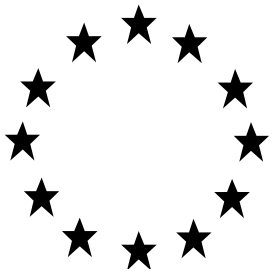
Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Decanoic acid

Product-type 4
(Food and feed area disinfectants)

December 2013

Austria

Decanoic acid (PT 4)

Assessment report

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

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1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Principle of evaluation

This assessment report has been established as a result of the evaluation of Decanoic acid as product-type 4 (Food and feed area disinfectants), 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 4 containing Decanoic acid that will fulfil the requirements laid down in Article 5(1) b), c) and d) of that Directive.

1.2. Purpose of the assessment

The aim of the assessment report is to support a decision on the approval of Decanoic acid for product-type 4, and should it be approved, to facilitate the authorisation of individual biocidal products in product-type 4 that contain Decanoic acid. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

The conclusions of this report were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Regulation (EU) No 528/2012.

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

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

1.3. Procedure followed

This assessment report has been established as a result of the evaluation of Decanoic acid as product-type 4 (Food and feed area disinfectants), carried out in the context of the work

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

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.

Decanoic acid (CAS no. 334-48-5) was notified as an existing active substance, by FATTY ACIDS Consortium, p.a. SOPURA N.V., hereafter referred to as the applicant, in product-type PT 4.

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

In accordance with the provisions of Article 7(1) of that Regulation, AT was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for Decanoic acid as an active substance in Product Type 4 was 31 July 2007, in accordance with Article 9 (c) of Regulation (EC) No 1451/2007.

On 28 February 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 14 August 2006. Due to several data gaps evaluation was suspended between 12 August 2008 and 30 June 2009.

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 3 February 2011. The competent authority report included a recommendation for the inclusion of Decanoic acid in Annex I to the Directive for product-type PT4.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 3 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. OVERALL SUMMARY AND CONCLUSIONS

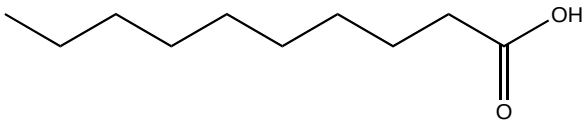
2.1. Presentation of the Active Substance

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

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

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

Structural formula:



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

The physico–chemical properties are studied for the purified active substance of stated specification (min. 99%w/w Decanoic acid) according to the demands of the data requirements.

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

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

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

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

Its flash point is 178°C. The heat of combustion is -6107.7 kJ/mol, therefore auto flammability is not expected. The substance is stable up to the boiling point (146.8°C). Decanoic acid starts to decompose at 264.5°C. Uncoated metal containers should be avoided. Plastic containers made of polyethylene or polypropylene and certified for use with acid are recommended.

The identification and quantification of Decanoic acid in the active substance as well as in the biocidal products SEPTACID BN and SEPTACID BN-PS is performed by using a GC system with FID detection. The method has been validated and shown to be sufficiently specific, accurate and sensitive.

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

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

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

As Decanoic acid is not classified as toxic or very toxic, analytical methods for detection and identification of residues in animal and human body fluids and tissues were not assessed.

An analytical method for the determination of residues of Decanoic acid in/on food or feedstuffs is not required because the active substance is not used in a manner that results in relevant concentrations in food for the intended use in this CAR (see section 2.2.2.3).

2.1.2. Intended Uses and Efficacy

This dossier is to support the use of Decanoic acid in disinfectants of product type PT 4 in food and feed areas performing cleaning in place (CIP) of installations in breweries, which represent closed systems of beer brewing and bottling. The product is used exclusively by professional workers in breweries and in the food industry. The active substance has bactericidal (e.g. *Escherichia coli, Pseudomonas aeruginosa, Enterococcus hirae, Staphylococcus aureus*) and yeasticidal (*Candida albicans*) activity. The assessment showed that the active substance has a certain level of efficacy against the target organisms. The efficacy of the active substance has been tested according to EN 1276 and EN 1650. The tests have been performed in an acidified solution in order to assess the active substance in its undissociated form.

However, concerning efficacy of the representative biocidal product containing the active substance there were some experimental shortcomings which shall be amended at product authorisation stage. (See chapter 3.3 of this document). No resistance has been reported with regard to the use of Octanoic acid as described above. However regular checks on the efficacy against the target organisms should be performed.The intended uses of the substance, as identified during the evaluation process, are listed in Appendix II of this document.

2.1.3. Classification and Labelling of the active substance

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

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

Proposed classification and labelling

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

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

*

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

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

*. Recently a RAC opinion was published confirming this proposal.

2.1.4. Classification and Labelling of the biocidal products

The representative products Septacid BN and Septacid BN-PS have a similar composition and the same classification. Therefore the C&L indicated below is valid for both of them.

Proposed classification and labelling

Classification and labelling for environmental hazards is neither required according to Directive 1999/45/EC nor according to Regulation (EC) No 1272/2008, Annex VI, Table 3.1 and Regulation (EU) No 286/2011

Table 2.1.4-1: Proposed classification and labelling of the PT 4 biocidal products by RMS according to Directive 1999/45/EC

Hazard symbol	
Indication of danger	C corrosive
R phrases	R35 Causes severe burns (calculation method and pH < 1)
S phrases	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 S2 Keep out of the reach of children
Classification	C; R35
Labelling	C R: 35 S: 2-26-36/37/39

Table 2.1.4-2: Proposed classification and labelling of the PT 4 biocidal products by RMS according to Reg. (EC) No 1272/2008, Annex VI, Table 3.1 and Reg. (EU) No 286/2011

GHS Pictograms		 GHS05
Signal words		Danger
Classification		Skin corrosion - Hazard Category 1A
Hazard statements		H314: Causes severe skin burns and eye damage (calculation m. and pH < 1)
Precautionary statement	**Prevention**	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.
	Response	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.
	Storage	P405: Store locked up.
	Disposal	P501: Dispose of contents/container in accordance with local/regional/ national/international regulation (to be specified).

2.2. Summary of the Risk Assessment

2.2.1. Risk arising from physico-chemical properties

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

2.2.2. Human Health Risk Assessment

2.2.2.1. Hazard identification

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

According to OECD guideline 405 the severe skin irritation of 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. 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. 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.

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

Table 2.2.2.3-1: Main paths of human exposure to Decanoic acid as SEPTACID BN (PS)

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[1]	Not relevant	Not relevant	Not relevant[2]
Dermal	No[1]	Not relevant	Not relevant	Not relevant[2]
Oral	No[1]	Not relevant	Not relevant	Not relevant[2]

[1] As realistic worst case, dermal and inhalative exposure were assessed.

[2] 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 professional workers for the cleaning of process installations by CIP (cleaning in place) in food industry, i.e.breweries. The whole cleaning processes are expected to be performed in closed systems preventing any contact of the operators with the biocidal product. No primary exposure is expected during the application.

Subsequent to the use of the biocidal product, exposure for a consumer drinking beer which was processed in a brewery where the processing installations were disinfected with SEPTACID BN (PS) may occur (Secondary exposure; dietary exposure). Reasonable estimations show that this scenario can be considered as not relevant.

Exposure of pets is considered to be not relevant.

2.2.2.4. Risk characterisation

Due to the nature of the active substances no quantitative AELs were derived (see chapter 2.2.2.2), but a qualitative risk assessment for local effects is carried out.

Strict exposure control measures are necessary since SEPTACID BN is classified as corrosive (R35 or Cat 1A- H314). The corrosive effects of SEPTACID BN containing Decanoic and Octanoic acid with 1.5% each is driven by the low pH of about 1 which is achieved with addition of co-formulants.

The product is not marketed for general public. The intended use of the representative products foresees dilution in closed systems. Dermal exposure as well as respiratory exposure to aerosols of the undiluted product has to be excluded. Where direct contact cannot be not fully excluded by the technology, eventually in case of exceptional maintenance work, full dermal and respiratory protection by appropriate personal protective equipment is necessary. However the intended use within professional workplace environments including the proper application of the precautionary measures can be considered as acceptable.

The final application solution contains between 0.3% and 2% biocidal product and may therefore be considered as less dangerous, eventually not corrosive but just skin and eye irritating. The application of the diluted product is still situated within closed systems (cleaning in place) which do not lead to daily exposure. Exceptional maintenance work may eventually lead to exposure and in this case personal protective gloves, eye protection and a filter mask will be necessary. Within professional workplace environment the risk for local effects due to exposure to the diluted product can be considered as acceptable.

Due to the nature of the active substance (see chapter 2.2.2.2.) no quantitative dietary risk assessment was carried out. Furthermore presence of relevant amounts of residues of the application solution in food or feeding is not expected with proper operation of CIP systems. Minimal residues of the application solution in food or feed are unlikely to cause local effects due to the high dilution rate in food expected.

2.2.3. Environmental Risk Assessment

2.2.3.1. Fate and distribution in the environment

Decanoic acid is readily biodegradable (91-92% mineralisation based on ThOD at day 28; pass level reached at day 5). The principal way of degradation of fatty acids under aerobic conditions is the microbial shortening by C2 pieces (β-oxidation of fatty acids). In addition the DT_{50} soil from Nonanoic acid of 2.1 days at 12°C (Draft Competent Authority Report, Document I, Nonanoic acid, Product Type 19, 2008) was used for read across in order to refine the risk characterisation for the soil compartment of PT 4. Read across was considered possible since the biotic degradation behaviour is very similar for Octa-, Nona- and Decanoic acid. Nonanoic acid is considered a worst case since it degrades a little less well than the two other fatty acids.

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

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

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

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

<u>Accumulation:</u>

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

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

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

- Decanoic acid is rapidly biodegradable
- Decanoic acid is a fatty acid. Fatty acids are ubiquitous available in the environment and important naturally occurring biological molecules, found in all living organisms. They may be regarded as having fundamental roles (i.e. they are the building blocks of structurally important molecules in cellular membranes and also serve as sources of energy for biological systems).

• Decanoic acid is metabolized via ß-oxidation. This is quantitatively the most significant pathway for catabolism of fatty acids and results in the final products CO_2 and acetyl-CoA which as such are further metabolized to CO_2 and water (for details of the degradation steps see Doc. II-A, 3.1.2).

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

Surface water used for drinking water

The maximum concentration in Scenario 2a (231/300 days of emission) for Decanoic acid in surface water exceeds the parametric value of 0.1 µg/L, according to Directive 98/83/EC (see Table 2.1.2-2).

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 Decanoic acid in water and dilution in surface water. At present there are no tools available to calculate such a PEC, taking into account these processes that may occur during the water flow from the STP to the water abstraction point.

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

2.2.3.2. Effects assessment

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

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

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

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

corrosive and irritating properties as the chain length increases. For aqueous toxicity it is expected that the higher lipophilicity of the longer fatty acid could cause an increase in toxicity. A non-GLP study of Decanoic acid conducted with Golden orfe (*Leuciscus idus*) show similar toxicity, therefore read across is justified.

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

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

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

Air compartment:

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

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

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

Terrestrial compartment:

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

2.2.3.3. PBT assessment

Persistence:

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

The P-criterion is not met: Not P

Bioaccumulation:

BCF_{fish} = 598 (calculated)

The B-criterion is not met: Not B

Toxicity:

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

Endocrine disrupting effects and CMR effects:

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

The T-criterion is not met: Not T

Conclusion:

Decanoic acid is neither a PBT nor a vBvP substance.

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

2.2.3.4. Exposure assessment

The environmental exposure assessment has been performed in accordance with the Draft Emission Scenario Document for Product Type 4 (Disinfectants used in food and feed areas)3 as well as the Technical Guidance Document (TGD II, European Commission 2003)[4] and the EUSES Background report (EC 2004)[5] and is based on information relating to the Intended Use. The environmental exposure assessment was conducted for the local scale only.

3 Technical Notes for Guidance: Supplement to the methodology for risk evaluation of biocides. Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas.

[4] 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.

5 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/.

In the ESD for PT 4 the environmental release pathway for substances used as disinfectants in food, drink and milk industries (FDM) is described. According to the Intended Use the disinfection is performed by CIP (Cleaning in Place = disinfectant is added to the circulating water) treatment. It is assumed that the CIP treatment is only used once and then poured into the sewage. According to the ESD most of the disinfectant applied by CIP ends up in a sewage treatment plant.

In the exposure scenario emission estimation is based on the annual tonnage of the active substance and the annual waste-water amount discharged by the plant. According to the ESD this is based on an industry survey, which showed that breweries have the lowest annual waste water release, thus representing a worst case with regard to the active substance concentration in the waste water. As recommended in the ESD two different default values for Temission (number of days for emission) were considered: 231 and 300 days.

Predicted Environmental Concentrations (PECs) for the active substance for the relevant compartments are calculated for the influent ($Clocal_{inf}$) and effluent ($Clocal_{eff}$ = PEC_{STP}) of a sewage treatment plant and for the environmental compartments surface water (PEC_{sw}) and sediment (PEC_{sed}). In addition to that concentration in STP_{sludge} (C_{sludge}) and the PECs for the active substance in soil after 30 and 180 days after sludge application (PEC_{soil}) and the porewater concentration (PEC_{gw}) are calculated.

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.

2.2.3.5. Risk characterisation

Air compartment:

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

Conclusion:

Decanoic acid poses an acceptable risk for the air compartment.

Aquatic compartment (including sediment):

STP:

Use of Decanoic acid as a disinfectant by CIP treatment will lead to emissions to sewage treatment plants, which are considered as the main receiving compartment. PECs were calculated for release of the waste water to an off-site STP (Scenario 2a) for 300 and 231 days

of emission (see Doc. II-B, chapters 5.1 Fate and distribution in the environment and 5.2.2 PEC in STP).

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

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

Table 2.2.3.5-1: PEC/PNEC ratios for STP

Exposure scenario	**PEC_{STP} (mg/L)**	**PEC/PNEC**
	STP ($PNEC_{aquatic\ micro-organisms}$ 100 mg/L)	
Scenario 2a (231 days of emission)	0.209	$2.09x10^{-3}$
Scenario 2a (300 days of emission)	0.161	$1.61x10^{-3}$

Conclusion:

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

Surface water incl. sediment:

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

As a **first tier** the PECs in surface water and sediment were calculated based on standard default values.

The PEC/PNEC ratios for the aquatic ecosystem are derived by dividing the local PECs in surface water and sediment by the PNECs for aquatic and benthic organisms, respectively. For the estimation of the PNECs for aquatic and benthic 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 the aquatic compartment based on default values (Tier 1)

Exposure scenario	PEC in mg/L or mg/kg$_{wwt}$	PEC/PNEC
	Water/local (PNEC$_{water}$: 0.0057 mg/L)	
Scenario 2a (231 days of emission)	0.0209	3.67
Scenario 2a (300 days of emission)	0.0161	2.82
Scenario 2a (231/300 days of emission) annual average	0.0132	2.32
	Sediment/local (PNEC$_{sediment}$: 0.0372 mg/kg$_{wwt}$)	
Scenario 2a (231 days of emission)	0.137	3.67
Scenario 2a (300 days of emission)	0.105	2.82

A slight risk to aquatic and benthic organisms could be identified, since PEC/PNEC ratios of 2.3 to 3.7 were calculated.

However, in a **second tier** the PECs in surface water and sediment were refined based on monitoring data provided by the applicant. This refinement was calculated by using average as well as maximum monitoring values (see Doc. II-B, chapter 5.2.3 PEC in surface water).

Table 2.2.3.5-3: Local PEC/PNEC ratios for the aquatic compartment based on monitoring data (Tier 2)

Exposure scenario	PEC$_{surface\ water}$ in mg/L	PEC/PNEC
	Water/local (PNEC$_{water}$: 0.0057 mg/L)	
Average values		
Scenario 2a (231/300 days of emission)	1.50×10^{-4}	2.63×10^{-2}
Scenario 2a (231 days of emission, annual average)	9.49×10^{-5}	1.66×10^{-2}
Scenario 2a (300 days of emission, annual average)	1.23×10^{-4}	2.16×10^{-2}
Maximum values		
Scenario 2a (231/300 days of emission)	1.30×10^{-3}	0.23
Scenario 2a (231 days of emission, annual average)	8.22×10^{-4}	0.14
Scenario 2a (300 days of emission, annual average)	1.07×10^{-3}	0.19
	Sediment/local (PNEC$_{water}$: 0.0372 mg/kg$_{wwt}$)	
Average values		

Scenario 2a (231/300 days of emission)	$9.79x10^{-4}$	$2.63x10^{-2}$
Maximum values		
Scenario 2a (231/300 days of emission)	$8.48\ x10^{-3}$	0.23

Conclusion

Considering tier 2 calculations based on monitoring data resulting in PEC/PNEC ratios <1, Decanoic acid poses an acceptable risk to aquatic and benthic organisms.

Groundwater:

According to the TDG II (EC 2003) the concentration in pore water of soil is taken as an indication for potential groundwater levels. The calculation of the predicted environmental concentration of Decanoic acid in groundwater after continuous sludge application over 10 years and taking into account degradation gives a value of 0.4 µg/L to 0.5 (see Doc. II-B, section 5.2.6). This slight above the parametric value of 0.1 µg/L according to Directive 98/83/EC. However, Decanoic acid has a low K_{oc} value of 264 L/kg (EUSES model calculations), which indicates that it will adsorb weakly onto soil. The calculation of the concentration according to formula 68 TGD neglects transformation and dilution in deeper soil layers. Thus this slight calculated exceedance is considered to be acceptable.

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 80^{th} percentile of 0.000000 µg/L).

Conclusion:

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

Persistence in sediment:

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

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

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

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

Conclusion:

Decanoic acid is not persistent in sediment.

Terrestrial compartment:

Indirect exposure of agricultural soil:

According to the intended use as a disinfectant applied by CIP in a closed system, direct emissions to the soil compartment are considered negligible. However indirect exposure of agricultural soils through fertilization with sludge from a STP is considered relevant.

PECs were calculated for scenario 2a (off-site STP) for arable soil and grassland as the average concentrations over certain time-periods in agricultural soil fertilized with sludge from a STP. Additionally PECs were calculated for 300 and 231 days of emission to STP (see Doc. II-B, chapters 5.1 Fate and distribution in the environment and 5.2.5 PEC in soil).

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

The PEC/PNEC ratio for soil was calculated by dividing the PEC_{soil} by the $PNEC_{soil}$ (see table 2.2.3.5-4).

Table 2.2.3.5-4: Local PEC/PNEC ratios for the terrestrial compartment exposed via sewage sludge

Exposure scenario	**PEC_{soil} (mg/kgwwt)**	**PEC/PNEC**
	$PNEC_{soil}$: 0.027 mg/kg_{wwt}	
Arable soil (averaged over 30 days)		
Scenario 2a (231 days of emission to STP)	0.0153	0.57
Scenario 2a (300 days of emission to STP)	0.0118	0.44
Arable soil (averaged over 180 days)		
Scenario 2a (231 days of emission to STP)	$2.55x10^{-3}$	0.094
Scenario 2a (300 days of emission to STP)	$1.96x10^{-3}$	0.073
Grassland (averaged over 180 days)		
Scenario 2a (231 days of emission to STP)	$1.02x10^{-3}$	0.038
Scenario 2a (300 days of emission to STP)	$7.84x10^{-4}$	0.229

Conclusion:

Indirect exposure to Decanoic acid via sludge application poses an acceptable risk to soil organisms.

Persistence in soil:

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

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

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

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

Conclusion:

Decanoic acid is not persistent in soil.

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

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

Risk for fish eating and worm eating predators

No toxicity tests in birds were submitted for Decanoic acid. However, data 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 based on default values **(tier 1)**. The risk to the fish- and worm eating predators is calculated in Table 2.4.1-1 as the ratio between the concentration in their food (fish or earthworms) (see Doc. II-B, chapter 5.2.7) and the predicted no-effect concentration for long term oral intake ($PNEC_{oral\ chron}$) (see Doc II-A, chapter 4.2.4).

Table 2.2.3.5-5: PEC/PNEC ratios for non-compartment specific effects (secondary poisoning, Tier 1)

Exposure scenario	**PEC**	**PEC/PNEC**
	$PNEC_{oral\ chron}$ 0.331 a.s. mg/kg diet	
Aquatic food chain:	3.96 mg a.s./$kg_{wet\ fish}$	12
Terrestrial food chain:		
Scenario 2a (231 days of emission)	0.0357 mg a.s./$kg_{wet\ earthworm}$	0.11
Scenario 2a (300 days of emission)	0.0275 mg a.s./$kg_{wet\ earthworm}$	0.08

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

The PEC/PNEC ratio for secondary poisoning calculated for the aquatic food chain is slight above 1 indicating a risk. Although the value is greater than 1, the risk can be seen as acceptable for the following reasons:

- The $PNEC_{oral\ chron}$ is derived from studies where at the maximum test concentration no effects could be seen.

- The $PNEC_{oral\ chron}$ is based on EC_{50} values and not on NOECs (but no mortalities or any other effects could be observed at the maximum test concentration).

- Decanoic acid is a fatty acid. Fatty acids are 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). Thus in predators no negative effects would be expected in concentrations higher than the concentrations tested and used for risk assessment accordingly.

- The $PEC_{oral,predator}$ is is based on the P_{ow} only, not taking into account the metabolism of the substance and that Decanoic acid is readily degradable.

However in a **second tier**, the PECs for fish- and worm eating predators were refined based on monitoring data provided by the applicant. This refinement was calculated by using average as well as maximum monitoring values (see Doc. II-B, chapter 5.2.3 PEC in surface water).

Table 2.2.3.5-6: PEC/PNEC ratios for non-compartment specific effects (secondary poisoning) based on monitoring data (Tier 2)

Exposure scenario	**PEC**	**PEC/PNEC**
	$PNEC_{oral\ chron}$ 0.331 a.s. mg/kg diet	
Average values		
Aquatic food chain (231 days of emission):	0.0284 mg a.s./$kg_{wet\ fish}$	0.086
Aquatic food chain (300 days of emission):	0.0368 mg a.s./$kg_{wet\ fish}$	0.11
Maximum values		
Aquatic food chain (231 days of emission):	0.246 mg a.s./$kg_{wet\ fish}$	0.74
Aquatic food chain (300 days of emission):	0.319 mg a.s./$kg_{wet\ fish}$	0.96

Conclusion

Considering all arguments above and refined tier 2 calculations resulting in PEC/PNEC values <1, the risk for fish eating and worm eating predators is acceptable. The non-compartment specific effects of secondary poisoning are low for the aquatic and terrestrial food chain.

2.2.4. List of endpoints

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

3. PROPOSED DECISION

3.1. Background to the proposed Decision

Decanoic acid is used as active substance in disinfectants for the food and feed industry, especially breweries. The active substance has bactericidal (e.g. *Escherichia coli, Pseudomonas aeruginosa, Enterococcus hirae, Staphylococcus aureus*) and yeasticidal (*Candida albicans*) activity. The assessment showed that the active substance has a certain level of efficacy against the target organisms.

The active substance has no hazardous physico-chemical properties.

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

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

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.

3.2. Proposed decision

The overall conclusion from the evaluation of Decanoic acid for use in product type 4 (desinfectants for food and feed area), is that it may be possible to issue authorisations of products containing Decanoic acid in accordance with the conditions laid down in Article 5(1) b), c) and d) of Dir. 98/8/EC.

It is therefore appropriate to approve Decanoic acid for use in biocidal products for product-type 4 (Food and feed area disinfectants), 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) For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment

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) Biocidal products containing decanoic acid shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of decanoic acid into food or it has been established pursuant to that Regulation that such limits are not necessary.

3.3. Elements to be taken into account when authorising products

1) In case the biocidal product is the same as the representative biocidal product, in addition to the information presented in the active substance CAR, a detailed specification of all ingredients will be necessary

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

3) Human exposure assessment: Rinsing efficiency of the post-rinse cycles is given by the applicant with 60% per cycle for small vessels and with 80% per cycle for big vessels without any justification for the provided numbers. The efficiency of the post-rinse process should be substantiated by data at product authorisation stage as residues of active substance remaining on the walls of the vessels are transferred to the manufactured beer resulting in secondary exposure of consumers.
4) At product authorisation stage reliable efficacy tests in respect to the bactericidal and yeasticidal activity should be provided. Information on suitable packaging material of the representative biocidal product should be submitted at product authorization stage.
5) This active substance is a potential candidate for cumulative risk assessment.
6) 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.
7) At product authorisation stage refined analytical methods have to be submitted addressing the deficiencies and ambiguities identified during evaluation
8) 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).
9) Regular tests of the efficacy against the target organisms should be performed in order to check for eventually emerging resistance.

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the approval of Decanoic acid.

3.5. Updating this Assessment Report

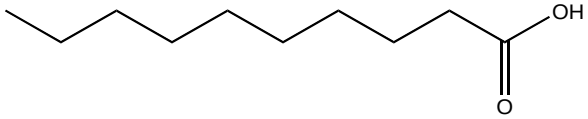
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information submitted in relation with Regulation (EU) No 528/2012. Such adaptations will be examined and finalised in connection with any amendment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

APPENDIX I: LIST OF ENDPOINTS

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

Active substance	Decanoic acid
Product-type	PT 4

Identity

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

Physical and chemical properties

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

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

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

Classification and proposed labelling

with regard to physical/chemical data	None
with regard to toxicological data	<u>Directive 67/548/EEC</u> Xi; R38 - Irritating to skin, R36 - Irritating to eyes S26 In case of contact with eyes rinse immediately with plenty of water and seek medical advice S36/37/39 Wear suitable protective clothing, gloves and eye/face protection <u>Reg. 1272/2008/EC</u> Serious eye irritation – Hazard Category 2 Skin irritation- Hazard Category 2 H319: Causes serious eye irritation H315: Causes skin irritation P264 Wash thoroughly after handling P280 Wear protective gloves/protective clothing/eye protection/face protection. P305 + P351 + P338: IF IN EYES: Rinse cautiously with

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

Chapter 2: Methods of Analysis

Analytical methods for the active substance

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

Analytical methods for residues

Soil (principle of method and LOQ)	Not required 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 LOD of 0.1 µg/l for Decanoic 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 irritation- Hazard Category 2 (total WoE evaluation)
Eye irritation	Serious eye irritation – Hazard Category 2 (total WoE evaluation)
Skin sensitization (test method used and result)	Non sensitizing (total WoE evaluation)

Repeated dose toxicity

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

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

Carcinogenicity

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

Reproductive toxicity

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

Neurotoxicity / Delayed neurotoxicity

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: professional)	Dermal and inhalation exposure during application for the cleaning of process installations by CIP (cleaning in place) in breweries.
Indirect exposure as a result of use	Drinking of beer from a brewery where the biocidal product is applied

Exposure of pets	Not considered relevant
Dietary Exposure	Drinking of beer from a brewery where the biocidal product is applied

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

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

Route and rate of degradation in soil

Read across from Nonanoic acid

Mineralization (aerobic)	-----
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): Neudosan (C14-C20 fatty acids): approx. 2 - 3 days in two different soils; n=2 DT_{50lab} (20°C, aerobic): Nonanoic acid: approx. 1.1 days
	DT_{90lab} (20°C, aerobic): Neudosan (C14-C20 fatty acids): approx. 8-10 days DT_{90lab} (20°C, aerobic): Nonanoic acid: approx. 1.8 days
	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 soil sterilisation, due to rapid degradation. For risk characterisation a default K_{oc} value for the non-ionised form of Decanoic acid of 264 L/kg (EUSES model calculation) was used.

Fate and behaviour in air

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

Monitoring data, if available

Soil (indicate location and type of study)	-----
Surface water (indicate location and type of study)	-----
Ground water (indicate location and type of study)	-----
Air (indicate location and type of study)	-----

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
Brachydanio Rerio	96 h, semi-static	Mortality, LC_{50}	81.2 mg/L
Invertebrates			
Daphnia magna	48 h, semi-static	Immobilisation, EC_{50}	16 mg/L
Algae			
Scenedesmus subspicatus	72 h, static	Growth and biomass inhibition, NOE_rC, E_bC_{50}, E_rC_{50}	0.57 mg/L 1.16 mg/L 2 mg/L
Microorganisms			

Activated sludge	3h	Respiration inhibition NOEC	≥ 1000 mg/L, nominal

Effects on earthworms or other soil non-target organisms

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

Effects on soil micro-organisms

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

Effects on terrestrial vertebrates

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

Effects on honeybees

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

Effects on other beneficial arthropods

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

Bioconcentration

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

Chapter 6: Other End Points

APPENDIX II: LIST OF INTENDED USES

The product is intended for disinfection of process installations by CIP (cleaning in place) in breweries in closed systems. The product is to be diluted with water (2%w/w biocidal product in application solution). Drums or IBC containers containing the biocidal product are connected to the system via the installed pipe installation. The whole cleaning process is operated by a valve system in a sequential order. No other human intervention as to operate of the process system is in place.

The acceptable intended use is given in the table below.

Table Appendix II-1:

Acceptable intended uses of the biocidal products SEPTACID BN and SEPTACID BN-PS

PT		PT 4
Formu -lation	**Type**	Liquid concentrate (emulsion in water), which needs to be diluted before use
	Conc. of a.s. in b.p.	1.5%w/w a.s.
Field of use envisaged		The disinfectant is applied as CIP (cleaning in place) in closed systems for processing installations in food industry, i.e. breweries.
User		Industrial
Target Organisms		*Bacteria :* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae* *Pseudomonas aeruginosa* *Yeast:* *Candida albicans*
Likely amount at which the a.s. will be used (all fields of use envisaged)	**Method of application**	Drums or IBC containers containing the b.p. are connected to the system via the installed pipe installation. The whole cleaning process is operated by a valve system in a sequential order. No other human intervention as to operate of the process system is in place.
	Applied amount of product	Concentration of b.p. in application solution at a temperature of 20°C (obligate test temperature) during the disinfection process: 1.5%v/v b.p. in application solution (~2%w/w b.p. in application solution corresponding to 0.03%w/w a.s.)
	Application rate of a.s.	0.03 g a.s /L application solution
	Number of treatments per year	Regular use on a daily basis is assumed for risk assessment
	Typical size of	n.a.

	application area	

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. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii). 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	Decanoic Acid: Complete Analysis of Four Batch Samples ChemService S.r.l. Study Number CH-632/2008 Unpublished	Y		SOPURA
A2.10/03	2006	Method to calculate the unavoidable residue Decanoic Acid SOPURA Unpublished	Y		SOPURA
A2.10/04	2006	Quantitative Evaluation Decanoic Acid Quantity likely to be found back in the Environment after Application SOPURA Unpublished	Y		SOPURA
Company statement	2010	INFORMATION FOLLOWING THE REQUEST FROM THE AUSTRIAN RMS (information regarding calculations)	Y		SOPURA
A3/01D	1999	Determination of some physico-chemical properties of Decanoic acid TNO Prins Maurits Laboratory PML 1999-C110 Unpublished	Y		SOPURA
A3/02D	1999	Expert statement: hydrolysis and dissociation constants of n-octanoic acid and n-decanoic acid TNO Voeding, report number V99.846 Unpublished	Y		SOPURA
A3/03rev09	2008	Decanoic Acid Determination of the bulk density Sopura, Study nr 5474-DECA- 5 Unpublished	Y		SOPURA

A3/03a	2008	Analysis report: Surface tension of Decanoic acid SOPURA, Unpublished	Y		SOPURA
A3/03b	2008	Decanoic Acid Determination of the Viscosity Sopura Study nr 5474-DECA-2 Unpublished	Y		SOPURA
A3/04	2006	Calculation of the Henry Law Constant and Log Kow Unpublished	Y		MCF-Consultancy GmbH
A3/05rev09	2008	Decanoic Acid Determination of some Physico-Chemical Properties Study nr 5474-DECA-4 Sopura Unpublished	Y		SOPURA
A3/06	2006	Expert statement Stability of decanoic acid in organic solvents Unpublished	Y		MCF-Consultancy GmbH
A3/07_rev	2008	Expert statement Thermal stability of decanoic acid Unpublished	Y		MCF-Consultancy GmbH
A3/08	2006	Expert statement Flammability , including auto flammability and identity of combustion product of decanoic acid Unpublished	Y		MCF-Consultancy GmbH
A3/12	2006	Expert statement Explosive properties of decanoic acid Unpublished	Y		MCF-Consultancy GmbH
A3/13	2006	Expert statement Oxidizing properties of decanoic acid Unpublished	Y		MCF-Consultancy GmbH
A3/14	2006	Expert statement Reactivity of decanoic acid towards container material Unpublished	Y		MCF-Consultancy GmbH
A3/15	2006	Expert statement Approval certificates Unpublished	Y		SOPURA
A3/16	2006	Edenor C 10 98-100 (decanoic acid): Determination of the water solubility considering also the effects of temperature and pH value ChemService S.r.l. Study nr CH-334/2006 Unpublished	Y		SOPURA
A3/17	2009	Decanoic Acid: Determination of the Solubility in organic Solvents considering also the Effect of Temperature ChemService S.r.l. Study nr CH-629/2008	Y		SOPURA

		Unpublished			
A3/18	2009	Decanoic Acid: Determination of the Flash Point ChemService S.r.l. Study nr CH-628/2008 Unpublished	Y		SOPURA
A3/18a	2009	Amendment Decanoic Acid: Determination of the Flash Point ChemService S.r.l. Study nr CH-628/2008 Unpublished	Y		SOPURA
A4.1/01	2009	Decanoic Acid: Validation of the Analytical Method for the Determination of the Active Ingredient Content ChemService S.r.l. Study nr CH-630/2008 GLP Unpublished	Y		SOPURA
A4.1/02	2008	Decanoic Acid: Validation of the Analytical Method for the Determination of the Significant Impurity Content ChemService S.r.l. Study nr CH-631/2008 GLP Unpublished	Y		SOPURA
A4.2/01a	1998	In-situ methylation of strongly polar organic acids in natural waters supported by ion-pairing agents for headspace GC-MSD analysis; Dresden University of technology Fresenius J Anal Chem (1998) 361:318-323 no GLP Published	N		SOPURA
A4.2/01b	2006	Methodenvalidierung 0,1 µg/L for decanoic acid and octanoic acid Böhler Analytik Ges.m.b.H no GLP Unpublished.	Y		SOPURA
A4.3/01	2006	Food occurrence / Risk assessments Gubler-Coaching, Pfäffikon, Switzerland no GLP Unpublished	Y		MCF-Consultancy GmbH .
A4.3/02	2006	Method to calculate the unavoidable residue SOPURA, Unpublished	Y		SOPURA
A4.3/03	2006	Quantitative evaluation decanoic acid quantity likely to be found back in the environment after application SOPURA	Y		SOPURA

		Unpublished			
A4.3/04	1990	Method for the Quantitative Analysis of Volatile Free and Total Branched-Chain Fatty Acids in Cheese and Milk Fat Kim J.H.A. and Lindsay R.C. J. Dairy Sci 73:1988-1999 Published	N		Published
A4.3/05	1990	Determination of Free Fatty Acids in Wort and Beer De Vries K ASBC Journal Published	N		Published
A4.3/06	1994	Analysis of Free Fatty Acids, Fusel Alcohols, and Esters in Beer: An Alternative to CS2 Extraction J. Am. Soc. Brew. Chem. 52(3):127-134 Alvarez P. and Malcorps P Published	N		Published
A4.3/07	1985	The Semi-Routine Use of Capillary Gas Chromatography for Analysis of Aroma Volatiles in Beer ASBC Journal:203-208 Stenroos L.E. et.al 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
A5/01	2006	Microbiological performance of SEPTACID BN on beer spoiling bacteria Unpublished	Y		SOPURA
A5.3_1/01D	2006	SOPURSEPT BN-10 + DT 6 in clean conditions report assay Haute école Lucia de Brouckère-Institut Meurice-Laboratoire de Microbiologie Unpublished	Y		SOPURA
A5.3_1/02D	2006	SOPURSEPT BN-10 + DT 6 in dirty conditions report assay Haute école Lucia de Brouckère-Institut Meurice-Laboratoire de Microbiologie Unpublished	Y		SOPURA
A5.3_2/01D	2006	SOPURSEPT BN-10 + DETAL HP in clean conditions report assay Haute école Lucia de Brouckère-Institut Meurice-Laboratoire de Microbiologie Unpublished	Y		SOPURA
A5.3_2/02D	2006	SOPURSEPT BN-10 + DETAL HP in dirty	Y		SOPURA

		conditions report assay Haute école Lucia de Brouckère-Institut Meurice-Laboratoire de Microbiologie Unpublished			
A5.3_3/01D	2006	SOPURSEPT BN-10 + ATR F in clean conditions report assay Haute école Lucia de Brouckère-Institut Meurice-Laboratoire de Microbiologie Unpublished	Y		SOPURA
A5.3_3/02D	2006	SOPURSEPT BN-10 + ATR F in dirty conditions report assay Haute école Lucia de Brouckère-Institut Meurice-Laboratoire de Microbiologie Unpublished	Y		SOPURA
A5.3_2/03D	2006	SOPURSEPT BN-10 + ATR B in clean conditions report assay Haute école Lucia de Brouckère-Institut Meurice-Laboratoire de Microbiologie Unpublished	Y		SOPURA
A5.3_2/04D	2006	SOPURSEPT BN-10 + ATR B in dirty conditions report assay Haute école Lucia de Brouckère-Institut Meurice-Laboratoire de Microbiologie Unpublished	Y		SOPURA
A5.3.4/01D	2010	SEPTACID BN without A.S.: Evaluation of the bactericidal and fungicidal activity according to the European standard test method EN1276 and EN1650. Haute école Lucia de Brouckère-Institut Meurice-Laboratoire de Microbiologie Unpublished	Y		SOPURA
A5.3.4/02D	2010	SEPTACID BN-PS without A.S.: Evaluation of the bactericidal and fungicidal activity according to the European standard test method EN1276 and EN1650. Haute école Lucia de Brouckère-Institut Meurice-Laboratoire de Microbiologie Unpublished	Y		SOPURA
A5.3.4/03D	2010	Decanoic acid.: Evaluation of the bactericidal and fungicidal activity according to the European standard test method EN1276 and EN1650. Haute école Lucia de Brouckère-Institut Meurice-Laboratoire de Microbiologie Unpublished	Y		SOPURA
A6/ 01	1976	Safety studies on a series of fatty acids. Briggs G.B; Doyler L.; Young J. A. American Industrial Hygiene Association Journal;	N		Published

		April, 1976 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		Published
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 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) Published	N		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		Published
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		unpublished
A6.1.1/01	1981	Prüfung der akuten oralen Toxizität Henkel, Düsseldorf	Y		Cognis (LoA available)
A6.1.2/01	2006	Decanoic acid: Acute Dermal Toxicity Study in Rats; RCC Ltd, Itingen Switzerland Study Number A86556 Unpublished	Y		SOPURA
A6.1.3/02	1998	THE BIOPESTICIDE MANUAL Copping L.G. British Crop Protection Council, 1st edition, p. 25 Report-No. not applicable Not GLP, Published	N		Published
A6.1.3/03	--	TOXICOLOGICAL SIMILARITY OF STRAIGHT CHAIN SATURATED FATTY	N		Published

		ACIDS OF GREATER THAN 8 CARBON CHAIN LENGTH BY VARIOUS ROUTES OF EXPOSURE Anonymous Safer Inc, Eden Prairie MN 55334-3585, USA Report-No. not applicable Not GLP, Published			
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		Published
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. The Journal of the American Oil Chemists' Society Department of Nutritional Research, Mead Johnson Research Center, Evansville, Indiana Published	N		Published
A6.6.1/1	1999a	Bacterial reverse mutation test with decanoic acid Netherlands Organisation for applied scientific research (TNO), Zeist, The Netherlands TNO-report V99.668 Ref nr A6.6.1/01	Y		SOPURA
A6.6.1/2	1999b	Bacterial reverse mutation test with octanoic acid Netherlands Organisation for applied scientific research (TNO) Zeist, Netherlands TNO-Report V99.668	Y		SOPURA

A6.6.2/1	1999a	Chromosomal aberration test with decanoic acid in cultured Chinese hamster ovary cells Netherlands Organisation for applied scientific research (TNO), Zeist, The Netherlands TNO-report V99.661 Ref nr A6.6.2/01	Y		SOPURA
A6.6.2/2	1999b	Chromosomal aberration test with octanoic acid in cultured Chinese hamster ovary cells Netherlands Organisation for applied scientific research (TNO) Zeist, Netherlands TNO-Report V99.660.	Y		SOPURA
A6.6.3/1	1999a	Gene mutation test at the TK-locus of L5178Y cells with Decanoic acid; Netherlands Organisation for applied scientific research (TNO), Zeist, The Netherlands TNO-report V99.715 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, and 1-methyl-1-cyclohexanecarboxylic acid Mei-JenLiu and Pollack G. M. Biopharmaceutics & Drug Disposition, vol. 14 Published	N		Published
A6.8.2 A6.4.1.1/ 02	1968	Nutritional Evaluation of Medium-Chain Triglycerides in the Rat Harkins R. W. and Sarett H. P. The Journal of the American Oil Chemists' Society Department of Nutritional Research, Mead Johnson Research Center, Evansville, Indiana Published	N		Published
A7.1.1.2.1/01	2005	Fragrances and Biodegradation Göteborgs Stad Miljö ISSN 1401-2448 ISRN GBG-M-R—05/05—SE Published	N		Published
A7.1.1.2.1/02	2006	DECANOIC ACID: READY BIODEGRADABILITY IN A MANOMETRIC RESPIROMETRY TEST; RCC LTD, Itingen, Switzerland; RCC Study Number: A86567	Y		SOPURA N.V.

		Unpublished			
A7.1.3/01	2008	ADSORPTION/DESORPTION OF DECANOIC ACID ON SOILS; RCC Ltd, Itingen; RCC Report No. A86466 Unpublished	Y		SOPURA N.V.
A7.4.1.1/01	2001	Decanoic acid – fish, Acute Toxicity, Final Report R-0100702 Henkel KgaA Department of Ecology Unpublished	Y		COGNIS Deutschland GmbH (LoA available)
A7.4.1.1/02 O	2006	Octanoic Acid: Acute Toxicity to Zebra Fish (Brachydanio Rerio) in a 96-hour semi-static Test RCC Ltd; Itingen, Switzerland RCC Study Number A86501	Y		SOPURA
A7.4.1.1/03 O	2006	First Amendment to Study Plan Octanoic Acid: Acute Toxicity to Zebra Fish (Brachydanio Rerio) in a 96-hour semi-static Test RCC Ltd; Itingen, Switzerland RCC Study Number A86501	Y		SOPURA
A.7.4.1.2/01	2006	DECANOIC ACID: ACUTE TOXICITY TO DAPHNIA MAGNA IN A 48-HOUR IMMOBILIZATION TEST; RCC Ltd, Itingen, Switzerland; RCC Study Number: A86488 Unpublished	Y		SOPURA
A7.4.1.3/01	2008	DECANOIC ACID: TOXICITY TO SCENEDESMUS SUBSPICATUS IN A 72-HOUR ALGAL GROWTH INHIBITION TEST; RCC Ltd, Itingen, Switzerland RCC Study Number: A86523 (inclusive A86534) Unpublished	Y		SOPURA
A7.4.1.4/01	2006	DECANOIC ACID: TOXICITY TO ACTIVATED SLUDGE IN A RESPIRATION INHIBITION TEST; RCC Ltd, Itingen Switzerland; RCC Study Number A86545 Unpublished	Y		SOPURA N.V.
A7.4.2/01	2006	Calculation of the BCF for decanoic acid with the US-EPA program BCF Program	Y		MCF-Consultancy GmbH

LIST OF STUDIES FOR THE ACTIVE SUBSTANCE – SUBMITTED ADDITIONAL LITERATURE

Section No / Reference No	**Author**	**Year**	**Title** **Source** **Institution; report nr**	**Data Protection**	**Date of 1st submission**	**Owner**

			GLP-, GEP-status **Published or unpublished**			
A.5	Cowles, P.B.	1941	The germicidal action of the hydrogen ion and of the lower fatty acids. Yale J. Biol. Med. 13:571	N	Not applicable as no data protection claimed	published

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 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/	N		published
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 Food Chem Toxicol. 35(8):845-52.	N		published

2007a	Does irritation potency contribute to the skin sensitization potency of contact allergens? 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 Cutaneous and Ocular Toxicology 26:4, 293 - 301	N		published
1998	Strategies for Identifying False Positive Responses in Predictive Skin Sensitization Tests 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. Contact Dermatitis 53(5):278-84	N		published
2006	Toxicological modes of action: relevance for human risk assessment Technical Report No. 99, July 2006	N		published
2007	statement on the validity of in-vitro tests for skin irritation 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 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 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	N		published

	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.			
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 Notox B.V, 's-Hertogenbosch, The Netherlands Report-no. 321582 GLP, Unpublished	Y		W. Neudorff 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	N		published

	Wahlberg J, Lindberg M. Contact Dermatitis 49: 117–123			
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. WHO/IPCS 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	Y		W. Neudorff GmbH KG

	GLP, Unpublished			
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		
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		

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT SEPTACID BN – 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
B2/01	2006	Biocidal product: SEPTACID BN SOPURA Upublished	Y		SOPURA
B3/01	2008	SEPTACID BN Determination of some Physico-Chemical Properties SOPURA Study nr 5474 BN-4 Unpublished	Y		SOPURA
B3/02	2006	Expert Statement Explosive properties of SEPTACID BN Unpublished	Y		MCF-Consultancy GmbH
B3/03a	2006	Report: Determination of the Oxidizing Properties of SEPTACID-BN, RCC Ltd Study Number A86580 Unpublished	Y		SOPURA
B3/03b	2006	First Amendment to Study Plan Determination of the Oxidizing Properties of SEPTACID-BN, RCC Ltd Study Number A86580 Unpublished	Y		SOPURA
B3/04	2008	SEPTACID BN Determination of the Bulk Density SOPURA, Study Number 5474-BN-5 Unpublished	Y		SOPURA
B3/05	2008	Determination of the Stability of SEPTACID BN SOPURA	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
		Unpublished			
B3/06	2008	SEPTACID BN Determination of Surface Tension SOPURA Study number 5474-BN-3 Unpublished	Y		SOPURA
B3/07	2008	SEPTACID BN Determination of the Viscosity SOPURA Study number 5474-BN-2 Unpublished	Y		SOPURA
B3/08	2008	Expert Statement regarding the Persistence of Foaming of SEPTACID BN and SEPTACID BN-PS SOPURA Unpublished	Y		SOPURA
B3/09	2006	SEPTACID BN: Determination of the flashpoint ChemService Study Nr CH-335/2006	Y		SOPURA
B3/12	2008	Analysis report: pH of SEPTACID BN Study number 5474-BN-1 Unpublished	Y		SOPURA
B4.1/01	2006	Assay of octanoic and decanoic acid by gaz chromatography Report No.: IT-LMA-61 no GLP Unpublished	Y		SOPURA
B4.1/02	1998	ASSAY of octanoic and decanoic acids in SEPTACID BN Report no 9802866/1 no GLP Unpublished	Y		SOPURA
B4.1/03	1998	SEPTACID BN – MEHODE GC Validation de la méthode de dosage des acides octanoïque et décanoïque dans le SEPTACID BN Report No. ANR-SEPTAC-A-001-001 no GLP Unpublished	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
B4.1/04	1998	Eng. Translation of SEPTACID BN-METHODE GC Report No. ANR-SEPTAC-A-001-001 no GLP Unpublished	Y		SOPURA
B5.10/13	2007	SEPTACID BN: Bactericide and fungicide efficacy on suspensions. Chemservice, Report CH-337/2006, GLP Unpublished	Y		SOPURA
B6.1.1/01	1998	Acute oral toxicity study with Septacid BN in rats TNO, Zeist, the Netherlands Report: V98.329 Unpublished	Y		SOPURA
B6.1.2/01	1998	Acute dermal toxicity study with Septacid BN in rats TNO, Zeist, Netherlands Report: V98.330 Unpublished	Y		SOPURA

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT SEPTACID BN – SUBMITTED ADDITIONAL LITERATURE

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
Heinz PETERSEN	1987	Brauereianlagen, Verlag Hans Carl	No	Not applicable as no data protection claimed	Published

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT SEPTACID BN – 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

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT SEPTACID BN PS – 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**
B2/01PS	2006	Biocidal product: SEPTACID BN-PS SOPURA Unpublished	Y		SOPURA
B3/01PS	2008	SEPTACID BN-PS Determination of some Physico-Chemical Properties SOPURA Study nr 5474 BN-PS-4 Unpublished	Y		SOPURA
B3/02PS	2006	Expert Statement Explosive properties of SEPTACID BN-PS Unpublished	Y		MCF-Consultancy GmbH
B3/03aPS	2006	Report: Determination of the Oxidizing Properties of SEPTACID-BN-PS, RCC Ltd Study Number A86591 Unpublished	Y		SOPURA
B3/03bPS	2006	First Amendment to Study Plan Determination of the oxidizing properties of Septacid BN-PS RCC Ltd Study Number A86591 Unpublished	Y		SOPURA
B3/04PS	2008	SEPTACID BN-PS Determination of the Bulk Density SOPURA, Study Number 5474-BN-PS-5 Unpublished	Y		SOPURA
B3/05PS	2008	Determination of the Stability of SEPTACID BN-PS	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			
B3/06PS	2008	SEPTACID BN-PS Determination of Surface Tension SOPURA Study number 5474-BN-PS-3 Unpublished	Y		SOPURA
B3/07PS	2008	SEPTACID BN-PS Determination of the Viscosity SOPURA Study number 5474-BN-PS-2 Unpublished	Y		SOPURA
B3/08PS	2008	Expert Statement regarding the Persistence of Foaming of SEPTACID BN and SEPTACID BN-PS SOPURA Unpublished	Y		SOPURA
B3/09PS	2006	SEPTACID BN-PS: Determination of the flash point ChemService Study Nr CH-336/2006 Unpublished	Y		SOPURA
B3/12PS	2008	Analysis report: pH of SEPTECID BN-PS SOPURA Unpublished	Y		SOPURA
B4.1/01PS	2006	Assay of octanoic and decanoic acid by gaz chromatography Report No.: IT-LMA-61 no GLP Unpublished	Y		SOPURA
B4.1/02PS	1998	ASSAY of octanoic and decanoic acids in SEPTACID BN Report no 9802866/1 no GLP Unpublished	Y		SOPURA
B4.1/03PS	1998	SEPTACID BN – MEHODE GC Validation de la méthode de dosage des acides octanoïque et décanoïque dans le SEPTACID BN Report No. ANR-SEPTAC-A-001-001 no GLP Unpublished	Y		SOPURA
B4.1/04PS	1998	Eng. Translation of SEPTACID BN- METHODE	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
		GC Report No. ANR-SEPTAC-A-001-001 no GLP Unpublished			
B4.1/05PS	2008	Justification Report Use of the SOP IT-LMA-61 method for the determination of the octanoic & decanoic Content in SEPTACID BN-PS Study No. 7084 Unpublished	Y		SOPURA
B5.10/14PS	2010	SEPTACID BN-PS: Evaluation of the bactericidal and fungicidal activity according to the European standard test method EN1276 and EN1650. Haute école Lucia de Brouckère-Institut Meurice-Laboratoire de Microbiologie. no GLP Unpublished	Y		SOPURA
B6.1.1/02	1998	Acurate oral toxicity study with Septacid BN-PS in rats TNO, Zeist, Netherlands Report: V98.717 Unpublished	Y		SOPURA
B6.1.2/02	1998	Acute dermal toxicity study with Septacid BN-PS in rats TNO, Zeist, the Netherlands Report nr: V98.719 Unpublished	Y		SOPURA

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT SEPTACID BN PS – SUBMITTED ADDITIONAL LITERATURE

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Heinz PETERSEN	1987	Brauereianlagen, Verlag Hans Carl	No	Published

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT SEPTACID BN PS – 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 ORGANISATION AND PUBLICATIONS

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

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

Abbreviation	Explanation
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