zhai H, Maibach HI. Contact Dermatitis 53(5):278-84	N		published
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LIST OF STUDIES FOR THE BIOCIDAL PRODUCT (PT 18) – SORTED BY SECTION NUMBER

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection	Date of 1st submission	Owner
B2/01a	2006	Interne Synonyme und Handelsbezeichnungen Unpublished	Y		SolNova
B2/01b	2006	Rezeptur Insect Shocker FL	Y		SolNova
B3.1/01a	2006	Information Insect Shocker FL (Physical Properties of Insect Shocker FL, Declaration regarding Flash-Point Measurement for Insect Shocker FL, Detailed Results Storage Stability Insect Shocker FL) SolNova; Unpublished	Y		SolNova
B3.1/01b	2006	Surface Tension and Flash Point of Insect Shocker FL and Repellent FS SolNova; Unpublished	Y		SolNova
B3.1/02	2006	Expert Statement Explosive properties of Insect Shocker FL Unpublished	Y		MCF-Consultancy GmbH
B3.1/03	2006	Expert Statement Oxidising properties of Insect Shocker FL Unpublished	Y		MCF-Consultancy GmbH
B3.1/05	2006	Declaration re "Technical Characteristics" Unpublished	Y		SolNova
B3.1/06	2006	Declaration re „Compatibility with other products" Unpublished	Y		SolNova
B3.5/01rev09	2008	Analysis report Ph-Value-Acidity/Alcalinity of Insect Shocker FL Unpublished	Y		SolNova
B3.6/01	2008	Analysis report Bulk Density Shocker FL Unpublished	Y		SolNova
B3.7/01	2008	Report Storage Stability Insect Shocker FL Unpublished	Y		SolNova
B3.10/01	2008	Analysis report Surface Tension of Insect Shocker FL Unpublished	Y		SolNova
B3.11/01	2008	Analysis report Viscosity of Insect Shocker FL Unpublished	Y		SolNova
A4.1/01a	1998	In-situ methylation of strongly polar organic acids in natural waters supported by ion-pairing agents for headspace GC-MSD	N		Published

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection	Date of 1st submission	Owner
		analysis; Dresden University of technology; Peter L. Neitzel, W. Walther, W. Nestler Fresenius J Anal Chem (1998) 361:318-323. Published			
A4.1/01b	2006	Validated for ocatonoic acid and decanoic acid;;	Y		SolNova
B4.1/01c	2006	Method of Determination of Active Substances in Insect Shocker FL and Repellent FS	Y		SolNova
B5-01a	2009	Label proposal product	Y		SolNova
B5-01b	2006	Picture spray bottle	N		SolNova
B5.10/01 (A5.3/01)	2006	Effect of the biocidal product Insect shocker FL, the active substances caprylic acid and carpric acid on crawling and flying insects including cockroaches. Institute of Zoology, Neuchatel, Switzerland.	Y		SolNova
B5.10/03	2009	Declaration Regarding Concentration Levels and Dose-Efficacy Data of Active Substances in Insect Shocker FS Unpublished	Y		SolNova

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT (PT 18) – ADDITIONAL REFERENCES INTEGRATED BY RMS

Section No / Reference No	Year	Title Source Institution; report nr GLP-, GEP-status Published or unpublished	Data Protection	Data of 1st submission	Owner
All sections	2010	Agreement regarding the transfer of test reports between Octanoic and Decanoic acid Fatty acids consortium No GLP unpublished	Y		Fatty acids consortium
All sections	2010	Agreement regarding the transfer of documents between the product types Fatty acids consortium No GLP unpublished	Y		Fatty acids consortium

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT (PT 19) – SORTED BY SECTION NUMBER

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection	Data of 1st submission	Owner
B2/01	2006	Rezeptur Repellent FS Unpublished	Y		SolNova
B3.1/01	2006	Physical Properties of Repellent FS SolNova; Unpublished	Y		SolNova
B3.2/01	2009	Expert Statement Explosive of Repellent FS Unpublished	Y		MCF-Consultancy GmbH
B3.3/01	2009	Expert Statement Oxidising of Repellent FS Unpublished	Y		MCF-Consultancy GmbH
B3.4/01a	2009	Analysis Report Flash Point Repellent FS Unpublished	Y		SolNova
B3.4/01b	2009	Flammpunkt nach Pensky-Martens Repellent Lotion Decanoic 10 Solution Böhler Analytik Ges.m.b.H., Feldkirch, Österreich Unpublished	Y		SolNova
B3.5/01	2009	Analysis Report Ph-Value-Acidity / Alclinity of Repellent FS SolNova, Zürich, Schweiz Unpublished	Y		SolNova
B3.6/01	2009	Analysis Report Bulk Density Repellent FS SolNova AG, Zürich, Schweiz Unpublished	Y		SolNova
B3.7/01	2009	Report Storage Stability Repellent FS SolNova Unpblished	Y		SolNova
B3.8/01	2009	Declaration re “Technical Characteristics“ Unpublished	Y		SolNova
B3.9/01	2009	Declaration re “Compatibility with other products” Unpublished	Y		SolNova
B3.10/01	2009	Messung der Statischen Oberflächenspannung von zwei Prüfflüssigkeiten Hamburg, Deutschland Unpublished	Y		SolNova

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection	Data of 1st submission	Owner
B3.11/01	2009	Analysis Report Viscosity of Repellent FS SolNova, Zürich, Schweiz Unpublished	Y		SolNova
A4.1/01a	1998	In-situ methylation of strongly polar organic acids in natural waters supported by ion-pairing agents for headspace GC-MSD analysis; Dresden University of technology; Peter L. Neitzel, W. Walther, W. Nestler Fresenius J Anal Chem (1998) 361:318-323. Published	N		Published
A4.1/01b	2006	Validated for ocatonoic acid and decanoic acid; Böhler Analytik Ges.m.b.H. Report No.: - no GLP unpublished	Y		SolNova
B4.1/01c	2006	Method of Determination of Active Substances in Insect Shocker FL and Repellent FS; SolNova Report No.: - no GLP unpublished	Y		SolNova
B5.10/01 A5.3/01	2006	Efficacy Tests with Decanoic Acid as Active Substance in Formulations as Biocidal Product Swiss Tropical Institut Unpublished of the University of Basel	Y		SolNova

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT (PT 19) – ADDITIONAL REFERENCES INTEGRATED BY RMS

Section No / Reference No	Year	Title Source Institution; report nr GLP-, GEP-status Published or unpublished	Data Protection	Date of 1st submission	Owner
All sections	2010	Agreement regarding the transfer of test reports between Octanoic and Decanoic acid Fatty acids consortium	Y		Fatty acids consortium

		No GLP unpublished			
All sections	2010	Agreement regarding the transfer of documents between the product types Fatty acids consortium No GLP unpublished	Y		Fatty acids consortium

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