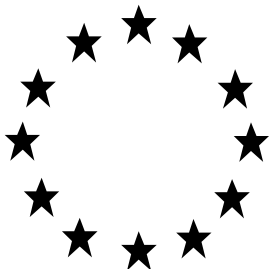
Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report

Modification of the conditions of approval



Nonanoic acid

Product-type 2
(Disinfectants and algaecides not intended for direct application to humans or animals)

September 2013

Austria

Nonanoic acid (PT 2)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 27 September 2013

CONTENTS

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 Nonanoic acid as product-type 10 (Masonry preservatives), 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 10 containing Nonanoic acid that will fulfil the requirements laid down in Article 5(1) b), c) and d) of that Directive..

Nonanoic acid has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 10, masonry preservatives, as defined in Annex V to that Directive, in particular as an algaecide used for the curative treatment of construction materials. That specific use is now covered by product-type 02 as defined in Annex V to Regulation (EU) No 528/2012.

Nonanoic acid has already been included into Annex I of Directive 98/8/EC for use in product-type 2 by Directive N° 2012/41/EU of 26 November 2012 , and is therefore considered as approved for that product-type by virtue of Article 86 of Regulation (EU) No 528/2012. The assessment will therefore conclude whether there is a need or not to review the conditions of approval of this active substance for product-type 2.

1.2. Purpose of the assessment

The aim of the assessment report is to support the decision on the approval of Nonanoic acid for product-type 2, and conclude whether there is a need or not to review the conditions of approval of this active substance for product-type 2. Should it still be approved, the aim of the assessment report is also to facilitate the authorisation of individual biocidal products in product-type 2 that contain Nonanoic 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.

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

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 Nonanoic acid as product-type 10 (Masonry preservatives), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market.

Nonanoic acid (CAS no. 112-05-0) was notified as an existing active substance, by W. Neudorff GmbH KG (Emmerthal, Germany), hereafter referred to as the applicant, in product-type PT 10.

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 Nonanoic acid as an active substance in Product Type 10 was 31 October 2008, in accordance with Article 9 (c) of Regulation (EC) No 1451/2007.

On 31 October 2008, AT competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 30 January 2009.

On 3 April 2012, 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 16 April 2012. The competent authority report included a recommendation for the inclusion of Nonanoic acid in Annex I to the Directive for product-type PT10.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 16 April 2012. 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.

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

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 27 September 2013.

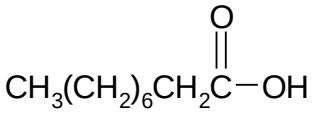
2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

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

The active substance Nonanoic acid (synonym: Pelargonic acid) is attributed the CAS-No 112-05-0 and the EC-No 203-931-2. The molecular formula is $C_9H_{18}O_2$, and the molecular weight is 158.2 g/mol. The acceptable range of purity is from 89.6 up to 100%w/w.

Structural formula:



The structure of Nonanoic 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. 90.0% Nonanoic acid) according to the demands of the data requirements. Nonanoic acid is an oily, slightly yellow to colourless liquid, has a strongly rancid smell. Its melting point is in the range of 11.7°C - 12.5°C and the boiling point is 258.39°C. The density is 0.906 kg/L at 19.8°C. The vapour pressure of the active substance is 0.9 Pa at 20°C, 1.4 Pa at 25°C and 10.6 Pa at 50°C, and the calculated Henry's law constant is 0.33 Pa x m^3/mol at 20°C. The water solubility of the Nonanoic acid (98.5%w/w) is 0.164 g/L (10°C; pH 3); 0.169 g/L (20°C; pH 3); 0.184 g/L (30°C; pH 3); 0.203 g/L (20°C; pH 4); 0.415 g/L (20°C; pH 5). The dissociation constant (pKa) is determined at pKa = 4.9. Nonanoic acid and n-Octanol are miscible in any proportion. The solubility of Nonanoic acid in n-Heptane, p-Xylene, 1,2-Dichloroethane, Methanol, Acetone and Ethylacetate is higher than 250 g/L at 20°C. The active substance does not contain any organic solvent. The partition coefficient octanol-water is 3.52 at pH 7 and 25°C. The substance is regarded to be surface active (surface tension is 34.6 mN/m at 20.1°C). The viscosity is 8.7 mPa x s at 20°C and 5.2 mPa x s at 40°C.

The active substance Nonanoic acid displays neither explosive nor oxidizing properties based on its structure. Its flash point is in the range of 132.9 to 133.9°C and its self ignition temperature is 220°C. The substance is stable up to 350°C. It is not considered to be reactive to container material (metal barrels coated with lacquer on the inside).

The identification and quantification of Nonanoic acid in the active substance 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 Nonanoic acid in the environment and its rapid metabolism and degradation in soil an analytical method for the determination of residues of Nonanoic acid in soil is not required according to the Draft Proposal for Revision of TNsG on Data Requirements, Chapter 2, Point 4 "Analytical Methods for Detection and Identification".

Methods for analysis of residues were validated for Nonanoic acid in air and water:

- The determination of residues in air can be performed by air-sampling of the fatty acid ingredients (i.e. Nonanoic acid) followed by acidification and esterification and determination by gas chromatography. It has to be kept in mind that Nonanoic acid is a naturally occurring compound and it would be impossible to distinguish between what occurs naturally and what occurs as a result of biocide usage.

- Nonanoic acid has been found to occur naturally in low concentrations in water. Although the degradation of Nonanoic acid applied to water happens rapidly a LC/MS method has been developed to analyze residues in water with a limit of quantification of 10 µg/L.

As Nonanoic 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 Nonanoic acid in/on food or feedstuffs is not required because the active substance is not used in a manner that may cause contact with food or feedstuffs.

2.1.2. Intended Uses and Efficacy

Nonanoic acid is used for remedial treatment of masonry, such as walls, facades, paths, terraces, fences or gravestones, to control an excessive development of green algae (Chlorophyta sp.). The efficacy has been tested with the representative product NEU 1170H. To obtain a formulated product it is required to achieve a good water solubility of Nonanoic acid during the formulation process. As Nonanoic acid itself has a low water solubility it has to be saponified with Ammonium hydroxide to form the water soluble salt, which is contained in the formulation NEU 1170 H. Therefore in the biocidal product NEU 1170H Nonanoic acid is contained as as Ammonium nonanoate as reaction product of Nonanoic acid with Ammonium hydroxide.

The mechanism of action of Nonanoic acid is the destruction of algae cell membranes. This results in an unspecific and uncontrolled release of cell contents and photosynthesis can no longer take place. Due to its lipophilic characteristics the active substance quickly penetrates into the algal cells and disrupts cell membrane permeability. The result is the destruction of the photosynthesis mechanisms and other membrane bound physiological processes. Finally, an uncontrolled leakage of cell contents occurs.

After application of the biocidal product on masonry the treated area is not rinsed. As the active substance is a fatty acid it will not tend to stick to the treated surface. Hence an application has to be done only if no rain is expected within a period of some hours.

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

In addition, in order to facilitate the work in granting or reviewing authorisations, details of 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 Nonanoic acid

Current classification according to Reg. (EU) No 1272/2008, Annex VI, Table 3.2

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

Classification	C; R34
Class of danger	Corrosive
R phrases	R34
S phrases	S1/2 S26 S28 S36/37/39 S45

Proposed classification and labelling

Environmental effects:

The available data for classification and labeling of Nonanoic acid for environmental effects according to Reg. (EU) No 1272/2008, Annex VI, Table 3.2 are not completely conclusive. The lowest LC_{50} value (fish) is >7.2 mg/L, which would lead to a classification with N; R51/53 in combination with log P_{ow} =3.52, although the substance is readily biodegradable.

7.2 mg/L Nonanoic acid was the highest concentration tested. No effects were observed at that concentration. In contrast to this value the long term NOEC (fish) for Nonanoic acid (C9 fatty acid) was found to be 19.2 mg/L. There is also a LC_{50} (fish) available from Octanoic acid (C8 fatty acid) with 68 mg/L (Draft Competent Authority Report, Document I, Octanoic acid, Product Type 4 and 18, 2011).

Therefore as a weight of evidence decision it is proposed to stay with no classification for environmental effects according to Reg. (EU) No 1272/2008, Annex VI, Table 3.2.

Table 2.1.3-2: Proposed classification and labelling according to Reg. (EU) No 1272/2008, Annex VI, Table 3.2 (proposed by RMS)

Hazard symbol	
Indication of danger	Xi Irritating
R phrases	R38 Irritating to skin R41 Risk of severe damage to eyes
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
Classification	Xi; R38-R41
Labelling	Xi; R: 38-41 S: 26-36/37/39

Table 2.1.3-3: Proposed classification and labelling according to Reg. (EU) No. 1272/2008, Annex VI, Table 3.1 and Reg. (EU) No 286/2011 (proposed by RMS)

Classification		Justification
Classification	Eye Damage, category 1 Skin Irritation, category 2 Aquatic Chronic 3	Weight of evidence evaluation supporting skin irritation and risk for serious eye damage, see Doc II-A 3.3 Specification of Prevention Phrases according to Regulation (EC) No 1272/2008 Rapidly degradable substance for which adequate chronic toxicity data are available. Lowest value is the NOE_rC from algae with 0.568 mg/L.
Hazard Statements	H318: Causes serious eye damage H315: Causes skin irritation H412: Harmful to aquatic life with long lasting effects	

Labelling		
GHS Pictograms		
Signal words		Danger
Hazard statements		H318: Causes serious eye damage 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. P310: Immediately call a POISON CENTER or doctor/physician 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 regulations (to be specified).

2.1.4. Classification and labelling of the biocidal product NEU 1170 H

Current classification

The product is a new biocidal product and not yet on the market, therefore there is no current classification. The product shall be classified as proposed below.

Proposed classification

Table 2.1.4-1 Classification and labelling of the biocidal product NEU 1170H according to Directive 1999/45/EC (proposed by the RMS)

Classification and Labelling	Xi
Hazard symbol	
Indication of danger	Irritating
R phrases	R36 Irritating to eyes
S phrases	S1/2 Keep locked up and out of the reach of children S25 Avoid contact with eyes S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S39 Wear eye/face protection S46 If swallowed, seek medical advice immediately and show this container or label
Classification	Xi: R36
Labelling	Xi R: 36 S: (1/2)-25-26-39-46

Table 2.1.4-2: Proposed classification and labelling of the biocidal product NEU 1170H according to Reg. (EC) No. 1272/2008, Annex VI, Table 3.1 and Reg. (EU) No 286/2011

Classification		Justification
Classification	Eye irritation, category 2	Result of eye irritation test with NEU 1170H.
Hazard statements	H319: Causes serious eye irritation	

Labelling		
GHS Pictograms		
Signal words		Warning
Hazard statements		H319: Causes serious eye irritation
Precautionary Statements	General	-
	Prevention	P262: Do not get in eyes, on skin, or on clothing. P264 Wash thoroughly after handling P280 Wear eye 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 P301 + P315 + P101 + P310: IF SWALLOWED: Get immediate medical advice/attention. If medical advice is needed, have product container or label at hand. Immediately call a POISON CENTER or doctor/physician.
	Storage	P405 + P102: Store locked up / Keep out of reach of children
	Disposal	-

2.2. Summary of the Risk Assessment

2.2.1. Risk arising from physico-chemical properties

No physico-chemical hazards could be identified for the active substance or for the biocidal product. Therefore there is no risk arising from physico-chemical properties.

2.2.2. Human Health Risk Assessment

2.2.2.1. Hazard identification

The only toxicological concern evident is the severely irritating property of Nonanoic acid. The available rabbit skin irritation test and a published ex vivo TER test with human skin (York et al. 1996) as well as the overall evidence in literature support the classification for skin irritation.

According to OECD guideline 405 the severe skin irritation excludes further eye irritation testing with animals and should result in classification as severely eye damaging. Furthermore a publication was identified (Smyth et al. 1962) attributing score 9 from 10 for corneal necrosis to Octanoic and Decanoic acid, which also rises concern for severe eye damage by Nonanoic acid.

It is proposed to change the classification of Nonanoic acid according to Regulation (EU) No. 1272/2008, Annex VI, from corrosive to skin irritant (R38, H315) and risk for serious damage to the eye (R41, H318).

2.2.2.2. Effects assessment

The nature of Nonanoic acid is a single chain saturated fatty acid and it is 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. Complete and rapid oral absorption can be expected and in the absence of any absorption tests and considering the physical-chemical properties dermal and inhalation absorption is assumed to be 100% for the purpose of exposure and risk assessment.

Neither the acute oral, dermal and inhalation studies, nor the subacute rat gavage or the developmental rat gavage studies give rise to concern for systemic toxicity, in spite of the high dose levels tested: 2000 mg/kg bw/d within the acute oral and dermal studies and 1000 mg/kg bw/d within the subacute gavage study and 1500 mg/kg bw/d within the rat developmental toxicity study.

A macroscopic irregular surface and a microscopic hyperplasia of the squamous epithelium of the forestomach were induced at the highest tested dose of 1000 mg/kg bw/d when applied daily for 28 days by gavage as a 0.2% solution in propylene glycol. This effect was not apparent after the 10 days of gavage application of a 0.3% solution within the rat developmental study and also not after the 14 days rat study with food containing 2% Nonanoic acid at doses of 1500 mg/kg bw/d and 1834 mg/kg bw/d, respectively. The latter 2 studies lack histological analysis. However the forestomach effect is assumed to be associated with the local irritant property of Nonanoic acid, thus not relevant for systemic hazard assessment.

The guinea pig maximisation test (GPMT) for Nonanoic acid and the overall literature evidence for skin-sensitisation is negative. Also the bacterial mutation test and the in vitro chromosomal aberration test with human lymphocytes are negative.

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

The developmental rat gavage study did not result in any toxicologically relevant maternal or foetal effects up to a dose of 1500 mg/kg bw/d.

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 assessment no further studies were required for genotoxicity, (sub)chronic or reproductive toxicity

In summary for Nonanoic acid no adverse systemic effects were observed at the highest doses tested (1000 mg/kg bw day for 28 days, 1500 mg/kg bw day for 10 days). 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 would support NOAELs above 1000 mg/kg bw day. In addition the ubiquitous nature of fatty acids leading to intake of fatty acids as natural component of food (~1800 mg/kg bw/d, e.g. Bell et al 1972) and knowledge of the common metabolic pathways have to be taken into consideration. Therefore the derivation of a systemic AEL and a risk assessment for systemic effects is considered unnecessary.

In the available 28 day rat gavage study local-oral effects were observed as forestomach irritation with a NOAEL of 150 mg/kg bw/d at a concentration of 3% in propylene glycol. It is assumed that the 28 day NOAEL and NOAEC for forestomach irritation in the rat is – if at all relevant- at least a conservative point of departure for estimating local oral effects in humans. Therefore a local-oral AEC may be derived from the local NOAEC without the application of kinetic and dynamic interspecies factors and without kinetic intraspecies factors. Application of just the intraspecies dynamic factor of 3.2. would result in a local-oral medium and long term of AEC of 3% / 3.2 ~ 1%. Besides variability and uncertainty with regard to human intraspecies differences (expectedly compensated by the assessment factor) the AEC contains uncertainty with regard to differences of the irritation effect between the active substance as acid solved in propylene glycol and the product NEU 1170H, a 20% aqueous solution of the ammonium salt of the acid with a pH of 7.

The available data are insufficient for the derivation of local dermal and local inhalation medium or long term AECs. Therefore a qualitative risk assessment for local effects of the product is preferred.

2.2.2.3. Exposure assessment

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 Nonanoic acid

Exposure path	Exposure of workers during production of b.p.	Primary (direct) exposure, during use of b.p.		Secondary (indirect) exposure Incidental contact after application	Via the environment[1]
	Professional	Professional use	General public	General Public	General Public
Inhalation	Yes	Yes	Yes	Not relevant[2]	Not relevant
Dermal	Not relevant	Yes	Yes	Yes[2]	Not relevant
Oral	Not relevant	Yes	Yes	Yes[2]	Not relevant

[1] From TNsG on Human Exposure, 2007: "Exposure via the environment is an element of secondary exposure. It includes bystanders and consumers, including children, who are inadvertently exposed to biocides by inhalation of plumes drifting off-site and ingesting contaminated food.

[2] Accidental dermal contact of infants with treated surfaces and mouthing of hands that came into contact with these surfaces were estimated to be potential sources of relevant exposure. On the contrary, dermal contamination is considered to be the only relevant route regarding secondary exposure of adults.

The active substance Nonanoic acid is used as algaecide for masonry such as walls, facades, paths or terraces by spraying (PT 10). No specific emission scenario is available for the assessment of Nonanoic acid and the biocidal product NEU 1170 H.

The biocidal product is intended to be applied by spraying by professionals and non-professionals. (For details on the intended use, please see Appendix II of this document.) Thereby inhalation and dermal exposures may occur, whereas oral exposure is considered to be not relevant.

Subsequent to the use of the biocidal product, wet/dried surfaces of treated areas give some potential for dermal exposure via skin contact regarding adults, children and infants. Whereas dermal exposure is expected to be the only relevant pathway for adults and children, oral exposure of infants is considered to be also relevant regarding mouthing and hand-to-mouth contact of infants.

The exposure values relevant for risk characterisation are presented in chapter 2.2.2.4 of this document.

2.2.2.4. Risk characterisation

Nonanoic acid is the active substance used in the representative product NEU 1170 H for the treatment of algae on masonry. The product is applied outdoors two to three times per year. For application the product is diluted with water resulting in a final spraying dilution of around 3% or 3.3 g Nonanoic acid/100 mL. The biocidal product has a higher pH (pH of 7) than the free acid due to the addition (in molar excess) of ammonium hydroxide forming the ammonium salt (or "soap") of Nonanoic acid.

No adverse systemic effects are apparent from the toxicological data up to high doses (> 1000 mg/kg bw day), but irritant properties of Nonanoic acid and NEU 1170 H are evident. Consequently

the risk characterization focuses just on local effects. In the absence of data allowing reliable quantitative estimates for local irritation thresholds of the biocidal product a respective qualitative assessment is provided:

NEU 1170 H is classified for serious eye irritation, but not for skin irritation according to the results in animal studies with the undiluted biocidal product. Nonanoic acid is not classified as skin sensitising. Risk management for acute exposure to general public (two to three applications per year for non-professionals) has to be covered by classification, labelling and packaging of the respective biocidal product.

Professionals may be exposed for long term and consequently the risk for local effects is increased. However the daily tasks leading to exposure are considered to be relatively short, data are available supporting full reversibility of skin irritation effects from repeated exposure to the structurally related Sodium-dodecyl-sulfate (Branco et al. 2005). Furthermore professional's are expected to behave compliant with label instructions and recommended precautions concerning handling and use including washing of hands immediately after work. Respiratory exposure is expected to be low due to handling of small volumes outdoors for short times. In addition no adverse effects of NEU 1171 H were observed in rats with 4 hours exposure up to about 5 g/m3.

Nevertheless labelling and packaging as well as instructions for use that reduce the risk of dermal, eye and respiratory exposure during the mixing and loading task as well as during the spray application task and child prove closures will be required for product authorisation.

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

In summary it is concluded that -with the intended use described- the risk for adverse local oral, dermal or respiratory effects is acceptable.

2.2.3. Environmental Risk Assessment

2.2.3.1. Fate and distribution in the environment

Nonanoic acid is readily biodegradable. Dissipation of fatty acids (C14-C20) in soil is very rapid with DT_{50} values of 3.8–5.7 days at 12°C (2-3 days at 20°C). The principal way of degradation of fatty acids under aerobic conditions is the microbial shortening by C2 pieces (β-oxidation of fatty acids). Dissipation of Nonanoic acid from soil is even faster with a DT_{50} value of approximately 2.1 days at 12°C (1.1 days at 20°C). Nonanoic acid has been found to be present in untreated soil at naturally occurring background levels (range found in the degradation study: 0.35–0.65 mg/kg soil).

Hydrolysis can be excluded by its structure, as free carbon acids cannot be hydrolysed in the absence of further functional groups.

Photolytic degradation in water is excluded for Nonanoic acid, as it does not display chromophore properties at wavelengths above 290 nm.

An estimation of photochemical degradation of Nonanoic acid in air according to TGD resulted in a half-life of 39.4h ($k_{deg, air} = 0.42d^{-1}$; $c(OH)^{air} = 5x10^5$ molecules/cm^3).

K_{oc} values are in the range of 63.1 L/kg (ionised form) to 100.0 L/kg (non-ionised form). Thus it is expected that Nonanoic acid does not strongly adsorb to soil.

Accumulation:

The log P_{ow} of Nonanoic acid is 3.52.

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

- Nonanoic acid is rapidly biodegradable
- Nonanoic 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).
- Nonanoic 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 Toxicokinetics, Metabolism and Distribution).

The calculated BCF_{fish} for Nonanoic acid is 195.88 L/kg and the BCF in earthworms is 40.57 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 Nonanoic acid.

Surface water used for drinking water:

The concentrations for Nonanoic acid in surface water exceed the parametric value of 0.1 µg/L, according to Directive 98/83/EC in all calculated scenarios (see Table 2.1.2-1 and 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 rapid degradation of Nonanoic acid in water, dilution in surface water and the "background concentration" of the active substance. 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 LC_{50}-value of Nonanoic acid in fish (golden ide) is >7.2 mg/L, the highest concentration tested, and no effect could be seen at this concentration. In a long term test in fish test according to OECD 204, no toxic effects could be observed up to the highest concentration tested, too. So the NOEC of Nonanoic acid is 19.2 mg a.s./L and indicates marginal toxicity to fish.

Nonanoic acid is slightly toxic to invertebrates, as indicated by the acute EC_{50} in *Daphnia magna* of 23.63 mg/L, the NOEC of chronic toxicity was determined to be 9.93 mg a.s./L.

Growth inhibition in green algae *(Scenedesmus subspicatus)* shows an E_rC_{50} of nominal 103.4 mg a.s./L. Algae are very sensitive to Nonanoic acid, as the NOE_rC of the growth rate is 0.568 mg a.s./L (mean measured).

Inhibitory effects against aquatic micro-organisms were only found at relatively high nominal concentrations (EC_{20}: 360.5 mg/L, EC_{50}: 565.2 mg/L).

The toxicity of the metabolites of Nonanoic acid can be regarded as not relevant, because fatty acids are regarded primarily as nutrients which yield a high amount of energy, contribute to various essential cell functions and do not have negative effects. Degradation occurs under aerobic conditions with beta-oxidation being the principal pathway of metabolism. As a result of the in details complicated degradation steps of fatty acids, the final products are CO_2 and water.

Air compartment:

With a half-life in air of 39.4h an accumulation of Nonanoic acid in air is not to be expected.

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

Based on an acute inhalation study with rats, no adverse biotic effects of Nonanoic acid in atmosphere are expected.

Terrestrial compartment:

Effect data are available for bees and terrestrial arthropods (*Poecilus cupreus L.*), earthworms (*Eisenia foetida*) and plants (*Brassica oleracea, Allium cepa, Lycopersicon esculentum, Avena sativa, Lactuca sativa and Phaseolus vulgaris*). No effect data on terrestrial micro-organisms were asked for. Due to the low effects of Nonanoic acid on aquatic micro-organisms and due to its very short half-life in soil degradation studies it was not expected that micro-organisms would be the most sensitive of the terrestrial species.

The acute oral toxicity test shows a LR_{50} of >98.35 µg/bee (mortality did not exceed 4.0%). In the contact toxicity test the mortality did not exceed 14.0% at the concentrations tested which results in a LR_{50} of >90.28 µg Nonanoic acid/bee.

In an acute toxicity test Nonanoic acid did not exert any harmful effects against *Poecilus cupreus L.* up to 32.0 kg/ha (corresponds to 80.58 mg/kg soil dry weight, after conversion to standard soil conditions). The EC_{50} is therefore >80.58 mg/kg soil dry weight.

At the highest concentration tested (202.2 mg/kg soil dry weight) Nonanoic acid did not have adverse effects against earthworms in an acute toxicity test. After conversion to standard European soil conditions this corresponds to an EC_{50} value of >68.75 mg/kg soil dry weight.

In an acute toxicity test on plants (vegetative vigour test; spray application) the EC_{50} values of the four most sensitive species were in a quite narrow range (10.25 to 11.40 kg/ha). The most sensitive species was *Brassica oleracea* with an EC_{50} value of 11.22 mg Nonanoic acid/kg soil dry weight (after conversion to standard European soil conditions). This low EC_{50} value for plants is caused by a non-selective herbicidal activity of Nonanoic acid, which damages any green plant tissue it contacts by destroying the cell wall integrity. Nonanoic acid does not exhibit systemic herbicidal activity.

Toxicity to birds:

Based on the absence of mortality, the oral acute LD_{50} value of NEUDOSAN NEU (plant protection product) in Bobwhite quail was estimated to exceed 5000 mg/kg body weight (equivalent to 2450 mg potassium salts of fatty acids/kg body weight). As NEUDOSAN NEU contains as active ingredient 49% potassium salts of fatty acids (mainly C18 fatty acids as it is produced from rapeseed oil) and based on the knowledge of fatty acid metabolism, it can be assumed that the

results of NEUDOSAN NEU can be extrapolated for the evaluation of the acute oral toxicity of Nonanoic acid in birds.

The EC_{50} of a dietary toxicity test with Nonanoic acid in Japanese quail and Mallard duck is expected to be higher than 993 mg/kg diet, because no mortality was observed nor any response to the exposure to the test article.

Nonanoic acid was not toxic to birds at a limit dose level of 2450 mg potassium salts of fatty acids/kg body weight and at a limit dose level of 993 mg/kg diet.

2.2.3.3. PBT assessment

Persistence:

Nonanoic acid is readily biodegradable (76-77% mineralization after 28 days). The only available DT_{50} value of 2.1 days at 12°C (ca. 1.1 days at 20°C) was determined in an aerobic degradation study in soil.

P-criterion: $T_{1/2}$ >120 days in soil – DT_{50} =2.1 days (12°C) => not P

Bioaccumulation:

BCF_{fish} = 195.9 L/kg (calculated)

B-criterion: BCF >2000 - BCF_{fish} = 195.9 L/kg => not B

Toxicity:

The chronic NOEC values for freshwater species are 19.2 mg/L for fish (nominal), 9.93 mg/L for invertebrates (nominal) and 0.568 mg/L for algae.

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).

T-criterion: NOEC <0.01mg/L – lowest chronic NOEC =0.568 mg/L => not T

Conclusion

Nonanoic acid is neither a vPvB, nor a PBT substance.

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

2.2.3.4. Exposure assessment

The biocidal product NEU 1170 H, containing 20% (w/w) of the active substance Nonanoic acid is used as algaecide (Product type 10) for masonry such as walls, facades, fences (other than wood), paved paths or terraces and gravestones by the general public. According to the Intended Use (For details on the Intended Use, please see Appendix II of this document) NEU 1170 H is sprayed over the surface of the masonry to be treated. Formulation and use of NEU 1170 H may lead to emission of Nonanoic acid to the environment.

According to the applicant the active substance Nonanoic acid is not produced in the European Union, and the formulation takes place in closed systems. In addition, the modeling of exposure and risk assessment/risk characterization during production of Nonanoic acid and the formulation of the biocidal product should be addressed under other EU legislation and not repeated under Directive 98/8/EC (agreed at the Biocides Technical Meeting TMI 06).

The estimation of environmental exposure during use and service life of the NEU 1170 H is made by calculating the emissions and then the concentrations for each environmental compartment on basis of the Intended Use and information in Doc. II-B confidential. The assessment has been performed in accordance with the ESD for PT 10 (Mignè 2002), the Guidance on leaching rate estimation for PT 07, 09 and 10 (endorsed at the 36th CA Meeting3) as well as the Technical Guidance Document (TGD II, European Commission 2003)[4], the Revised Emission Scenario Document for Wood Preservatives (OECD, 20115) and the EUSES Background report (EC 2004)[6]. The Revised Emission Scenario Document for Wood Preservatives (OECD, 2011) was consulted for calculating a scenario, which is not covered by the ESD for PT 10 (direct release into a static water body). The exposure assessment has been performed for the substance Nonanoic acid and was conducted for the local scale only. The House in the City–Scenario was calculated for 1 treated house as agreed at the Technical Meeting IV12 and additional for 13 treated houses based on market share data. Due to confidentiality of market share data, the calculations are archived in Doc_II_B_PT10_Confidential. The refine groundwater assessment was performed using FOCUS Pearl 4.4.4.

Subsequent to the use of the biocidal product secondary exposure to the food chain 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).

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3 http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/doc/TNsG/Guidance_leaching_rate_PT_07_09_10.pdf

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 OECD (2011) Revised Emisssion Scenario Document for Wood Preservatives. OECD Series on Emission Scenario Documents – Number 2

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

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

2.2.3.5. Risk characterisation

Air compartment:

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

Conclusion

In summary, no risk could be identified for the air compartment.

Aquatic compartment (including sediment):

STP:

Based on the ESD for PT 10 releases to STP are only considered relevant for the House in the City Scenario.

Losses during application due to spray drift and dripping (or runoff), as well as losses during service life due to leaching subsequent to rainfall are likely to fall upon paved ground and are washed to the sewer system during rain episodes. The rainwater may then be discharged to a STP. Additionally, as agreed in TMIV12, a worst case scenario assuming 100% wash off immediately after application of the substance due to i.e. heavy rain was calculated.

PECs were calculated for 1 and for 13 treated houses per day and subsequent release into one single STP.

The PEC/PNEC ratios for the House in the City Scenario are calculated by dividing the $PECs_{STP}$ for application and service life by the $PNEC_{micro\text{-}organisms}$ (see Table 2.2.3.5-1)

Table 2.2.3.5-1: PEC/PNEC ratios for House in the City Scenario via STP

Exposure scenario	**PEC_{STP} (mg/L)**	**$PEC/PNEC_{STP}$**
	$PNEC_{micro\text{-}organisms}$ = 5.652 mg/L	
1 treated house/day		
Application	7.74×10^{-3}	1.37×10^{-3}
Service life, TIME1	1.23×10^{-3}	2.17×10^{-4}
Worst case: 100% wash off after application	2.58×10^{-2}	4.56×10^{-3}
13 treated houses/day		
Application	0.101	1.79×10^{-2}
Service life, TIME1	1.60×10^{-2}	2.83×10^{-3}
Worst case: 100% wash off after application	0.336	5.94×10^{-2}

Conclusion

All PEC/PNEC ratios for emissions into one single STP for 1 and 13 treated houses per day are <1 for application and service life. A back calculation (performed for the worst case of 100% wash off after application) shows that emissions to STP from 218 houses of the same dimension will still lead to an acceptable risk if discharged to one single STP.

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

Surface water incl. sediment:

Risk to aquatic organisms - House in the City Scenario

According to the House in the City Scenario, contamination of surface water is expected. As a worst case scenario according to ESD PT 10 it is assumed that a fraction of the substance reaches the effluent of the STP and enters into the surface water. It is also possible that the substance reaches surface water directly, bypassing STP. Additionally a worst case scenario assuming 100% wash off immediately after application of the substance due to i.e. heavy rain was calculated.

PECs were calculated for 1 and for 13 treated houses per day and subsequent release into one single water body.

The PEC/PNEC ratios for the aquatic ecosystem are then derived by dividing the local PEC in surface water by the PNEC for aquatic organisms (see Table 2.2.3.5-2).

Table 2.2.3.5-2: PEC/PNEC ratios for the House in the City Scenario for the aquatic compartment

Exposure scenario	**PEC in mg/L**	**PEC/PNEC**
	Water/local ($PNEC_{water}$ = 0.0568 mg/L)	
Via STP		
1 treated house/day		
Appl.: Local PEC in surface water during emission episode (dissolved)	7.74×10^{-4}	1.36×10^{-2}
SL: Local PEC in surface water during emission episode (dissolved, TIME 1)	1.23×10^{-4}	2.17×10^{-3}
Worst case: 100% wash off after application; local PEC in surface water during emission episode (dissolved)	2.58×10^{-3}	4.54×10^{-2}
13 treated houses/day		
Appl.: Local PEC in surface water during emission episode (dissolved)	1.01×10^{-2}	0.18
SL: Local PEC in surface water during emission episode (dissolved, TIME 1)	1.60×10^{-3}	2.82×10^{-2}
Worst case: 100% wash off after application; local PEC in surface water during emission episode (dissolved)	3.36×10^{-2}	0.59
Bypassing STP		
1 treated house/day		
Appl.: Local PEC in surface water during emission episode (dissolved)	6.16×10^{-3}	0.11
SL: Local PEC in surface water during emission episode (dissolved, TIME 1)	9.79×10^{-4}	1.72×10^{-2}
Worst case: 100% wash off after application; local PEC in surface water	2.06×10^{-2}	0.36
13 treated houses/day		
Appl.: Local PEC in surface water during emission episode (dissolved)	8.01×10^{-2}	1.41
SL: Local PEC in surface water during emission episode (dissolved, TIME 1)	1.27×10^{-2}	0.22

Worst case: 100% wash off after application; local PEC in surface water	0.267	4.70

PEC/PNEC ratios are all below 1, with the exception of the scenarios for 13 treated houses, application, bypassing STP and for 13 treated houses, worst case.

In the applied calculations the risk is dramatically overestimated. 13 houses is the number which, according to marked share date from DK, is treated per day in the whole country. In the calculations it is assumed that the emissions from these 13 houses (during application or 100% wash off by heavy rain fall after application) then collectively enter one single surface water body. The more realistic scenario that emissions from only one treated house are diluted into one water body leads to PEC/PNEC values <1.

In addition after 6 hours Nonanoic acid will be bound to algae. The mode of action is a physical effect on plant cell walls which affects cell wall integrity. Due to its lipophilic characteristics the active substance quickly penetrates into the plant tissue and disrupts normal cell membrane permeability. Because of this quick penetration, it is expected that after 6 hours only a fractional amount is disposable.

It is not possible to take degradation processes into accout for a refinement of the PEC values of the concerned scenarios, therefore risk mitigation measures (RMM) are considered in a **second Tier** in order to reduce the calculated risk to acceptable values.

Application, 13 treated houses, Tier 2:

In accordance with the calculations performed for the soil compartment (2.3.1 Terrestrial compartment, House in the Countryside, direct release to soil) it is assumed that the soil adjacent to the construction material is protected by an impermeable cover during application. This simple RMM reduces the emissions during application to negligible values. Therefore no further calculations are deemed necessary for the application scenario for 13 treated houses and the emission is set to zero.

Worst case, 13 houses, Tier 2:

In order to avoid the worst case scenario and any thinkable risk two risk mitigation measures are proposed: "The soil adjacent to the construction material shall be protected by an impermeable cover during the application of the product." and "Products can only be used if the weather forecasts show no rain for the day of application or at least for the next 6 hours of application.". Again no further calculations are deemed necessary.

Risk to aquatic organisms - Bridge over Pond Scenario

Furthermore, emissions to surface water are also expected according to the Bridge over Pond Scenario.

The PEC_{sw} was calculated without removal through degradation processes.

Table 2.2.3.5-3: PEC/PNEC ratios for the the Bridge over Pond Scenario for the aquatic compartment (ignoring degradation processes)

Exposure scenario	**PEC in mg/L**	**PEC/PNEC**
	Water/local ($PNEC_{water}$ = 0.0568 mg/L)	
Appl. (drift and runoff): Local PEC in surface water during emission episode	9.86×10^{-3}	0.17
SL: Local PEC in surface water during emission episode (TIME 1)	3.29×10^{-2}	0.58

Conclusion:

Tier 1 PEC/PNEC ratios for the surface water compartment are all <1, with the exception of the scenarios for 13 treated houses, application, bypassing STP and for 13 treated houses, worst case. In these scenarios the risk is reduced to acceptable levels, if RMM are applied.

For the reasons discussed above the calculated risk for all scenarios, particularely for those in which emissions from 13 treated houses were calculated, is still considered overestimated.

However in order to avoid any thinkable risk two risk mitigation measures are proposed:

- The soil adjacent to the construction material shall be protected by an impermeable cover during the application of the product.
- Products can only be used if the weather forecasts show no rain for the day of application or at least for the next 6 hours of application.

Based on the PEC/PNEC calculations in combination with the proposed risk mitigation measures the risk for aquatic organisms through direct and indirect exposure to Nonanoic acid is considered to be acceptable.

Risk and persistence in sediment:

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.

Nonanoic acid was found to be readily biodegradable. Therefore no further degradation testing for the aquatic compartment has been performed.

Furthermore it is known that fatty acids are nutrients for micro-organisms and are mineralised to CO_2 and water through β-oxidation. The consequences or effects on non-target organisms have been assessed in the risk assessment above and are acceptable.

Conclusion

The Intended Use of Nonanoic acid in PT 10 will not pose a risk to benthic organisms. Nonanoic acid is not persistent in sediment and doesn't fulfil the Annex I exclusion criteria.

Terrestrial compartment:

According to the Indented Use (see Doc. II-B - Chapter 3) indirect release to the soil compartment via sludge application is considered relevant for the House in the City Scenario from application and service life. Direct release to the soil compartment is considered relevant for the House in the Countryside Scenario during application as well as service life. Therefore $PECs_{soil}$ were calculated for direct and indirect exposure scenarios (see Doc. II-B – chapter 5.2.5 PEC in soil).

The $PNEC_{soil}$ was determined with 0.112 mg/kg_{dwt} (see Doc. II-A – chapter 4.2.3 Terrestrial compartment).

House in the City Scenario - indirect release to soil via sludge application:

PECs were calculated for 1 and for 13 treated houses per day and release into one STP. Additionally a worst case scenario assuming 100% wash off immediately after application of the substance due to i.e. heavy rain was calculated for 1 and 13 treated houses.

As a **first Tier**, the $PECs_{soil}$ were calculated without considering removal through degradation processes according to TGD II (EC 2003).

Table 2.2.3.5-4: PEC/PENEC ratios for agricultural soil exposed via sewage sludge (Tier 1: ignoring degradation processes)

Exposure scenario	PEC_{soil} (mg/kg_{dwt})	PEC/PNEC
	$PNEC_{soil}$: 0.112 mg/kg $soil_{dwt}$	
1 treated house/day		
Application, arable soil (30 days)	1.54×10^{-3}	1.38×10^{-2}
Service life (TIME 1), arable soil (30 days)	2.44×10^{-4}	2.18×10^{-3}
Worst case, 100% wash off after application, arable soil (30 days)	5.12×10^{-3}	4.67×10^{-2}
13 treated houses/day		
Application, arable soil (30 days)	2.00×10^{-2}	0.18
Service life (TIME 1), arable soil (30 days)	3.16×10^{-3}	2.82×10^{-2}
Worst case, 100% wash off after application, arable soil (30 days)	6.65×10^{-2}	0.59

All Tier 1 PEC/PNEC ratios for indirect exposure of soil are <1, showing an acceptable risk, even though degradation processes were not taken into account.

A back calculation (performed for the worst case of 100% wash off after application) shows that indirect emissions to soil from 21 houses of the same dimension would still lead to an acceptable risk.

However in a **second Tier** the rapid degradation (DT_{50} soil for Nonanoic acid 2.1 days at 12°C) was taken into account for the calculation of the $PECs_{soil}$, as a consequence the concentration of Nonanoic acid decreases considerably (TGD 2003).

Table 2.2.3.5-5: PEC/PENEC ratios for agricultural soil exposed via sewage sludge (Tier 2: considering degradation processes: DT_{50} in soil =2.1 d)

Exposure scenario	PEC_{soil} (mg/kg_{dwt})	PEC/PNEC
	$PNEC_{soil}$: 0.112 mg/kg $soil_{dwt}$	
1 treated house/day		
Application, arable soil (30 days)	1.51×10^{-4}	1.35×10^{-3}
Service life (TIME 1), arable soil (30 days)	2.41×10^{-5}	2.15×10^{-4}
Worst case, 100% wash off after application, arable soil (30 days)	5.06×10^{-4}	4.52×10^{-3}
13 treated houses/day		
Application, arable soil (30 days)	1.97×10^{-3}	1.76×10^{-2}
Service life TIME 1), arable soil (30 days)	3.13×10^{-4}	2.79×10^{-3}
Worst case, 100% wash off after application, arable soil (30 days)	6.58×10^{-3}	5.88×10^{-2}

All Tier 1 and Tier 2 PEC/PNEC ratios for indirect release to the rerrestrial compartment are far below 1.

A back calculation (performed for the worst case of 100% wash off after application) shows that indirect emissions to soil from 221 houses of the same dimension will still lead to an acceptable risk, if degradation is taken into account.

Conclusion

Indirect release of Nonanoic acid to soil poses an acceptable risk to soil organisms.

House in the Countryside Scenario - direct release to soil:

During spray application, two phenomena occur: drift and runoff (ESD PT 10). In the countryside, releases from spray drift and runoff directly reach the soil compartment. Runoff reaches soil adjacent to the treated house, whereas spray drift reaches soil further away from the treated house. Therefore for the application stage PECs were calculated for soil adjacent and for soil distant to the treated house. For service life only release due to runoff was considered relevant. Additionally a worst case scenario assuming 100% wash off immediately after application of the substance due to i.e. heavy rain was calculated.

A **first Tier** was calculated according to ESD PT 10, in which degradation of the substance is not considered (see also Doc. II-B – chapter 5.2.5 PEC in soil, Tier 1).

Table 2.2.3.5-6: PEC/PENEC ratios for direct release to soil (Tier 1: ignoring degradation process)

Exposure scenario	**PEC_{soil} (mg/kg_{dwt})**	**PEC/PNEC**
	$PNEC_{soil}$: 0.112 mg/kg $soil_{dwt}$	
Application		
Soil adjacent to house (wash off), 0.5 m soil depth	4.20	37.5
Soil distant to house (spray drift), 0.5 m soil depth	0.19	1.7
Service life		
Soil adjacent to house (wash off), 0.5 m soil depth, (TIME1)	21.01	187.6

The PEC/PNEC ratios for terrestrial organisms are all >1 indicating a possible risk for the terrestrial ecosystem.

Therefore a **second Tier** was calculated taking degradation processes into account (see Doc. II-B – chapter 5.2.5 PEC in soil, Tier 2).

Table 2.2.3.5-7: PEC/PENEC ratios for direct release to soil (Tier 2: taking into account degradationa process, TIME1)

Exposure scenario	**PEC_{soil} (mg/kg_{dwt})**	**PEC/PNEC**
	$PNEC_{soil}$: 0.112 mg/kg $soil_{dwt}$	
Application and Service life		
Soil adjacent to house (wash off and leaching), 0.5 m soil depth	0.61	5.44
Soil distant to house (spray drift), 0.5 m soil depth	2.76×10^{-2}	0.25

As expected in Tier 2 calculations (taking into account degradation processes), the PEC/PNEC ratios are decreasing considerably. Therfore the PEC/PNEC ratio for direct release to soil distant to a house (spray drift) is <1 indicating an acceptable risk.

However, in soil adjacent to a house, the PEC/PNEC ratio for terrestrial organisms is still >1, even if degradation processes are taken into account, indicating a possible risk for the terrestrial ecosystem.

Therefore in a **third Tier** one risk mitigation measure for soil adjacent to house was taken into account. Calculations consider that the soil adjacent to the construction material shall be protected by an impermeable cover during the application of the product. It is assumed that this leads to negligible emissions during applications. Therefore the application scenario is not considered further in the calculations. Only the leaching rate during service life (100% of applied substance) is considered in the table below (see also Doc. II-B – chapter 5.2.5 PEC in soil, Tier 3).

Table 2.2.3.5-8: PEC/PENEC ratios for direct release to soil (Tier 3: taking into account RMM at application, and degradation process, TIME1)

Exposure scenario	**PECsoil (mg/kg$_{dwt}$)**	**PEC/PNEC**
	PNEC$_{soil}$: 0.112 mg/kg soil$_{dwt}$	
Service life		
Soil adjacent to house (leaching rate 100%), 0.5 m soil depth	2.97×10^{-3}	2.65×10^{-2}

The Tier 3 calculation results in PEC/PNEC ratios <1, although the risk is still overestimated, since it is based on 100% of the applied substance instead of only 70%. This result shows that with a simple RMM the safety of soil organisms can be assured.

Another reason for the overestimation of the risk is that plants are affected by Nonanoic acid only through contact with the green plant tissues. In this report the PNEC is based on the most sensitive species (plants) and expressed in mg/kg soil, however, the effects caused are not correlated to the concentration mixed into soil but in fact expressed in the concentration sprayed on plants. This is in line with the fact that Nonanoic acid is also used as herbicide (4th priority list within the review program according to Directive 91/414/EEC) or as a harvest aid (Anonymous, 1998, Pesticide Fact Sheet). However, based on the knowledge of its mode of action against plants (see also Doc. II-A - chapter 4.2.3) it is clear that Nonanoic acid doesn't exhibit systemic herbicidal activity, but that it damages any green plant tissue via direct contact to the sprayed product (mode of application if used as herbicide). This means that in fact only plants which get in contact with Nonanoic acid via spray drift will be harmed. But spray drift poses an acceptable risk to soil organisms (see table 2.3.1-4 above).

Green parts of plants, which are growing in the soil adjacent to a house (if there are any) will only in very rare cases get in contact with the active substance via run off. It is therefore questioned whether runoff from a treated house can affect plants at all. It is much more likely that the runoff with the active substance will directly seep into the soil, than get in contact with the green parts of a plant. Once in the soil Nonanoic acid won't be of any harm or risk to plants. This is proven by the fact that roots and tubers remain unaffected by Nonanoic acid when used as herbicide or as a harvest aid.

A worst case scenario was additionally calculated assuming that 100% of the applied amount will be washed off in one day immediately after application due to e.g. a heavy rain event and ignoring any possible RMM.

Table 2.2.3.5-9: PEC/PENEC ratios for direct release to soil (1 application, washout of 100% and taking into account degradation processes).

Exposure scenario	PEC_{soil} (mg/kg_{dwt})	PEC/PNEC
	$PNEC_{soil}$: 0.112 mg/kg $soil_{dwt}$	
Country-Application		
Soil adjacent to house (100 % wash off), 0.5 m soil depth, day 0	21.02	187.68
Soil adjacent to house (100 % wash off), 0.5 m soil depth, day 7	2.086	18.6
Soil adjacent to house (100 % wash off), 0.5 m soil depth, day 14	0.207	1.8
Soil adjacent to house (100 % wash off), 0.5 m soil depth, day 16	0.107	0.95
Soil adjacent to house (100 % wash off), 0.5 m soil depth, day 21	0.021	0.19

If the total application rate is washed into soil immediately after application (because of e.g. heavy rain and without applying any RMM), the PEC/PNEC ratio is >1 until day 15. But due to rapid degradation in soil, the PEC/PNEC ratio decreases to one-tenth every 7 days. Therefore the PEC/PNEC ratio is acceptable for plants starting on day 16 after application. For all other soil organisms, for which data were provided no risk was identified already on day 0.

Furthermore after 6 hours Nonanoic acid will be bound to algae. The mode of action is a physical effect on plant cell walls which affects cell wall integrity. Due to its lipophilic characteristics the active substance quickly penetrates into the plant tissue and disrupts normal cell membrane permeability. Because of this quick penetration, it is expected that after 6 hours only a fractional amount is disposable. The worst case scenario will therefore be overruled by the calculations shown in Table 2.3.1-5, which are considered more relevant and the corresponding discussion.

Therefore calculating the risk by assuming a 100% wash off by heavy rainfall immediately after application is a dramatic overestimation of the risk for several reasons and only possibly if 2 important RMM are ignored: “Products can only be used if the weather forecasts show no rain for the day of application, or at least for the next 6 hours of application.” and “The soil adjacent to the construction material shall be protected by an impermeable cover during the application of the product.”.

Conclusion:

Tier 1 and 2 PEC/PNEC ratios for the terrestrial compartment are all <1, with the exception of the scenario “House in the countryside, application and service life, soil adjacent to house”.

In the discussed worst case scenario with 100% wash off directly after application the PEC/PNEC ratios are >1, but due to rapid degradation in soil they are <1 starting on day 16 after the rain event.

In both scenarios the PEC/PNEC ratios are reduced to acceptable values, if RMM are applied.

For the reasons discussed above the calculated risk for all scenarios is still considered overestimated.

Since plants are sensitive to the product and will singe/burn when getting in contact with the product the following risk mitigation measures are recommended, in order to avoid any possible harm:

- The soil adjacent to the construction material shall be protected by an impermeable cover during the application of the product.
- Products can only be used if the weather forecasts show no rain for the day of application, or at least for the next 6 hours of application.

Based on the PEC/PNEC calculations in combination with the proposed risk mitigation measures the risk for soil organisms through direct exposure to Nonanoic acid is considered to be acceptable.

Persistence in soil

Nonanoic acid was found to be readily biodegradable (see Doc. II-A – chapter 4.1.1.1 Biodegradation).

In the two submitted laboratory soil degradation studies (see Doc. II-A – chapter 4.1.1.3 Degradation in soil), DT_{50} values of approximately 2 and 3 days at 20°C (3.8 and 5.7 days at 12°C) were found in two different soils for a mixture of fatty acids (C14 – C20). For Nonanoic acid a DT_{50} value of approximately 1.1 days at 20°C (2.1 days at 12°C) was found.

No field soil degradation studies are available for Nonanoic acid.

There are no data available about the formation of not extractable residues, which is not expected due to the low K_{oc} values (see Doc. II-A – chapter 4.1.1.4 Distribution).

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 3.1 Metabolism and excretion).

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

Conclusion

Nonanoic acid is not persistent in soil and doesn't fulfil the Annex I exclusion criteria..

Groundwater:

For the House in the City Scenario with indirect release to soil via sludge application, the concentration in the pore water of agricultural soil after 10 continuous years of sludge application is taken as an indication for potential groundwater concentrations.

The $PEC_{groundwater}$ value for 1 treated house per day is 0.018 µg a.s./L for the application scenario and 0.0029 µg a.s./L for service life. For the worst case scenario (100% wash off immediately after application) for 1 treated house per day the $PEC_{groundwater}$ value is 0.06 µg a.s./L.

For 13 treated houses per day the $PEC_{groundwater}$ value is 0.24 µg a.s./L for application and 0.038 µg a.s./L for service life. For the worst case scenario the $PEC_{groundwater}$ value is 0.79 µg a.s./L (see Doc. II-B – chapter 5.2.6 PEC in groundwater).

Groundwater values for 13 treated houses per day for application and for the worst case scenario with 100% wash off after application exceed the parametric value of 0.1 µg/L, according to Directive 98/83/EC.

Therefore, potential groundwater concentrations were additionally calculated using FOCUS Pearl groundwater model. The calculated values for 13 treated houses for the application scenario as well as for the worst case scenario are well below the threshold value of 0.1 µg/L (closest to the 80th percentile of <0.000001 µg/L).

Conclusion

Nonanoic acid is not likely to have unacceptable effects on groundwater and the requirements of Directives 80/68/EC, 98/83/EC and 2006/118/EC are complied with.

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

Secondary poisoning:

As the calculated octanol-water partition coefficient for Nonanoic acid indicates a potential for bioaccumulation (log K_{ow} =3.52), the TGD on risk assessment Part II demands an initial standard assessment for secondary poisoning. For assessment of secondary poisoning, the risk to fish- and worm eating predators is calculated in Table 2.2.3.5-10 for 1 treated house per day and in Table 2.2.3.5-11 for 13 treated per day as the ratio between the concentration in their food (fish or earthworms) and the predicted no-effect concentration for long term oral intake ($PNEC_{oral\ chron}$).

Long term PNECoral chron: 0.331 mg a.s./kg diet

Table 2.2.3.5-10: PEC/PNEC ratios for non compartment specific effects for 1 treated house/day (secondary poisoning)

Exposure scenario		PEC	PEC/PNEC
		$PNEC_{oral\ chron}$ 0.331 a.s. mg/kg diet	
1 treated house/day			
Aquatic food chain			
City scenario application	direct release:	1.65×10^{-3} mg a.s./$kg_{wet\ fish}$	4.98×10^{-3}
	via STP:	2.08×10^{-4} mg a.s./$kg_{wet\ fish}$	6.28×10^{-4}
City scenario service life	direct release:	1.66×10^{-2} mg a.s./$kg_{wet\ fish}$	5.0×10^{-2}
	via STP:	2.08×10^{-3} mg a.s./$kg_{wet\ fish}$	6.28×10^{-3}
Bridge over pond application	direct release:	8.71×10^{-5} mg a.s./$kg_{wet\ fish}$	2.63×10^{-4}
Bridge over pond service life	direct release:	7.83×10^{-4} mg a.s./$kg_{wet\ fish}$	2.37×10^{-3}
Worst case 100% wash off after application	direct release:	5.52×10^{-3} mg a.s./$kg_{wet\ fish}$	1.67×10^{-2}
	via STP:	6.93×10^{-4} mg a.s./$kg_{wet\ fish}$	2.09×10^{-3}
Terrestrial food chain			
City scenario application	sludge application:	3.32×10^{-4} mg a.s./$kg_{wet\ earthworm}$	1.0×10^{-3}
City scenario service life	sludge application:	5.28×10^{-5} mg a.s./$kg_{wet\ earthworm}$	1.59×10^{-4}
Worst case 100% wash off after application	sludge application:	1.11×10^{-3} mg a.s./$kg_{wet\ earthworm}$	3.35×10^{-3}

Table 2.2.3.5-11: PEC/PNEC ratios for non compartment specific effects for 13 treated houses/day (secondary poisoning)

Exposure scenario		PEC	PEC/PNEC
		$PNEC_{oral\ chron}$ 0.331 a.s. mg/kg diet	
13 treated houses/day			
Aquatic food chain			
City scenario application	direct release:	2.15×10^{-2} mg a.s./$kg_{wet\ fish}$	6.50×10^{-2}
	via STP:	2.70×10^{-3} mg a.s./$kg_{wet\ fish}$	8.16×10^{-3}
City scenario service life	direct release:	0.215 mg a.s./$kg_{wet\ fish}$	0.65
	via STP:	2.70×10^{-2} mg a.s./$kg_{wet\ fish}$	8.16×10^{-2}
Worst case 100% wash off after application	direct release:	7.17×10^{-2} mg a.s./$kg_{wet\ fish}$	0.22
	via STP:	9.01×10^{-3} mg a.s./$kg_{wet\ fish}$	2.72×10^{-2}
Terrestrial food chain			
City scenario application	sludge application	4.32×10^{-3} mg a.s./$kg_{wet\ earthworm}$	1.31×10^{-2}
City scenario service life	sludge application	5.28×10^{-5} mg a.s./$kg_{wet\ earthworm}$	1.60×10^{-4}
Worst case 100% wash off after application	sludge application	1.44×10^{-2} mg a.s./$kg_{wet\ earthworm}$	4.35×10^{-2}

Back calculations were performed for the worst case scenario of 100% wash off after application, for the aquatic food chain (direct release to surface water) and the terrestrial food chain (indirect exposure via sludge application).

For the aquatic food chain (worst case) it was shown that 60 houses of the same dimension would still lead to an acceptable risk. For the terrestrial food chain it was shown that 298 houses would still lead to an acceptable risk for the worst case scenario.

Back calculations were additionally performed for the city scenario, service life, direct release to surface water, since this scenario gives the highest values on the basis of three applications per year. It was shown that 20 houses of the same dimension would still lead to an acceptable risk for this scenario.

Conclusion

All PEC/PNEC ratios for secondary poisoning calculated for the aquatic and the terrestrial food chain are <1, indicating an acceptable risk.

List of endpoints

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

3. PROPOSED DECISION

3.1. Background to the proposed decision

The specific mode of action of Nonanoic acid is the destruction of algae cell membranes . As the active substance is also used as herbicide it is known that the active substance quickly penetrates into the plant tissue and disrupts normal cell membrane permeability. This causes a destruction of photosynthesis mechanisms and other membrane bound physiological processes. Hence the mode of action against algae is assumed to rely on similar mechanisms. During efficacy testing it was proofed that the biocidal product is capable to reduce algal development on masonry structures.

The active substance has no hazardous physico-chemical properties.

The probability that the substance has CMR or endocrine properties that are relevant to humans is low. The substance has local irritant properties, i.e. eye damage (cat 1) and skin irritation (cat 2). However the calculation method is not applicable, test results with the product lead to classification just for eye irritation (cat 2) and not for skin irritation, though the active substance content is above the classification limits.

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

In the environmental risk assessment no risk was identified for the air compartment, for the aquatic compartment including sediment, for the terrestrial compartment (indirect release to soil) as well as for groundwater and for secondary poisoning.

If Nonanoic acid is directly released to soil, risk mitigation measures have to be applied in order to reduce the risk to an acceptable level.

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

3.2. Proposed decision

The overall conclusion from the evaluation of nonanoic acid for use in Product Type 10 (masonry preservative) , in particular as an algaecide used for the curative treatment of construction materials, is that it may be possible to issue authorisations of products containing nonanoic acid in accordance with the conditions laid down in Article 5(1) b), c) and d) of Dir. 98/8/EC.

The particular use as an algaecide used for the curative treatment of construction materials is now covered by product-type 02 as defined in Annex V to Regulation (EU) No 528/2012.

Nonanoic acid has already been included into Annex I of Directive 98/8/EC for use in product-type 2 by Directive N° 2012/41/EU of 26 November 2012, and is therefore considered as already approved for that product-type by virtue of Article 86 of Regulation (EU) No 528/2012. Nonetheless, some risks has been identified for the use as an algaecide used for the curative treatment of construction materials, that would need to be reflected in the conditions of approval of that active substance for product-type 2.

It is therefore proposed to modify the approval nonanoic acid as an active substance for use in product-type 2 (Disinfectants and algaecides not intended for direct application to humans or animals), and that the approval is 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 subject to the following conditions:

a) Unless it can be demonstrated in the application for product authorisation that risks for human health can be reduced to acceptable levels by other means, authorisation shall be subject to the following conditions: Instructions for use informing on how to minimize aerosol exposure.

b) Authorisations of products for non-professional use are subject to the packaging being designed to minimise user exposure.

2) Authorisation of products used as algaecide for outdoor remedial treatment of construction materials shall be subject to safe operating procedures and risk mitigation measures in order to protect the environment.

3.3. Elements to be taken into account when authorising products

1. At product authorization stage the applicant shall provide appropriate measures reducing the risk for severe eye irritation by application of the biocidal product, e.g. appropriate instructions of use informing on how to minimize aearsol exposure, including that products shall not be applied under windy conditions, bottle form (to reduce the risk of splashing) or reformulation of the product (to reduce the eye irritant property).

   Justification: The representative product NEU 1170H is classified as eye irritant. Consequently the CLP regulation 1272/2008/EC foresees labelling with "P280 – Wear eye protection". However Annex VI, article 73 of the Biocidal Products Directive 98/8/EC is worded as follows: "If for non-professional users the wearing of personal protective equipment would be the only possible means of reducing exposure [to acceptable levels, comment by RMS], the product shall not normally be authorized"

2. In case the biocidal product is the same as the representative biocidal product, in addition to the information presented in the active substance CAR, further data might be requested, i.a. on commercial packaging.

3. The reference product contains also ammonia at a molar concentration that is at least equal or greater than of the active substance. Ammonia or eventually the ammonium cation NH_4^+ should be taken into consideration for the risk assessment of the product at product authorisation stage.

4. At product authorisation stage studies showing the specific algicidal efficacy should be provided, especially specifying sufficiently the target organisms, such as Chlorophyta sp.

5. 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).

6. Products used as algaecide for outdoor remedial treatment of construction materials, safe operational procedures and risk mitigation measures shall be established in order to protect the environment, for instance :

    a. Products can only be used if the weather forecasts show no rain for the day of application, or at least for the next 6 hours of application.

    b. The soil adjacent to the construction material is protected by an impermeable cover during the application of the product.

    c. Areas covered by plants which may have been exposed unintentionally are watered extensively in order to avoid any damage to plants.

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 maintain of the approval of Nonanoic acid for product type 2 under Regulation (EU) No 528/2012.

3.5. Updating this Assessment Report

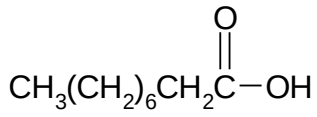
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information submitted in relation with Regulation (EU) No 528/2012. Such adaptations will be examined and finalised in connection with any amendment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

APPENDIX I: LIST OF ENDPOINTS

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

Active substance	Nonanoic acid
Product-type	The representative product assessed is an algaecide used for the curative treatment of construction materials. This corresponds to product-type 10 under Directive 98/8/EC, 2 under the Regulation (EU) No 528/2012

Identity

Chemical name (IUPAC)	Nonanoic acid
Chemical name (CA)	Nonanoic acid
CAS No	112-05-0
EC No	203-931-2
Other substance No.	No other registration number (e.g. CIPAC) is available
Minimum purity of the active substance as manufactured (g/kg or g/l)	896 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_9H_{18}O_2$
Molecular mass	158.2
Structural formula	

Physical and chemical properties

Melting point (state purity)	11.7°C - 12.5°C (Nonanoic acid (99.5%))
Boiling point (state purity)	258.4°C (Nonanoic acid (99.5%))
Temperature of decomposition	No exothermal decomposition up to 350°C (~100%)
Appearance (state purity)	Oily liquid, slightly yellow to colourless, strongly rancid odour
Relative density (state purity)	Density: ρ=0.90588 kg/L (19.8°C) (Nonanoic acid (99.5%)); relative density: $\rho^{19\,8}{}_{4\,0}$= 0.90588 [-]
Surface tension	34.6 mN/m (20.1°C) (90% saturated aqueous solution of Nonanoic acid)
Vapour pressure (in Pa, state temperature)	0.9 Pa (20°C) Nonanoic acid (~100%) 1.4 Pa (25°C) Nonanoic acid (~100%) 10.6 Pa (50°C) Nonanoic acid (~100%)
Henry's law constant (Pa m^3 mol^{-1})	0.33 Pa x m^3/mol (20°C)
Solubility in water (g/l or mg/l, state temperature)	0.164 g/L (10°C, pH 3)

	0.169 g/L (20°C, pH 3) 0.184 g/L (30°C, pH 3) 0.203 g/L (20°C, pH 4) 0.415 g/L (20°C; pH 5)
Solubility in organic solvents (in g/l or mg/l, state temperature)	The solubility of Nonanoic acid in n-Heptane, p-Xylene, 1,2-Dichloroethane, Methanol, Acetone and Ethylacetate was determined to be >250 g/L(T = 20 ± 1°C). Octanol and Nonanoic acid are miscible in any proportion.
Stability in organic solvents used in biocidal products including relevant breakdown products	The active substance does not contain any organic solvent
Partition coefficient (log P_{OW}) (state temperature)	pH 7: estimated log Pow: 3.52 (T=25°C)
Dissociation constant	pK_a = 4.9 at 20°C (Nonanoic acid (92.0%))
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	There is no absorption max. above 290 nm.
Flammability	Self-ignition temperature: 220°C Flash point: 132.9°C – 133.9°C
Explosive properties	Based on its structure Nonanoic acid is not considered explosive

Classification and proposed labelling

with regard to physical/chemical data	---
with regard to toxicological data	Reg. (EU) 1272/2008, Annex VI, Table 3.2 R38: Irritating to skin R41: Risk of serious damage to eye Reg. (EU) 1272/2008, Annex VI, Table 3.1 H315: Causes skin irritation H318: Causes serious eye damage
with regard to fate and behaviour and ecotoxicological data	Reg. (EU) 1272/2008, Annex VI, Table 3.2 n.c. (weight of evidence decision) LC_{50} value (fish) is >7.2 mg/L and log P_{ow} =3.52; at 7.2 mg/L (highest conc. tested no effects; long term NOEC (fish) = 19.2 mg/L; LC_{50} (fish) from Octanoic acid (C8 fatty acid) with 68 mg/L. 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. P501: Dispose of contents/container in accordance with local/regional/national/international regulations (to be specified).

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	GC/FID method
Impurities in technical active substance (principle of method)	GC/FID method

Analytical methods for residues

Soil (principle of method and LOQ)	Not required accord. to the TNsG on Data Requirements, Chapter 2, Point 4 "Analytical Methods for Detection and Identification"
Air (principle of method and LOQ)	GC/FID method providing a limit of quantification of 0.55 mg/L for Nonanoic acid
Water (principle of method and LOQ)	LC/MS method with a limit of quantification of 10 µg/L for Nonanoic acid
Body fluids and tissues (principle of method and LOQ)	Not required accord. chapter 2 of Technical Guidance Document in support of Directive 98/8/EC
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required accord. chapter 2 of Technical Guidance Document in support of Directive 98/8/EC
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required accord. chapter 2 of Technical Guidance Document in support of Directive 98/8/EC

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Readily absorbed to 100%
Rate and extent of dermal absorption:	100%, assumption based on physical-chemical properties
Distribution:	In all tissues except brain (free fatty acid)
Potential for accumulation:	No
Rate and extent of excretion:	Complete excretion as CO_2 and water or storage in fat
Toxicologically significant metabolite(s):	No toxicologically significant metabolites are formed

Acute toxicity

Rat LD_{50} oral	>2000 mg/kg bw
Rat LD_{50} dermal	>2000 mg/kg bw
Rat LC_{50} inhalation	>5mg a.s./L (overall database)
Skin irritation	Severely irritant
Eye irritation	Risk for serious damage to eye (based on literature, no study available)
Skin sensitization (test method used and result)	Non sensitising (GPMT, Magnusson and Kligman test)

Repeated dose toxicity

Species/ target / critical effect	Rat / forestomach / hyperplasia of the epithelium
Lowest relevant oral NOAEL / LOAEL	Rat gavage, subacute local NOEL = 150 mg/kg bw/day subacute local NOEC = 3% in propylene glycol subacute systemic NOAEL = 1000 mg/kg bw/day
Lowest relevant dermal NOAEL / LOAEL	Not available
Lowest relevant inhalation NOAEL / LOAEL	Not available

Genotoxicity	Ames Test (S. typh., E. coli): negative Cytogenicity in vitro (human lymphocytes): negative

Carcinogenicity

	No study available; waiving accepted based primarily on

	consideration of the nature of Nonanoic acid (linear saturated fatty acid), the high purity and the knowledge about kinetics and metabolism of fatty acids and the negative genotoxicity tests.

Reproductive toxicity

Species/ Reproduction target / critical effect	No study available; waiving accepted based primarily on consideration of the nature of nonanoic acid (linear saturated fatty acid), the high purity, the knowledge about kinetics and metabolism of fatty acids and the negative developmental toxicity test with rats.
Species/Developmental target / critical effect	Rat / no maternal or developmental toxicity observed
Developmental toxicity	
Lowest relevant developmental NOAEL / LOAEL	NOAEL maternal and foetal >1500 mg/kg bw/day

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	There are no indications from the standard systemic toxicity studies that the active substance Nonanoic acid has neurotoxic properties. The subacute gavage study included also a functional analysis. No studies on neurotoxicity were considered necessary.

Other toxicological studies

.....	no

Medical data

.....	no

Summary

	Value	Study	Safety factor
Systemic short, medium and long term AEL (acceptable exposure level)	Not relevant (only qualitative RC for local effects provided)	-	-

Acceptable exposure scenarios (including method of calculation)

Production of active substance	Not assessed
Formulation of biocidal product (user: professional)	Formulation is performed in an almost closed system of an automated facility. Potential inhalation exposure is possible during mixing and loading tasks (performance under a ventilated hood). Dermal and oral exposure are considered to be not relevant.

Application of biocidal product (user: general public/ professional)	Dermal and inhalative exposure of operator during spraying treatment solution on masonry such as walls, facades, paths, terraces, fences or grave stones (treatment solution: 32.8 g a.s./L). Spraying device: low or medium pressure sprayer or hand held trigger sprayer.
Indirect exposure as a result of use	Dermal exposure (infant crawling over treated floor) Oral exposure (infant crawling over treated floor)
Exposure of pets	Not considered to be relevant
Dietary Exposure	Not considered to be relevant

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	----
Readily biodegradable (yes/no)	Yes; 76-77% after 28 days
Biodegradation in seawater	----
Non-extractable residues	----
Distribution in water / sediment systems (active substance)	----
Distribution in water / sediment systems (metabolites)	----

Route and rate of degradation in soil

Mineralization (aerobic)	----
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic) Neudosan (C14-C20 fatty acids): approx. 2 - 3 days in two different soils; n=2 DT_{50lab} (12°C, aerobic) Neudosan (C14-C20 fatty acids): approx. 3.8 – 5.7 days in two different soils; n=2 DT_{50lab} (20°C, aerobic) Nonanoic acid: approx. 1.1 days DT_{50lab} (12°C, aerobic) Nonanoic acid: approx. 2.1 days
	DT_{90lab} (20°C, aerobic): Neudosan (C14-C20 fatty acids): approx. 8-10 days DT_{90lab} (20°C, aerobic): Neudosan (C14-C20 fatty acids): approx. 15.2 -19 days DT_{90lab} (20°C, aerobic): Nonanoic acid: approx. 1.8 days DT_{90lab} (12°C, aerobic): Nonanoic acid: approx. 3.4 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)	K_{oc}: 63.1 L/kg (using methanol/pure water) K_{oc}: 100.0 L/kg (using methanol/buffer solution pH 4) Yes, slightly lower mobility at lower pH.

Fate and behaviour in air

Direct photolysis in air	----
Quantum yield of direct photolysis	----
Photo-oxidative degradation in air	with $c(OH)_{air}$ =5x10^5 molecules x cm^{-3}: DT_{50} = 39.4 hours $k_{deg, air}$ =0.42d^{-1}
Volatilization	Volatilization potential: $K_{air-water}$ =1.4x10^{-4}

Monitoring data, if available

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	No data available
Ground water (indicate location and type of study)	No data available
Air (indicate location and type of study)	No data available

Chapter 5: Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity
Fish			
Leuciscus idus	96h, semi-static	Mortality, LC_{50}	>7.2 mg/L
Oncorhynchus mykiss	28d, flow-through	Mortality and non-lethal effects, NOEC	19.2 mg/L
Invertebrates			
Daphnia magna	48h, semi-static	Immobilisation, EC_{50}	23.63 mg/L
Daphnia magna	21d, semi-static	Mortality and repro-duction, NOEC	9.93 mg/L
Algae			
Scenedesmus subspicatus	72h, static	Growth and biomass inhibition, NOE_rC, E_bC_{50}, E_rC_{50}	0.568 mg/L 15.19 mg/L, nominal 103.4 mg/L, nominal

Microorganisms			
Activated sludge	3h	Respiration inhibition: EC_{20}: EC_{50}:	 360.5 mg/L, nominal 565.2 mg/L, nominal

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms	NOEC artificial soil: ≥202.2 mg/kg soil d.w. LC_{50} artificial soil: >202.2 mg/kg soil d.w. LC_{50} standard soil: >68.75 mg/kg soil d.w.
Acute toxicity to plants	EC_{50} =6.83 mg/kg soil d.w. EC_{50} standard soil =11.22 mg/kg soil d.w.

Effects on soil micro-organisms

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

Effects on terrestrial vertebrates

Acute toxicity to mammals	Rat: LD_{50} >2000 mg/kg bw
Acute toxicity to birds	Bobwhite quail: LD_{50} >2450 mg potassium salts of fatty acids/kg bw
Dietary toxicity to birds	Japanese Quail and Mallard duck: LD_{50} >993 mg/kg diet
Reproductive toxicity to birds	----

Effects on honeybees

Acute oral toxicity	LR_{50} >98.35 µg/bee
Acute contact toxicity	LR_{50} >90.28 µg/bee

Effects on other beneficial arthropods

Acute oral toxicity	----
Acute contact toxicity	*Poecilus cupreus*: Laboratory test: NOEL ≥21.33 mg/kg soil d.w. EC_{50} >21.33 mg/kg soil d.w. EC_{50} standard soil =80.58 mg/kg soil d.w.
Acute toxicity to ……..	

Bioconcentration

Bioconcentration factor (BCF)	195.88 L/kg (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 to control an excessive development of algae on masonry such as walls, facades, paths, terraces fences or gravestones. The area to be protected against an excessive algal development is treated with 16.6 mL/m^2 (relative density 0.99 g/cm^3) diluted to 100 mL H_2O/m^2. The final concentration in the spray solution will amount to 32.9 g Nonanoic acid/L. This spray solution is then sprayed with a spraying device (low or medium pressure sprayer or hand held trigger sprayer) evenly over the surface of the masonry to be treated.

Intended use as accepted by the Competent Authority

The information given by the applicant was reviewed by the Competent Authority. The intended use as **accepted by the Competent Authority** is as follows:

Table 3.3-1: Acceptable Intended uses of the algaecide "NEU 1170 H"

PT		The representative product assessed is an algaecide used for the curative treatment of construction materials. This corresponds to product-type 10 under Directive 98/8/EC, but product-type 2 under the Regulation (EU) No 528/2012
Formulation	**Type**	EC (emulsifiable concentrate)
	Conc. of a.s.	20% (w/w)
Field of use envisaged		Algaecide for masonry such as walls, facades, paved paths or terraces and fences (other than wood), gravestones
User		by professionals and non professionals
Amount at which the a.s. may be used	**Method**	The spray solution is sprayed with a spraying device (low or medium pressure sprayer or hand held trigger sprayer) evenly over the surface to be treated.
	Applied amount of product	16.6 mL product/m^2 (corresponding to 3.29 g a.s./m^2) (166 mL product are diluted with water to 1 L treatment solution)
	Number treatments/year	2-3 times at least with a 3-4 weeks interval between applications
	g a.s./m^2	3.29 g a.s./m^2 corresponding to 32.9 g a.s. /L treatment solution
Limitations		Not for use on wooden structures, as this would be considered as use in product type 8.

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 Claimed (Yes/No)	Date of 1st submission	Owner
A2.10/03	2006c	PERCENTAGE DISTRIBUTION OF PELARGONIC ACID BETWEEN THE DIFFERENT ENVIRONMENTAL COMPARTMENTS ESTIMATED FROM THE MACKAY MODEL TB-Agrartechnik Service, A-2540 Bad Vöslau, Austria Report-No. 0601NEU-03 Unpublished	Y	Sept 2006 (PT 2+19)	W. Neudorff GmbH KG
A2.10/06	2008	EXPOSURE ASSESSMENT FOR HUMAN HEALTH FOR THE ACTIVE SUBSTANCE PELARGONIC ACID AND THE BIOCIDAL PRODUCT NEU 1170 H FOR PT10 TB-Agrartechnik Service, A-2540 Bad Vöslau, Austria Report-No. 0806NEU-01 Unpublished	Y	Oct 2008 (PT 10)	W. Neudorff GmbH KG
A2.10/05	2007b	ENVIRONMENTAL EXPOSURE ASSESSMENT FOR THE ACTIVE SUBSTANCE PELARGONIC ACID AND THE BIOCIDAL PRODUCT NEU 1170 H TB-Agrartechnik Service, A-2540 Bad Vöslau, Austria Report-No. 0706NEU-01 Unpublished	Y	Sept 2006 (PT 2+19)	W. Neudorff GmbH KG
A2.10/07	2008b	ENVIRONMENTAL EXPOSURE ASSESSMENT FOR THE ACTIVE SUBSTANCE PELARGONIC ACID AND THE BIOCIDAL PRODUCT NEU 1170 H FOR PT10 TB-Agrartechnik Service, A-2540 Bad Vöslau, Austria Report-No. 0806NEU-02	Y	Oct 2008 (PT 10)	W. Neudorff GmbH KG

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Unpublished			
A3.1.1/01	2000a	MELTING TEMPERATURE OF NONANOIC ACID ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report-No. 20001414/01-PCMP GLP, Unpublished	Y	Sept 2006 (PT 2+19)	W. Neudorff GmbH KG
A3.1.2/01	2000b	BOILING TEMPERATURE OF NONANOIC ACID ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report-No. 20001414/01-PCBP GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.1.3/01	2000c	REALATIVE DENSITY OF EMERY 1202/PELARGONSÄURE ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report-No. 20001276/01-PCRD GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.1.3/02	1999	Determination of the density (Liquid) of NEU 1170 H NOTOX B.V., `s-Hertogenbosch, The Netherlands NOTOX Project 282847 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.2.1/01	2003a	PELARGONIC ACID – HENRY'S LAW CONSTANT GAB Consulting GmbH, 21769 Lamstedt, Germany Report-No. 105155-A2-020302-01 Not GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.2/01	2001	EMERY 1202/PELARGONSÄURE 55 4800: VAPOUR PRESSURE Siemens Axiva GmbH&Co.KG, Frankfurt/Main, Germany Report-No. 20011198.01 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.3/01	1998	VERSUCHSBEZEICHNUNG NEU-01170-H-0-EC Not applicable Report-No. Not applicable Not GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.4/01	2003a	UV-VIS SPECTRUM: E-1202 Source: Not stated Report-No. not stated Not GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
A3.4/02	2000d	INFRARED ABSORPTION-SPECTRUM OF EMERY 1202/PELARGONSÄURE ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report-No. 20001276/01-PCIR GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.4/03	2003b	NMR SPECTRUM: PELARGONIC ACID Source: Not stated Report-No. not stated Not GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.4/04	2003c	MS SPECTRUM: PELARGONIC ACID Source: Not stated Report-No. not stated Not GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.4/05	2006	NMR SPECTRUM: EMERY 1202 - PELARGONIC ACID Cognis Oleochemicals GmbH, Düsseldorf, Germany Report-No. not stated Not GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.5/01	2006a	DETERMINATION OF THE WATER SOLUBILITY OF PELARGONIC ACID (EMERY 1202) IBACON GmbH, Rossdorf, Germany Report-No. 31571185 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.6/01	2006b	DETERMINATION OF THE DISSOCIATION CONSTANT OF PELARGONIC ACID (EMERY 1202) IBACON GmbH, Rossdorf, Germany Report-No. 31572194 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.6/02	2006a	DETERMINATION OF THE DISSOCIATION CONSTANT OF AMMONIUM SALT OF PELARGONIC ACID (EMERY 1202) IBACON GmbH, Rossdorf, Germany Report-No. 31581194 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.7/01	2000e	SOLUBILITY OF EMERY 1202/PLARGONSÄURE IN ORGANIC SOLVENTS ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report-No. 20001276/01-PSBO GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
A3.9/01	2000f	PARTITION COEFFICIENT OF NONANOIC ACID ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report-No. 20001414/01-PCPC GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.11/01	2000	EMERY 1202/PELARGONSÄURE: AUTOFLAMMABILITY (DETERMINATION OF THE TEMPERATURE OF SELF-IGNITION OF VOLATILE LIQUIDS AND OF GASES) Siemens Axiva GmbH&Co. KG, Frankfurt/Main, Germany Report-No. SI156-00 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.12/01	2000g	FLASH POINT OF EMERY 1202/PELARGONSÄURE ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report-No. 20001276/01-PCFB GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.13/01	2000h	SURFACE TENSION OF EMERY 1202/PELARGONSÄURE ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report-No. 20001276/01-PCST GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A3.14/01	2006	VISCOSITY OF PELARGONSÄURE GAB Biotechnologie GmbH & GAB Analytik GmbH, Niefern-Öschelbronn, Germany Report-No. 20061248/01-PCVC GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A4.1/01, A4.1/02	2003	QUANTITATIVE DETERMINATION OF WATER AND FATTY ACIDS (C_6, C_7, C_8, C_9, C_{10}, C_{11}, C_{12} FATTY ACIDS) IN 5 LOTS EMERY 1202 BioChem GmbH, Daimlerstr. 5b, D-76185 Karlsruhe Report-No. 035040108C GLP, Unpublished **Confidential Document**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A4.1/03	2005	DETERMINATION OF METHOD PRECISION FOR C6, C7, C8, C9, C10, C11, C12 FATTY ACID AND DETERMINATION OF RECOVERY FOR C6, C11, C12 FATTY ACID IN EMERY 1202	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		BioChem GmbH, Daimlerstr. 5b, D-76185 Karlsruhe Report-No. 05 50 40 107 GLP, Unpublished **Confidential Document**			
A4.1/04	2005	1st SUPPLEMENT TO THE QUANTITATIVE DETERMINATION OF WATER AND FATTY ACIDS (C_6, C_7, C_8, C_9, C_{10}, C_{11}, C_{12} FATTY ACIDS) IN 5 LOTS EMERY 1202 **Confidential Document**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A4.2c	2007	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF PELARGONIC ACID (EMERY 1202) IN WATER IBACON GmbH, Rossdorf, Germany Report-No. 31574101 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A6.1.1/01	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	Sept 2006 (PT 2 + 19)	NEU
A6.1.2/01	2001b	ASSESSMENT OF ACUTE DERMAL TOXICITY WITH PELARGONSÄURE IN THE RAT Notox B.V, 's-Hertogenbosch, The Netherlands Report-No. 321558 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	NEU
A6.1.3/01	1998	THE BIOPESTICIDE MANUAL British Crop Protection Council, 1st edition, p. 25 Report-No. not applicable Not GLP, Published	N	Not applicable as no data protection claimed	--
A6.1.3/02	--	TOXICOLOGICAL SIMILARITY OF STRAIGHT CHAIN SATURATED FATTY ACIDS OF GREATER THAN 8 CARBON CHAIN LENGTH BY VARIOUS ROUTES OF EXPOSURE Safer Inc, Eden Prairie MN 55334-3585, USA Report-No. not applicable Not GLP, Published	N	Not applicable as no data protection claimed	--
A6.1.3/03	2004	AMMONIUM NONANOATE; NOTICE OF FILING A PESTICIDE PETITION TO ESTABLISH A TOLERANCE FOR A CERTAIN PESTICIDE CHEMICAL	N	Not applicable as no data protection	--

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		IN OR ON FOOD. Federal Register: March 17, 2004, Volume 69, Number 52 http://www.epa.gov/EPA-PEST/2004/March/Day-17/p553.htm		claimed	
A6.1.3/04	2006	BIOPESTICIDES REGISTRATION ACTION DOCUMENT AMMONIUM NONANOATE (PC code 031802) http://www.epa.gov/pesticides/biopesticides/ingredients/ tech_docs/brad_031802.pdf	N	N	--

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
A6.1.3/05	1982	ALIPHATIC CARBOXYLIC ACIDS IN PATTY´S INDUSTRIAL HYGIENE AND TOXICOLOGY, Clayton GD and Clayton FE (eds), 3rd Ed. Vol 2C: Toxicology, New York: John Wiley & Sons, Inc., pp. 4901-4987. published	N	Not applicable as no data protection claimed	-
A6.1.3/06	2002	HUMAN AND ENVIRONMENTAL RISK ASSESSMENT ON INGREDIENTS OF EUROPEAN HOUSEHOLD CLEANING PRODUCTS: FATTY ACID SALTS, HUMAN HEALTH RISK ASSESSMENT: DRAFT FOR PUBLIC COMMENT, JUNE 2002. PUBLISHED.	N	Not applicable as no data protection claimed	-
A6.1.4s/01	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	Sept 2006 (PT 2 + 19)	NEU
A6.1.5/01	2001d	ASSESSMENT OF CONTACT HYPERSENSITIVITY TO PELARGONSÄURE IN THE ALBINO GUINEA PIG (MAXIMISATION-TEST) Notox B.V, 's-Hertogenbosch, The Netherlands Report-no. 321615 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	NEU
A6.2. non-sub	2000	THE NATURE OF DIETARY FATTY ACIDS AND THEIR NUTRIENT ROLE Source: Report-no. not applicable Not GLP; Published	N	Not applicable as no data protection claimed	--
A6.2/01 non-sub	2003	THE ABSORPTION, DISTRIBUTION, METABOLISM AND EXCRETION OF FATTY ACIDS INCLUDING PELARGONIC ACID IN MAMMALS - EXTRACT FROM LITERATURE GAB Consulting GmbH, Lamstedt, Germany Report-no. not stated Not GLP, Unpublished	N	Not applicable as no data protection claimed	NEU
A6.2/02 non-sub	1972	TEXTBOOK OF PHYSIOLOGY AND BIOCHEMISTRY Source: Textbook of Physiology and Biochemistry, Churchill Livingstone, Edingburgh and London Report-no. not applicable Not GLP; Published	N	Not applicable as no data protection claimed	--
A6.2/03 non-sub	1975	FATS OR LIPIDS Source: Introductory Nutrition, 3rd edition, pp. 37-51, C.V. Mosby Co., St. Louis, USA Report-no. not applicable	N	Not applicable as no data protection claimed	--

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Not GLP; Published			
A6.2/04 non-sub	1971	BIOLOGICAL CHEMISTRY Source: Biological Chemistry, Harper & Row, New York, USA, 2nd edition, pp. 583-604, 712-755 Report-no. not applicable Not GLP; Published	N	Not applicable as no data protection claimed	--
A6.2/05 non-sub	1975	HUMAN BIOCHEMISTRY Source: Human Biochemistry, C.V. Mosby Company, St. Louis, USA, 9th edition, pp. 253-292 Report-no. not applicable Not GLP; Published	N	Not applicable as no data protection claimed	--
A6.2/06 non-sub	2001	BIOCHEMISTRY FOR CLINICAL MEDICINE Source: Greenwich Medical Media LTD, London, UK, pp. 85 - 109 Report-no. not applicable Not GLP; Published	N	Not applicable as no data protection claimed	--
A6.2/07 non-sub	1983	BIOCHEMISTRY Source: Bichemistry, Addison-Wesley Publishing Company, pp. 471 - 503 Report-no. not applicable Not GLP; Published	N	Not applicable as no data protection claimed	--
A6.2/08 non-sub	1976	TEXTBOOK OF PHYSIOLOGY AND BIOCHEMISTRY Source: Textbook of Physiology and Biochemistry, Churchill Livingstone, Edingburgh and London; pp. 124 - 130 Report-no. not applicable Not GLP; Published	N	Not applicable as no data protection claimed	--
A6.2/09 non-sub	2002	RESEARCH Source: Arch. Biochem. Biophys. Vol 404, pp. 136 - 146 Report-no. not applicable Not GLP; Published	N	Not applicable as no data protection claimed	--
A6.3.1/01	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	Sept 2006 (PT 2 + 19)	NEU
A6.6.1/01	2001	EVALUATION OF THE MUTAGENIC ACTIVITY OF PELARGONSÄURE IN THE SALMONELLA TYPHIMURIUM REVERSE MUTATION ASSAY AND THE ESCHERICHIA COLI REVERSE MUTATION ASSAY (WITH INDEPENDENT REPEAT) Notox B.V, 's-Hertogenbosch, The Netherlands	Y	Sept 2006 (PT 2 + 19)	NEU

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Report-No. 321569 GLP, Unpublished			
A6.6.2/01	2001	EVALUATION OF THE ABILITY OF PELARGONSÄURE TO INDUCE CHROMOSOME ABERRATIONS IN CULTURED PERIPHERAL HUMAN LYMPHOCYTES (INCLUDING AMENDMENT NO.1) Notox B.V, 's-Hertogenbosch, The Netherlands Report No. 321571 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	NEU
A6.6.2/02	2002	EVALUATION OF THE INDUCTION OF CHROMOSOME ABERRATION BY PELARGONIC ACID GAB Consulting GmbH, Hinter den Höfen, 21769 Lamstedt, Deuschland GLP, unpublished	Y	Sept 2006 (PT 2 + 19)	NEU
A6.8.1.1/01	1994	TERATOLOGY SCREEN IN RATS Hazleton Washington Inc., Vienna, U.S.A. Report No. HWA 2689-101 Not GLP, Published	N	Not applicable as no data protection claimed	--
A7.1.1.2.1/01	2002	READY BIODEGRADABILITY OF PELARGONIC ACID IN A MANOMITRIC RESPIROMETRY TEST INCLUDING 1ST AMENDMENT FROM JULY 2006 IBACON GmbH, Rossdorf, Germany Report-no. 14737160, Report No.: 11841087 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.1.3/01	2006b	ESTIMATION OF THE ADSORPTION COEFFICIENT (K_{OC}) OF PELARGONIC ACID (EMERY 1202) USING HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) IBACON GmbH, Rossdorf, Germany Report-No. 31573195 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.2.1/01	1990	TESTING THE BIOLOGICAL DEGRADABILITY OF NEUDOSAN IN TWO SOILS Biochem GmbH, Daimlerstr. 5b, D-76185 Karlsruhe 21, Germany Report-no. not stated Not GLP, Unpublished	N	Not applicable as no data protection claimed	W. Neudorff GmbH KG
A7.2.1/02	1986	FATE OF CAPRIC AND PELARGONIC FATTY ACIDS IN SOIL Unpublished Report Report-no. not stated	N	Not applicable as no data protection claimed	W. Neudorff GmbH KG

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Not GLP, Unpublished			
A7.3.1/01	2003b	PELARGONIC ACID - ESTIMATION OF THE PHOTOCHEMICAL OXIDATIVE DEGRADATION GAB Consulting GmbH, Lamstedt, Germany Report-No. 105155-A2-0210-01 Not GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.4.1.1/01-non-sub	1999a	NEU 1170 H – ACUTE TOXICITY TESTING OF NEU 1170 H IN RAINBOW TROUT (ONCORHYNCHUS MYKISS) (TELEOSTEI, SALMONIDAE) ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report No. 99024/01-AAOm GLP, Unpublished **Submitted in: B7.7.1.1.1/01**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.4.1.1/02-non-sub	1999b	NEU 1170 H – ACUTE TOXICITY TESTING OF NEU 1170 H IN GOLDEN ITE (LEUCISCUS IDUS) (TELEOSTEI, SALMONIDAE) ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report No. 99024/01-AALi GLP, Unpublished **Submitted in: B7.7.1.1.1/02**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.4.1.2/01-non-sub	1998	ACUTE IMMOBILISATION TEST DAPHNIA – DAPHINA MAGNA BioChem Agrar, Labor für biologische und chemische Analytik, D-04451 Cunnersdorf Report No. 981048039 GLP, Unpublished **Submitted in: B7.7.1.1.2/01**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.4.1.3/01-non-sub	1999	ALGAE GROWTH INHIBITION TEST SCENEDESMUS SUBSPICATUS BioChem Agrar, Labor für biologische und chemische Analytik D-04451 Cunnersdorf Report No. 981048040 GLP, Unpublished **Submitted in: B7.7.1.1.3/01**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.4.1.3/02-non-sub	1999a	TESTING OF TOXIC EFFECTS OF NEU 1170 H ON THE BLUE-GREEN ALGA ANABAENA FLOS-AQUAE ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report No. 99024/01-AAAf GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Submitted in: B7.7.1.1.3/02			
A7.4.1.4/01	2006	TOXICITY OF PELARGONIC ACID (EMERY 1202) TO ACTIVATED SLUDGE IN A RESPIRATION INHIBITION TEST IBACON GmbH, Rossdorf, Germany Report-No. 31575171 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.4.3.1/01	1999c	28 – DAY PROLONGED TOXICITY TEST OF NEU 1170 H IN RAINBOW TROUT (ONCORHYNCHUS MYKISS) (TELEOSTEI, SALMONIDAE) ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report No. 99024/01-ACOm GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.4.3.4/01	1999d	ASSESSMENT OF TOXIC EFFECTS OF NEU 1170 H ON DAPHNIA MAGNA USING THE 21 DAY REPRODUCTION TEST ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report No. 99024/01-ARDm GLP, Unpublished.	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.4.3.5.2/01	1999b	ASSESSMENT OF TOXIC EFFECTS OF NEU 1170 H ON AQUATIC PLANTS USING THE DUCKWEED LEMNA GIBBA ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report No. 99024/01-AALG GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.5.1.2/01	1998	ACUTE TOXICITY OF NEU 1170 H ON EARTHWORMS, EISENIA FOETIDA USING AN ARTIFICIAL SOIL TEST Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, D-75223 Niefern-Öschelbronn Report No. 97253/01-NLEf GLP, Unpublished **Submitted in: B7.8.4/01**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.5.1.3/01	2003	EFFECTS OF NEU 1170 H ON TERRESTRIAL (NON-TARGET) PLANTS: VEGETATIVE VIGOUR TEST IBACON GmbH, Rossdorf, Germany Report No. 15411087 GLP, Unpublished **Submitted in: B7.8.6/01**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.5.3.1.1/01	1996	ACUTE ORAL TOXICITY STUDY IN BOBWHITE QUAIL WITH NEUDOSAN NEU	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		NOTOX B.V., 's-Hertogenbosch The Netherlands Report-no. 185052 GLP, Unpublished			
A7.5.3.1.2/01	2003	AVIAN DIETARY TOXICITY TEST OF "NEU 1170 H" IN JAPANESE QUAIL Harlan Bioservice for Science GmbH, Walsrode, Germany Report No. 10-16-0146-03 GLP, Unpublished **Submitted in: B7.6.1/01**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.5.3.1.2/02	2004	AVIAN DIETARY TOXICITY TEST OF "NEU 1170 H" IN THE MALLARD DUCK Harlan Bioservice for Science GmbH, Walsrode, Germany Report No. 10-16-0119-04 GLP, Unpublished **Submitted in: B7.6.1/02**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.5.4.1/01	1998	ASSESSMENT OF SIDE EFFECTS OF NEU 1170 H TO THE HONEY BEE, APIS MELLIFERA L. IN THE LABORATORY FOLLOWING THE EPPO GUIDELINE NO. 170 ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report No. 97253/01-BLEU GLP, Unpublished **Submitted in: B7.8.2/01**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
A7.5.4.1/02	2003	AN EXTENDED LABORATORY TEST TO DETERMINE THE EFFECTS OF NEU 1170 H ON THE GROUND-ACTIVE BEETLE, POECILUS CUPREUS Mambo-Tox Ltd., Southampton, U.K. Report No. NEU-03-5 GLP, Unpublished **Submitted in: B7.8.3/01**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
Company statement	2008	ANALYSENZERTIFIKAT VISKOSITÄT (ANALYSIS CERTIFICATE VISCOSITY) W. Neudorff GmbH KG, Emmerthal, Germany Report-No. not applicable, statement Not GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
Company statement	2007	GENERAL INFORMATION ON THE ACTIVE SUBSTANCE AND THE BIOCIDAL PRODUCT; active substance: Pelargonic Acid biocidal product: NEU 1170 H **W. Neudorff GmbH KG,** **Emmerthal, Germany**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Report-No. Not applicable (statement) **Not GLP, unpublished**			
Company statement	2008	CONFIRMATION: PELARGONSÄUREGEHALT IN ÄLTEREN UNTERSUCHUNGEN (PELARGONIC ACID CONTENT IN OLDER STUDIES) W. Neudorff GmbH KG, Emmerthal, Germany Report-No. not applicable, statement Not GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
Company statement	2008	MODE OD ACTION OF NONANOIC ACID (PELARGONIC ACID): W. Neudorff GmbH KG, Emmerthal, Germany Report-N. not applicable, statement Not GLP, Unpublished	N	Not applicable as no data protection claimed	W. Neudorff GmbH KG
Company statement	2007	Water solubility of Pelargonic acid; W. Neudorff GmbH KG, Emmerthal, Germany Report no:20061535/01-PCSB GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG

LIST OF STUDIES FOR THE ACTIVE SUBSTANCE – SUBMITTED ADDITIONAL LITERATURE

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
A6.5.1/01 non-sub	1985	CHRONIC MOUSE DERMAL TOXICITY STUDY, TEST MATERIAL C-182 = PELARGONIC ACID Kettering Laboratory, Univ. Cincinnati, OH, U.S.A. Report No. not stated Not GLP, Published	N	Not applicable as no data protection claimed	--
A6.6.3/01 non-sub	1993	MUTAGENICITY TEST ON PELARGONIC ACID (TECHNICAL GRADE) IN THE L5178Y TK +/- MOUSE LMPHOMA FORWARD MUTATION ASSAY WITH A CONFIRMATORY ASSAY Hazleton Washington, Vienna, VA, U.S.A Report No. 15656-0-431R GLP, PUBLISHED	N	Not applicable as no data protection claimed	--
A6.7.1/01	1985	CHRONIC MOUSE DERMAL TOXICITY STUDY, TEST MATERIAL C-182 = PELARGONIC ACID Kettering Laboratory, Univ. Cincinnati, OH, U.S.A. Report No. not stated Not GLP, Published **Submitted in 6.5.1/01 non-sub**	N	Not applicable as no data protection claimed	--

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**
Anonymous	1998	PESTICIDE FACT SHEET (FOR PELARGONIC ACID, DATE ISSUED: JANUARY 1998. SOURCE: US EPA REPORT-NO.: NOT APPLICABLE NOT GLP, PUBLISHED	N	Not applicable as no data protection claimed	--
Anonymous	2003	PELARGONIC ACID (NONANOIC ACID); EXEMPTION FROM THE REQUIREMENT OF A PESTICIDE TOLERANCE SOURCE: US ENVIRONMENTAL PROTECTION AGENCY REPORT-NO.: NOT APPLICABLE NOT GLP; PUBLISHED	N	Not applicable as no data protection claimed	--
Barkley W.	1985	CHRONIC MOUSE DERMAL TOXICITY STUDY, TEST MATERIAL C-182 = PELARGONIC ACID Kettering Laboratory, Univ. Cincinnati, OH, U.S.A. Report No. not stated Not GLP, Published **Submitted in 6.5.1/01 non-sub and A6.7.1 non-sub**	just EPA study summary, no letter of access from applicant available	Not applicable as no data protection claimed	--
Cifone M.A.	1993	MUTAGENICITY TEST ON PELARGONIC ACID (TECHNICAL GRADE) IN THE L5178Y TK +/- MOUSE LMPHOMA FORWARD MUTATION ASSAY WITH A CONFIRMATORY ASSAY Hazleton Washington, Vienna, VA, U.S.A Report No. 15656-0-431R GLP, PUBLISHED **Submitted in A6.6.3 non-sub**	just EPA study summary, no letter of access from applicant available	Not applicable as no data protection claimed	--
Harrison PT.	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	Not applicable as no data protection claimed	--
Kuhn J.O.	1995	PELARGONIC ACID-RANGE-FINDING FOR A 90-DAY RAT ORAL TOXICITY (DIET) Stillmeadow Inc., Sugar Land, Texas, U.S.A. Report No. 1941-95 GLP, Published **Submitted as A6.3.1/02**	just EPA study summary, no letter of access from applicant available	Not applicable as no data protection claimed	--
Lawlor T. E.	1993	MUTAGENICITY TEST ON PELARGONIC ACID (TECHNICAL GRADE) IN THE SALMONELLA/MAMMALIAN-MICROSOME REVERSE MUTATION ASSAY (AMES TEST) Hazleton Washington Inc., Vienna, VA, U.S.A. Report No. 15656-0-401R	just EPA study summary, no letter of access from applicant	Not applicable as no data protection claimed	--

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**
		GLP, Published **Submitted as A6.6.1/02**	available		
Li C.Y.	1978	SOIL FATTY ACIDS UNDER ALDER CONIFER STANDS OF COASTAL OREGON SOIL SCIENCE; Vol 125, No. 2, 92-94 Report-No.: not applicable, not GLP, Published	N	Not applicable as no data protection claimed	--
Metcalf L.D., Schmitz A.A.; Pelka J.	1966	RAPID PREPARATION OF FATTY ACID ESTERS FROM LIPIDS FOR GAS CHROMATOGRAPHIC ANALYSIS Source: Anal. Chem., 38, p 514 Report-no. not applicable Not GLP; Published	N	Not applicable as no data protection claimed	--
Murli H.	1993	MUTAGENICITY TEST ON N-PELARGONIC ACID IN VIVO MICRONUCLEUS ASSAY Hazleton Washington, Vienna, VA, U.S.A. Report No. 15656-0-455CO GLP, Published **Submitted as 6.6.4/01**	just EPA study summary, no letter of access from applicant available Draft CAR for fatty acids (C7-C20) prepared by RMS Ireland in the context of 91/414/EEC indicates no data protection	Not applicable as no data protection claimed	Mycogen Corp
US EPA, Anonymous	1992	THE REREGISTRATION ELIGIBILITY DOCUMENT (RED) ON SOAP SALTS. Source: US EPA Report-No.: Not applicable Not GLP, Published	N	Not applicable as no data protection claimed	--
US EPA, Mycogen Corporation	1997	PELARGONIC ACID; PESTICIDE TOLERANCE PETITION 1/97 Source: Cornell University, 5123 Comstock Hall, Ithaca, New York Report-No.: not applicable, Not GLP, published	N	Not applicable as no data protection claimed	--
Wester PW., Kroes R.	1988	FORESTOMACH CARCINOGENS: PATHOLOGY AND RELEVANCE TO MAN. National Institute of Public Health and Environmental Protection, Bilthoven, The Netherlands Toxicol Pathol. 1988; 16(2): 165-71	N	Not applicable as no data protection claimed	--

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**
		Report-No. Not applicable Not GLP, Published			

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

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
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.	2008	THE COLIPA STRATEGY FOR THE DEVELOPMENT OF IN VITRO ALTERNATIVES: SKIN SENSITISATION AATEX 14, Special Issue, 375-379 http://altweb.jhsph.edu/wc6/	N	Not applicable as no data protection claimed	published
Basketter DA, Chamberlain M, Griffiths HA, Rowson M, Whittle E, York M.	1997	THE CLASSIFICATION OF SKIN IRRITANTS BY HUMAN PATCH TEST Food Chem Toxicol. 35(8):845-52.	N	Not applicable as no data protection claimed	published
B	1996	INDIVIDUAL, ETHNIC AND SEASONAL VARIABILITY IN IRRITANT SUSCEPTIBILITY OF SKIN: THE IMPLICATIONS FOR A PREDICTIVE HUMAN PATCH TEST. Contact Dermatitis 35(4), 208-13.	N	Not applicable as no data protection claimed	published

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
B	2007 a	DOES IRRITATION POTENCY CONTRIBUTE TO THE SKIN SENSITIZATION POTENCY OF CONTACT ALLERGENS-- Cutan Ocul Toxicol. 26(4): 279-86.	N	Not applicable as no data protection claimed	published

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
Basketter DA, York MY, McFadden JP, Robinson MK	2004	DETERMINATINO OF SKIN IRRITATION POTENTIAL IN THE HUMAN 4-H PATCH TEST Contact Dermatitis, 51:1-4	N	Not applicable as no data protection claimed	published
Basketter DA., Gerberick GF., Kimber I.	2007 b	THE LOCAL LYMPH NODE ASSAY: CURRENT POSITION IN THE REGULATORY CLASSIFICATION OF SKIN SENSITIZING CHEMICALS Cutaneous and Ocular Toxicology 26:4, 293 - 301	N	Not applicable as no data protection claimed	published
Basketter DA., Gerberick GF., Kimber I.	1998	STRATEGIES FOR IDENTIFYING FALSE POSITIVE RESPONSES IN PREDICTIVE SKIN SENSITIZATION TESTS Food and Chemical Toxicology 36: 327-333	N	Not applicable as no data protection claimed	published
Briggs G.B., Doyle R. L., Young J. A.	1976	SAFETY STUDIES ON A SERIES OF FATTY ACIDS. American Industrial Hygiene Association Journal; April 1976	N	Not applicable as no data protection claimed	published
ECETOC	2003	DERIVATION OF ASSESSMENT FACTORS FOR HUMAN HEALTH RISK ASSESSMENT. Technical Report No. 86	N	Not applicable as no data protection	published

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
		ISSN-0773-6347-86		claimed	
ECETOC	2006	TOXICOLOGICAL MODES OF ACTION: RELEVANCE FOR HUMAN RISK ASSESSMENT Technical Report No. 99, July 2006	N	Not applicable as no data protection claimed	published
ESAC	2007	STATEMENT ON THE VALIDITY OF IN-VITRO TESTS FOR SKIN IRRITATION http://ecvam.jrc.it/index htm	N	Not applicable as no data protection claimed	published
Fluhr JW, Darlensky R, Angelova-Fischer I, Tsankov N, Basketter D	2008	SKIN IRRITATION AND SENSITIZATION. MECHANISMS AND NEW APPROACHES FOR RISK ASSESSMENT: Skin Pharmacology and Physiology 2008, 21: 124-135	N	Not applicable as no data protection claimed	published
G	1982	ALIPHATIC CARBOXYLIC ACIDS IN: PATTY'S INDUSTRIAL HYGIENE AND TOXICOLOGY, Clayton, GD and Clayton, FE (eds.), 3rd Ed., Vol. 2C: Toxicology, New York: John Wiley & Sons, Inc., pp. 4901-4987. Published	N	Not applicable as no data protection claimed	--
Harkins R. W. and Sarett H. P.	1968	NUTRITIONAL EVALUATION OF MEDIUM-CHAIN TRIGLYCERIDES IN THE RAT The Journal of the American Oil Chemists' Society	N	Not applicable as no data protection	published

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
		Department of Nutritional Research, Mead Johnson Research Center, Evansville, Indiana Published		claimed	
Henderson L., Gregory J., Irving K., Swan G.	2003.	The National Diet and Nutrition Survey: Adults Aged 19-64 years, Volume 2: Energy, protein, carbohydrate, fat and alcohol intake. London, HMSO. Published	N	Not applicable as no data protection claimed	published
HERA	2002	HUMAN AND ENVIRONMENTAL RISK ASSESSMENT ON INGREDIENTS OF EUROPEAN HOUSEHOLD CLEANING PRODUCTS: FATTY ACID SALTS, HUMAN HEALTH RISK ASSESSMENT: Draft for public comment. June 2002. Published	N	Not applicable as no data protection claimed	-
IARC	1999	PREDICTIVE VALUE OF RODENT FORESTOMACH AND GASTRIC NEUROENDOCRINE TUMOURS IN EVALUATING CARCINOGENIC RISKS TO HUMANS IARC Technical Publication No. 39, 1999	N	Not applicable as no data protection claimed	published
Ji	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	Not applicable as no data protection claimed	published

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

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
Kalberlah F, Föst U, Schneider K.	2002.	TIME EXTRAPOLATION AND INTERSPECIES EXTRAPOLATION FOR LOCALLY ACTING SUBSTANCES IN CASE OF LIMITED TOXICOLOGICAL DATA. Ann Occup Hyg. 46(2):175-85.	N	Not applicable as no data protection claimed	-
K	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) Food Chem Toxicol. 46(6): 1896-1904	N	Not applicable as no data protection claimed	published

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
K					

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
Ku HO, Jeong SH, Kang HG, Pyo HM, Cho JH, Son SW, Ryu DY	2008	ANALYSIS OF DIFFERENTIAL GENE EXPRESSION IN AURICULAR LYMPH NODES DRAINING SKIN EXPOSED TO SENSITIZERS AND IRRITANTS Toxicol Lett. 177(1):1-9.	N	Not applicable as no data protection claimed	published
Loveren H., Cockshott A., Gebel T., Gundert-Remy U., Jong W.H., Matheson J., Garry H., Musset L., Selgrade M.M., Vickers C.	2002	SKIN SENSITITZATION IN CHEMICAL RISK ASSESSMENT: REPORT OF A WHO/IPCS INTERNATIONAL WORKSHOP FOCUSING ON DOSE RESPONSE ASSESSMENT. Regulatory Toxicology and Pharmakology 50, 155-199.	N	Not applicable as no data protection claimed	published
M	1998	MURINE LOCAL LYMPH NODE ASSAY FOR PREDICTIVE TESTING OF ALLERGENICITY: TWO IRRITANTS CAUSED SIGNIFICANT PROLIFERATION. Acta Derm Venereol. 78(6): 433-7	N	Not applicable as no data protection claimed	published

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
Mori K.	1953	PRODUCTION OF GASTRIC LESIONS IN THE RAT BY THE DIET CONTAINING FATTY ACIDS. GANN, Vol. 44; December	N	Not applicable as no data protection claimed	published
NTP (National Toxicology Program	1994	COMPARATIVE TOXICOLOGY STUDIES OF CORN OIL, SAFFLOWER OIL AND TRICAPRYLIN (CAS NOS. 8001-30-7, 8001-23-8, 538-23-8) IN MALE F344/N RATS AS VEHICLES FOR GAVAGE. Technical report series No. 426, NIH publications 94-3157. U.S. Department of Health and Human Services, National Institutes of Health, Washington, CD. GLP: yes	N	Not applicable as no data protection claimed	published

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
		published			
Proctor DM, Gatto NM, Hong SJ, Allamneni KP.	2007	MODE-OF-ACTION FRAMEWORK FOR EVALUATING THE RELEVANCE OF RODENT FORESTOMACH TUMORS IN CANCER RISK ASSESSMENT. Toxicol Sci. 98(2):313-26 Report-No. Not applicable Not GLP, Published	N	Not applicable as no data protection claimed	published
Renner, H., W.	1986	THE ANTICLASTOGENIC POTENTIAL OF FATTY ACID METHYL ESTERS. Mutation Research, 172: 265-269 Published	N	Not applicable as no data protection claimed	published
Robinson M.K., Whittle E. and Basketter D.A.	1999	A TWO-CENTER STUDY OF THE DEVELOPMENT OF ACUTE IRRITATION RESPONSES TO FATTY ACIDS. American Journal of Contact Dermatitis, Vol. 10, No 3	N	Not applicable as no data protection claimed	published
R	2001	VALIDITY AND ETHICS OF THE HUMAN 4-H PATCH TEST AS AN ALTERNATIVE METHOD TO ASSESS ACUTE SKIN IRRITATION POTENTIAL CONTACT DERMATITIS 45(1):1-12	N	Not applicable as no data protection claimed	published

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
R	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. London, HMSO.	N	Not applicable as no data protection claimed	published

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
S	1962	RANGE-FINDING TOXICITY DATA: LIST VI American Industrial Hygiene Association Journal 23:95-107	N	Not applicable as no data protection claimed	published

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

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
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.	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. Altern Lab Anim. 35(6):559-601	N	Not applicable as no data protection claimed	published
TalviOja et al.	2006	DECANOIC ACID: ACUTE DERMAL TOXICITY STUDY IN RATS RcC study No A86556	Y		Sopura S.A
TalviOja et al.	2006	DECANOIC ACID: ACUTE DERMAL TOXICITY STUDY IN RATS RcC study No A86556	Y		Sopura S.A
TM Biocides	2010	RISK CHARACTERISATION OF LOCAL EFFECTS IN THE ABSENCE OF SYSTEMIC EFFECTS 2010-03-05 http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/doc/TNsG/Guidance_Risk_Characterization_Local_Effects_Working_Document_2010.pdf	TM Biocides	Not applicable as no data protection claimed	2010
Traul K.A., Driedger A., Ingle D.L., Nakhasi D.	1999	Review of the Toxicologic Prop erties of Medium-chain triglycerides Food and chemical Toxicology 38 (2000), 79-98	N	Not applicable as no data protection claimed	-
US-EPA	2003	PELARGONIC ACID (NONANOIC ACID); EXEMPTION FROM THE REQUIREMENT OF A PESTICIDE TOLERANCE Federal Register: February 19,Volume 68, Number 33 http://www.epa.gov/fedrgstr/EPA-PEST/2003/February/Day-19/p3842.htm	N	Not applicable as no data protection claimed	published
Wahlberg J, Lindberg M.	2003	NONANOIC ACID – AN EXPERIMENTAL IRRITANT Contact Dermatitis 49: 117–123	N	Not applicable as no data protection	published

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
				claimed	
Wahlberg JE	1983	ASSESSMENT OF SKIN IRRITANCY: MEASUREMENT OF SKIN FOLD THICKNESS Contact Dermatitis 9(1):21-6	N	Not applicable as no data protection claimed	published
Wahlberg JE, Maibach HI	1980	NONANOIC ACID IRRITATION - A POSITIVE CONTROL AT ROUTINE PATCH TESTING-- Contact Dermatitis 6(2):128-30	N	Not applicable as no data protection claimed	published
W	1985	SKIN IRRITANCY FROM NONANOIC ACID Contact Dermatitis 13(4):266-9	N	Not applicable as no data protection claimed	published
Webb, D.R.; Wood, F.E.; Bertram, T.A.; Fortier, N.E.	1993	A 91-DAY FEEDING STUDY IN RATS WITH CARPENIN; FD CHEM. TOX. VOL 31, NO 12, PAGE 935-946, 1993; NO A6.4.1.1.A/01.	N	Not applicable as no data protection claimed	published

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
WHO/IPCS	2005	GUIDANCE DOCUMENT FOR THE USE OF DATA IN DEVELOPMENT OF CHEMICAL-SPECIFIC ADJUSTMENT FACTORS (CSAFS) FOR INTERSPECIES DIFFERENCES IN HUMAN VARIABILITY IN DOSE/CONCENTRATION-RESPONSE ASSESSMENT. IPCS harmonization project document ; no. 2 http://www.inchem.org/documents/harmproj/harmproj/harmproj2.pdf		Not applicable as no data protection claimed	
Willis CM, Stephens CJ, Wilkinson JD.	1988 b	ASSESSMENT OF ERYTHEMA IN IRRITANT CONTACT DERMATITIS. COMPARISON BETWEEN VISUAL SCORING AND LASER DOPPLER FLOWMETRY Contact Dermatitis 18(3):138-42	N	Not applicable as no data protection claimed	published
Willis CM, Stephens JM, Wilkinson JD	1988 a	EXPERIMENTALLY-INDUCED IRRITANT CONTACT DERMATITIS. DETERMINATION OF OPTIMUM IRRITANT CONCENTRATIONS Contact Dermatitis 18(1):20-4.	N	Not applicable as no data protection claimed	published
York M, Griffiths HA, Whittle E, Basketter DA.	1996	EVALUATION OF A HUMAN PATCH TEST FOR THE IDENTIFICATION AND CLASSIFICATION OF SKIN IRRITATION POTENTIAL. Contact Dermatitis 34(3):204-12.	N	Not applicable as no data protection claimed	published
K	2008	MARIN MUNICIAPAL WATER DISTRICT HERBICIDE RISK ASSESSMENT, (Draft), Chapter 7 HTTP://WWW.MARINWATER.ORG/DOCUMENTS/CHAP7_PELARGONICACID_8_28_08.PDF	N	Not applicable as no data protection claimed	published

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

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT – SORTED BY SECTION NUMBER

Section No / Reference No	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
B3.1.1/01	Almond D.S.	2001	STORAGE STABILITY OF NEU 1170H Eco-Care Technologies Inc., Sidney, BC V8L 5L6, Canada Report No. NEU1170-990409 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B3.1.2/01	Almond D.S.	2001	STORAGE STABILITY OF NEU 1170H Eco-Care Technologies Inc., Sidney, BC V8L 5L6, Canada Report No. NEU1170-990409 GLP, Unpublished **Submitted in: B3.1.1/01**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B3.4/01	Werle H.	1998a	NEU 1170 H 22% - FLASH POINT BioChem GmbH, Daimlerstr. 5 b, D-76185 Karlsruhe, Germany Report No. 985040801A GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B3.4/02	Werle H.	1998b	NEU 1170 H 22% - AUTO- IGNITION TEMPERATURE BioChem GmbH, Daimlerstr. 5 b, D-76185 Karlsruhe, Germany Report No. 985040801B GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B3.5/01	Krips H.J.	1999a	DETERMINATION OF THE PH OF AN AQUEOUS DISPERSION OF NEU 1170 H Notox B.V, 's-Hertogenbosch, The Netherlands Report No. 282858 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B3.6/01	Krips H.J.	1999b	DETERMINATION OF THE DENSITY (LIQUID) OF NEU 1170 H Notox B.V, 's-Hertogenbosch, The Netherlands Report No. 282847 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B3.7/01	Almond D.S.	1997a	STORAGE STABILITY OF H01-22 Eco-Care Technologies Inc., Sidney, BC V8L 5L6, Canada Report No. not stated GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B3.7/02	Almond D.S.	2001	STORAGE STABILITY OF NEU 1170H	Y	Sept 2006	W. Neudorff

Section No / Reference No	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
			Eco-Care Technologies Inc., Sidney, BC V8L 5L6, Canada Report No. NEU1170-990409 GLP, Unpublished **Submitted in: B3.1.1/01**		(PT 2 + 19)	GmbH KG
B3.7/03	Plastikpack GmbH	2001	SPECIFICATION 5 SK 5, 10 SK 4 Plastikpack GmbH, Neckartailfingen, Germany Report No. not applicable Not GLP, Unpublished	N	Not applicable as no data protection claimed	W. Neudorff GmbH KG
B3.8/01	Almond D.S.	2001	STORAGE STABILITY OF NEU 1170H Eco-Care Technologies Inc., Sidney, BC V8L 5L6, Canada Report No. NEU1170-990409 GLP, Unpublished **Submitted in: B3.1.1/01**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B3.8/02	Almond D.S.	1997b	FOAMING OF H01-22 Eco-Care Technologies Inc., Sidney, BC V8L 5L6, Canada Report No. not stated GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B3.10/01	Krips H.J.	1999c	DETERMINATION OF THE SURFACE TENSION OF AN AQUEOUS SOLUTION OF NEU 1170 H Notox B.V, 's-Hertogenbosch, The Netherlands Report No. 259717 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B3.11/01	Krips H.J.	2000	DETERMINATION OF THE VISCOSITY OF NEU 1170 H Notox B.V, 's-Hertogenbosch, The Netherlands Report No. 277864 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B4.1/01	Werle H.	2000	NEU 1170 H 22% - DETERMINATION OF FATTY ACIDS BioChem GmbH, Daimlerstr. 5 b, D-76185 Karlsruhe, Germany Report No. 005040801 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B5.10.2/02	Krebs	2000	PRÜFUNG NACH RICHTLINE: EPPO PP 1/117(2) Pflanzenschutzamt der Landwirtschaftskammer Hannover,	Y	Oct 2008 (PT 10)	NEU

Section No / Reference No	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
			Hannover, Germany Report No. HR6H00NEU001 GEP, unpublished			
B5.10.2/03	Sell P.	2000	ERGEBNISSE DER PRÜFUNG VON HERBIZIDEN 2000 GEGEN ALGEN AUF WEGEN, PLÄTZEN UND GEHWEGPLATTEN Biologische Bundesanstalt für Land- und Forstwirtschaft, Hamburg, Germany Report No. NEU00H3 GEP, unpublished	Y	Oct 2008 (PT 10)	NEU
B5.10.2/04	Niesar M.	2000	NEU 1170 H GEGEN ALGEN AUF WEGEN UND PLÄTZEN Pflanzenschutzamt Bonn, Landwirtschaftskammer Rheinland, Bonn, Germany Report No. 20000048 GEP, unpublished	Y	Oct 2008 (PT 10)	NEU
B5.10.2/05	Arndt R	2006	EFFICACY OF FINALSAN ON ALGAE ON THE TRUNKS OF TREES W. Neudorff GmbH, Versuchsgärtnerei Hamelin, Germany Report No. HERB 06/58 GEP, unpublished	Y	Oct 2008 (PT 10)	NEU
B5.10.2/06	Arndt R	2007	EFFICACY OF FINALSAN ON ALGAE ON THE TRUNKS OF TREES W. Neudorff GmbH, Versuchsgärtnerei Hamelin, Germany Report No. HERB 06/59 GEP, unpublished	Y	Oct 2008 (PT 10)	NEU
B5.10.2/07	Arndt R	2010	EFFICACY OF NEU 1170H AGAINST ALGAE ON STONES W. Neudorff GmbH KG, Research and Development, Aerzen, Germany Report No. HERB 01/12	Y	Oct 2008 (PT 10)	NEU
B5.10.2/08	Arndt R	2010	EFFICACY OF NEU 1170H AGAINST ALGAE ON WOOD W. Neudorff GmbH KG, Research and Development, Aerzen, Germany Report No. HERB 06/32	Y	Oct 2008 (PT 10)	NEU
B5.10.2/09	Arndt R	2010	EFFICACY OF NEU 1170H AGAINST ALGAE ON WOOD W. Neudorff GmbH KG, Research and Development, Aerzen, Germany Report No. HERB 07/13	Y	Oct 2008 (PT 10)	NEU
B5.10.2/10	Arndt R	2010	EFFICACY OF NEU 1170H AGAINST	Y	Oct 2008	NEU

Section No / Reference No	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
			ALGAE ON SANDSTONE W. Neudorff GmbH KG, Research and Development, Aerzen, Germany Report No. HERB 07/14		(PT 10)	
B6.1.1/01	Rijcken W.R.P.	1997a	ASSESSMENT OF ACUTE ORAL TOXICITY WITH NEU 1170 H IN THE RAT Notox B.V, 's-Hertogenbosch, The Netherlands Report No. 197009 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	NEU
B6.1.2/01	Rijcken W.R.P.	1997b	ASSESSMENT OF ACUTE DERMAL TOXICITY WITH NEU 1170 H IN THE RAT Notox B.V, 's-Hertogenbosch, The Netherlands Report No. 197011 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	NEU
B6.1.3/01	Kramer H.J.	1997a	NEU 1170 H - ACUTE INHALATION TOXICITY BioChem GmbH, Daimlerstr. 5 b, D-76185 Karlsruhe, Germany Report No. 97 10 42 026 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B6.1.3/02	Chevalier	2003	ACUTE INHALATION TOXICITY STUDY OF NEU 1171H IN RATS. LPT Laboratory of pharmacology and toxicology KG, Redderweg 8, 21147 Hamburg Report No. 17134/03 GLP, unpublished	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B6.2.s/01	Kramer H.J.	1997b	ACUTE DERMAL IRRITATION/CORROSION NEU 1170 H 21%IG BioChem GmbH, Daimlerstr. 5 b, D-76185 Karlsruhe, Germany Report No. 97 10 42 803 A GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	NEU
B6.2.e/01	Kramer H.J.	1997c	ACUTE EYE IRRITATION/CORROSION NEU 1170 H 21%IG BioChem GmbH, Daimlerstr. 5 b, D-76185 Karlsruhe, Germany Report No. 97 10 42 803 B GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	NEU
B6.3/01	Huygewoort	2000	ASSESSMENT OF CONTACT	Y	Sept 2006	NEU

Section No / Reference No	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
	van A.H.B.M		HYPERSENSITIVITY TO NEU 1170 H IN THE ALBINO GUINEA PIG (MAXIMISATION-TEST) Notox B.V, 's-Hertogenbosch, The Netherlands Report No. 274591 GLP, Unpublished		(PT 2 + 19)	
B6.5/01	Anonymous	2000	IUCLID DATASET CAS NO. 1336-21-6 Source: European Commission – European Chemicals Bureau, 18 FEB 2000 Report-no. not applicable Not GLP; Published	N	Not applicable as no data protection claimed	--
B6.5/02	Anonymous	Not stated	RTECS DATA BASE – RTECS NUMBER: BQ9625000 Source: RTECS Data Base Report-no. not applicable Not GLP; Published	N	Not applicable as no data protection claimed	--
B6.5/03	Anonymous	2003	HSDB DATA BASE – AMMONIUM HYDROXIDE CASRN: 1336-21-6 Source: HSDB Data Base, last revision date 14 FEB 2003 Report-no. not applicable Not GLP; Published	N	Not applicable as no data protection claimed	--
B6.6/02	Kempernek H.	2007b	ENVIRONMENTAL EXPOSURE ASSESSMENT FOR THE ACTIVE SUBSTANCE PELARGONIC ACID AND THE BIOCIDAL PRODUCT NEU 1170 H TB-Agrartechnik Service, A-2540 Bad Vöslau, Austria Report-No. 0706NEU-01 Unpublished **Submitted in: A2.10/05**	Y	Sept 2006 (PT 2 + 19)	W. Neudorff GmbH KG
B7.7.1.1.1/01	Heintze A.	1999a	NEU 1170 H – ACUTE TOXICITY TESTING OF NEU 1170 H IN RAINBOW TROUT (ONCORHYNCHUS MYKISS) (TELEOSTEI, SALMONIDAE) ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report No. 99024/01-AAOm GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	NEU
B7.7.1.1.1/02	Heintze A.	1999b	NEU 1170 H – ACUTE TOXICITY TESTING OF NEU 1170 H IN GOLDEN ITE (LEUCISCUS IDUS)	Y	Sept 2006 (PT 2 + 19)	NEU

Section No / Reference No	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
			(TELEOSTEI, SALMONIDAE) ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report No. 99024/01-AALi GLP, Unpublished			
B7.7.1.1.2/01	Kleiner R.	1998	ACUTE IMMOBILISATION TEST DAPHNIA – DAPHINA MAGNA BioChem Agrar, Labor für biologische und chemische Analytik, D-04451 Cunnersdorf Report No. 981048039 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	NEU
B7.7.1.1.3/01	Kleiner R.	1999	ALGAE GROWTH INHIBITION TEST SCENEDESMUS SUBSPICATUS BioChem Agrar, Labor für biologische und chemische Analytik D-04451 Cunnersdorf Report No. 981048040 GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	NEU
B7.7.1.1.3/02	Dengler D.	1999a	TESTING OF TOXIC EFFECTS OF NEU 1170 H ON THE BLUE-GREEN ALGA ANABAENA FLOS-AQUAE ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report No. 99024/01-AAAf GLP, Unpublished	Y	Sept 2006 (PT 2 + 19)	NEU

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
AEC	Acceptable exposure concentration
AEL	Acceptable exposure level
AF	assessment factor
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
Ann.	Annex
AOEL	acceptable operator exposure level
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
BOD	biological oxygen demand
bp	boiling point
BP	Biocidal Product
BPD	Biocidal Products Directive
BSAF	biota-sediment accumulation factor
BSP	bromosulfophthalein
bw	body weight

Stand. Term / Abbreviation	Explanation
°C	degrees Celsius (centigrade)
CAS	Chemical Abstracts Service
CEC	cation exchange capacity
cf	confer, compare to
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)
DIS	draft international standard *(ISO)*
DNA	deoxyribonucleic acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
$DT_{50(lab)}$	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
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

Stand. Term / Abbreviation	Explanation
ECD	electron capture detector
ED_{50}	median effective dose
EDI	estimated daily intake
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm
EPA	U.S. Environmental Protection Agency
EPMA	electron probe micro-analysis
EUSES	European Union system for the evaluation of substances
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
FID	flame ionisation detector
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
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GPC	gel-permeation chromatography
GSH	glutathione
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value)
ha	hectare(s)
Hb	haemoglobin
HC5	concentration which will be harmless to at least 95 % of the species present with a given level of confidence (usually 95 %)
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

Stand. Term / Abbreviation	Explanation
I	indoor
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration or median inhibitory concentration 1
ID	ionisation detector
im	intramuscular
inh	inhalation
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
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
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry

Stand. Term / Abbreviation	Explanation
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
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
MC	moisture content
MDL	method detection limit
µg	microgram
mg	milligram
MHC	moisture holding capacity
MIC	minimum inhibitory concentration
min	minute(s)
MKC	minimum killing concentration
mL	millilitre

Stand. Term / Abbreviation	Explanation
MLD	median lethal dose
MLT	minimum lethal time
mm	millimetre
mo	month(s)
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
Mp	melting point
MRL	maximum residue level or limit
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
nd	not detected
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
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
OC	organic carbon content

Stand. Term / Abbreviation	Explanation
OEL	occupational exposure limit
OH	hydroxide
OJ	Official Journal
OM	organic matter content
Pa	pascal
PAD	pulsed amperometric detection
pc	paper chromatography
PC	personal computer
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
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})
PRL	practical residue limit
PT	product type
PT(CEN)	project team CEN
PTT	partial thromboplastin time
Q*1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model

Stand. Term / Abbreviation	Explanation
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RA	risk assessment
RC	risk characterisation
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RP	reversed phase
RRT	relative retention time
RS	Registration Standard
RSD	relative standard deviation
s	second
S	solubility
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
SCAS	semi-continous activated sludge
SCTER	smallest chronic toxicity exposure ratio (TER)
SD	standard deviation
se	standard error
SEM	standard error of the mean
SF	safety factor
SIMS	secondary ion mass spectroscopy
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
ssp	subspecies
STP	sewage treatment plant
t	tonne(s) (metric ton)
$t_{½}$	half-life (define method of estimation)
TC	Toxic Concentration
TD	Toxic Dose
TG	technical guideline, technical group

Stand. Term / Abbreviation	Explanation
TGD	Technical guidance document
TID	thermionic detector, alkali flame detector
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)
TLC	thin layer chromatography
TMDI	theoretical maximum daily intake
TNsG	technical notes for guidance
TOC	total organic carbon
TTC	Toxicological-Threshold-of-Concern
TWA	time weighted average
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
Yr	year
<	less than
≤	less than or equal to
>	greater than

Stand. Term / Abbreviation	Explanation
≥	greater than or equal to

APPENDIX IV-2: ABBREVIATIONS OF ORGANISATION AND PUBLICATIONS

Abbreviation	Explanation
ASTM	American Society for Testing and Materials
CA(S)	Chemical Abstracts (System)
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CE	Council of Europe
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
DG	Directorate General
DIN	German Institute for Standardisation
EC	European Commission
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
EPA	Environmental Protection Agency
EU	European Union
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
IARC	International Agency for Research on Cancer
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
ISO	International Organization for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JECFA FAO/WHO	Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme

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)
OECD	Organization for Economic Co-operation and Development
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SETAC	Society of Environmental Toxicology and Chemistry
WHO	World Health Organization