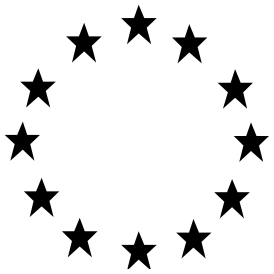
Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Octanoic acid

Product-type 18
(Insecticides, acaricides and products to control other arthropods)

December 2013

Austria

Octanoic acid (PT 18)

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 Octanoic acid as product-type 18 (Insecticide), 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 containing Octanoic 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 Octanoic acid for product-type 6, and should it be approved, to facilitate the authorisation of individual biocidal products in product-type 18 that contain Octanoic 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 Octanoic acid as product-type 18 (Insecticide), 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

Octanoic acid (CAS no. 124-07-2) 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.

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 Octanoic acid as an active substance in Product Type 18 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 Octanoic acid in Annex I to the Directive for product-type PT18.

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

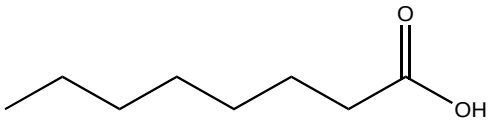
2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

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

The active substance Octanoic acid is attributed the CAS-No 124-07-2 and the EC-No 204-677-5. The molecular formula is $C_8H_{16}O_2$, and the molecular weight is 144.21 g/mol. The minimum degree of purity is 99.3%w/w.

Structural formula:



The structure of Octanoic 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. 99.5%w/w Octanoic acid) according to the demands of the data requirements.

Octanoic acid is a colourless liquid, has a slightly unpleasant rancid smell. Its melting point is 16.6°C, and the boiling point is 237°C. The density is ρ = 0.900 kg/L at 20°C. The vapour pressure of the active substance is $1.35*10^{-2}$ Pa at 25°C, $8.90*10^{-3}$ Pa at 20°C. The calculated Henry's law constant is 0.237 Pa m^3 mol^{-1}.

The water solubility of the water test item is; 88 g/L (20°C, unpuffered), 0.92 g/L (50°C, pH 4), and 0.75 g/L (20°C, pH 4), and 3.18 g/L (50°C, pH 7), and 2.97 g/L (20°C, pH 7) and 3.68 g/L (50°C, pH 9), and 3.35 g/L (20°C, pH 9). Reference literature from Merck 1989 is 0.68 g/L at 20 °C

The dissociation constant (pKa) is determined to be 4.89 at 25°C. The solubility of Octanoic acid is >1 kg/L Hexane at 22°C in g/L at >1 kg/L Ethanol 22°C. The active substance as manufactured does not include any organic solvent. The calculated partition coefficient octanol-water is 3.03 for the undissociated acid.. The substance is regarded to be surface active (surface tension is 53.2 mN/m at 20°C.) The viscosity is 7.7 mPas at 20°C.

The active substance does not contain structural elements such as peroxide, nitro-group known to cause explosions. It is unlikely that Octanoic acid shows oxidizing properties under the condition of the test described in the EU method A.14.

Its flash point is 133.0°C at 1005 mbar. The heat of combustion is -4799.9 kJ/mol, therefore auto flammability is not expected. Octanoic acid is expected to be stable up to the boiling point. 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 Octanoic acid in the active substance as well as in the biocidal products Insect shocker FL 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 Octanoic acid in the environment and its rapid metabolism and degradation in soil an analytical method for the determination of residues of Octanoic 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 Octanoic acid no significant concentrations of Octanoic acid in air will occur. In accordance with the provisions given in the TNsG on Data requirements no analytical method for Octanoic acid in air has been submitted.

Deacnoic acid has been found to occur naturally in low concentrations in water. Although the degradation of Octanoic 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 Octanoic 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 Octanoic 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

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.

2.1.3. Classification and Labelling of the active substance

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

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

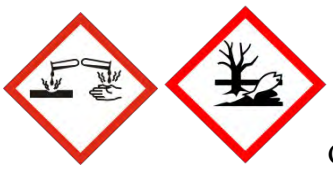
Proposed classification and labelling

The C&L proposal for environmental hazards according to Regulation (EC) No 1272/2008, Annex VI, Table 3.2 (DSD) is not based on the lowest EC_{50} (1.67 mg/L, read across from Decanoic acid) presented in this CAR, but on the lowest EC_{50} values available for Octanoic acid on European level (all EC_{50} values >10 mg/L, measured, TWA). This proposal is therefore coherent with the latest proposal presented in the CLH-report: Rapidly degradable substance for which adequate acute toxicity data (all EC_{50} values >10 mg/L) are available for all three trophic levels, which lead to no classification according to DSD.

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

Classification and Labelling	
Hazard symbol	
Indication of danger	C Corrosive
R phrases	R34 Causes burns
S phrases	S2 Keep out of the reach of children S20/21 When using do not eat, drink or smoke 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
Classification	C; R34
Labelling	C; R: 34 S: 2-20/21-26-36/37/39

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

<table>
<tr><th colspan="3">Classification and Labelling</th><th>Justification</th></tr>
<tr><td colspan="2">GHS Pictograms</td><td> 
GHS 09</td><td rowspan="9">Weight of evidence evaluation supporting skin corrosion hazard category 1

Specification of Prevention Phrases according to Regulation (EC) No 1272/2008

C&L proposal for environmental hazards for acute effects is not based on the lowest EC_{50} (1.67 mg/L, read across from Decanoic acid) presented in this CAR, but on the lowest EC_{50} values available for Octanoic acid on European level (all >10 mg/L, measured, TWA).

For chronic effects it is not based on the lowest NOEC (0.47 mg/L) presented in this CAR, but on the lowest NOEC available on European level (0.07 mg/L).

This proposal is therefore coherent with the latest proposal presented in the CLH-report: Rapidly degradable substance for which adequate chronic toxicity data are available for algae (NOE_rC =0.07 mg/L). Short term toxicity doesn't lead to any classification.</td></tr>
<tr><td colspan="2">Signal words</td><td>Danger</td></tr>
<tr><td colspan="2">Classification</td><td>Skin corrosion – Hazard Category 1C*

Aquatic Chronic 2</td></tr>
<tr><td colspan="2">Hazard statements</td><td>H314: Causes severe skin burn and eye damage*

H411: Toxic to aquatic life with long lasting effects</td></tr>
<tr><td rowspan="5">Precautionary Statements</td><td>General</td><td>-</td></tr>
<tr><td>Prevention</td><td>P260: Do not breathe dust/fume/gas/mist/vapours/spray.

P264: Wash thoroughly after handling

P273: Avoid release to the environment

P280: Wear protective gloves/protective clothing/eye protection/face protection.</td></tr>
<tr><td>Response</td><td>P301 + P330 + P331: IF SWALLOWED rinse mouth, do NOT induce vomiting.

P303 + P361 + P353: IF ON SKIN (or hair) remove/take off immediately all contaminated clothing, rinse skin with water/shower.

P304 + P340: IF INHALED remove victim to fresh air and keep at rest in a position comfortable for breathing.

P310: Immediately call a POISON CENTER or doctor/physician.

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P391: Collect spillage.</td></tr>
<tr><td>Storage</td><td>-</td><td></td></tr>
<tr><td>Disposal</td><td>P501: Dispose of contents/container in</td><td></td></tr>
</table>

		accordance with local/regional/national/international regulations (to be specified).	

*Recently a RAC opinion was published confirming this proposal.

2.1.4. Classification and Labelling of the biocidal product

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

		Justification
GHS Pictograms	 GHS07	
Signal words	Warning	
Classification*	Irritating to eyes – 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 (from 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 statement	**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.

2.2. 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 Ocatnoic acid (indicating skin corrosion) and a negative in vitro TER test with human skin for Decanoic acid support the classification of Octanoic acid for severe skin burns and eye damage (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

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 Octanoic 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 Octanoic 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 PT18

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 including specific risk mitigation measures 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.

2.2.3. Environmental Risk Assessment

2.2.3.1. Fate and distribution in the environment

Octanoic acid is readily biodegradable (81-88% mineralisation based on ThOD at day 28; pass level reached at day 8). 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 Octanoic 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 Octanoic 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 Octanoic acid in air according to TGD resulted in a half-life of 46.1h ($k_{deg, air}$ = 0.361 d^{-1}; $c(OH)_{air}$ = 5x10^5 molecules/cm^3). Based on this result an accumulation of Octanoic acid in air is not expected.

No adsorption equilibrium could be reached and no K_{oc} values could be calculated, since Octanoic acid rapidly degraded in the test soils despite soil sterilisation. Therefore there is negligible likelihood for leakage of Octanoic acid to groundwater due to rapid degradation. EUSES calculations resulted in a K_{oc} value of 83.9 L/kg, which was used for risk characterisation.

Accumulation:

The log P_{ow} of Octanoic acid is 3.03.

Octanoic acid is 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.

However, for Octanoic acid, bioaccumulation is not an important issue, because

- Octanoic acid is rapidly biodegradable
- Octanoic 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).
- Octanoic 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 Octanoic acid is 75L/kg and the BCF in earthworms is 14 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 Octanoic acid.

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. The calculated LC_{50} is 68 mg/L.

The acute toxicity study in daphnids is read across from Decanoic acid.

Decanoic acid, Nonanoic and Octanoic acids are linear saturated fatty acids differing only in the chain length (10, 9 or 8 C-atoms). Fatty acids like Octanoic, Nonanoic 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 would cause an increase in toxicity As the tests are conducted with the fatty acid with the longer chain length, a 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 (corresponding to 8.4 mg/L Octanoic acid). The EC_{50} was 16 mg /L (corresponding to 13.4 mg/L Octanoic acid).

The acute toxicity study in algae is read across from Decanoic acid.

Decanoic acid, Nonanoic and Octanoic acids are linear saturated fatty acids differing only in the chain length (10, 9 or 8 C-atoms). Fatty acids like Octanoic, Nonanoic 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 would cause an increase in toxicity As the tests are conducted with the fatty acid with the longer chain length, a read across is justified.

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 (corresponding to 0.47 mg/L Octanoic acid) (NOE_rC). The E_rC_{50} was 2 mg/L (corresponding to 1.67 mg/L Octanoic acid). 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 data on the inhibition of the aquatic microbial activity were generated for Octanoic acid.
To demonstrate the inhibition to microbial activity the data submitted for Decanoic acid were

accepted for read across although physico-chemical data are different for Octa-, and Decanoic acid (Water solubility decreases from 2.97 g/L (Octa) to 1.84 g/L (Deca) at 20°C and pH 7; $logP_{ow}$ rises from 3.03 (Octa) to 4.09 (Deca), as expected; no K_{oc} values could be established due to rapid degradation of Octa- and Decanoic acid in soil; but both substances are equally well readily biodegradable.).
In the study with Decanoic acid no inhibitory effects against aquatic micro-organisms were found up to a nominal concentration of 1000 mg/L. The respiration rates were enhanced up to the highest concentration. The NOEC was determined with ≥1000 mg/L (nominal) for Decanoic acid. Taking into account the molecular weight of Octanoic acid (144.21 g/mol) and Decanoic acid (172.27 g/mol) a conservative nominal NOEC for Octanoic acid was determined with ≥837.12 mg/L.

Air compartment:

The half-life of Octanoic acid is estimated to be 46.1h. Based on this result an accumulation of Octanoic acid in air is not to be 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, Octanoic acid is not expected to display adverse abiotic effects on the atmospheric environment.

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

Terrestrial compartment:

No initial terrestrial toxicity tests were submitted. According to the intended use of the biocidal product 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:

Octanoic acid is readily biodegradable (81-88% mineralization after 28 days). At the end of the 10 days window at day 11 the mineralization rate was already 66-73%.

The P-criterion is not met: Not P

Bioaccumulation:

BCF_{fish} = 75 (calculated)

The B-criterion is not met: Not B

Toxicity:

Chronic toxicity is available for algae only, the NOEC is 0.47 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:

Octanoic acid is neither a PBT nor a vBvP substance.

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

2.2.3.4. Exposure assessment

The environmental exposure assessment has been performed in accordance with the Emission Scenario Document for insecticides, acaricides and products to control arthropods (PT18) for household and professional use (OECD, 2008)[3] as well as the results of the Workshop on ESD for PT18[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 Octanoic acid and INSECT SHOCKER FL are produced in Europe, these stages have not been addressed here. The modeling of exposure and risk assessment/risk characterisation during production of Octanoic 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 reach directly 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.

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

Air compartment:

The PEC of Octanoic acid in air from its use may be considered negligible (see Doc. II-B, chapter 5.2.1). Moreover, Octanoic 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:

Octanoic acid poses an acceptable risk for the air compartment.

Aquatic compartment (including sediment):

STP:

Octanoic 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 (see Doc. II-B, chapter 5.2.2 PEC in STP).

The PNEC for aquatic micro-organisms was determined with 83.71 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 $PNEC_{aquatic\ micro\text{-}organisms}$ (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 ($PNEC_{aquatic\ micro\text{-}organisms}$: 83.71 mg/L)	
0.00124 mg/L	$1.48x10^{-5}$

Conclusion:

Octanoic 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

	PEC (mg/L or mg/kg_{wwt})	**PEC/PNEC**
Water/local ($PNEC_{water}$: 0.0047 mg/L)		
Local PEC in surface water during emission episode (dissolved)	$1.24x10^{-4}$	$2.64x10^{-2}$
Annual average local PEC in surface water (dissolved), 1 emission day:	$3.41x10^{-7}$	$7.26x10^{-5}$
Annual average local PEC in surface water (dissolved), 270 emission days:	$9.17x10^{-5}$	$1.95x10^{-2}$
Sediment/local ($PNEC_{sediment}$: 0.01226 mg/kg kg_{wwt})		
Local PEC in fresh-water sediment during emission episode:	$3.24x10^{-4}$	$2.6x10^{-2}$

Conclusion:

Octanoic 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 Octanoic acid in groundwater after continuous sludge application over 10

years gives a value of 0.039 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:

Octanoic 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:

Octanoic acid is readily biodegradable (81-88% 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 Octanoic 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

Octanoic acid is not persistent in sediment

Surface water used for drinking water

The maximum concentration in Scenario 2a (231/300 days of emission) for Octanoic acid in surface water exceeds the parametric value of 0.1 µg/L, according to Directive 98/83/EC (see Table 2.2.3.5-2).

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 Octanoic 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).

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 0.0075 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 is 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**
	$PNEC_{soil}$: 0.0075 $mg/kg\ soil_{wwt}$	
Arable soil (30 days)	2.02×10^{-4}	2.69×10^{-2}
Arable soil (180 days)	6.22×10^{-5}	8.29×10^{-3}
Grassland (180 days)	2.28×10^{-5}	3.04×10^{-3}

Conclusion:

Octanoic acid poses an acceptable risk to soil organisms.

Persistence in soil:

Octanoic acid is readily biodegradable (81-88% 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 Octanoic 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

Octanoic 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 Octanoic acid indicates a potential for bioaccumulation (log K_{ow}=3.03), a standard assessment for secondary poisoning was conducted.

Risk for fish eating and worm eating predators:

No toxicity tests in birds were submitted for Octanoic acid. However, data of 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 2.2.3.5.-4 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	$1.28x10^{-5}$ mg a.s./$kg_{wet\ fish}$	$3.87x10^{-5}$
270 emission days	$3.4x10^{-3}$ mg a.s./$kg_{wet\ fish}$	$1.03x10^{-2}$
Terrestrial food chain:	$2.43x10^{-4}$ mg a.s./$kg_{wet\ earthworm}$	$7.34x10^{-4}$

Conclusion:

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

2.2.4. List of endpoints

In order to facilitate the work of Member States 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

Octanoic acid is used as active substance in insecticides. Upon contact with an appropriate dose crawling insects and isopods 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.

The active substance has no hazardous physico-chemical properties.

Octanoic 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 Octanoic acid poses CMR or other human health hazards except for its local skin and eye effects. 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 Octanoic acid is neither a vPvB, nor a PBT substance and it is no candidate for substitution.

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

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

3.2. Proposed Decision

The overall conclusion from the evaluation of Octanoic acid for use in product type 18 (insecticides, acaricides and products to control other arthropods), is that it may be possible to issue authorisations of products containing Octanoic 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 Octanoic acid for use in biocidal products for product-type 18 (Insecticides, acaricides and products to control other arthropods), and subject to the following specific conditions:

The product assessment shall pay particular attention to the exposure, 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 also subject to the following particular 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 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

3.3. Elements to be taken into account when authorising products

1) 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. 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) 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.

3) Based on the calculation method and in addition considering the 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.

4) 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”

5) 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. Substitution of skin sensitizing co-formulants should be considered. Otherwise a qualitative risk assessment of potential sensitizing effects including specific risk mitigation measures has to be provided with product authorisation in order to decide on acceptability of risk for local effects.

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

7) 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.

8) At product authorisation stage refined analytical methods have to be submitted clarifying the deficiencies and ambiguities identified during evaluation.

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).

3.4. 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 Octanoic acid

3.5. Updating this Assessment Report

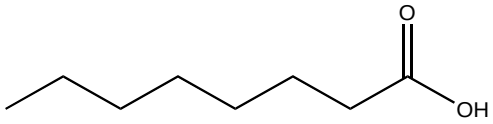
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information submitted in relation with Regulation (EU) No 528/2012..Such adaptations will be examined and finalised in connection with any amendment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

APPENDIX I: LIST OF ENDPOINTS

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

Active substance	Octanoic acid
Product-type	PT 18

Identity

Chemical name (IUPAC)	n-Octanoic acid
Common name, synonyma	Caprylic acid
CAS No	124-07-2
EC No	204-677-5
Other substance No.	n.a.
Minimum purity of the active substance as manufactured (g/kg or g/l)	99.3%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	$C_8H_{16}O_2$
Molecular mass	144.21 g/mol
Structural formula	

Physical and chemical properties

Melting point (state purity)	16.6 °C
Boiling point (state purity)	237°C at atmospheric pressure
Temperature of decomposition	The heat of combustion is -4799.9 kJ/mol (Kirk-Othmer Encyclopedia of Chemical Technology, 4th ed. Volumes 1: 1991),
Appearance (state purity)	Liquid; Colourless liquid; Slightly unpleasant rancid
Relative density (state purity)	density ρ = 0.900 kg/L
Surface tension	mean 53.2 mN/M (20°C) at 0.61 g/L Octanoic Acid is surface active
Vapour pressure (in Pa, state temperature)	$1.35*10^{-2}$ Pa (25°C) $8.90*10^{-3}$ Pa (20°C)
Henry’s law constant (Pa m^3 mol^{-1})	0.237 Pa x m^3 x mol^{-1}(calculated)
Solubility in water (g/l or mg/l, state temperature)	Water: 0.88 g/L without a buffer (20 °C)

	pH 4: 0.92 g/L (50 °C) 0.75 g/L (20 °C) pH 7: 3.18 g/L (50 °C) 2.97 g/L (20 °C) pH 9: 3.68 g/L (50 °C) 3.35 g/L (20 °C) Reference literature(Merck 1989) 0.68 g/L at 20 °C

Solubility in organic solvents (in g/l or mg/l, state temperature)	Solubility in organic solvents of Octanoic 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	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 = 3.03
Dissociation constant	4.89 at 25 ^{0}C (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).
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	There are no absorption maxima above 290 nm.
Flammability	The heat of combustion is -4799.9 kJ/mol (Kirk-Othmer Encyclopedia of Chemical Technology, 4th ed. Volumes 1: 1991), therefore auto flammability is not expected.
Explosive properties	Octanoic 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	Reg. (EU) No 1272/2008, Annex VI, Table 3.2 C; R34 R34 Causes burns S2 Keep out of the reach of children S20/21 When using do not eat, drink or smoke 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 Reg. (EU) No 1272/2008, Annex VI, Table 3.1 Skin corrosion- Hazard Category 1C H314: Causes severe skin burn and eye damage* P260: Do not breathe dust/fume/gas/mist/vapours/spray. P264 Wash thoroughly after handling P280 Wear protective gloves/protective clothing/eye protection/face protection. P301 + P330 + P331: IF SWALLOWED rinse mouth, do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair) remove/take off immediately all contaminated clothing, rinse skin with water/shower. P304 + P340: IF INHALED remove victim to fresh air and keep at rest in a position comfortable for breathing. P310: Immediately call a POISON CENTER or doctor/physician. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
with regard to fate and behaviour data and ecotoxicological data	Reg. (EU) No 1272/2008, Annex VI, Table 3.2 No classification, based not only on data presented in this report, but on all available data on EU level (all EC_{50} >10 mg/L). Proposal in coherence with latest CLH proposal. Reg. (EU) No 1272/2008, Annex VI, Table 3.1and 286/2011 Proposal based not only on data presented in this report, but on all available data on EU level (lowest NOEC =0.07 mg/L). Proposal in coherence with latest CLH proposal. Aquatic Chronic 2 H411: Toxic to aquatic life with long lasting effects P273: Avoid release to the environment P391: Collect spillage P501: Dispose of contents/container in accordance with local/regional/national/international regulations (to be specified).

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)	Karl Fischer titration method

Analytical methods for residues

Soil (principle of method and LOQ)	Not required according to the TNsG on Data Requirements, Addendum, Part A, Chapter 2, Point 4 "Analytical Methods for Detection and Identification"
Air (principle of method and LOQ)	Not required according to TGD on data requirements
Water (principle of method and LOQ)	GC/MS method with a LOQ of 0.1 µg/l for Octanoic acid
Body fluids and tissues (principle of method and LOQ)	Not required according to TGD on data requirements
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required according to TGD on data requirements
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required according to TGD on data requirements

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	> 5 mg a.s./L (total WoE evaluation)
Skin irritation	Skin corrosive, Cat 1C (Total WoE evaluation)
Eye irritation	Risk for serious damage to eye (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 based on 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

No study available; waiving accepted based primarily on consideration of the nature of Octanoic acid and Decanoic 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

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)

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

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	Octanoic acid does not display UV/VIS maxima at wavelengths above 290 nm. Therefore, photolytic degradation in water is excluded.
Readily biodegradable (yes/no)	Yes; 81-88% in 28days;
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 Octanoic acid of 83.9 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	$T_{1/2}$ = 46.1 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}	68 mg/L
Invertebrates			
Daphnia magna	48 h, semi-static	Immobilisation, EC_{50}	13.4 mg/L
Algae			
Scenedesmus subspicatus	72 h, static	Growth and biomass inhibition, NOE_rC, E_bC_{50}, E_rC_{50}	0.47 mg/L 0.97 mg/L 1.67 mg/L
Microorganisms			
Activated sludge	3h	Respiration inhibition Read across from Decanoic acid NOEC ≥ 1000 mg/L. Taking into account the molecular weights of Octa- and Decanoic acid the nominal NOEC for Octanoic acid was calculated: NOEC	≥ 837.12 mg/L (nominal)

Effects on earthworms or other soil non-target organisms

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

Effects on soil micro-organisms

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

Effects on terrestrial vertebrates

Acute toxicity to mammals	Rat: LD_{50} > 5 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)	75 (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

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 use) 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.

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 (where different from company) Company, Report No. GLP (where relevant) / (Un)published	Data Protection	Date of 1st submission	Owner
A2/01	2009	Octanoic Acid: Complete Analysis of Four Batch Samples ChemService S.r.l. Study Number CH-627/2008 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
A2.10/02	2009	INSECT SHOCKER FL - Exposure assessment	Y		MCF-Consultancy GmbH
A3/01	1999	Determination of some physico-chemical properties of Octanoic acid TNO Prins Maurits Laboratory Report number: PML 1999-C109 Unpublished	Y		SOPURA
A3/02	1999	Expert statement: hydrolysis and dissociation constants of n-octanoic acid and n-decanoic acid Report number: V99.846 TNO Voeding Unpublished	Y		SOPURA
A3/03	1989	Merck Index 11 th Edition – 1989; No. 1765	N		Published
A3/05	2006	Calculation of the Henry Law Constant and Log Kow for Octanoic acid with the Program HENRYWIN v3.10 Unpublished	Y		MCF-Consultancy GmbH
A3/06	2006	Expert statement Stability of octanoic acid in organic solvents	Y		MCF-Consultanc

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
		Unpublished			y GmbH
A3/07	2006	Expert statement Thermal stability of octanoic acid Unpublished	Y		MCF-Consultancy GmbH
A3/08	2006	Expert statement Flammability, including auto flammability and identity of combustion product of octanoic acid Unpublished	Y		MCF-Consultancy GmbH
A3/10_rev09a	2008	Octanoic acid Determination of the surface tension; Report No. 5474-OCTA-3 Sopura, Unpublished	Y		SOPURA
A3/11_rev09	2008	Octanoic acid Determination of the bulk density Report No. 5474-OCTA-5 Sopura Unpublished	Y		SOPURA
A3/12	2006	Expert statement Explosive properties of octanoic acid Unpublished	Y		MCF-Consultancy GmbH
A3/13	2006	Expert statement Oxidizing properties of octanoic acid Unpublished	Y		MCF-Consultancy GmbH
A3/14	2006	Expert statement Reactivity towards container material of octanoic acid Unpublished	Y		MCF-Consultancy GmbH
A3/15	2006	Expert statement Approval certificates Unpublished	Y		SOPURA
A3/16	2006	Edenor C 8 98-100 (octanoic acid): Determination of the water solubility considering also the effects of temperature and pH value ChemService S.r.l. Study nr CH-333/2006 Unpublished	Y		SOPURA
A3/17	2006	Analysis Certificate-Addendum SGS Unpublished	Y		SOPURA
A3/17a	2009	Octanoic Acid: Determination of the Flash Point ChemService S.r.l. Study nr CH-623/2008 Unpublished	Y		SOPURA
A3/18_rev09a	2008	Octanoic acid Determination of the Viscosity Report No. 5474-OCTA-2	Y		SOPURA

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
		Sopura Unpublished			
A3/19_rev09	2009	Octanoic Acid: Determination of the Solubility in organic Solvents considering also the Effect of Temperature ChemService S.r.l. Study nr CH-624/2008 Unpublished	Y		SOPURA
A4.1/01	2009	Octanoic Acid: Validation of the Analytical Method for the Determination of the Active Ingredient Content ChemService S.r.l. Study nr CH-625/2008 GLP Unpublished	Y		SOPURA
A4.1/02	2009	Octanoic Acid: Validation of the Analytical Method for the Determination of the Significant Impurity Content ChemService S.r.l. Study nr CH-626/2008 GLP Unpublished	Y		SOPURA
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; Unpublished	N		Published
A4.1/01b	2006	Methodenvalidierung 0,1 µg/L for decanoic acid and octanoic acid Böhler Analytik Ges.m.b.H no GLP Unpublished.	Y		SolNova
A4.3/04	1990	Method for the Quantitative Analysis of Volatile Free and Total Branched-Chain Fatty Acids in Chees 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 ASBC Journal De Vries K.	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
		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
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. Laboratories Engelhardt, Grandfontaine, Switzerland Unpublished	Y		SolNova
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
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	N		-

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
		Published			
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) TNO BIBRA --- Published	N		published
A6/04b	1988	Toxicity Profile , n-Octanoic acid (and its sodium and potassium salts) TNO BIBRA --- Published	N		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 WHO/IPCS the forty-ninth meeting of the JECFA, Joint FAO/WHO Expert Committee on Food Additives	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 Traul K.A., Driedger A., Ingle D.L., Nakhasi D. Food and Chemical Toxicology 38 (2000)	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
		Published			
A6/12	1982	Medium-chain triglycerides: an update Bach A.C., Babayan V.K. The American Journal of Nutrition 36 pages 950 – 962 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	http://ecb.jrc.ec.europa.eu/esis/index.php IUCLID entry	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	Y		SOPURA

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
		Study Number A86556 Unpublished			
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 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 Sciences Toxicology, Seibersdorf, Austria; Report Nr: ARC-L2241; Unpublished	Y		SOPURA
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.	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
		The Journal of the American Oil Chemists' Society Department of Nutritional Research, Mead Johnson Research Center, Evansville, Indiana 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 Ref nr A6.6.3/01	Y		SOPURA
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,	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
		and 1-methyl-1-cyclohexanecarboxylic acid Mei-JenLiu and Pollack G. M. Biopharmaceutics & Drug Disposition, vol. 14 Published			
A6.8.2 A6.4.1.1/ 02	1968	Nutritional Evaluation of Medium-Chain Triglycerides in the Rat The Journal of the American Oil Chemists' Society Harkins R. W. and Sarett H. P. 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	OCTANOIC ACID: READY BIODEGRADABILITY IN A MANOMETRIC RESPIROMETRY TEST; RCC LTD, Itingen, Switzerland; RCC Study Number: A86578 Unpublished	Y		SOPURA N.V.
A7.1.3/01	2008	ADSORPTION/DESORPTION OF OCTANOIC ACID ON SOILS; RCC Ltd, Itingen; RCC Report No. A86477 Unpublished	Y		SOPURA N.V.
A7.4.1.1/02	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	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
A7.4.1.2/01	2001	Octanoic acid Daphnia magna, Acute Toxicity; Henkel KgaA Department of Ecology; Final Report R-0100717 Unpublished	Y		Henkel KGaA

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
A7.4.1.2/02 D	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 D	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
A7.4.1.4/02 D	2006	DECANOIC ACID: TOXICITY TO ACTIVATED SLUDGE IN A RESPIRATION INHIBITION TEST; RCC Ltd, Itingen Switzerland; RCC Study Number A86545 Unpublished; cross reference	Y		SOPURA N.V.
A7.4.2/01	2006	Calculation of the BCF for octanoic acid with the US-EPA program BCF Program	Y		MCF-Consultancy GmbH

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	N		published

	Aeby P., Ashikaga T., Diembeck W.,, Eschrich D., Gerberick F.,, Kimber I, Marrec-Fairley M., Maxwell G., Ovigne J.M., Sakaguchi1H., Tailhardat M., Teissier S. AATEX 14, Special Issue, 375-379 http://altweb.jhsph.edu/wc6/			
1995	Skin irritation in man: a comparative bioengineering study using improved reflectance spectroscopy Andersen PH, Maibach HI Contact Dermatitis 33(5):315-22	N		published
1985	Chronic mouse dermal toxicity study, test material C-182 = Pelargonic Acid Barkley W. Kettering Laboratory, Univ. Cincinnati, OH, U.S.A. Report No. not stated Not GLP, Published	just EPA study summary, no letter of access from applicant available		published
1997	The classification of skin irritants by human patch test Basketter DA, Chamberlain M, Griffiths HA, Rowson M, Whittle E, York M. Food Chem Toxicol. 35(8):845-52.	N		published
2007a	Does irritation potency contribute to the skin sensitization potency of contact allergens? Basketter DA, Kan-King-Yu D, Dierkes P, Jowsey IR. Cutan Ocul Toxicol. 26(4): 279-86.	N		published
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
1998	Strategies for Identifying False Positive Responses in Predictive Skin Sensitization Tests Basketter DA., Gerberick GF., Kimber I. Food and Chemical Toxicology 36: 327-333	N		published
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
2006	Toxicological modes of action: relevance for human risk assessment ECETOC Technical Report No. 99, July 2006	N		published
2007	statement on the validity of in-vitro tests for skin irritation ESAC http://ecvam.jrc.it/index.htm	N		published

1992	Propionic acid and the phenomenon of rodent forestomach tumorigenesis: a review BP group Occupational Health Centre, Guilford, Surrey, U. K Harrison PT. Food Chem Toxicol. 1992 Apr; 30(4): 333-40 Report-No. Not applicable Not GLP, Published	N		published
1999	Predictive Value of Rodent Forestomach and Gastric Neuroendocrine Tumours in Evaluating Carcinogenic Risks to Humans IARC Technical Publication No. 39, 1999	N		published
2007	Comparison of human skin irritation and photo-irritation patch test data with cellular in vitro assays and animal in vivo data Jirova D., Liebsch M., Basketter D., Kandarova H., Kejlova K., Bendova H., Marriot M., Spiller E. AATEX 14, Special Issue, 359-365; Proc. 6th World Congress on Alternatives & Animal Use in the Life Sciences; August 21-25, 2007, Tokyo, Japan http://altweb.jhsph.edu/wc6/paper359.pdf	N		published
2008	Comparison of the skin sensitizing potential of unsaturated compounds as assessed by the murine local lymph node assay (LLNA) and the guinea pig maximization test (GPMT) Kreiling R., Hollnagel H.M., Hareng L., Eigler D., Lee M.S., Griem P., Dreeßen B., Kleber M., Albrecht A, Garcia C., Wendel A. Food Chem Toxicol. 46(6): 1896-1904	N		published
2008	Analysis of differential gene expression in auricular lymph nodes draining skin exposed to sensitizers and irritants Ku HO, Jeong SH, Kang HG, Pyo HM, Cho JH, Son SW, Ryu DY Toxicol Lett. 177(1):1-9.	N		published
2008	Skin sensitization in chemical risk assessment: report of a WHO/IPCS international workshop focusing on dose-response assessment Loveren van H, Cockshott A, Gebel T, Gundert-Remy U, de Jong WH, Matheson J, McGarry H, Musset L, Selgrade MK, Vickers C. Regul Toxicol Pharmacol. 50(2):155-99.	N		published
2007	McLean J. et al. Journal of Chemical Ecology 33:1997-2009	N		published
1998	Murine local lymph node assay for predictive testing of allergenicity: two irritants caused significant proliferation. Montelius J, Wahlkvist H, Boman A, Wahlberg JE. Acta Derm Venereol. 78(6): 433-7	N		published
2002	Subacute 28-Day Oral toxicity with Pelagonsäure by Daily Gavage in the Rat	Y		W. Neudorff

	Notox B.V, 's-Hertogenbosch, The Netherlands Report-no. 321582 GLP, Unpublished			GmbH KG
2001a	Assessment of Acute oral Toxicity with Pelargonsäure in the Rat (Acute Toxic Class Method) Notox B.V, 's-Hertogenbosch, The Netherlands Report-No. 321547 GLP, Unpublished	Y		W. Neudorff GmbH KG
2001b	Assessment of Acute Dermal Toxicity with Pelargonsäure in the Rat Notox B.V, 's-Hertogenbosch, The Netherlands Report-No. 321558 GLP, Unpublished	Y		W. Neudorff GmbH KG
2007	Mode-of-action framework for evaluating the relevance of rodent forestomach tumors in cancer risk assessment. Proctor DM, Gatto NM, Hong SJ, Allamneni KP. Toxicol Sci. 98(2):313-26 Report-No. Not applicable Not GLP, Published	N		--
2001	Validity and ethics of the human 4-h patch test as an alternative method to assess acute skin irritation potential Robinson MK, McFadden JP, Basketter DA. Contact Dermatitis 45(1):1-12	N		published
1991	Schilder M. Applied Animal Behaviour Science, 32:227-236	N		published
2007	The ECVAM international validation study on in vitro tests for acute skin irritation: report on the validity of the EPISKIN and EpiDerm assays and on the Skin Integrity Function Test. Spielmann H, Hoffmann S, Liebsch M, Botham P, Fentem JH, Eskes C, Roguet R, Cotovio J, Cole T, Worth A, Heylings J, Jones P, Robles C, Kandárová H, Gamer A, Remmele M, Curren R, Raabe H, Cockshott A, Gerner I, Zuang V. Altern Lab Anim. 35(6):559-601	N		published
2003	Nonanoic acid – an experimental irritant Wahlberg J, Lindberg M. Contact Dermatitis 49: 117–123	N		published
1983	Assessment of skin irritancy: measurement of skin fold thickness Wahlberg JE Contact Dermatitis 9(1):21-6	N		published
1980	Nonanoic acid irritation - a positive control at routine patch testing? Wahlberg JE, Maibach HI Contact Dermatitis 6(2):128-30	N		published
1985	Skin irritancy from nonanoic acid Wahlberg JE, Wrangsjö K, Hietasalo A. Contact Dermatitis 13(4):266-9	N		published

1988	Forestomach carcinogens: pathology and relevance to man. National Institute of Public Health and Environmental Protection, Bilthoven, The Netherlands Wester PW., Kroes R. Toxicol Pathol. 1988; 16(2): 165-71 Report-No. Not applicable Not GLP, Published	N		published
2005	Guidance document for the use of data in development of chemical-specific adjustment factors (CSAFs) for interspecies differences in human variability in dose/concentration-response assessment. IPCS harmonization project document ; no. 2 http://www.inchem.org/documents/harmproj/harmproj/harmproj2.pdf			
1988b	Assessment of erythema in irritant contact dermatitis. Comparison between visual scoring and laser Doppler flowmetry Willis CM, Stephens CJ, Wilkinson JD. Contact Dermatitis 18(3):138-42	N		published
1988a	Experimentally-induced irritant contact dermatitis. Determination of optimum irritant concentrations Willis CM, Stephens JM, Wilkinson JD Contact Dermatitis 18(1):20-4.	N		published
1996	Evaluation of a human patch test for the identification and classification of skin irritation potential. York M, Griffiths HA, Whittle E, Basketter DA. Contact Dermatitis 34(3):204-12.	N		published
2001c	Primary Skin Irritation/Corrosion Study with Pelargonsäure in the Rabbit (4-Hour Semi-Occlusive Application) Notox B.V, 's-Hertogenbosch, The Netherlands Report-no. 321604 GLP, Unpublished	Y		W. Neudorff GmbH KG
2001d	Assessment of Contact Hypersensitivity to Pelargonsäure in the Albino Guinea Pig (Maximisation-Test) Notox B.V, 's-Hertogenbosch, The Netherlands Report-no. 321615 GLP, Unpublished	Y		W. Neudorff GmbH KG
2003	The National Diet and Nutrition Survey: Adults Aged 19-64 years, Volume 2: Energy, protein, carbohydrate, fat and alcohol intake. Henderson L., Gregory J., Irving K., Swan G. London, HMSO	N		published
2006	The National Diet and Nutrition Survey: Adults Aged 19-64 years, Volume 4: Nutritional status (anthropometry and blood analytes), blood pressure and physical activity. Ruston D., Horare J., Henderson L., Gregory J., Bates C.J., Prentice A., Birch M., Swan G., Farron M. London, HMSO.	N		published

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT – 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 analysis;	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
		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 – 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 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

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 ORGANISATIONS 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