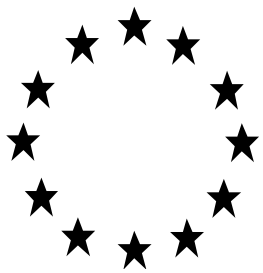
Directive 98/8/EC concerning the placing biocidal products on the market

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

Assessment Report



Nonanoic acid

Product-type 19
(repellents and attractants)

Date of SCB vote: 24th September 2010

Annex I - Austria

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. PROCEDURE FOLLOWED

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

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 19.

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

In accordance with the provisions of Article 7(1) of that Regulation, Austria was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for NONANOIC ACID as an active substance in product-type 19 was 1 March 2006, in accordance with 4b of Regulation (EC) No 1048/2005.

On 23 February 2006, the Austrian Competent Authority received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 14 August 2006.

On 10 October 2008, 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 22 October 2008. The competent authority report included a recommendation for the inclusion of Active substance NONANOIC ACID in Annex I to the Directive for product-type 19.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 22 October 2008. 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.

1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4 98, p 1

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

On the basis of the final competent authority report, the Commission proposed the inclusion of Active substance name in Annex I or IA to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on date SCB.

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 24th September 2010.

1.2. PURPOSE OF THE ASSESSMENT REPORT

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

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

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

1.3. OVERALL CONCLUSION IN THE CONTEXT OF DIRECTIVE 98/8/EC

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

- compliance with the particular requirements in the following sections of this assessment report,
- the implementation of the provisions of Article 5(1) of Directive 98/8/EC, and
- the common principles laid down in Annex VI to Directive 98/8/EC

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

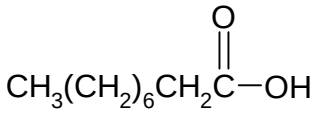
2. OVERALL SUMMARY AND CONCLUSIONS

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 (pK_a) is determined at pK_a =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 mPas at 20°C and 5.2 mPas 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:

- 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. According to SANCO/825/00 rev. 7 no analytical method for the determination of residues in air has to be provided if relevant exposure according to application techniques is unlikely to occur and for naturally occurring non-toxic active substances. Therefore, the analytical method should be considered as additional information. 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.

- 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 analyse 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

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.

The active substance is used outdoors (user: general public) as repellent against cats at the rate of 0.02 g a.s./m^2. Although the biocidal product does not act as a repellent sensu stricto – cats are not driven away from the treated area – the behaviour of cats is modified such that defecation is massively reduced in treated areas.

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

2.1.3. Classification and Labelling

Current classification according to Directive 67/548/EEC

Table 2.1.3-1: Current classification according to Directive 67/548/EEC

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

Proposed classification and labelling

Table 2.1.3-2: Proposed classification and labelling according to Directive 67/548/EEC

Classification and Labelling proposal		Justification
Hazard symbol		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 Directive 67/548/EEC
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. 1272/2008/EC

Classification and Labelling			Justification
GHS Pictograms			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
Signal words		Danger	
Classification		Serious eye damage – Hazard Category 1 Skin irritation- Hazard Category 2	
Hazard statements		H318: Causes serious eye damage H315: Causes skin irritation	
Precautionary Statements	General	-	
	Prevention	P264 Wash thoroughly after handling 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	-	

<u>Proposed classification of the representative biocidal product</u>

Table 2.1.3-4 Classification and labelling of the representative product 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 S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S39 Wear eye/face protection
Classification	
Labelling	

Table 2.1.3-5: Proposed classification and labelling of the representative product according to Reg. 1272/2008/EC

Classification and Labelling			Justification
GHS Pictograms			Study data summarized in Doc IIB.
Signal words		Warning	
Classification		Hazard Category 2	
Hazard statements		H319: Causes serious eye irritation	
Precautionary Statements	General	-	
	Prevention	P264 Wash thoroughly after handling P280 Wear protective gloves/protective clothing/eye protection/face protection.	
	Response	P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if	

		present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: get medical advice/attention	
	Storage	-	
	Disposal	-	

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. 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 Annex I of Directive 67/548/EEC from corrosive to skin irritant and risk for serious damage to the eye; Nonanoic acid has to be reclassified according to the rules of REACH and an Annex XV Dossier containing the evaluation of these endpoints has to be submitted to ECHA.

2.2.1.2. 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 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 day within the acute oral and dermal studies and 1000 mg/kg bw day within the subacute gavage study and 1500 mg/kg bw day 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 day 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 day and 1834 mg/kg bw day, 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. Furthermore, since a human counterpart for the rodent forestomach does not exist in terms of function, histology, pH value and epithelial contact time (Proctor 2007) the forestomach effect was also not taken into consideration for the local-oral hazard assessment. No-observable-effect levels should be determined in those parts of the gastro-intestinal tract having a counterpart in humans, such as pharynx and oesophagus (Harrison 1992) or glandular stomach or intestine. No effects were observed in these tissues.
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 day.

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.

Based on the absence of systemic effects relevant for humans at 1000 mg/kg bw day in the rat subacute gavage study and by considerations of intake of fatty acids as natural component of food (~1800 mg/kg bw day, e.g. Bell et al 1972) a short, medium and long term systemic AEL of 10 mg/kg bw day is proposed.

In the available 28 day rat gavage study local-oral effects were observed as forestomach irritation with a NOAEL of 150 mg/kg bw day 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 free active substance solved in propylene glycol and the product Katzenschreck that contains 1% NEU 1170H (a 20% aqueous solution of the a.s. as ammonium salt in with a pH of 7) in pumic stone resulting in a Nonanoic acid content of 0.2%.

The available data are insufficient for the derivation of local dermal and local inhalation medium or long term AECs. Therefore –in case necessary and adequate- a qualitative risk assessment for local effects of the product may be preferred. The data are summarized in the CAR may be taken into consideration including the respective uncertainties.

2.2.1.3. 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 2.2.1.3-1).

Table 2.2.1.3-1: Main paths of human exposure to Nonanoic acid

	Exposure type				
	Production of a.s.[1]	**Production of b.p.**	**Primary exposure, during use of the b.p.**		**Secondary exposure**
Users / Route	**Industrial use**	**Industrial use**	**Industrial use / Professional use[2]**	**General public**	**General public**
Inhalation	n.a.	Yes	Not relevant	Negligible	Negligible
Dermal	n.a.	Not relevant	Not relevant	Yes	Yes[3]
Oral	n.a.	Not relevant	Not relevant	Not relevant	Yes[3]

[1] As the active substance Nonanoic acid is produced outside the European Union, no data on exposure to the active substance during production are required.
[2] The biocidal product „Katzenschreck" is only intended to be used by the general public.
[3] Accidental ingestion and skin contact by infants/children were identified as the only relevant exposure routes.

The assessment of human exposure follows the recommendations of "Technical Notes for Guidance on Human Exposure to Biocidal Products (European Commission, 2002)" and "Human Exposure to Biocidal Products (TNsG June 2002) User guidance version 1". The guidance documents contain only sparse information concerning attractants and repellents not applied directly on human skin. Therefore, the human exposure assessment follows in many aspects the proposals given for PT 14 (rodenticides), as the exposure scenarios for pellets and grain in open areas fit best to the use-concept of the repellent.

A tiered approach is followed for exposure estimation. In tier 1 the maximum theoretically possible exposure is calculated (conservative assumptions, realistic worst case), considering validated toxicological parameters (e.g. dermal absorption). If this exposure assessment produces an unacceptable outcome in risk assessment, a tier 2 assessment is performed (i.e. refinement of the exposure studies/models, considering specific data like for example time budgets, transfer factors and the effects of exposure reduction measures, e.g. personal protective equipment).

Assessment of exposure during manufacturing of the active substance is not required, since the active substance Nonanoic acid is produced outside the European Union. During formulation of the biocidal product, which takes place in an almost closed system, only inhalation exposure may occur.

The biocidal product is intended to be applied by the general public via spreading by hand. (For details on the intended use, please see Appendix II of this document.) Thereby dermal exposure may occur, whereas inhalation exposure is considered negligible compared to dermal exposure. Oral exposure is considered not relevant.

Subsequent to the use of the biocidal product, acute dermal and oral exposure may occur when an infant/child is playing outside at the site of application, crawling on the soil, touching the granules with its hands, resp. hands, legs and feet. (Assumption: all of the exposed skin area comes into contact with the biocidal product). After dermal contact it might lick its hands (Assumption: The entire amount of active substance on hands is taken up orally) and even ingest 5 grams of the granules. Inhalation exposure is considered negligible; as the scenarios for children and infants in this case only differ in the assumption of body weight, it is assumed that exposure of infants also covers the exposure of children as a worst case. Secondary acute exposure of adults as well as medium-term and chronic secondary exposure are regarded as not relevant.

Also combined exposure (i.e. total exposure via all exposure routes arising from individual tasks through different phases of use), as well as aggregate exposure (i.e. exposure to a single chemical from multiple sources i.e. through primary exposure and secondary exposure; scenario: an industrial worker is exposed at work during the formulation process and at home by applying the biocidal product) are assessed. Cumulative exposure which covers concurrent exposure to the same active substance from different biocidal products was not evaluated at present for Nonanoic acid.

The exposure values relevant for risk characterisation are presented in chapter 2.2.1.4 of this document.

2.2.1.4. Risk characterisation

The systemic toxicity of Nonanoic acid is low; a systemic short, medium and long term AEL of 10 mg/kg bw day is estimated based on no toxicological effects relevant for humans at 1000 mg/kg bw day in an oral, 28 day rat study and consideration of daily uptake and metabolism of fatty acids as natural food content. Taking into consideration the relevant exposure paths, which is dermal exposure due to application, the risk is clearly acceptable with an MOE above 4000 and an exposure/AEL ratio of 0.23 even for tier 1 exposure estimates.

Table 2.2.1.4 – 1: Primary Exposure

Exposure Scenario:		Estimated Internal Exposure [mg/kg bw/day]				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value	AF MOE_{ref}	MOE	Exposure / AEL
Application of the biocidal product (short term); Handling dry objects; Calculation according to "Impregnated grains and pellets, application phase"		**Estim. oral uptake**	**Estim. inhal. uptake**	**Estim. dermal uptake**	**Estim. total uptake (combined exposure)**				
Tier 1	Reasonable worst case (Model "Impregnated grains and pellets, appl. phase"; application directly by hand, 100% dermal abs., no PPE; adult, 60 kg bw)	n r.[1]	negli-gible	0.23	**0.23**	NOAEL: 1000 AEL syst.: **10**	100	4412	0.023

Also the risk for systemic effects within infants or children playing outside at the site of application is clearly acceptable with an MOE of 454 and an exposure/AEL ratio of 0.22 for tier 1 exposure estimates combined for dermal and oral exposure.

Table 2.2.1.4 - 2: Combined Exposure

Exposure Scenarios: see below		Estimated Internal Exposure [mg/kg bw/day]				Relevant NOAEL [mg/kg b.w/day] & Reference Value	AF MOE_{ref}	MOE	Exposure / AEL
		Estim. oral uptake	**Estim. inhal. uptake**	**Estim. dermal uptake**	**Estim. total uptake (combined exposure)**				
Tier 1 (total)	**Combined Exposure***	1.00	n.r.	1.20	**2.20**	NOAEL: 1000 AEL system.: 10	100	454	0.22

n.r. = not relevant

* Acute dermal exposure of infant; Model "Impregnated grains and pellets, appl. phase" - conservative assumptions (hands, feet and legs exposed), no PPE, 100% dermal absorption, 10 kg bw combined with acute oral exposure of infant by ingestion of 5 g granules (infant), Model “Impregnated grains and pellets, use phase”, “all of the a.s. is taken up”, 100% oral abs., 10 kg bw.

The irritant properties of Nonanoic acid require also consideration of local effects at the port of entry.

No severe skin irritation is to be expected from the use of the product Katzenschreck with acute exposure scenarios. NEU 1170H is classified just for serious eye irritation, but not for skin irritation. The representative product Katzenschreck contains 1% w/w NEU 1170H in pumic stone with final Nonanoic acid content of 0.2% (w/w). This further reduces exposure and risk for acute local irritation.

Neither Nonanoic acid nor NEU 1170H are classified for acute oral toxicity. For Nonanoic acid an oral local medium and long term AEC of 1% was proposed.

Also no severe local respiratory effects are to be expected from the use of the product with acute exposure scenarios. Within rats no clinical signs and no macroscopic pathological effects were observed after 4 hours of exposure to 1g/m3 Nonanoic acid as ammonium salt within a formulation (pH 7) containing also 3% Maleic hydrazid. The overall database for Nonanoic acid indicates a respiratory LC50 >5g/m3. The data are insufficient for classification for respiratory irritation (STOT –SE). From these data no threshold for local respiratory effects can be derived but it is likely that with an acute exposure of 1g/m3 Nonanoic acid as ammonium salt no severe respiratory irritation occurred in the rat. The intended use of the product Katzenschreck containing Nonanoic acid with 0.2% (w/w) in pumic stone is outdoors, about 10 times per year in amounts of 10 g/m2.

It is concluded that the probability for adverse acute local oral, dermal or respiratory effects is very low.

2.2.2. Environmental Risk Assessment

2.2.2.1. 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 ($k_{deg, air} = 0.42 d^{-1}$; $c(OH)_{air} = 5x10^5$ 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 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 as 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, 1.1).

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

2.2.2.2. Effects assessment

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

The LC_{50}-value of Nonanoic acid in fish (golden ide) is >36.3 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.

2.2.2.3. 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.

The P-criterion is not met: Not P

Bioaccumulation:

BCF_{fish} = 195.9 (calculated)

The B-criterion is not met: 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).

The T-criterion is not met: Not T

Nonanoic acid does not meet the PBT criteria.

2.2.2.4. Exposure assessment

Formulation and use of the repellent “Katzenschreck” may lead to emission of Nonanoic acid to the environment.

As the active substance Nonanoic acid is not produced in the European Union, exposure assessment is not required for the process of manufacture of the active substance.

Environmental exposure during formulation of the biocidal product, which takes place in an almost closed system, is considered insignificant.

The estimation of environmental exposure during use of the repellent is made by calculating the emissions and then the concentrations for each environmental compartment on basis of the intended use. (For details on the intended use, please see Appendix II of this document). Until now no specific document or guidance are developed for products belonging to PT 19. Furthermore, the exposure scenarios for pellets and grain in open areas as described in the ESD for PT 14 "Emission Scenario Document for biocides used as rodenticides" (Larsen, 2003) and in the ESD for PT 18 "OECD series on emission scenario documents number 18 emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses" fit best to the use-concept of "Katzenschreck" (OECD, 2008).

Therefore, the environmental exposure assessment follows in many aspects the proposals published in the Emission Scenario Documents and in the Technical Guidance Document on Risk Assessment (European Commission, 2003).

Dependent on the intended use (see Appendix II of this document) of "Katzenschreck", it is assumed that releases will end up at the most on unpaved soil. Considering that the ground surface can also be paved, releases of the repellent could also be washed by rain to rain water/sewer systems.

For the purpose of the risk assessment of "Katzenschreck" it is therefore assumed to use two theoretical environments:

- Environment 1: 100% of the releases end up to unpaved soil.

  The relevant environmental compartments will here be the soil and the groundwater.

- Environment 2: 100% of the releases end up on non permeable materials and are sent to sewers. In this scenario, it will be considered that releases are collected in rain water/sewer systems, which will act as a point source.

  For separate systems (rain water), it can be considered that no removal takes place at this point source, that would mean that STP is by-passed. The relevant environmental compartment will here be the surface water.

  For mixed waste/rain water systems, (STP is not by-passed), the relevant environmental compartments would then be the sewage treatment plant (STP), the surface water, the agricultural soil (from sludge application), and the groundwater.

As a worst case the risk is assessed for both environments. No determination of regional concentrations was made, since the repellent's use outlined is not considered to be of sufficiently large scale.

Subsequent to the use of the biocidal product, direct (primary) and indirect (secondary) exposure to the food chain may occur.

Due to the application of the biocidal product "Katzenschreck" as granules the incidental or intentional uptake by birds was considered, based on the equations and default values proposed by the ESD (Larsen, 2003).

The product's potential for secondary poisoning was assessed following the Technical Guidance Document on Risk Assessment (European Commission, 2003).

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

2.2.2.5. Risk characterisation

Air compartment:

The PEC of Nonanoic acid in air from its outdoor use as repellent against cats may be considered negligible based on its physico-chemical properties. Moreover, Nonanoic acid is not expected to have adverse abiotic or biotic effects on the atmosphere. (Please see chapter 2.2.2.2 of this document).

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

Aquatic compartment (including sediment):

The risk characterisation for the aquatic and sediment compartment was done by comparing the PECs of the compartments with the relevant PNECs.

STP:

Due to its outdoor use as repellent against cats Nonanoic acid will be released into sewage systems in cases where the product is applied on non permeable ground and mixed waste/rain water systems are used. Hence the active substance will pass through wastewater treatment plants before entering into surface water, agricultural soil (through sludge application) and the groundwater. Therefore calculation of a PEC in sewage treatment plants (PEC_{STP}) was considered relevant for this use scenario. (see Doc. II-B – chapter 5.2.2 STP)

The PNEC for aquatic micro-organisms was determined to be 5.652 mg/L (see Doc. II-A – chapter 4.2.1 Aquatic compartment).

The PEC/PNEC ratio for STP is calculated by dividing the PEC_{STP} by the $PNEC_{aquatic\ micro\text{-}organisms}$ (see table 2.2.2.5-1).

Table 2.2.2.5-1: PEC/PNEC ratios for STP

PEC	PEC/PNEC
Sewage treatment plant ($PNEC_{aquatic\ micro\text{-}organisms}$: 5.652 mg/L)	
0.024 mg/L	0.0042

Conclusion

Nonanoic acid poses an acceptable risk to aquatic micro-organisms in sewage treatment plants since the PEC/PNEC ratio is <1.

Surface water incl. sediment:

As a worst case scenario it is assumed that after a heavy rain, immediately following to the application in 400 households, the entire amount which is applied is washed into an adjacent rain water/sewer system (see Doc. II-B – chapter 5).

Table 2.2.2.5-2: Local PEC/PNEC ratios for aquatic compartment

PEC	PEC/PNEC
Water/local ($PNEC_{water}$: 0.0568 mg/L)	
$2.00x10^{-2}$ mg/L	0.35
Sediment/local ($PNEC_{sed}$: 0.1223 mg/kg)	
$4.31\ x10^{-2}$ mg/kg	0.352

This indicates that the risk of Nonanoic acid to aquatic and sediment dwelling organisms is acceptable, even in a very worst case estimation (see point 2.4.2, secondary poisoning).

Drinking water

Based on extreme conservative exposure assumptions for surface water (400 households use the product on the same time in conjuction with an immediate heavy rain event after the usage; continuous entry in surface water, conservative dilution factor of 10, no degradation) the PEC calculation for surface water (see table 2.2.2.5-2) is above the parametric value of 0.1 µg/L for Nonanoic acid according to Directive 98/83/EC. However based on the extreme conservative calculations in conjuction with the fate of Nonanoic acid in the environment and its natural occurrence in living organisms including food items the calculated exceedance is acceptable.

For the groundwater assessment the K_{oc} indicates that Nonanoic acid adsorbs weakly onto soil. However, Nonanoic acid degrades rapidly in soil (DT_{50} 1 day at 20°C). In addition a model simulation according to the Plant Protection Products Directive 91/414/EC showed <0.1 µg/L in all FOCUS scenarios using much higher pesticidal application rates (than listed under 1.1.2). Therefore it can be assumed that Nonanoic acid is – under the proposed conditions – not likely to have unacceptable effects on groundwater and the requirements of Directive 80/68/EC[4], 98/83/EC[5] and 2006/118/EC[6] are complied with.

Terrestrial compartment:

4 Council Directive 80/68/EEC of 17th December 1979 on the protection of groundwater against pollution caused by certain dangerous substances. OJ L 20, 26.1.1980, p. 43–48

5 Council Directive 98/83/EC of 3rd November 1998 on the quality of water intended for human consumption OJ L 330 , 05.12.1998, p. 3-54

6 Directive 2006/118/EC of the European Parliament and of the Council on the protection of groundwater against pollution and deterioration. OJ L 372, 27.12. 2006, p. 19-31.

The PNEC for terrestrial organisms was based on the nominal $L(E)C_{50}$ values, since the DT_{50} value for Nonanoic acid in soil is <2 days. The PNEC was determined to be 0.112 mg/kg_{dwt} (see Doc. II-A – chapter 4.2.3 Terrestrial compartment).

The PEC/PNEC ratio for soil is calculated by dividing the local PEC in soil by the PNEC in soil (see tables 2.2.2.5-3, 2.2.2.5-4 and 2.2.2.5-5).

Ground surface: non permeable materials

An indirect exposure route to soil is given by the application of sewage sludge from a STP onto agricultural soil.

To fulfil the requirements of the TWA Guidance[7] document, a scenario without removal by degradation processes was applied for the calculation of the local PECs for arable soil and grassland (see Doc. II-B – chapter 5.2.5 PEC in soil).

Table 2.2.2.5-3: PEC/PENEC ratios for the terrestrial compartment exposed via sewage sludge without degradation processes

	PEC_{soil} (mg/kg_{dwt})	**PEC/PNEC**
	$PNEC_{soil}$: 0.112 mg/kg $soil_{dwt}$	
Arable soil	0.150	**1.34**
Grassland	0.060	0.54

A slight risk to soil organisms in arable soil considering a soil depth of 20 cm was identified, since a PEC/PNEC ratio of 1.34 was calculated.

However it is questioned if soil depths of 20 cm should be considered relevant for substances like fatty acids, which adsorb very weakly onto soil (K_{oc} values for Nonanoic acid are 63.1 and 100.0 L/kg) and are therefore transported rapidly through soil.

Furthermore, if the rapid degradation (DT_{50} for Nonanoic acid 2.1 days at 12°C) is taken into account for the calculation of the PECs, the amount of Nonanoic acid will be lowered considerably (e.g. a PEC of 0.15 mg/kg_{dwt} will be reduced to 0.075 mg/kg_{dwt} within 2 days and therefore the risk will last for less than 1 day).

This finding is confirmed by the calculation of the average concentration in soil according to TGD:

In this scenario the PECs were calculated for arable soil and grassland as the average concentrations over certain time-periods in agricultural soil fertilized with sludge from a STP.

7 Technical Notes for Guidance on "Assessment of environmental effects of biocidal active substances that rapidly degrade in environmental compartments of concern" endorsed during the 29th CA-Meeting (2008)

Table 2.2.2.5-4: Local concentrations/PNEC ratios for the terrestrial compartment exposed via sewage sludge considering degradation processes

	PEC_{soil} (mg/kg_{dwt})	**PEC/PNEC**
	$PNEC_{soil}$: 0.112 mg/kg $soil_{dwt}$	
Arable soil (30 days)	1.51×10^{-2}	0.135
Arable soil (180 days)	2.51×10^{-3}	0.0224
Grassland (180 days)	1.00×10^{-3}	0.0089

The calculated ratios for terrestrial organisms are <1 indicating an acceptable risk for the terrestrial ecosystem.

Conclusion

The calculation of PECs without taking into account degradation processes (requirement in the TWA Guidance document) results in a slight risk (PEC/PNEC 1.34) for arable soil at a soil depth of 20 cm after a single sludge application. However the standard calculation according to the TGD taking into account degradation processes results in an acceptable risk for the soil compartment.

Therefore the risk is considered to be acceptable and no risk mitigation measures are needed.

Ground surface: unpaved soil

The local PEC in soil (see Doc. II B – chapter 5.2.5 PEC in soil) has been determined at a leaching distance of 10 cm. In a refined approach higher leaching distances up to 50 cm soil depth were considered.

Table 2.2.2.5-5: PEC/PNEC ratios for the terrestrial compartment direct exposure

	PEC_{soil} (mg/kg_{dwt})	**PEC/PNEC**
	$PNEC_{soil}$: 0.112 mg/kg $soil_{dwt}$	
Soil depth 10 cm	0.133	**1.2**
Soil depth 20 cm	0.067	0.6
Soil depth 30 cm	0.044	0.4
Soil depth 40 cm	0.033	0.3
Soil depth 50 cm	0.027	0.24

A slight risk to soil organisms at a soil depth of 10 cm was identified, since a PEC/PNEC ratio of 1.2 was calculated.

However it is questioned if this soil depth should be considered relevant for substances like fatty acids, which adsorb very weakly onto soil (K_{oc} values for Nonanoic acid are 63.1 and 100.0 L/kg) and are therefore transported rapidly through soil.

Furthermore, if the rapid degradation (DT_{50} for Nonanoic acid 2.1 days at 12°C) is applied to the calculated PEC at a soil depth of 10 cm, it can be seen that under environmentally relevant conditions the calculated risk for soil organisms will only last for less than one day.

Conclusion

The risk is considered to be acceptable and no risk mitigation measures are needed.

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

The risk characterisation for primary and secondary poisoning was done by comparing the PECs of the compartments with the relevant PNECs. As the TGD does not give a detailed guidance for derivation of an acute $PNEC_{oral}$, an acute risk assessment referring to LD_{50} and LC_{50} –values and a reverse reference calculation was performed also.

Primary poisoning

Non-target vertebrates (mammals and birds) may be exposed by direct consumption of the biocidal product "Katzenschreck", because it is applied to the soil surface. As "Katzenschreck" is a granular formulation consisting on pumice stone, it could be ingested intentionally by birds when searching for grit. As mammals do not feed on pumice stone at all, no risk is expected.

Acute primary poisoning

In a first tier scenario, a worst case estimation, it is assumed that the feed of non-target animals consists to 100% of the product. The calculation shows that no risk could be indicated even if birds feed on the 3.5-fold daily food requirements.

A second way to express the risk to birds is to calculate the number of granules that have to be taken up to cause an effect (reverse reference calculation). This calculation shows that birds can consume ca. 88000 (comparison based on the LD_{50}) up to 1671717 granules which are about ½ kg (comparison based on the LC_{50}) without causing effects. Both calculations indicate an extremely low risk.

So an acute risk to birds resulting from the use of Nonanoic acid according to the intended use can be excluded.

Long-term primary poisoning:

Table 2.2.2.5-6: ETE and PEC/PNEC ratios for long term primary poisoning

Exposure scenario	PEC or ETE		PECor ETE/PNEC
	$PNEC_{oral\ chron}$ 0.816 mg/kg bw/day		
First tier:	Tree sparrow:	691 mg/kg bw/day	**847**
Second tier:	Tree sparrow:	8.8 mg a.s./kg bw/day	**10.7**
	Chaffinch:	9 mg a.s.kg bw/day	**11**
	Woodpigeon:	1.5 mg a.s./kg bw/day	**1.8**
	Pheasant:	0.8 mg a.s./kg bw/day	0.9

In a worst case estimation (tier 1) it is assumed that the feed of non-target birds consists to 100% of the product over a long time period. In this approach, the PEC/PNEC ratio indicates a risk, so a refined assessment was done as a tier 2 evaluation, taking into account more realistic conditions: Granules consisting on pumice stone are therefore not used for nutrition purposes of birds, but they could be ingested intentionally by birds when searching for grit, but only as a small component of the daily food ingestion. Furthermore, the intended use implies no large area-application and tier 2 also estimates the daily uptake per day related to the body weight, which is the more relevant figure. As the particle size of the granules is very small, only little birds will use them for grit. So the risk calculation for sparrows and finches

are listed in the table above, indicating that the risk of primary poisoning is not acceptable when Nonanoic acid is incorporated for grit. Further refinements in a tier 2 step indicate still a risk when Nonanoic acid is incorporated as grit by birds, especially by small birds.

Although the refinements done, the risk assessment is still conservative because

- The $PNEC_{oral\ chron}$ is derived from studies where at the maximum test concentration no effects could be seen.
- The $PNEC_{oral\ chron}$ is based on EC_{50} values and not on NOECs (but no mortalities or any other effects could be observed at the maximum test concentration).
- Nonanoic acid is a fatty acid. Fatty acids are important naturally occurring biological molecules, found in all living organisms. They may be regarded as having fundamental roles (i.e. they are the building blocks of structurally important molecules in cellular membranes and also serve as sources of energy for biological systems). Thus no negative effects would be expected in concentrations higher than the concentrations tested and used for risk assessment accordingly.
- No degradation or volatilisation of the a.s. is taken into account.
- "Katzenschreck" is not applied constantly all over the year which is also not taken into account.
- Second tier ETE is calculated assuming that 50% of the grit comes from a treated and 50% of the grit comes from an untreated area. As the area treated with "Katzenschreck" is very small and the use limited, it is most likely that the fraction of the diet deriving from a treated area is far less than 50%.
- Second tier ETE is calculated assuming that all of the grit uptake on treated areas consists on treated pumic stone only. Birds with will also pickup other soil particles in all varieties and different sizes, so the risk is lowered further.

Considering the results of the qualitative risk assessment and summing up all the arguments above, the acute and long term risk of primary poisoning for birds could be regarded acceptable and no risk mitigation measures are needed.

Secondary poisoning

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

Table 2.2.2.5-7: PEC/PNEC ratios for non compartment specific effects (secondary poisoning)

Exposure scenario	PEC	PEC/PNEC
	$PNEC_{oral\ chron}$ 0.331 a.s. mg/kg diet	

Aquatic food chain:	1.96 mg a.s./$kg_{wet\ fish}$	**5.9**
Terrestrial food chain_	2.23 mg a.s./$kg_{wet\ earthworm}$	**6.7**
	(additionally, degradation considered) 0.03335 mg a.s./$kg_{wet\ earthworm}$	0.1

The PEC/PNEC ratio for secondary poisoning calculated for the aquatic and terrestrial food chain as well indicate that a risk would be possible. Although the values are greater than 1, the risk can be seen as acceptable for the following reasons:

- The $PNEC_{oral\ chron}$ is derived from studies where at the maximum test concentration no effects could be seen. So the $PNEC_{oral\ chron}$ is based on EC_{50} values and not on NOECs.

- Nonanoic acid is a fatty acid. Fatty acids are important naturally occurring biological molecules, found in all living organisms. They may be regarded as having fundamental roles (i.e. they are the building blocks of structurally important molecules in cellular membranes and also serve as sources of energy for biological systems). Thus in predators no negative effects would be expected in concentrations higher than the concentrations tested and used for risk assessment accordingly.

- The $PEC_{oral,predator}$=1.96 mg a.s./$kg_{wet\ fish}$ and $PEC_{oral,predator}$=0.35 mg/$kg_{wet\ earthworm}$ is calculated as very worst case, because the BCF is based on the P_{ow} only, not taking into account the metabolism of the substance and that Nonanoic acid is readily degradable.

- The PEC_{water} is based on the assumption that 400 households use the product on the same time and that immediately after application a heavy rain starts, which is almost unlikely. Furthermore, the scenario considers a continuous entry in surface water whereas the release of Nonanoic acid is intermittend according to the intended use. Also a dilution factor of 10 in surface water is very conservative, not taking into account degradation or volatilisation of the a.s. in water.

- The PEC_{soil} does not consider the weak adsorption of the substance onto soil and also the rapid degradation (DT_{50} for Nonanoic acid 2.1 days at 12°C). Under environmentally relevant conditions no risk is indicated as demonstrated in an additional calculation.

Considering all the arguments above, the risk for fish eating and worm eating predators as well is considered to be acceptable.

2.2.3. List of endpoints

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

3. DECISION

3.1. Background to the Decision

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

3.2. Decision regarding Inclusion in Annex I

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

Common names:	Nonanoic acid, Pelargonic acid
IUPAC name:	Nonanoic acid
CAS No.:	112-05-0
EC No.:	203-931-2
Minimum degree of purity of the a.s.:	89.6%w/w
Product types:	Repellents and attractants (product-type 19)
Specific provisions:	No special provisions are required.

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

Member states have to take into account at product authorisation stage that the original intended use (e.g. protection of birds, prevention of territory marking) was not supported by data. If the original product efficacy claims should be restored at this stage, the applicant should therefore have to submit respective data at the stage of national product authorisation.

Member states have to take into account at product authorisation stage that weather conditions can influence efficacy.

3.4. Requirement for further information

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

3.5. Updating this Assessment Report

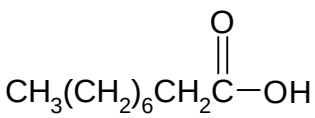
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any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

Appendix I: List of endpoints

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

Active substance (ISO Common Name)	Nonanoic acid
Product-type	19

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
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%))
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 (Pam^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)
Hydrolytic stability (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.
Dissociation constant	pK_a=4.9 at 20°C (Nonanoic acid (92.0%))
UV/VIS absorption (max.) (if absorption>290nm state ε at wavelength)	There is no absorption max. above 290 nm.
Photostability (DT_{50}) (aqueous, sunlight, state pH)	Photolysis can be excluded, since there is no adsorption above 290 nm.
Quantum yield of direct phototransformation in water at Σ>290nm	---
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	Xi; R38-R41
with regard to fate and behaviour data	---
with regard to ecotoxicological data	---

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 Draft Proposal for Revision of TNsG on Data Requirements, Chapter 2, Point 4 "Analytical Methods for Detection and Identification"
Air (principle of method and LOQ)	GC/FID method
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 NOAEC / LOAEC	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
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)	>10 mg/kg bw/day	Rat subacute gavage study	100
Local-oral short, medium and long term AEC (acceptable exposure concentration)	1%	Rat subacute gavage study	3.2

Acceptable exposure scenarios (including method of calculation)	
Professional users	Not relevant.
Production of active substance	Not relevant.
Formulation of biocidal product	Not relevant.
Intended uses	Please see Appendix II of this document
Non-professional users	Application of the product, dermal exposure (Scenario “Impregnated grains and pellets, application phase, dermal” as presented in “Human Exposure to Biocidal Products User guidance version 1”, chapter “Human Exposure to Rodenticides (Product Type 14)”)
Secondary exposure	Estimations are based on the respective scenarios in “Human Exposure to Biocidal Products User guidance version 1”, chapter “Human Exposure to Rodenticides (Product Type 14)”, as well as “Technical Notes for Guidance on Human Exposure to Biocidal Products”, Part 3, chapter “7.2 Rodenticide”: – An infant/child is playing outside at the site of application, crawling on the soil and touching the granules with its hands, resp. hands, legs and feet, Model "Impregnated grains and pellets, appl. phase" – An infant/child is licking its hands after dermal contact with the granules, Model “Transient mouthing”, "all of the product that ends up on the hands is taken in orally" – An infant ingests 5 grams of the granules, Model "Impregnated grains and pellets, use phase"

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 o 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 and 3 days in two different soils; n=2 DT_{50lab} (20°C, aerobic) Nonanoic acid: approx. 1.1 days
	DT_{90lab} (20°C, aerobic): Neudosan (C14-C20 fatty acids): approx. 8 - 10 days DT_{90lab} (20°C, aerobic): Nonanoic acid: approx. 1.8 days
	DT_{50lab} (10°C, aerobic): ---
	DT_{50lab} (20°C, anaerobic):----
	degradation in the saturated zone:----
Field studies (state location, range or median with number of measurements)	DT_{50f}:---
	DT_{90f}:----
Anaerobic degradation	---
Soil photolysis	---
Non-extractable residues	---
Relevant metabolites - name and/or code, % of applied active ingredient (range and maximum)	---
Soil accumulation and plateau concentration	---

Adsorption/desorption

Ka, Kd	K_{oc}: 63.1 L/kg (using methanol/pure water)
Ka_{oc}, Kd_{oc}	K_{oc}: 100.0 L/kg (using methanol/buffer solution pH 4)
pH dependence (yes/no) (if yes, type of dependence)	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 (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

Nonanoic acid is intended to be used in the biocidal product "Katzenschreck" (granules containing Ammonium nonanoate corresponding to 0.2%w/w Nonanoic acid) which is to be applied as repellent (product type 19) outdoors via spreading directly from the sachet. The category of users is designated as general public. Although the biocidal product does not act as a repellent sensu stricto – cats are not driven away from the treated area – the behaviour of cats is modified such that defecation is massively reduced in treated areas. Thus, the field of use is to inhibit defecation by domestic cats in backyards, terraces, sand tables and other places where children play.

The acceptable applications of the repellent "Katzenschreck" on which the risk assessment is based can be summarised as listed in table II-1.

Table II-1: Acceptable use of the repellent "KATZENSCHRECK"

PT	Formulation		Field of use envisaged	Likely amount at which the a.s. will be used				
	Type	Conc. of a.s.		Method	Applied amount of product	Number treatments /year	Typical size of application area	g a.s./m^2
PT 19	GR	0.2% (w/w)	Inhibition of defecation by domestic cats	Spreading directly from the sachet	10 g/m^2	10	50 m^2	0.02 g a.s./m^2

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:

Section No / Reference No	**Year**	**Title** **Source (where different from company)** **Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
A2.10/01	2006a	EXPOSURE ASSESSMENT FOR HUMAN HEALTH FOR THE ACTIVE SUBSTANCE PELARGONIC ACID AND THE BIOCIDAL PRODUCT KATZENSCHRECK TB-Agrartechnik Service, A-2540 Bad Vöslau, Austria Report-No. 0601NEU-02 Unpublished	Y	W. Neudorff GmbH KG
A2.10/02	2006b	ENVIRONMENTAL EXPOSURE ASSESSMENT FOR THE ACTIVE SUBSTANCE PELARGONIC ACID AND THE BIOCIDAL PRODUCT KATZENSCHRECK TB-Agrartechnik Service, A-2540 Bad Vöslau, Austria Report-No. 0601NEU-01 Unpublished	Y	W. Neudorff GmbH KG
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	W. Neudorff GmbH KG
A3.1.1/01	2000a	MELTING TEMPERATURE OF NONANOIC ACID Arbeitsgemeinschaft GAB Biotechnologie GmbH &	Y	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)	Owner
		IFU Umweltanalytik GmbH, D-75223 Niefern-Öschelbronn Report-No. 20001414/01-PCMP GLP, Unpublished		
A3.1.2/01	2000b	BOILING TEMPERATURE OF NONANOIC ACID Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, D-75223 Niefern-Öschelbronn Report-No. 20001414/01-PCBP GLP, Unpublished	Y	W. Neudorff GmbH KG
A3.1.3/01	2000c	REALATIVE DENSITY OF EMERY 1202/PELARGONSÄURE Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, D-75223 Niefern-Öschelbronn Report-No. 20001276/01-PCRD GLP, Unpublished	Y	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	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	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	W. Neudorff GmbH KG
A3.3/01	1998	VERSUCHSBEZEICHNUNG NEU-01170-H-0-EC Not applicable	Y	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)	Owner
		Report-No. Not applicable Not GLP, Unpublished		
A3.4/01	2003a	UV-VIS SPECTRUM: E-1202 Source: Not stated Report-No. not stated Not GLP, Unpublished	Y	W. Neudorff GmbH KG
A3.4/02	2000d	INFRARED ABSORPTION-SPECTRUM OF EMERY 1202/PELARGONSÄURE Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, D-75223 Niefern-Öschelbronn Report-No. 20001276/01-PCIR GLP, Unpublished	Y	W. Neudorff GmbH KG
A3.4/03	2003b	NMR SPECTRUM: PELARGONIC ACID Source: Not stated Report-No. not stated Not GLP, Unpublished	Y	W. Neudorff GmbH KG
A3.4/04	2003c	MS SPECTRUM: PELARGONIC ACID Source: Not stated Report-No. not stated Not GLP, Unpublished	Y	W. Neudorff GmbH KG
A3.4/05	2006	NMR SPECTRUM: EMERY 1202 – PELARGONIC ACID Cognis Oleochemicals GmbH, 40551 Düsseldorf, Germany Report-No. not stated Not GLP, Unpublished	Y	W. Neudorff GmbH KG
A3.5/01	2006a	DETERMINATION OF THE WATER SOLUBILITY OF PELARGONIC ACID (EMERY 1202) Institut Für Biologische Analytik und Consulting IBACON GmbH, 64380 Rossdorf, Germany Report-No. 31571185 GLP, Unpublished	Y	W. Neudorff GmbH KG
A3.6/01	2006b	DETERMINATION OF THE DISSOCIATION CONSTANT OF PELARGONIC ACID (EMERY	Y	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)	Owner
		1202) Institut Für Biologische Analytik und Consulting IBACON GmbH, 64380 Rossdorf, Germany Report-No. 31572194 GLP, Unpublished		
A3.6/02	2006a	DETERMINATION OF THE DISSOCIATION CONSTANT OF AMMONIUM SALT OF PELARGONIC ACID (EMERY 1202) Institut Für Biologische Analytik und Consulting IBACON GmbH, 64380 Rossdorf, Germany Report-No. 31581194 GLP, Unpublished	Y	W. Neudorff GmbH KG
A3.7/01	2000e	SOLUBILITY OF EMERY 1202/PLARGONSÄURE IN ORGANIC SOLVENTS Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, D-75223 Niefern-Öschelbronn Report-No. 20001276/01-PSBO GLP, Unpublished	Y	W. Neudorff GmbH KG
A3.9/01	2000f	PARTITION COEFFICIENT OF NONANOIC ACID Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, D-75223 Niefern-Öschelbronn Report-No. 20001414/01-PCPC GLP, Unpublished	Y	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) Axiva GmbH of the Siemens Axiva GmbH & Co. KG, 65926 Frankfurt/Main, Germany Report-No. SI156-00 GLP, Unpublished	Y	W. Neudorff GmbH KG
A3.12/01	2000g	FLASH POINT OF EMERY 1202/PELARGONSÄURE	Y	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)	Owner
		Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, D-75223 Niefern-Öschelbronn Report-No. 20001276/01-PCFB GLP, Unpublished		
A3.13/01	2000h	SURFACE TENSION OF EMERY 1202/PELARGONSÄURE Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, D-75223 Niefern-Öschelbronn Report-No. 20001276/01-PCST GLP, Unpublished	Y	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	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	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 BioChem GmbH, Daimlerstr. 5b, D-76185 Karlsruhe Report-No. 05 50 40 107 GLP, Unpublished **Confidential Document**	Y	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)	Owner
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	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	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	W. Neudorff GmbH KG
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	W. Neudorff GmbH KG
A6.1.3/01	1998	THE BIOPESTICIDE MANUAL British Crop Protection Council, 1st edition, p. 25 Report-No. not applicable Not GLP, Published	N	--
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	--
A6.1.3/03	2004	AMMONIUM NONANOATE; NOTICE OF FILING A PESTICIDE PETITION TO ESTABLISH A TOLERANCE FOR A CERTAIN PESTICIDE CHEMICAL IN OR ON FOOD. FEDERAL REGISTER: MARCH 17, 2004,	Y	?

Section No / Reference No	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
		VOLUME 69, NUMBER 52 http://www.epa.gov/EPA-PEST/2004/March/Day-17/p553.htm		
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	Y	?
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	-
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	-
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	W. Neudorff GmbH KG
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	W. Neudorff GmbH KG
A6.2. non-sub	2000	THE NATURE OF DIETARY FATTY ACIDS AND THEIR NUTRIENT ROLE Source: Eco-Care Technologies Inc., Sidney, BC	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)	Owner
		V8L 5L6, Canada Report-No. Not applicable Not GLP, Published		
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	W. Neudorff GmbH KG
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	--
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 Not GLP; Published	N	--
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	--
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	--
A6.2/06 non-sub	2001	BIOCHEMISTRY FOR CLINICAL MEDICINE Source: Greenwich Medical Media LTD, London,	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)	Owner
		UK, pp. 85-109 Report-no. not applicable Not GLP; Published		
A6.2/07 non-sub	1983	BIOCHEMISTRY Source: Biochemistry, Addison-Wesley Publishing Company, pp. 471-503 Report-no. not applicable Not GLP; Published	N	--
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	--
A6.2/09 non-sub	2002	RESEARCH Source: Arch. Biochem. Biophys. Vol 404, pp. 136-146 Report-no. not applicable Not GLP; Published	N	--
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	W. Neudorff GmbH KG
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 Report-No. 321569 GLP, Unpublished	Y	W. Neudorff GmbH KG
A6.6.2/01	2001	EVALUATION OF THE ABILITY OF	Y	W. Neudorff

Section No / Reference No	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
		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		GmbH KG
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	Y	Mycogen Corporation Dow Agrosciences LLC Data Compen-sation Department 9330 Zionsville Road IN 46268-1054 Indianapolis US Companies with letter of access: The applicant W. Neudorff GmbH KG
A7.1.1.2.1/01	2002	READY BIODEGRADABILITY OF PELARGONIC ACID IN A MANOMETRIC RESPIROMETRY TEST INCLUDING 1ST AMENDMENT FROM JULY 2006 IBACON GmbH, Rossdorf, Germany Project 14737160, Report No.: 11841087 GLP, Unpublished	Y	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	Y	W. Neudorff GmbH KG

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A7.2.1/01	1990	TESTING THE BIOLOGICAL DEGRADABILITY OF NEUDOSAN IN TWO SOILS Biochem GmbH, Daimlerstr. 5b, D-7500 Karlsruhe 21, Germany Report-no. not stated Not GLP, Unpublished	N	W. Neudorff GmbH KG
A7.2.1/02	1986	FATE OF CAPRIC AND PELARGONIC FATTY ACIDS IN SOIL Unpublished Report Report-no. not stated Not GLP, Unpublished	N	W. Neudorff GmbH KG
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	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	Y	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	Y	W. Neudorff GmbH KG
A7.4.1.2/01-non-sub	1998	ACUTE IMMOBILISATION TEST DAPHNIA – *DAPHINA MAGNA* ACCORDING TO OECD GUIDELINE 202-I (1984) NEU 1170 H (22 %) BioChem Agrar, Labor für biologische und	Y	W. Neudorff GmbH KG

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		chemische Analytik, D-04451 Cunnersdorf Report No. 981048039 GLP, Unpublished		
A7.4.1.3/01-non-sub	1999	ALGAE GROWTH INHIBITION TEST *SCENEDESMUS SUBSPICATUS* OECD GUIDELINE 201 (1984) NEU 1170 H (22%) BioChem Agrar, Labor für biologische und chemische Analytik D-04451 Cunnersdorf Report No. 981048040 GLP, Unpublished	Y	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	W. Neudorff GmbH KG
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	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	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	W. Neudorff GmbH KG
A7.4.3.5.2/01	1999b	ASSESSMENT OF TOXIC EFFECTS OF NEU 1170 H ON AQUATIC PLANTS USING THE	Y	W. Neudorff

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		DUCKWEED *LEMNA GIBBA* ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Report No. 99024/01-AALG GLP, Unpublished		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	Y	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	Y	W. Neudorff GmbH KG
A7.5.3.1.1/01	1996	ACUTE ORAL TOXICITY STUDY IN BOBWHITE QUAIL WITH NEUDOSAN NEU NOTOX B.V., 's-Hertogenbosch , The Netherlands Report-no. 185052 GLP, Unpublished	Y	W. Neudorff GmbH KG
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	Y	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	Y	W. Neudorff GmbH KG

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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	Y	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	Y	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	W. Neudorff GmbH KG
Company statement	2007	GENERAL INFORMATION ON THE ACTIVE SUBSTANCE AND THE BIOCIDAL PRODUCT; active substance: Pelargonic Acid biocidal product: Katzenschreck W. Neudorff GmbH KG, Emmerthal, Germany Report-No. Not applicable (statement) Not GLP, Unpublished		W. Neudorff GmbH KG
Company statement	2006	MODE OF ACTION OF PELARGONIC ACID IN CAT REPELLENT PRODUCT W. Neudorff GmbH KG, Emmerthal, Germany Report-No. not applicable, statement Not GLP, Unpublished	N	W. Neudorff GmbH KG
Company statement	2008	CONFIRMATION: PELARGONSÄUREGEHALT IN ÄLTEREN UNTERSUCHUNGEN (PELARGONIC ACID CONTENT IN OLDER STUDIES) W. Neudorff GmbH KG, Emmerthal, Germany	Y	W. Neudorff GmbH KG

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		Report-No. not applicable, statement Not GLP, Unpublished		
Company statement	2008	MODE OF ACTION OF NONANOIC ACID (PELARGONIC ACID): W. Neudorff GmbH KG, Emmerthal, Germany Report-No. not applicable, statement Not GLP, Unpublished	N	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	W. Neudorff GmbH KG

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Anonymous	1998	PESTICIDE FACT SHEET (FOR PELARGONIC ACID, DATE ISSUED: JANUARY 1998 Source: US EPA Report-No.: Not applicable Not GLP, Published	N	--
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	--
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**	just EPA study summary, no letter of access from applicant available	?
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	?
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	--
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	just EPA study summary, no letter of access from applicant available	?

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		Submitted as A6.3.1/02		
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 GLP, Published Submitted as A6.6.1/02	just EPA study summary, no letter of access from applicant 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	?
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US EPA, Anonymous	1992	THE REREGISTRATION ELIGIBILITY DOCUMENT (RED) ON SOAP SALTS Source: US EPA Report-No.: Not applicable Not GLP, Published	N	--
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,	N	?

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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	published
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Basketter DA., Gerberick GF., Kimber I.	1998	STRATEGIES FOR IDENTIFYING FALSE POSITIVE RESPONSES IN PREDICTIVE SKIN SENSITIZATION TESTS	N	published

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ECETOC	2006	TOXICOLOGICAL MODES OF ACTION: RELEVANCE FOR HUMAN RISK ASSESSMENT Technical Report No. 99, July 2006	N	published
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Kreiling R., Hollnagel H.M., Hareng L., Eigler D., Lee M.S., Griem P., Dreeßen B., Kleber M., Albrecht A, Garcia C., Wendel A.	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	published
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Wahlberg JE, Maibach HI	1980	NONANOIC ACID IRRITATION - A POSITIVE CONTROL AT ROUTINE PATCH TESTING? Contact Dermatitis 6(2): 128-30	N	published
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"B3.1.1_01, B3.1.2_01; B3.1.3_01, B3.5_01, B3.7_01, B3.8_03, B3.12-01 Accelerated storage"	2006a	PHYSICO-CHEMICAL PROPERTIES OF THE FORMULATION KATZENSCHRECK AFTER ACCELERATED STORAGE AT 54°C FOR 2 WEEKS GAB Analisi S.r.l., Poggio Renatico (Ferrara), Italy Report No. 20065012/01-PCAS GLP, Unpublished	Y	W. Neudorff GmbH KG
B3.4/01	1998a	NEU 1170 H 22% - FLASH POINT BioChem GmbH, Daimlerstr. 5 b, D-76185 Karlsruhe Report No. 985040801A GLP, Unpublished	Y	W. Neudorff GmbH KG
B3.4/02	1998b	NEU 1170 H 22% - AUTO- IGNITION TEMPERATURE BioChem GmbH, Daimlerstr. 5 b, D-76185 Karlsruhe Report No. 985040801B GLP, Unpublished	Y	W. Neudorff GmbH KG
B3.6/01	2006b	POUR AND TAP DENSITY OF THE FORMULATION KATZENSCHRECK GAB Analisi S.r.l., Poggio Renatico (Ferrara), Italy Report No. 20065012/01-PCTD GLP, Unpublished	Y	W. Neudorff GmbH KG
B3.8/01	2006c	FRIABILITY/ATTRITION CHARACTERISTIC OF THE FORMULATION KATZENSCHRECK GAB Analisi S.r.l., Poggio Renatico (Ferrara), Italy Report No. 20065012/01-PCAT GLP, Unpublished	Y	W. Neudorff GmbH KG
B3.8/02	2006d	FLOWABILITY OF THE FORMULATION KATZENSCHRECK GAB Analisi S.r.l., Poggio Renatico (Ferrara), Italy Report No. 20065012/01-PCFL GLP, Unpublished	Y	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)	Owner
B4.1/01	2006e	DEVELOPMENT AND VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF THE CONTENT OF ACTIVE INGREDIENT IN THE FORMULATION KATZENSCHRECK GAB Analisi S.r.l., Poggio Renatico (Ferrara), Italy Report No. 20065012/01-PCVE GLP, Unpublished	Y	W. Neudorff GmbH KG
B 5.10.2/01	2006	EFFICACY OF NEUDORFF KATZENSCHRECK 618 070 PROOF OF PRINCIPLE REPELLENCE AGAINST CATS LHS Institut für Hygieneforschung und Schädlingsbekämfung in Labor und Praxis, Wr. Neustadt, Austria Report No. 2060717-R Not GLP, Unpublished	Y	W. Neudorff GmbH KG
B 5.10.2/02	2007	EFFICACY OF NEUDORFF KATZENSCHRECK REPELLENCE AGAINST CATS – FIELD TEST LHS Institut für Hygieneforschung und Schädlingsbekämfung in Labor und Praxis, Wr. Neustadt, Austria Report No. 20070516-N Not GLP, Unpublished	Y	W. Neudorff GmbH KG
B6.1.1/01	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	W. Neudorff GmbH KG
B6.1.2/01	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	W. Neudorff GmbH KG
B6.1.3/01	1997a	NEU 1170 H - ACUTE INHALATION TOXICITY BioChem GmbH, Daimlerstr. 5 b, D-76185 Karlsruhe, Germany Report No. 97 10 42 026	Y	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)	Owner
		GLP, Unpublished		
B6.1.3/02	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	W. Neudorff GmbH KG
B6.2.s/01	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	W. Neudorff GmbH KG
B6.2.e/01	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	W. Neudorff GmbH KG
B6.3/01	2000	ASSESSMENT OF CONTACT HYPERSENSITIVITY TO NEU 1170 H IN THE ALBINO GUINEA PIG (MAXIMISATION-TEST) Notox B.V, 's-Hertogenbosch, The Netherlands Report No. 274591 GLP, Unpublished	Y	W. Neudorff GmbH KG
B6.5/01	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	--
B6.5/02	Not stated	RTECS DATA BASE – RTECS NUMBER: BQ9625000 Source: RTECS Data Base Report-No. not applicable Not GLP; Published	N	--
B6.5/03	2003	HSDB DATA BASE – AMMONIUM HYDROXIDE CASRN: 1336-21-6	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)	Owner
		Source: HSDB Data Base, last revision date 14 FEB 2003 Report-No. not applicable Not GLP; Published		
B7.1/01	2003	NEU 1170 H, ANNEX III, POINT 9.6; CALCULATION OF PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUND WATER (PECGW) FOR PELARGONIC ACID USING THE MODEL SOFTWARE FOCUSPELMO 2.2.2 GAB Consulting GmbH, Lamstedt, Germany Report No. 105156-A3-0906-01 Not GLP, Unpublished	Y	W. Neudorff GmbH KG
B7.6.1/01	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	Y	W. Neudorff GmbH KG
B7.6.1/02	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	Y	W. Neudorff GmbH KG
B7.6.1/03	1996	ACUTE ORAL TOXICITY STUDY IN BOBWHITE QUAIL WITH NEUDOSAN NEU NOTOX B.V., ‘s-Hertogenbosch The Netherlands Report-No. 185052 GLP, Unpublished	Y	W. Neudorff GmbH KG

REFERENCE LIST: SUBMITTED ADDITIONAL LITERATURE

Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
EPPO	2002	ENVIRONMENTAL RISK ASSESSMENT SCHEME FOR PLANT PROTECTION PRODUCTS. CHAPTER 11. TERRESTRIAL VERTEBRATES (SPRAYED PRODUCTS, SEED TREATMENTS AND GRANULAR FORMULATIONS). Source: European and Mediterranean Plant Protection Organization Report-No. PP 3/11(2) Not GLP, Published	N	--
US EPA, Anonymous	1992	THE REREGISTRATION ELIGIBILITY DOCUMENT (RED) ON SOAP SALTS. SOURCE: US EPA REPORT-NO.: NOT APPLICABLE NOT GLP, PUBLISHED	N	--

Appendix IV-1: Standard terms and abbreviations

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

Stand. Term / Abbreviation	Explanation
A	ampere
Ach	acetylcholine
AchE	acetylcholinesterase
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
ADP	adenosine diphosphate
AE	acid equivalent
AF	assessment factor
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD_{50}	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
Ann.	Annex
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BAF	bioaccumulation factor
BCF	bioconcentration factor
bfa	body fluid assay

Stand. Term / Abbreviation	Explanation
BOD	biological oxygen demand
bp	boiling point
BP	Biocidal Product
BPD	Biocidal Products Directive
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathy
BSP	bromosulfophthalein
Bt	*Bacillus thuringiensis*
Bti	*Bacillus thuringiensis israelensis*
Btk	*Bacillus thuringiensis kurstaki*
Btt	*Bacillus thuringiensis tenebrionis*
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10^{-2})
°C	degrees Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DANN
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre

Stand. Term / Abbreviation	Explanation
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
d	day(s)
DES	diethylstilboestrol
DIS	draft international standard *(ISO)*
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation
DRP	detailed review paper *(OECD)*
$DT_{50(lab)}$	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
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
E_bC_{50}	median effective concentration, biomass
E_rC_{50}	median effective concentration, growth rate
EC_{50}	median effective concentration
ECD	electron capture detector
ED_{50}	median effective dose
EDI	estimated daily intake
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
ELISA	enzyme linked immunosorbent assay

Stand. Term / Abbreviation	Explanation
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm
EPMA	electron probe micro-analysis
ERL	extraneous residue limit
ESPE46/51	evaluation system for pesticides
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
FELS	fish early-life stage
FIA	fluorescence immuno-assay
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
GFP	good field practice

Stand. Term / Abbreviation	Explanation
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
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPS	global positioning system
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%)
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_S	Shannon-Weaver index
Ht	haematocrit
HUSS	human and use safety standard
I	indoor
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration or median inhibitory concentration 1
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
INT	2-p-iodophenyl-3-p-nitrophenyl-5-phenyltetrazoliumchloride testing method
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
IUCLID	International Uniform Chemical Information Database
iv	intravenous
IVF	*in vitro* fertilisation
k *(in combination)*	kilo
k	rate constant for biodegradation
K	Kelvin
Ka	acid dissociation constant
Kb	base dissociation constant
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient

Stand. Term / Abbreviation	Explanation
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
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
ln	natural logarithm
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
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

Stand. Term / Abbreviation	Explanation
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	□icrometer (micron)
MAC	maximum allowable concentration
MAK	maximum allowable concentration
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
MIC	minimum inhibitory concentration
min	minute(s)
MKC	minimum killing concentration
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
MMAD	mass median aerodynamic diameter
mo	month(s)
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
mp	melting point
MRE	maximum residue expected

Stand. Term / Abbreviation	Explanation
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MT	material test
MW	molecular weight
n.a.	not applicable
n-	normal (defining isomeric configuration)
n	number of observations
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometre
NMR	nuclear magnetic resonance
no, n°	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOE_rC	no observed effect concentration, growth rate
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances

Stand. Term / Abbreviation	Explanation
OEL	occupational exposure limit
OH	hydroxide
OJ	Official Journal
OM	organic matter content
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the acid dissociation constant
pKb	negative logarithm (to the base 10) of the base dissociation constant
PNEC	predicted no effect concentration (compartment to be added as subscript)
po	by mouth
POP	persistent organic pollutants
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})

Stand. Term / Abbreviation	Explanation
PPP	plant protection product
ppq	parts per quadrillion (10^{-24})
ppt	parts per trillion (10^{-12})
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	product type
PT(CEN)	project team CEN
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QA	quality assurance
QAU	quality assurance unit
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RA	risk assessment
RBC	red blood cell
REI	restricted entry interval
RENI	Registry Nomenclature Information System
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	revolutions per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
S	solubility
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship

Stand. Term / Abbreviation	Explanation
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SCAS	semi-continous activated sludge
SCTER	smallest chronic toxicity exposure ratio (TER)
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
S/L	short term to long term ratio
SMEs	small and medium sized enterprises
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STER	smallest toxicity exposure ratio (TER)
STMR	supervised trials median residue
STP	sewage treatment plant
t	tonne(s) (metric ton)
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
T_{25}	tumorigenic dose that causes tumours in 25 % of the test

Stand. Term / Abbreviation	Explanation
	animals
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TG	technical guideline, technical group
TGD	Technical guidance document
TID	thermionic detector, alkali flame detector
TDR	time domain reflectrometry
TER	toxicity exposure ratio
TER_I	toxicity exposure ratio for initial exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TNsG	technical notes for guidance
TOC	total organic carbon
Tremcard	transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TTC	2,3,5-triphenylterazoliumchloride testing method
TWA	time weighted average

Stand. Term / Abbreviation	Explanation
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UR	unit risk
UV	ultraviolet
UVC	unknown or variable composition, complex reaction products
UVCB	undefined or variable composition, complex reaction products in biological material
v/v	volume ratio (volume per volume)
vis	visible
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

Appendix IV-2: Abbreviations of Organisations and Publications

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

Abbreviation	Explanation
EWMP	European Wood Preservation Manufacturers
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System
GRIN	Germplasm Resources Information Network
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
ICBP	International Council for Bird Preservation
ICCA	International Council of Chemical Associations
ICES	International Council for the Exploration of the Seas
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organization for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee

Abbreviation	Explanation
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JECFA FAO/WHO	Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
MITI	Ministry of International Trade and Industry, Japan
NATO	North Atlantic Treaty Organization
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Center for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Program (USA)
OECD	Organization for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
OPPTS	Office of Prevention, Pesticides and Toxic Substances (US EPA)
OSPAR	Oslo Paris Convention (Convention for the Protection of the Marine Environment of the North-East Atlantic)
PAN	Pesticide Action Network
RIVM	Netherlands National Institute of Public Health and Environmental Protection

Abbreviation	Explanation
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SETAC	Society of Environmental Toxicology and Chemistry
SI	Système International d'Unitès
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UBA	German Environmental Protection Agency
UN	United Nations
UNEP	United Nations Environment Programme
WFP	World Food Programme
WHO	World Health Organization
WPRS	West Palearctic Regional Section
WTO	World Trade Organization
WWF	World Wildlife Fund