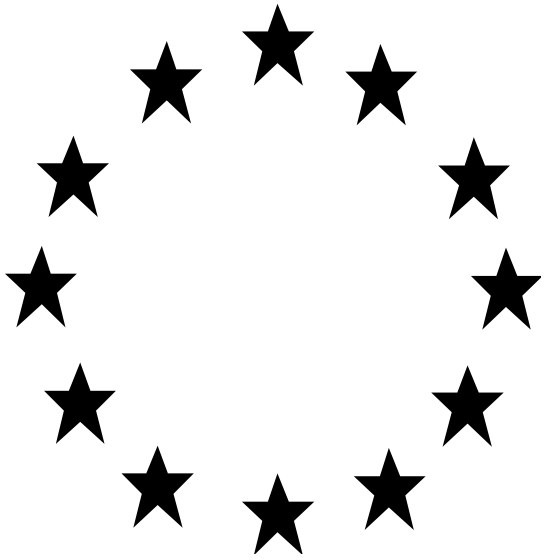


Draft Assessment Report (DAR)

- public version -

Initial risk assessment provided by the rapporteur Member State Spain for the existing active substance

RAPESEED OIL

of the fourth stage of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC

Volume 3, Annex B, part 4, B.8

September 2008

ANNEX B

RAPESEED OIL

B - 8 : ENVIRONMENTAL FATE AND BEHAVIOUR

B.8 Environmental fate and Behaviour

Overall conclusion

Rapeseed oil is a mixture of triglycerides of fatty acids, therefore the degradation, transformation and metabolism follows the same principle as they are generally described for fatty acids and lipids (IIA, 7.1.1.1.1/01).

Rapeseed oil is composed mostly by oleic acid (C18:1), linoleic acid (C18:2) and linolenic acid (C18:3). These fatty acids are frequently found in cellular structures (Table 8 -1 and IIA 7.1.1.1/02 /03 /05 /08).

Table 8-1: Structure of some fatty acids found in cells[1]

Strucuture	Systematic name	Common name
Saturated fatty acids		
$CH_3(CH_2)_{10}COOH$	*n*-Dodecanoic acid	Lauric acid
$CH_3(CH_2)_{12}COOH$	*n*-Tetradecanoic acid	Miristic acid
$CH_3(CH_2)_{14}COOH$	*n*-hexadecanoic acid	Palmitic acid
$CH_3(CH_2)_{16}COOH$	*n*-Octadecanoic acid	Stearic acid
$CH_3(CH_2)_{18}COOH$	*n*-Eicosanoic acid	Arachidic acid
$CH_3(CH_2)_{22}COOH$	*n*-tetracosanoic acid	Lignocerid acid
Unsaturated fatty acids		
Structure		Common name
$CH_3(CH_2)_5CH=CH(CH_2)_7COOH$		Palmitoleic acid
$CH_3(CH_2)_7CH=CH(CH_2)_7COOH$		Oleic acid
$CH_3(CH_2)_4CH=CHCH_2CH=CH(CH_2)_7COOH$		Linoleic acid
$CH_3CH_2CH=CHCH_2CH=CHCH_2CH=CH\ (CH_2)_7COOH$		Linolenic acid
$CH_3(CH_2)_4(CH=CHCH_2)_3CH=CH(CH_2)_3COOH$		Arachidonic acid

Besides, fatty acids can be found in the soil as result of the plant and soil metabolism (IIA 7.1.1.1.1/03, /06,/07/08), and they are expected to be non-toxic and biodegradable.

The public literature reveals that the degradation of fatty acids in soil is biologically mediated (IIA 7.1.1.1/01 /02 /03 /05 /08) Fatty acids are excellent substrate for microbial growth, serving both as carbon source and as energy source (IIA 7.1.1.1.1/05). Differences lipid composition in soil are probably related to differences in the requirement for fatty acids of the different soil microflora species and the plant ground materials (IIA 7.1.1.1.1/03 /06/07). The decomposition of typical lipids is influenced by soils properties to which they were added, as it is shown in the report IIA, 7.1.1.1.1/03.

Thus, in microbiology-active soils the rate of decomposition of C-18 lipid is expected to be high in soil wherein the microbiota is abundant and diversified.

[1] Darnell, J., Lodish H. and Baltimore, D. 1993. Molecular Cell Biology (Spanish edition). Ediciones Omega. Barcelona.

Two studies of the rate of degradation were submitted. The first one was carried out with Neudosan (IIA, 7.1.1.2.1/01) and second one with C9:0 and C10:0 (AII, 7.1.1.2.1/02). The two studies give a similar DT50 value, 3.0 days.

Neudosan (50% fatty acids potassium salt) is a PPP different of the one proposed for Annex I inclusion (triglyceride of fatty acids). According to the notifier, the results obtained can be extrapolated to the active substance, since the product is based on similar fatty acids. However, it should be highlight that the solubility of the salts of fatty acids is higher than the solubility in the triglycerides of fatty acids.

This fact can have an influence in the bio-availability and degradation rate of the active substance. Nevertheless, according to IIA; 7.1.1.1.1/01 in the case of lipids (glycerol esters of fatty acids) or waxes (Monoalcohol ester of fatty acids), enzymic hydrolysis can occur very readily., IIA, 7.1.1.1.1/03 reveals, however, that the rate of degradation of the fatty acids will depend on the soil properties and the fatty acid requirements of the microorganisms.

Fresh water algae, like marine algae, are also rich in fatty acid composition as demonstrated by reports 7.1.1.1.1/08, 7.2.1.3/01, /02, /03, /04, /05, /06, /07.

The ready biodegradation was demonstrated in Pelargonic Acid (C10:0) (IIA, 7.2.1.3.1/01). The test substance (C10:0) does not corresponds to the active substance (trygliceride of fatty acids).

According to the notifier, the degradation of fatty acids in water is similar in almost all respects to the degradation in soil. Water in its natural environment is a habitat for a wide variety of algae, bacteria, yeasts and fungi as well as higher organisms. Each of these organisms contain fatty acids as part of their cellular membranes and food reserves. They also metabolize the fatty acids to release energy for normal growth and development. However, with the information available it is not possible to extrapolate the information on the fate and behaviour to soil to the water compartment.

For active substances like Rapeseed oil, which represent a mixture of fatty acids, experimental determination of adsorption/desorption will not give reliable results. Alternatively, adsorption/desorption was calculated form the chemical structure (SAR determination) of the leading ester, i.e. oleic acid ester. This approximation sowed a Koc > 10.000 L/Kg . Taking this into account and based on the biodegradation of fatty acids in soil, no calculation of PEC (ground water) was done.

The predicted environmental concentrations were submitted for soil, surface water and sediment. The uses used for these calculation are

Ornamentals in glasshouse conditions: 3x 70.64 Kg ai /Ha; Interval between application: 7d
Orchards in filed: 1x 8.83 Kg ai/Ha m crown height (assuming 3 m)
Ornamental in field:1x 21.129 Kg ai /Ha

The calculations are given in the section 8.3.1 and 8.6.2

B.8.1 Route and rate of degradation in soil

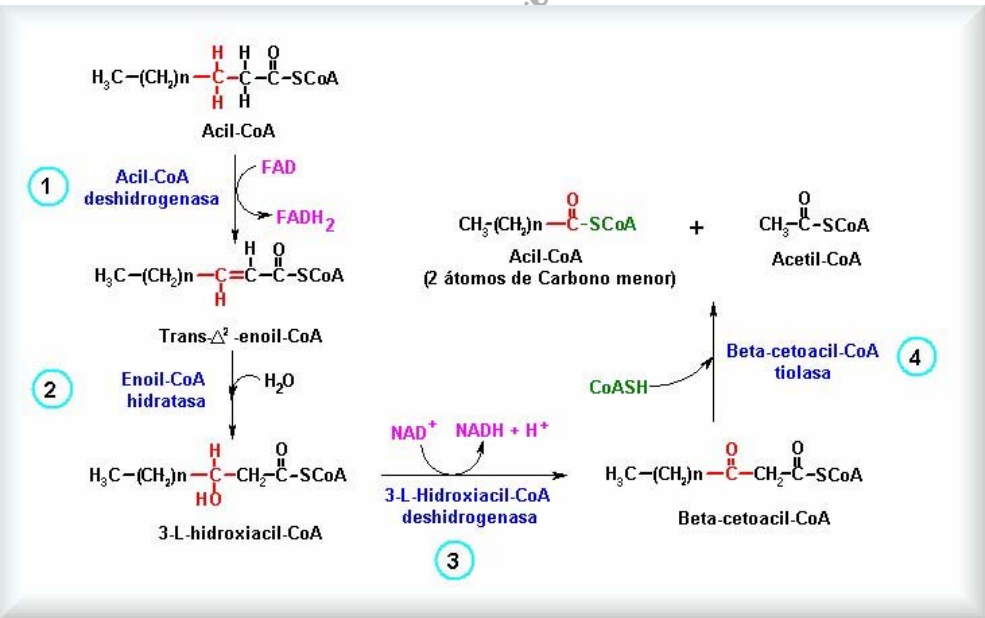
B.8.1.1 Route of degradation

B.8.1.1.1 Aerobic degradation studies

Report: Goring Clave, A.I and Hamaker, J.W 1972 . Annex point /reference IIA 7.1.1.1.1/01

Under aerobic conditions, degradation of fatty acids may occur by beta-oxidation, with a consequent chain-length reduction by multiples of 2-carbon units. The normal operation of the beta-oxidation system is common to all microorganisms and is shown in the figure below.

Figure 8.1.1.1-1: Reactions that take place during the beta-oxidation



Simple alkanoic and alkenoic acids undergo beta-oxidation readily.

Ester formation does take place with aliphatic carboxilic acids in microorganisms.

In soil, the only significant reaction of the ester group is hydrolysis reaction. The microbial hydrolysis of ester is catalysed by hydrolases. Many of these may be extracelullar as well as intracellular. Extracellular enzymes may not normally diffuse into soil environment. They can remain tightly bound

to the microoganisms either within the cell wall or on the outside of cytoplasmatic membrane. However, when the microorganisms are grown in solution culture substantial diffusion does occur and the enzymes can be isolated from these cultures. If the esters, are lipids (glycerol ester s of fatty acids) or waxes (monoalchol ester of fatty acids), enzymic hydrolysis can occur very readily. These compounds are among the most highly reduced substrates available to microogansims and, as such, are potential sources of energy.

Other degradation reactions mediated by soil microorganisms can occur in the hydrocarbon chain and are summarised as follows

1.- long chain fatty alkanoic acids and related compound also undergo ω-hydroxylation, i.e hydroxylation at the opposite end of the chain. Fatty acids and related compounds also undergo ω-1 hydroxylation. Where both ω and ω-1 positions are available for hydroxylation, the relative portions of the hydroxylation products depend upon the substrate chain length and to some extent on the nature of the polar terminal group.

The relative importance of beta-oxidation and ω or ω-1 hydroxylation depends upon the chain length of the acid. Implications are that acids longer that C16 –C18-alkanoic acids are near the optimum length for hydroxylation. Acids longer than this are largely (C19-C20) or completely (C22-C24) metabolised by beta-oxidation to a chain more favourable for hydroxylation. Acids shorter than C16 are too short for efficient hydroxylation and are largely metabolized by way of beta oxidation.

2.- Unsaturated aliphatic hydrocarbons serve as substrates for a wide variety of microorganisms. The molecule may be oxidised at a terminal methyl or methylen group, it may be oxidised at the double bond, multiple double bonds may be isomerised to conjugated systems, and double bonds may be reduced

Oxidative attack at a terminal methyl group appears to be the major degradation pathway for unsaturated aliphatic hydrocarbons. The corresponding ω-unsaturated acids and primary alcohols are products of this reaction.

Oxidation at the terminal methylene group and double bond of unsaturated aliphatic hydrocarbons can lead to a variety of products. Some of these reactions lead to cleavage of the molecule at the double bond., while others lead to the addition of an atom of oxygen or two hydroxyl groups to the ethylenic linkage

Assessment: The report describes the main reactions that can occur in the soil environment mediated by microorganisms.

The information is considered valid for understanding the possible route of degradation of the fatty acids that form part of the compostion of rapeseed oil

Report: Smith, J.H 1974. Annex point/reference IIA 7.1.1.1.1/02

The research was conducted to determine the decomposition rate of palm and soybean oils in soil to determine if large amounts of edible oil can be applied to soil without being toxic or hindering decomposition.

Materials and methods: Palm and soybean oils were added to portneuf silt loam at rates of 0.1; 0.5; 1.0 and 5.0 g of oil in 100 g of air dried soil (2.2; 11.2; 22.4 and 112 metric tons /ha, respectively). 20 ml of distilled water was added to each soil sample, equivalent to 80% of the soil moisture content of 1/3 atm tension, and an aeration fitting was installed in each bottle. The bottles were incubated at 26 ºC . The samples were continuously aerated with CO_2-free compressed air, and the air coming from the bottles was scrubbed in small bottles containing standard sodium hydroxide solution to remove CO_2 produced during the decomposition of the oil and soil organic matter. At appropriate intervals NaOH scrubbers were replaced and the Carbonate was precipitated with barium chloride, the excess of NaOH was tritated with standard sulfuric acid, and the amount of CO_2 evolved was calculated. All samples were incubated in triplicate.

Control samples containing no oil were used to determine soil organic decomposition and blank samples without soil or oil were also incubated. Nitrogen was added as ammonium nitrate at the rate of 1.25% of the weight of the added oil.

The incubations were continued for 12 weeks

Results: Both palm and soybean oils decomposed very rapidly in Portneuf silt loam. At each application, there were not differences between the two oils in their amount of decomposition for the 12 weeks. Maximum weekly decompostion was approximately 8 and 2.5 metric tons/ha for the 112 and 11.2 metric ton applications, respectively. There was not evidence for toxicity to the decomposition systems with the high application of oil . Decomposition percentages were 70, 76, 44 and 44 for the lowest to highest oil application rates based on 76% calculated C content

Assessment: The study demonstrates the degradation by soil microflora of fatty acids. The study is considered relevant for the evaluation.

Report: Moucawi J., Fustec, E. and Jambu, P. 1981. Annex point/reference IIA 7.1.1.1.1/03

The objective of this study was to investigate the extent of decomposition of total lipid extracts of plants in relation to the microbial activity in different soils upon which these plants were growing. The extent of decomposition of glucose and cellulose in the same soils were compared. Because of the complexity

and variability of the lipid fraction in plants and soils, the fate of pure oxygenated lipids was also studied. Most of the lipids chosen are commonly found either in the cuticular part of the higher plants or in the cellular material of microorganisms. Emphasis was placed on the effects of functional groups and chain length of the lipids on their decomposition in typical acid and non acid soils.

Test soils: The characteristics of the soils are given in table 8.1.1.1-1.

Table 8.1.1.1-1: Characteristics of the soils studied

Soil	pH	Clay %	OC %	Unbound lipids (mg/kg o.d soil)	Neutral unbound lipids (mg/kg o.d soil)	Acid unbound lipids (mg/kg o.d soil)	Polar unbound lipids (mg/kg o.d soil)
Rendzina	8.1	34.8	2.66	534	189 (35.4)	241 (45.1)	104 (19.5)
Brunic luvisol	6.5	21.2	1.23	230	ND	ND	ND
Glossic luvisol	4.1	13.5	6.99	3180	896 (28.2)	1706 (53.6)	578 (18.2)
Dystric histosol	4.1	13.3	12.38	3408	948 (27.9)	174.3 (51.1)	717 (21.0)

Figures in parenthesis represent the percentage of the total lipids

The plant ground materials sampled in the field were: chestnut leaves from the glossic luvisol and maize straw from the rendizina and the brunic luvisol. The amount of lipids in percent of dry matter was 4.2 in chestnut leaves and 2.0 in maize straw.

The amounts of lipids extracted from the acid and non acid soils were significantly different . Comparision between the rendizina and the glossic luvisol showed a significantly lower amount of free fatty monacids in the former soil (116 and 348 µg/g, respectively). Important differences were also found in the amounts of individual components , e.g. the amounts of *n*-C18 (18:0 and 18:1) and *n*-C28:0 fatty acids were 3.8 and 14.5 µg/g, respectively in the rendzina, whereas they were 14.8 and 53.6 µg/g, respectively in the glossic luvisol

The biodegradation experiments were done as follows:

After sieving, 100 g dried soil samples were weighed in 750 mL flasks. The substrates were thoroughly mixed with the soils and the mixtures adjusted to 2/3 of the water holding capacity of the soils. Controls and treatments were run in triplicate at 28 ºC for 30 d and continuously aerated in a closed system with moist CO_2 free air. The evolved CO_2 was collected in 0.2 N NaOH and determined regulary by tritation with $H_2 SO_4$ after addition of $BaCl_2$.

The results are expressed as evolved CO_2 (mg CO_2 100 g^{-1} oven dried soi)l. As the soils studied contained different amounts of total organic C, the results are also expressed as: carbon mineralization factor (Cm.f).

Cmf of control= 1000x (Cco_2 [mg]/Csoil[mg])

Cfm of tretment= 1000x (Cco_2 [mg]/(Csoil+Ctreatment[mg])

The estimated percent of substrate decomposition %= 100 x(Cco_2 of treatment-Cco_2 of control)/Csubstrate)

Results: Rendizina, and Brunic and Glossic luvisols were chosen to investigate their ability to degradate total lipid extracts from plant materials. These results were compared to those obtained for the rate of decomposition of glucose and cellulose. The decomposition of all substrates was highest in the brunic luvisol . However, no important differences between the soils were observed in the biodegradation of glucose and the lipids from maize straw. Conversely, the lipids extracted from chestnut leaves were readily decomposed only in the non acid rendzina and brunic luvisol. The biodegrdation of cellulose was slow with significant differences between the soil brunic luvisol> rendizina> glossic luvisol.

Table 8.1.1.1-2: Decomposition of glucose, cellulose and total lipid extracts of plants in different soils.

			Rendizina		
Treatment	**Weigh of added carbon (mg C/ 100g o.d soil)**	**Days**	**(mg CO_2/100g o.d soil)**	**Cmf**	**% Decomposition**
Control		8	65.2±0.9	6.7±0.1	
		30	174.3± 2.3	17.9±0.2	
Glucose	80.35	8	164.6±1.9	16.4± 0.2	33.9±0.1
Cellulose	905	8	193.2±4.5	14.8± 0.3	3.9±0.1
		30	484.2±12.2	37.0± 0.9	9.3±0.4
Lipids of chestnut leaves	122.8	8	102.8±0.3	10.1± 0.1	8.3±0.3
		30	304.7±7.9	29.9± 0.8	29.9±2.2
Lipids of maize straw	121.4	8	158.2±2.0	15.5± 0.2	20.8±0.6
		30	335.1±6.7	32.9± 2.0	36.2±2.0
			Brunic luvisol		
Treatment	Weigh of added carbon (mg C/ 100g o.d soil)	days	(mg CO_2/100g o.d soil)	Cmf	% decomposition
Control		8	30.1±0.8	6.7±0.2	
		30	84.0±5.4	18.6±1.2	
Glucose	80.35	8	147.8±1.2	30.8±0.3	40.1±0.7
Cellulose	905	8	128.5±3.2	16.4±0.4	3.0±0.1
		30	856.0±28.0	109.3±3.6	23.3±1.0
Lipids of chestnut leaves	122.8	8	76.2±0.5	15.4±0.1	10.3±0.3
		30	234.3±9.6	47.2±1.9	33.4±3.3
Lipids of maize straw	121.4	8	100.7±0.6	20.3±0.1	15.9±0.3
		30	251.7±4.1	50.8±0.8	37.6±2.1
			Glossic luvisol		
Treatment	Weigh of added carbon (mg C/ 100g o.d soil)	days	(mg CO_2/100g o.d soil)	Cmf	% decomposition

			Rendizina		
Treatment	**Weigh of added carbon (mg C/ 100g o.d soil)**	**Days**	**(mg CO_2/100g o.d soil)**	**Cmf**	**% Decomposition**
Control		8	117.5±3.5	4.6±0.8	
		30	363±7.9	14.2±1.8	
Glucose	80.35	8	216.5±3.4	8.3±0.7	33.7±2.3
Cellulose	905	8	137.8±4.1	4.8±0.5	0.6±0.2
		30	534.8±16.2	18.5±2.0	5.2±0.7
Lipids of chestnut leaves	122.8	8	131.2±1.9	5.0±0.4	3.1±1.2
		30	408.2±7.7	15.6±1.5	9.9±3.4
Lipids of maize straw	121.4	8	179.3±3.9	6.9±0.8	13.9±1.7
		30	491.7±9.0	18.9±1.8	28.8±3.8

The C.m.f measures the extent to which a soil can biodegrdade the organic C that it contains or is added to it. The values of C.m.f were significantly higher than those of the acid soils. The degradation of glucose was approx. the ssame in all soils as w3as the degradation of total lipids extracts of maize straw, which contained more fatas than waxes. Converserly, mopre complex dubdtrates, such cellulose and the ttotal-lipids extracts of chestnut leaves rich in waxes, were decomposed less rapidly in acid than non acid soils

The addition of pure stearic acid (*n*C18:0) was followed in non acid soils by an immediate and large evolution of CO_2, indicating rapid mineralization of the added substrate. In the acid soils (i.e glossic luvisol and dystric histosol) the rate of decomposition of the saturated *n*C18:0. was slow and a lag period was apparent, especially in the former soil. Conversely, the unsaturated *n*C18:1 oleic acid was rapidly decomposed in all soilsand there was little difference in the rate between the rendizina and the acid soils (Table 8.1.1.1-3).

The effect of the chain length of the fatty acids on the extent of biodegradation was illustrated by differences observed when the soils were supplemented with either stearic acid (*n*C18:0) or a longer chained fatty acid, such as montanic acid (*n*C28:0). In the soils supplemented with the montanic acid the C.m.f was similar to the corresponding controls whereas in the soils supllmented with stearic acid the C.m.f was significantly greater than in the controls.

Table 8.1.1.1-3: Decomposition of free fatty acids in different soils after 4 weeks at 28 ºC

Treatment	Rendzina	Brunic luvisol	Glossic luvisol	Dystric histosol
Control				
Total organic carbon (g C/100g o.d soil)	2.6	1.35	5.70	12.38
CO_2 evolved (mg CO_2/100g o.d soil)	188.3±3.6	85.6±6.1	249.9±4.3	213.1±5.0
Cmf	19.2±0.4	17.3±1.2	11.9±0.2	4.7±0.1
Stearic acid (151.99 mg C/100g o.d soil)				
Total organic carbon (g C/100g o.d soil)	334.7±11.4	259.6±7.8	271.7±3.4	245.5±
CO_2 evolved (mg CO_2/100g o.d soil)	32.3±1.1	47.1±1.4	12.7±0.2	5.3±
Cmf	23.6±2.7	31.2±2.5	3.9±1.4	5.1±
Oleic acid (153.07 mg C/100g o.d soil)				
Total organic carbon (g C/100g o.d soil)	373.4±12.2	318.2±8.6	381.1±14.2	356.2±
CO_2 evolved (mg CO_2/100g o.d soil)	**36.1±1.2**	**57.7±1.5**	**17.8±0.7**	**7.7±**
Cmf	33.0±2.8	41.4±2.6	23.4±3.3	24.8±
Montanic acid (158.35 mg C/100g o.d soil)				
Total organic carbon (g C/100g o.d soil)	200.2±8.0	91.2±3.1	239.4±1.6	222.0±4.1
CO_2 evolved (mg CO_2/100g o.d soil)	19.3±0.8	16.5±0.6	11.1±0.1	4.8±0.1
Cmf	2.1±2.0	0.9±1.6	*	0.2±1.6

* Total CO_2 evolved lower in the treatment than in control

The degradation of the stearyl stearate and the mono-, di- and triglycerids was also evaluated. The trends for the free and the esterified acid were similar although a definite inhibition was noted in the glossic luvisol when supplanted with stearyl stearate or with stearins. This inhibition was less pronounced in the dystric histosl. It is possible that a lag longer than 4 weeks is necessary for the microbes to adapt and decompose these esters in the glossic luvisol.

According to the authors, the decomposition of C-18 lipids and sterified stearic acid, appeared to depend primarily on the microbial activity of the soils. Oleic acid was the most rapidly degraded of the lipids studied, but the extent of its decomposition was dependant on the soil characteristics.

In microbiologically active soils, stearic acid was almost as easily utilized as was oleic acid (its relative extent of biodegradation was 75% of that of oleic acid in the brunic luvisol), whereas in acid soils, stearic acid was only weakly degraded (its relative extent of biodegradation was 20% of that of oleic acid in the dystric histosol). This phenomenon was probably related to differences between various groups of microorganisms in their requirements for fatty acids. For instance, under anaerobic conditions oleic acid is essential to the growth of some yeast species, whereas no growth is observed in the presence of stearic acid. In the dystric histosol, which is water logged in the field, the number of

yeast was high (84 x 10^3 g^{-1} o.d soil and did not vary during the incubation period). In the glossic luvisol, there was also a significant difference in the rates of biodegradation between oleic and stearic acid. Although the number of yeasts was not determined in this case, it was probably also high in this acid forest soil. Conversarly, in the non acid soils, where bacteria are predominant, such a discrepancy between saturated and unsataurated acids was not observed.

The rate of decomposition of C-18 lipid is expected to be high in soil wherein the microbiota is abundant and diversified, regardless of the structure of the lipids. In the acid soils, where the microbiota is probably less diversified and filamentous yeasts were abundant, the rates were lower

Conclusions: The decomposition of typical lipids was influenced by the physico-chemical factors of the soils to which they were added. In microbiology-active soils, such as the rendzine or brunic luvisol all compounds were easily degraded and to a similar extent (the difference did not exceed 25%). In acid soils, such as the glossic luvisol or dystric histosl, the rates and extent if biodegradation were always lower and were affected by the functional group and chain length of the lipids. Because of its effect on microbial activity of soil, pH appeared to be of major importance in the decomposition of lipids.

Assessment: the study is considered valid for the evaluation of the a.s

Report: Anonymous. 1992. Annex point/reference IIA 7.1.1.1.1/05

The US EPA has evaluated soap salts and published a reregistration eligibility document on this active ingredient. The Agency believes that these chemicals, when used as directed, will not persist in the environment. Thus it is regarded not necessary to conduct a specific study on the ready biodegradability of Rapeseed oil.

According to this summary, the half-life of fatty acids is less than one day in soil. Microbial metabolism of fatty acids has the effect of either converting the degradates to CO_2 (if used as an energy source) or converting the carbon content of the fatty acid to any of the thousands of naturally occurring organic substances produced by the soil microflora (if used as a carbon source). The active ingredient cannot totally dissipate from soil, because there is a natural content of fatty acids in soil resulting from plant metabolism or from formation by microbial organisms.

Assessment: The summary confirms the statement of the notifier. RMS did not have access to the original study for the evaluation

Report : Li, C.Y 1977. Annex pint reference IIA 7.1.1.1.1/06

The study was designed to compare fatty acids among forest types . The three forest types are represented In experimental plots of coastal Oregon: red alder (*Alnus rubra*, Bong), conifer and mixed

alder-conifer.

The upper 30 of soil, excluding litter, was collected from the five randomly selected sites around each of the three plots, 60 cm away from the randomly slected stems, in each f the three forest types. A sample was composited from the five sunbsamples of each plot and immediately sieved through a 10 mesh screen.

The extraction and analysis is summarised in chapter related to analytical methods.

Data from the three plots within each these three stands were subjected to analyses of variance. The mean levels of fatty acids for the three stands were further pairwise compared with Scheffé test

Results: Fatty acid composition was similar in all stands. The fatty acids compositions of soil lipids under these stands were qualitatively similar; concentration levels of several fatty acids differ significantly among stands. Oleic acid was the most abundant and constituted over 21% of the total fatty acids in all stands.

Table 8.1.1.1-4: Total lipids and fatty acid composition of soil under conifer, red alder and mixed alder-conifer stands

	Alder soil	**Conifer soil**	**Mixed alder-conifer**
Total lipids, % dry weight	**0.3a**	**0.2a**	**0.3a**
Composition of fatty acids, relative %			
Lauric	0.8b	0.6b	1.0a
Myristic	3.9a	2.3b	4.6a
Myristoleic	5.4a	3.9a	5.0a
Unknown 1	2.6a	Traceb	Traceb
Palmitc	19a	9.3c	13.0b
Palmtoleic	8.4a	7.8a	8.7a
Heptadecanoic	2.1a	1.6a	2.3a
Stearic	5.2a	2.9b	3.9ab
Oleic	21.0a	21.4a	23.4a
Linoleic	4.3a	4.9a	5.9a
Unknown 2	7.2a	6.6a	7.3a
Archidic	4.9a	7.7a	6.3a
Behenic	8.9a	14.2a	10.4a
Unknown 3	1.6a	1.4a	1.2a
Lignoceric	4.7b	15.4a	7.0b

a: average of three replicates;
b means within was not sharing a common postscriot differ significantly at 5% confidence level with e Schefflé test;
c Fatty acid less than 0.1%

According to the author, in addition to effects of vegetation of these forest types on soil lipid composition, soil microorganisms may have played a role in degrading soil lipids from dying plant tissue and dead residue to produce new lipids, which themselves differ in fatty acid composition. Thus the differences in soil lipid composition among the three stands are probably related to differences in the composition of the vascular vegetation as they affect the species composition of soil microflora.

Assessment: the information is considered valid.

Report: Metting, B., Rayburn W. 1979. Annex point reference IIA 7.1.1.1.1/07

A silt loam soil under a pine canopy from eastern Washington, U.S.A. was analyzed for the presence of algae, bacteria and fungi. The quantities of the microorganisms varied according to the location of the soil within the canopy and the date of sampling. Table 8.1.1.1-5 shows the actual amounts of the algae, bacteria and fungi isolated per gram of water-free soils. It is evident that these soils contained a significant amount of microorganisms. Within the algae, Metting and Rayburn identified thirteen genera belonging to three divisions. The greatest diversity was found at the mineral surface beneath the canopy.

Table 8.1.1.1-5: Viable counts of algae, bacteria, and fungi per gram of water-free soil (from Metting and Rayburn, 1979).

Soil microenvironment	Date (1976)	Algae x 10^3	Bacteria x 10^6	Fungi x 10^4
Mineral surface,	April 6	35.3	32.2	91.7
beyond canopy	June 13	124.4	114.4	204.2
	August 31	50.0	50.0	24.2
5 cm below surface,	April 6	10.7	36.0	49.7
beyond canopy	June 13	22.0	154.4	199.4
	August 31	13.6	36.2	35.6
Mineral surface,	April 6	92.0	61.7	60.0
beneath canopy	June 13	137.2	168.0	210.0
	August 31	16.6	21.3	23.8
5 cm below surface,	April 6	13.7	22.7	38.3
beneath canopy	June 13	20.8	90.0	210.3
	August 31	-	30.2	18.0

Assessment: The study give information of diversity of the soil microflora under a pine canopy . One of the major organic constituents common to all of these soil micro organisms are the fatty acids and their derivatives and supports the argument that fatty acids can be found in the soil as result of metabolism

Report: Wood 1974. Annex point/reference IIA 7.1.1.1.1/08

This document corresponds to a detailed review of the fatty acid composition in the various algal groups. Table 8.1.1.1-6 shows the different fatty acids in certain *Chlorophyceae*, *Prasinophyceae* and *Euglenophyceae*. The saturated fatty acids, especially C16 and the unsaturated C18's are the most prominent of the various fatty acid chain lengths.

Table 8.1.1.1-6: Fatty acids of certain Chlorophyceae, Prasinophyceae and Euglenophyceae*

		Fatty acid as % of total acid					
	Double bond	***Chlorella vulgaris***			***Chlorella pyrenoidosa***	***Scenedesmus obliquus***	***Scenedesmus quadricauda***
Acid	**positions**	**Fr.Au.****	**Fr.He.**	**Fr.He.D.(1) *****	**Fr.Au.(2)**	**Fr.Au.(2)**	**Fr.Au.(3)**
14:0	--	2	2	⊥	--	1	--
16:0	--	26	16	26	20--	35	14
16:1	9 and/or 7	8	14	11	3	2	2
16:2 16:2	6,9 9,12	⟩7	⟩6	⟩4	--	⟩⊥	1
16:3	6,9,12	2	⊥	--	7	†	2
16:4	6,9,12,15	--	--	--	--	15(Δ.4.7. 10.13)	(20)
18:0	--	2	3	4	--	--	--
18:1	9. etc.	2	30	18	46	8	6
18:2	9,12	34	26	36	10	6	14
γ18:3	6,9,12	--	--	--	--	--	1
α18:3	9,12,15	20	4	1	12	30	34
18:4	6,9,12,15	--	--	--	--	2	4
20:0	--	--	--	--	--	--	--
20:1	11. etc.	--	--	--	--	--	--
20:2	8,11	--	--	--	--	1	--
20:3	8,11,14	--	--	--	--	--	--
20:4	5,8,11,14	--	--	--	--	--	--
20:4	8,11,14,17	--	--	--	--	--	--
20:5	5,8,11,14,17	--	--	--	--	--	--
22:0	--	--	--	--	--	--	--
22:5	4,7,10,13,16	--	--	--	---	--	--
22:5	7,10,13,16,19	--	--	--	--		

* All genera listed in the table are members of the Chlorophyceae apart from Heteromastix (Prasinophyceae) and Euglena and Astasia (*Eugleno-phyceae*).

** Abbreviations: Fr, freshwater; Au, photoautotophic growth; He, Photoheterotrophic growth; D, dark heterotrophic growth; M, marine.

*** References: (1) Nichols 1965; (2) Klenk et al. 1963; (3) Shaw 1966; (4) Chuecas & Riley 1969; (5) Schlenk & Gellerman 1965; (6) Erwin & Bloch 1963.

⊥ detected in low amounts

Table 8.1.1.1-6: cont.

		Fatty acid as % of total acid				
	Double bond	**Enteromorpha compressa**	**Enteromorpha sp.**	**Spirogyra sp.**	**Heteromastix rotunda**	**Euglena gracilis**
Acid	positions	M(2).Wild	Fr(3).Wild	FR(3).Wild	M.Au.(4)	Fr.He.(6)
14:0	--	1	1(2% 14:1)	6	9	5
16:0	--	22	20	23	11	14
16:1	9 and/or 7	⊥ (2% 16:1Δ3)	2	6	16	3(+2% trans-Δ3-16:1)
16:2 16:2	6,9 9,12	⎫1	⎫3	⎫1	1 2	⎫8
16:3	6,9,12	2	1	4	3	(5)
16:4	6,9,12,15	15	14(Δ4.7.10.13)	8	1	⊥
18:0	--	--	⊥	1	--	6
18:1	9. etc.	8	8	12	2	5
18:2	9,12	5	4	7	3	11
γ18:3 α18:3	6,9,12 9,12,15	⎫26	⎫18	⎫17	-- 4	-- 15
18:4	6,9,12,15	9	16	4	9	--
20:0	--	--	--	--	--	⊥
20:1	11. etc.	--	⊥	⊥	--	--
20:2	8,11	--	⊥	⊥	--	(5)
20:3	8,11,14	2	⊥	⊥	--	⊥
20:4 20:4	5,8,11,14 8,11,14,17	⎫4	⎫⊥	⎫(1)	1 ⊥	⎫(8)
20:5	5,8, 11,14,17	2	(+20:6)3	(+20:6)4	28	(9)
22:0	--	--	--	--	--	--
22:5 22:5	4,7,10,13,16 7,10,13,16,19	⎫2	⎫3	22:x - 2%	2 5	⎫⊥

* All genera listed in the table are members of the Chlorophyceae apart from Heteromastix (Prasinophyceae) and Euglena and Astasia (*Eugleno-phyceae*).

** Abbreviations: Fr, freshwater; Au, photoautotophic growth; He, Photoheterotrophic growth; D, dark heterotrophic growth; M, marine.

*** References: (1) Nichols 1965; (2) Klenk et al. 1963; (3) Shaw 1966; (4) Chuecas & Riley 1969; (5) Schlenk & Gellerman 1965; (6) Erwin & Bloch 1963.

⊥ detected in low amounts

Table 8.1.1.1-6: cont.

		Fatty acid as % of total acid				
	Double bond	**Euglena gracilis z. strain (6)**			**Eugena gracilis var. bacillaris**	**Astasia**
Acid	**positions**	**Fr.He.D**	**Fr.He.**	**Fr.Au.(7)**	**Fr.He. longa**	**Fr.He.(7)**
14:0	--	13	7	7	13	10
16:0	--	13	15	14	14	18
16:1	9 and/or 7	5	6	6	4	1
16:2	6.9	--	--	--	--	--
16:2	9,12	--	--	--	--	--
16:3	6,9,12	--	--	--	--	--
16:4	6,9,12,15	--	Ã	16	--	--
18:0	--	2	7	1	7	2
18:1	9. etc.	9	7	10	8	4
18:2	9,12	3	5	4	3	1
γ18:3	6,9,12	--	--	--	--	--
α18:3	9,12,15	1	21	32	16	--
18:4	6,9,12,15	--	--	--	--	--
20:0	--	--	--	--	--	--
20:1	11. etc.	--	--	--	C20 to	C20 to
20:2	8,11	⎫			C24	C24
20:3	8,11,14	⎪			PUFA:	PUFA:
20:4	5,8,11,14	⎪			16	55
20:4	8,11,14,17	⎪ C20+C22+C24				
20:4	8,11,14,17	⎬ PUFA:				
20:5	5,8,11,14,17	⎪ 54	25	8		
22:0	--	⎪				
22:5	4,7,10,13,16	⎪				
22:5	7,10,13,16,19	⎭				

* All genera listed in the table are members of the Chlorophyceae apart from Heteromastix (Prasinophyceae) and Euglena and Astasia (*Eugleno-phyceae*).

** Abbreviations: Fr, freshwater; Au, photoautotophic growth; He, Photoheterotrophic growth; D, dark heterotrophic growth; M, marine.

*** References: (1) Nichols 1965; (2) Klenk et al. 1963; (3) Shaw 1966; (4) Chuecas & Riley 1969; (5) Schlenk & Gellerman 1965; (6) Erwin & Bloch 1963.

Table 8.1.1.1-6: cont.

		Fatty acid as % of total acid					
	Double bond	**Chlorella vulgaris**			**Chlorella pyrenoidosa**	**Scenedesmus obliquus**	**Scenedesmus quadricauda**
Acid	positions	Fr.Au.**	Fr.He.	Fr.He.D (1)***	Fr.Au.(2)	Fr.Au.(2)	Fr.Au.(3)
14:0	--	1	1	4	5	6	1
16:0	--	24	17	15	11	13	28
16:1	9 and/or 7	3	7	2	10	10	2
16:2 16:2	6,9 9,12	-- --	⊥ ⊥	3 4	-- 8	-- 3	⟩1
16:3	6,9,12	--	⊥	7	7	5	12
16:4	6,9,12,15	--	⊥	⊥	6	7	--
18:0	--	2	⊥	--	⊥	--	1
18:1	9. etc.	24	7	17	6	8	11
18:2	9,12	5	28	10	6	6	6
γ18:3 α18:3	6,9,12 9,12,15	6 31	1 ⊥	3 2 8	2 10	1 8	⟩27
18:4	6,9,12,15	--	19	1	7	8	2
20:0	--	--	⊥	--	⊥	--	⊥
20:1	11. etc.	2**	16	1	⊥	--	--
20:2	8,11	--	--	⊥	1	1	--
20:3	8,11,14	--	--	--	1	2	--
20:4 20:4	5,8,11,14 8,11,14,17	-- --	-- --	-- --	⊥ 2	⊥ 4	⟩3
20:5	5,8,11,14,17	--	--	--	10	10	2
22:0	--	--	--	--	⊥	1	3
22:5	4,7,10,13,16	--	⊥	--	--	--	--
22:5	7,10,13,16,19	--	--	--	⊥	6	--

* All genera listed in the table are members of the Chlorophyceae apart from Heteromastix (Prasinophyceae) and Euglena and Astasia (*Eugleno-phyceae*).

** Abbreviations: Fr, freshwater; Au, photoautotophic growth; He, Photoheterotrophic growth; D, dark heterotrophic growth; M, marine.

*** References: (1) Nichols 1965; (2) Klenk et al. 1963; (3) Shaw 1966; (4) Chuecas & Riley 1969; (5) Schlenk & Gellerman 1965; (6) Erwin & Bloch 1963.

⊥ detected in low amounts

B.8.1.1.2 Supplementary studies

Anaerobic degradation

Insecticides based on Rapeseed oil are recommended to be applied against spider mites, mealy bugs and scales. Anaerobic conditions are unlikely to occur. Therefore no studies under anaerobic conditions are required.

Photolysis study

According to the notifier, the degradation of Rapeseed oil in soil occurs very rapidly by microbial means, not through photolysis.

B.8.1.2 Rate of degradation in soil

B.8.1.2.1 Laboratory studies

Report: Süsser, P. 1990. Report nº: not stated. Annex point/reference AII, 7.1.1.2.1/01
Guidelines: BBA-Richtlinie IV 4-1 (Dez. 1986), Deviations: None.
GLP: conducted before GLP requirement.

Test Susbstance: Neudosan. The pesticide consists of 50% potassium salts of fatty acids.

Test soils:

Table 8.1.2.1-1: Soil characteristics

	Soil Series Name	
	Sandfeld	**Eisengrund**
Soil Property		
Particle size distribution (%)		
Sand	77.6	58.4
Silt coarse	5.6	17.2
Silt middle	4.3	7.8
Silt fine	4.6	7.8
Clay	7.9	8.8
Organic carbon (%)	0.8	1.7
Classification	"Braunerde" Loamy sand lS	"Braunerde" from an old river sediment Sandy loam sL

	Soil Series Name	
	Sandfeld	**Eisengrund**
pH ($CaCl_2$)	5.2	7.4 (calcareous)
Microbial biomass	25 mg C/100 g dry soil	50 mg C/100 g dry soil
Maximum water holding capacity (%)	22	28

Study design: Aliquots of 50 g of the wet soils were filled into 250 mL Erlenmeyer flasks. Two series were prepared. Each series consisted of at least 8 flasks, which were spiked with 100 mg Neudosan/kg soil. The spiking solution contained Neudosan dissolved in methanol (stock solution: 5 mg Neudosan/mL methanol). Each sample was spiked with 1 mL of the stock solution. The water content of the soils was held at 40% of the max. water capacity by periodically weighing and adding of H_2O deion. The soils were incubated at 20°C for up to 100 days.

Soil samples were taken on day 0, 2, 6, 13, 20, 33, 64, 100 for subsequent analysis and were stored at + 4°C.

Soil extraction: Soil extractions were carried out using the following solvent sequence:

a) 50 mL H_2O deion and 1 mL methanol (99.5%) added to soil to suppress excess foaming

b) 20 mL 1:5 diluted H2SO4 (95-97 %)

c) 100 ml toluene

d) The dry residue of the toluene-layer (50 mL) is redissolved in 5-8 mL toluene and evaporated to dryness by nitrogen

e) Residue redissolved in 2 mL toluene and evaporated by N_2

For derivatisation 100 µL Trimethylanilinehydroxide (TMAH) (0.1 M in methanol) were pipetted into the autosampler vials containing the residue. The residue was redissolved and the solution pipetted into a 200 µL autosampler vial.

Analytical method: The fatty acids were then analysed by gas chromatography using a flame-ionisation-detector. The derivatisation reaction needs 250°C and happens during the injection in the hot injection port.

A 100% reference standard contains only half of the spiked substance, this is 2.5 mg Neudosan/100 µL TMAH, since only half of the added toluene is withdrawn.

DT50/DT90 calculation: Two evaluation methods were used to describe the degradation of Neudosan. The first method was used to determine the absolute content of Neudosan in the soils using the sum of the peak areas of the six largest peaks.

The second method was used to document the changes in the peak area of the major component in relation to its peak area at day 0 (100%). Blanks (extraction of the unspiked soils) were determined for both soils and subtracted from the area values.

The decrease of the substances in the samples is described by an inverted growth curve. The calculations are made with the SPSS PC + statistical program package. Transformation of the growth curve formula gives the day, where 50% resp. 10% of the day 0 content can be determined.

Findings: The degradation behaviour of Neudosan using the areas of the largest peak (peak 4) and the peak area sum of the 6 largest peaks (peaks 1-6) are shown in the table below

Table 8.1.2.1-2: The degradation behaviour of Neudosan using the areas of the largest peak (peak 4) and the peak area sum of the 6 largest peaks (peaks 1-6) (average values)

Days	Eisengrund Neudosan		Sandfeld Neudosan	
	Peak 4 (rel. content %)	Peak area sum peak 1-6 (mg/50g soil)	Peak 4 (rel. content %)	Peak area sum peak 1-6 (mg/50g soil)
0	100.0	2.4	100.0	2.6
2	70.2	1.7	50.3	1.2
6	16.6	0.4	28.6	0.7
13	4.1	0.1	3.7	0.1
20	< 0.2	< 0.1	1.4	0.1
33	< 0.2	< 0.1	0.5	< 0.1
64	< 0.2	< 0.1	< 0.2	< 0.1
100	< 0.2	< 0.1	0.6	0.1

By comparing the chromatograms of a Neudosan reference standard and the internal standard Heptodecane acid (C 17), it is assumed that: Peak 1: C14 fatty acid; Peak 2 and 3: C16 fatty acids ,with different degree of saturation; Peak 4 and 5: C18 fatty acid, with different degree of saturation; Peak 6: C20 fatty acid

The major component of Neudosan (peak 4) was degraded in a few days in both soils. The evaluation with the peak area sum of the six largest peaks lead to the same result. The evaluation method also demonstrates that fatty acids are degraded very rapidly during the first 10 days of incubation. One possible way of degradation of the fatty acids is the shortening of the fatty acid chains by C2 pieces (ß-oxidation of the fatty acids).

The DT50 values are presented in Table .8.1.2.1-3

Table .8.1.2.1-3: DT50 for the main components of Neudosan

Endpoints	Eisengrund Neudosan		Sandfeld Neudosan	
	Peak 4	**peak 1-6**	**Peak 4**	**peak 1-6**
DT50 (20°C) (original data)	3	3	3	3
DT90 (20°C) (original data)	10	9	8	9
r^2 (original data)	0.98	0.98	0.98	0.98
DT50 (20°C) (recalculated by Notifier according to SFO)	2.8	2.8	2.8	2.5
DT90 (20°C) (recalculated by Notifier according to SFO)	9.3	9.4	9.1	8.3
r^2 (recalculated by Notifier according to SFO)	No given	No given	No given	No given

Assessment: Neudosan is a PPP different of the one proposed for Annex I inclusion (triglyceride of fatty acids). According to the notifier, the results obtained in a study conducted with "Neudosan" (50% fatty acids potassium salt) can be extrapolated to the active substance Rapeseed oil since the product is based on similar fatty acids.

Although, the identification of the fatty acids of Neudosan is not rigorous in the original report (it consists of assumptions based on the comparison of the Neudosan reference standard with the fatty acid Heptadecane acid (C17)), the study gives a general idea of the persistence of fatty acids in soil.

It should be highlight that the solubility of the salts of fatty acids is higher than the solubility in the triglycerides of fatty acids. This can have an influence in the bio-disponibility and degradation rate. Nevertheless, according to IIA; 7.1.1.1.1/01 if the esters, are lipids (glycerol ester s of fatty acids) or waxes (monoalchol ester of fatty acids), enzymic hydrolysis can occur very readily. These compounds are among the most highly reduced substrates available to microogansims and, as such, are potential sources of energy.

The information is considered valid.

Report: Mozol, V., Nijholt W.W., McHarg, D. 1986 Report nº: not stated. Annex point/reference AII, 7.1.1.2.1/02

Guidelines: No stated

GLP: conducted before GLP requirement.

Test substance: Decanoic (capric) acid – $C_{10}H_{20}O_2$ (CAS Number 334-48-5) ; Nonanoic (pelargonic) acid – $C_9H_{18}O_2$ (CAS Number 112-05-0)

Test soils: Soil collected from below lawn turf (10 cm) and sifted through 2 mm wire mesh was used with one portion sterilized at 125°C at 25 psi for 20 minutes. The pH of the lawn soil was 6.10. The soil was classified as sandy loam. To monitor moisture conditions during the experiment, dry weight determinations were made at intervals over a 3 week period.

Moisture tests indicated that the humidity of the soil environments was kept reasonably constant (Table .8.1.2.1-4).

Table 8.1.2.1-4: Moisture analysis of soil environments.

Time	Sample Number [1]			
	1	2	3	4
Start	13.7	11.9	19.1	18.0
Day 7	13.22	10.0	18.1	16.2
Day 14	13.0	10.3	18.6	16.3
Day 21	13.4	10.1	18.1	16.0

[1] 1. unsterilized soil, 2. sterilized soil, 3. unsterilized soil + 2% fatty acid salts, 4. sterilized soil + 2% fatty acid salts.
[2] % moisture based on differential dry weight measurement.

Study design: Recovery of fatty acids from soils was accomplished by leaching, extraction and GL chromatography analysis both from untreated and treated with a known amount of a fatty acid salt mixture. An amount of 40 g of a 2% solution (fatty acid salt mixture) was applied to 600 gm soil.

For the leaching procedure, 20 g of soil sample were placed on a coarse filter paper in a 100 mL Buchner funnel. Using vacuum suction, 200 mL of distilled water were washed over the soil and the leachate placed in a 500 mL separatory funnel (containing 10 mL CHC_{l3}) for extraction. Two consecutive amounts of 10 mL $CHCl_3$ were followed by two amounts of 10 mL CH_3OH and mixed with the soil for 2 minutes, then leached through and placed into another 250 mL separatory funnel (containing 100 ml distilled water) for extraction.

For the extraction procedure, the contents of the separatory funnels were acidified with one drop conc. H_2SO_4 and, after shaking, left to separate. Any cloudiness or emulsion was removed by direct addition of 2 - 4 mL CH3OH to the CHCl3 layer. The CHCl3 layer was drawn off and two additional extractions with 10 mL CHCl3 each, were performed. To the combined extracts 5 mL of 0.5% C11:1 (10-undecenoic acid) in CHCl3, was added as an internal standard.

Methylation of the sample aliquot was based on the method by Metcalfe et al. 1966. The $CHCl_3$ was evaporated and the residue transferred with petroleum ether to a 10 ml screw cap vial and the ether evaporated to dryness. After addition of 0.5 ml BF3/CH3OH (14%), the vial was tightly sealed and placed in boiling water for two minutes. Upon cooling 1 ml of hexane and 0.5 ml of distilled water were

added. The vial contents were shaken for 20 seconds and centrifuged. The top (hexane) layer was removed and used for G.L.C. analysis.

Results: The data given in Tables .8.1.2.1-5/6 and Figure 8.1.2.1-1 for total recovery of C9, C10 and C12 showed that the natural fatty acid content of sterilized and unsterilized soils was low compared to the fatty acid content of the treated soils. For both soils the major portion of the applied fatty acids (± 60%) complexed with the soil. Within 2 days the fatty acid content in the treated, unsterilized soil drastically decreased, and by day 10 the fatty acid content had dropped to almost its original level. The fatty acid content of the sterile soil remained high during this time, implying that the fatty acid degradation in the unsterilized soil was of a biological nature. This conclusion is supported by the literature referred to previously. After 20 days the fatty acid content in the treated sterile soil decreased as well indicating re-establishment of microbiological activity in this soil. The data revealed that the non-complexed fatty acids, from the water leach, degraded faster than the complexed acids. The order of degradation appears to be C9, C10, followed by C12, though the difference in rates was very slight.

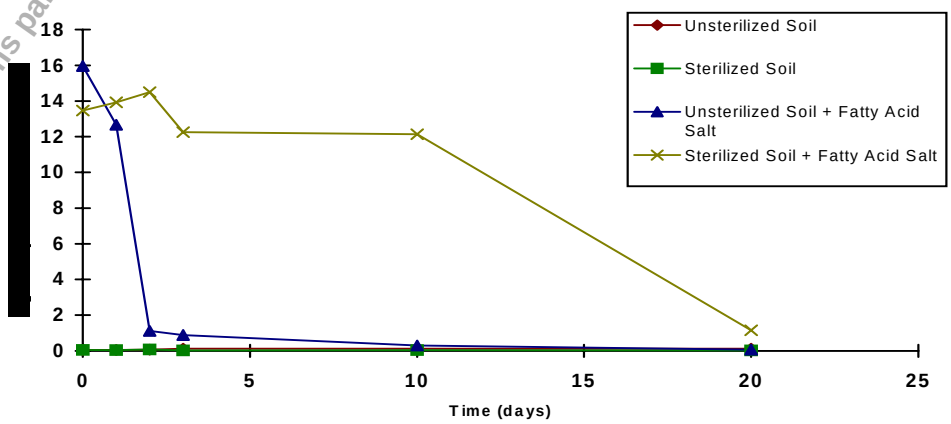
Table .8.1.2.1-5: Recovery of fatty acid from soil samples without treatment with fatty acid salts, after water leaching and $CHCl_3$ extraction.

		Amount of fatty acids found (mg/mL)							
		Unsterilized soil				**Sterilized soil**			
Time	Extract	C_9	C_{10}	C_{12}	Total	C_9	C_{10}	C_{12}	Total
Start	H_2O	-	0.004	0.005	0.009	-	-	0.008	0.008
	$CHCl_3$	0.007	0.010	0.020	0.037	0.013	0.016	0.016	0.045
	Combined	0.007	0.014	0.025	0.048	0.013	0.016	0.024	0.053
Day 1	H_2O	-	0.004	0.005	0.009	-	-	0.008	0.008
	$CHCl_3$	0.008	0.009	0.014	0.031	0.013	0.015	0.019	0.047
	Combined	0.008	0.013	0.019	0.040	0.013	0.015	0.027	0.055
Day 2	H_2O	-	0.004	0.005	0.009	-	0.005	0.011	0.016
	$CHCl_3$	-	0.029	0.036	0.065	0.007	0.018	0.024	0.049
	Combined	-	0.033	0.041	0.074	0.007	0.023	0.035	0.065
Day 3	H_2O	-	-	0.010	0.010	-	0.004	0.010	0.014
	$CHCl_3$	-	0.005	0.013	0.018	0.023	0.038	0.046	0.107
	Combined	-	0.005	0.023	0.028	0.023	0.042	0.056	0.121
Day 10	H_2O	-	-	0.010	0.010	-	0.004	0.008	0.012
	$CHCl_3$	-	-	0.025	0.025	0.008	0.047	0.050	0.111
	Combined	-	-	0.035	0.035	0.008	0.051	0.050	0.123
Day 20	H_2O	-	0.004	0.006	0.010	-	0.004	0.010	0.014
	$CHCl_3$	-	0.005	0.014	0.019	0.010	0.050	0.044	0.104
	Combined	-	0.009	0.020	0.029	0.010	0.054	0.054	0.118

Table 8.1.2.1-6: Recovery of fatty acid from soil samples with treatment with fatty acid salts, after water leaching and $CHCl_3$ extraction.

		Amount of fatty acids found (mg/mL)							
		Unsterilized soil with fatty acid salt solution added				Sterilized soil with fatty acid salt solution added			
Time	Extract	C_9	C_{10}	C_{12}	Total	C_9	C_{10}	C_{12}	Total
Start	H_2O	4.982	5.241	2.403	12.626	3.630	3.590	1.769	8.989
	$CHCl_3$	0.189	0.587	2.553	3.329	0.506	1.236	2.735	4.477
	Combined	5.171	5.828	4.956	15.955	4.136	4.826	4.504	13.466
Day 1	H_2O	1.455	2.850	2.011	6.316	3.923	4.172	2.024	10.119
	$CHCl_3$	1.468	2.848	2.037	6.353	0.516	1.049	2.252	3.812
	Combined	2.923	5.698	4.048	12.669	4.439	5.216	4.275	13.931
Day 2	H_2O	0.109	0.231	0.229	0.569	0.818	3.910	1.600	9.328
	$CHCl_3$	0.054	0.139	0.346	0.539	0.641	1.443	3.086	5.170
	Combined	0.163	0.370	0.575	1.108	4.459	5.353	4.686	14.498
Day 3	H_2O	-	0.043	0.201	0.244	3.240	3.797	1.799	8.836
	$CHCl_3$	-	0.103	0.541	0.644	0.501	1.091	1.905	3.425
	Combined	-	0.146	0.742	0.888	3.741	4.888	3.704	12.261
Day 10	H_2O	-	0.007	0.024	0.031	2.954	3.642	1.777	8.368
	$CHCl_3$	0.009	0.101	0.159	0.269	0.456	0.984	2.321	3.769
	Combined	0.009	0.108	0.183	0.300	3.410	4.626	4.098	12.137
Day 20	H_2O	-	0.007	0.270	0.034	0.021	0.051	0.099	0.171
	$CHCl_3$	-	0.008	0.025	0.033	0.045	0.143	0.799	0.987
	Combined	-	0.015	0.052	0.067	0.066	0.174	0.898	1.158

Figure 8.1.2.1-1: Combined recovery of C9, C10 and C12 fatty acids



Capric and pelargonic fatty acids were found to occur naturally in low concentrations in a typical sandy loam lawn soil. In the environment, a large percentage of applied capric and pelargonic acids complex with soil particles (100% for C9, 76.8% for c10). Degradation of capric and pelargonic acid proceeds very rapidly (within 2 days) in aerobic conditions. The slightly faster degradation rate of pelargonic acid suggests the less complexed acid molecule to be metabo0lised easier than capric acid by micro-organisms

Effects of leaching, adsorption and desorption by caprioc and pelargonic acid in a soil environment would be very minimal due to strong acid-soil particle interaction and acid biding to the upper portion of the soil . The effects of acid dissipation in the soil would be negligible due to the acid-soil affinity and rapid total degradation of capric and pelargonic acids.

Assessment: the study gives a general idea of the persistence of fatty acids in soil and their leaching behaviour. The study is considered as valid

B.8.1.2.2 Field studies

Further field studies are not required since biological degradation of Rapeseed oil occurs rapidly. Fatty acids are not residual enough to be taken up by second generation plants.

B.8.2 Adsorption, desorption and mobility in soil

B.8.2.1 Adsorption and desorption

For active substances like Rapeseed oil, which represent a mixture of fatty acids, experimental determination of adsorption/desorption will not give reliable results. Alternatively, adsorption/desorption was calculated form the chemical structure (SAR determination) of the leading ester, i.e. oleic acid ester.

Report: Tiemann 2005. Annex point/reference IIA, 7.1.2/01

The coefficient of adsorption/desorption on soil for oleic acid ester was estimated at 1 x 10^{10} using the model PCKOCWIN

Assessment: The results of this calculation are confirmed by the study AII, 7.1.1.2.1/02 (see point 8.1.2.1)

B.8.2.2 Mobility in soil

B.8.2.2.1 Column leaching studies

No information submitted. Refer to point 8.2.1

B.8.2.2.2 Aged residue column leaching

No information submitted. Refer to point 8.2.1

B.8.2.2.3 Lysimeter studies or field leaching studies

Further lysimeter studies and field leaching studies are not required due to the high coefficient of adsorption/desorption on soil for oleic acid. Refer to point 8.2.1

B.8.3 Predicted environmental concentrations in soil

NEU 1160 I is an emulsion concentrate containing 883 g Rapeseed oil/L. The recommended representative use for NEU 1160 I is presented in Table 8.3-1.

Table 8.3-1: Good agricultural practice (GAP) for NEU 1160 I

Crop and/ or situation / Country	Product name	Field, glasshouse or indoor use	Pests or group of pest controlled	Formulation		Application							PHI (days)	Remarks
				Type	Conc. of as (g/L)	Method kind	Growth stage & season	Number per growing season (max)	Interval between applications	kg as/hL	Water (L/ha)	kg as/ha		
Europe Representative use: Ornamentals	NEU 1160 I	Glass house (professional and home garden use)	Spider mites, mealy bugs, scales	EC	883	Knapsack sprayer and hand sprayer	When infestation is visible	3	7	1.766	2000 - 4000	35.32 - 70.64 (40-80 L* product/ha)	-	Effect: killing of adults
Europe Representative use: Orchards	NEU 1160 I	Field (professional and home garden use)	Eggs of spider mites	EC	883	Knapsack sprayer, motor sprayer, hand sprayer	start of vegetation up to mouse ear stage or bud swelling up to bud break	1	-	1.766	500 per m crown height	8.83 per m crown height (10 L product/ha and m crown height)	-	Effect: suppression of winter stages
Europe Representative use: woody ornamentals	NEU 1160 I	Field (professional and home garden use)	Eggs of spider mites	EC	883	Knapsack sprayer, motor sprayer; hand sprayer	Start of vegetation up to bud break	1	-	1.766	600-1200	10.596-21.192 (12-24 L** product/ha)	-	Effect: suppression of winter stages

* plant height < 50 cm: 40 L product/ha (2000 L water/ha), 50-125 cm: 60 L product /ha (3000 L water/ha), > 125 cm: 80 L product /ha (4000 L water/ha)
** plant height < 50 cm: 12 L product/ha (600 L water/ha), 50-125 cm: 18 L product /ha (900 L water/ha), > 125 cm: 24 L product /ha (1200 L water/ha)

B.8.3.1 Estimation of expected concentrations in soil.

Parent

To calculate the initial PEC in soil an even distribution of the compounds within a soil layer with a depth of 5 cm and a bulk density of 1.5 g/cm³ is assumed. The initial PEC values are calculated according to the following formula2 :

$$PEC_{ini,s} = A \text{ x } \frac{(1 - f_d)}{(100 \text{ x } depth \text{ x } bd)}$$

where

PECini,s= predicted environmental concentration in soil [mg/kg] immediately followin the last application

A = application rate [g/ha]

fd = fraction intercepted by crop canopy

depth = mixing depth (cm)

bd = bulk density (g/cm³)

The predicted environmental concentrations are calculated for several time points below as "actual concentration") using the formula:

$$\text{actual PEC}_{1\,(t)} = \text{PEC}_{ini,\,s} \cdot \left(e^{(-t \cdot \ln(2)/DT_{50})}\right)$$

In addition, the "time-weighted average concentrations" are calculated using the formula:

$$\text{twa PEC}_{1\,(t)} = \text{PEC}_{ini,\,s} \cdot \frac{DT_{50}}{t \cdot \ln(2)} \left(1 - e^{(-t \cdot \ln(2)/DT_{50})}\right)$$

where

actual PECl= actual concentration at time "t"

twa PECl = time-weighted average concentration

PECini = initial concentration

T= time period.

The twa PEC reflects the average concentration an organism would be exposed to within a given time period t.

For Rapeseed oil no data on degradation in soil are available. The natural oil mainly consists of C-18 fatty acids, i.e. oleic acid, which are practically insoluble in water. In soil, fatty acids are rapidly degraded, mainly by β-oxidation (refer to Annex IIA, point 7.1.1). In a study conducted with

[2] Guidance document on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment, Draft working document EC 7193/VI/99 rev.0, 09.08.1999

"Neudosan" (refer to Annex IIA, point 7.2.1/01), DT50 from two test soils was determined at 3 days. For the present risk assessment on NEU 1160 I, a half-life of 2.8 days was used (recalculated value).

NEU 1160 I is applied three times with an interval of 7 days between applications at a max. rate of 70.64 kg a.s./ha in ornamentals in the glasshouse (plant interception 25%). NEU 1160 I is also applied once at 26.49 kg a.s./ha in orchards with 3 m height (plant interception: 50%) and at 21.192 kg a.s./ha in ornamentals in the field (plant interception: 25%).

The initial PECs of NEU 1160 I of both crop scenarios is given in Tables 8.3.1-1, 8.3.1-2 and 8.3.3-3.

Table 8.3.1-1: Actual concentration and time-weighted average (TWA) PEC_s of NEU 1160 I in ornamentals (glass house)

Day	Application number	Days post application	PECs[1]	
			Actual concentration (mg a.s./kg)	TWA (mg a.s./kg)
0	1	-	70.64	-
1	-	-	55.15	-
2	-	-	43.06	-
4	-	-	26.24	
7	2	-	83.13	-
8	-	-	64.90	-
9	-	-	50.67	-
14	3	0	85.34	85.34
15	-	1	66.62	75.59
16	-	2	52.01	67.30
18	-	4	31.70	54.16
21	-	7	15.09	40.54
28	-	14	2.67	23.85
35	-	21	0.47	16.32
42	-	28	0.08	12.30
64	-	50	0.00	6.89
114	-	100	0.00	3.45
365	-	351	0.00	0.96

1 Assumption: use rate: 3 applications of 70.64 kg a.s./ha; interval of 7 days between applications, 25% interception by plants; bulk density of soil: 1.5 g/cm3; soil depth: 5 cm; DT50 = 2.8 days

The model calculation shows that the Rapeseed oil concentration in soil directly after 3 applications of 70.64 kg Rapeseed oil/ha will be 85.34 mg a.s./kg soil.

The Rapeseed oil concentration in soil declines by ca. 73% of the initial concentration 2 days after the last application which is equivalent to 52.01 mg a.s./kg. The time course for the average PECs is shown in Figure 8.3.1

Figure 8.3.1-1: Time course of the PEC of Rapeseed oil in soil (half-life 2.8 days) after 3 applications of NEU 1160 I

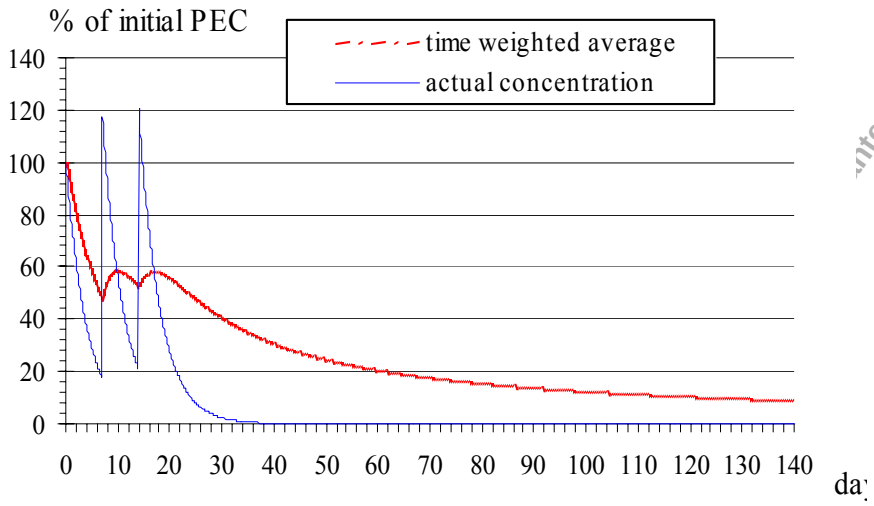


Table 8.3.1-2: Actual concentration and time-weighted average (TWA) PEC of NEU 1160 I in orchards

Day	Application number	PECs[1]	
		Actual concentration (mg a.s./kg)	TWA (mg a.s./kg)
0	1	17.66	17.66
1	-	13.79	15.64
2	-	10.76	13.93
4	-	6.56	11.21
7	-	3.12	8.39
14	-	0.55	4.94
21	-	0.10	3.38
28	-	0.02	2.55
50	-	0.00	1.43
100	-	0.00	0.71
365	-	0.00	0.20

[1]Assumption: use rate: 1 applications of 26.49 kg a.s./ha (corresponding to 3 m height); 50% interception by plants; bulk density of soil: 1.5 g/cm^3; soil depth: 5 cm; DT_{50} = 2.8 days

The model calculation shows that the Rapeseed oil concentration in soil directly after application of 26.49 kg Rapeseed oil/ha will be 17.66 mg a.s./kg soil.

The Rapeseed oil concentration in soil declines to ca. 61% of the initial concentration 2 days after application which is equivalent to 10.76 mg a.s./kg in orchards. The time course for the average PECS is shown in Figure 8.3.1-2

The model calculation shows that the Rapeseed oil concentration in soil directly after application of 21.19 kg Rapeseed oil/ha will be 21.19 mg a.s./kg soil.

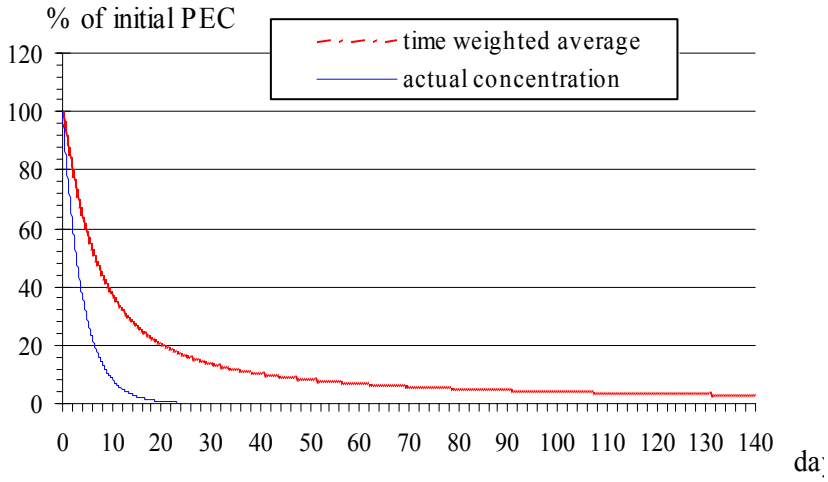
Table 8.3.1-3: Actual concentration and time-weighted average (TWA) PEC of NEU 1160 I in ornamentals (field)

Day	Application number	PECs1	
		Actual concentration (mg a.s./kg)	TWA (mg a.s./kg)
0	1	21.19	21.19
1	-	16.54	18.77
2	-	12.92	16.71
4	-	7.87	13.45
7	-	3.75	10.07
14	-	0.66	5.92
21	-	0.12	4.05
28	-	0.02	3.05
50	-	0.00	1.71
100	-	0.00	0.86
365	-	0.00	0.24

[1]Assumption: use rate: 1 applications of 21.19 kg a.s./ha; 25% interception by plants; bulk density of soil: 1.5 g/cm^3; soil depth: 5 cm; DT_{50} = 2.8 days

The Rapeseed oil concentration in soil declines by ca. 61% of the initial concentration 2 days after application which is equivalent to 12.92 mg a.s./kg in orchards. The time course for the average PECS is shown in Figure 8.3.1-2

Figure 8.3.1-2: Time course of the PEC of Rapeseed oil in soil (half-life 1.5 days) after 1 application of NEU 1160 I



Assessment: The calculation is valid. The calculation made for orchards corresponds to an application rate of 26.49 kg ai/ha that corresponds to a height of 3 m.

B.8.4 Fate an behaviour in water

B.8.4.1 Route an rate of degradation in aquatic systems

B.8.4.1.1 Hydrolytic degradation

Parent

No information submitted

RMS comment: Taking out the characteristics of the active substance the hydrolysis is not expected to occur

B.8.4.1.2 Photochemical degradation

No information submitted

B.8.4.1.3 Biological degradation

Fresh water algae, like marine algae, are also rich in fatty acid composition as demonstrated by reports 7.1.1.1.1/08, 7.2.1.3/01, /02, /03, /04, /05, /06, /07. The ready biodegradation was demonstrated in Pelargonic Acid (C10:0) (IIA, 7.2.1.3.1/01).

According to the notifier, the degradation of fatty acids in water is similar in almost all respects to the degradation in soil. Water in its natural environment is a habitat for a wide variety of algae, bacteria, yeasts and fungi as well as higher organisms. Each of these organisms contain fatty acids as part of their cellular membranes and food reserves. They also metabolize the fatty acids to release energy for normal growth and development. However, with the information available it is not possible to extrapolate the information on the fate and behaviour to soil to the water compartment.

Report: Chu and DuPuy 1980 Annex point/reference 7.2.1.3/01

Abstract: Fatty acids in the microorganisms, especially algae, provide a major nutrient source for aquatic organisms in the ocean as part of the planktonic food chain. In this study the fatty acids in three algal species Pyramimonar virginica, Pseudoisochrysis paradoxa and Chlorella sp., which were successfully used as food sources for rearing larvae of the American oyster are analyzed. The major fatty acid constituents of the total lipids of the three species were the C12, C14, C16 and C18 saturated fatty acids and the C16 and C18 mono- and polyunsaturated acids.

Report: Nichols, B.W 1995 Annex point/reference 7.2.1.3/02

Abstract: In this paper a detailed fatty acid analyses have been carried out on the isolated lipids of *Chlorella vulgaris* grown in a purely inorganic medium in the light and on an organic medium both in the light and in the dark. Cells grown in the light on an inorganic medium contaINmore alpha- linolenic acid than do those grown on an organic medium. The isolated lipids of *Chlorellavulgaris* are similar to those occurring in the leaves of higher plants, and the proportion of those polar lipids associated with leaf chlorplasts (the galactosyl diglucerides, sulphoquinovosyl diglyceride (sulpholipid), phosphatidyl glycerol) increases when purely photosynthetic cell growth is increased. The fatty acid composition of the lipids isolated from cells groen under conditions favouring photosynthesis are comparable to those found in leaves

Report: Thomas, K 1963 Annex point/reference 7.2.1.3/03

Abstract: The composition of the fatty acid mixture from the lipids of different species of green, brown and red algae was determined by GC. Besides, several unsaturated C16 and C18 fatty acids, the C20 and C22-polynoic acids (found especially in the brown and red algae) were isolated and characterised more closely. These were $\Delta^{8,11,14}$-eicosatrioneonic , $\Delta^{5,8,11,14}$ - eicosatetraenoic (arachidonic), $\Delta^{5,8,11,14,17}$ –eicosapentaenoic and $\Delta^{7,10,16,16,19}$ –docosapentaenoic acid. They are thus of the linoeic and linolenic acid type ; this also applies to all the C16 and C18 polyenoic acids isolated here. The occurrence of *trans*- Δ^3 cis- Δ^7 and *cis*- Δ^9- hexadecanoic acid, *cis*- Δ^9 and *cis*- Δ^{11}-octadecenoic acid was also shown.

Report: Shaw, R 1967 Annex point/reference 7.2.1.3/04

This publication refers to the polyunsaturated fatty acids in Protists. The information is equivalent to that one found in other public literature.

Report: Chuecas, L and Rley, J. 1969 Annex point/reference 7.2.1.3/05

Abstract: A range of 27 marine phytoplankton species, representative of several of the principle classes, has been grown under similar conditions in Erd- Schreiber medium with abundant nutrients. Harvesting was carried out 20 days after inoculation while vigorous growth was proceeding. The component fatty acids of lipids extractable with chloroform-methanol were determined by Gas liquid chromatography. In all, 40 fatty acids were determined . It is likely that the componeney fattya cid distribution may be valuable for taxonomic purposes. Thus, specific fatty-acid assemblages may characterize particular phyla or even classes. For example, the *Bacillariophyceae* are differentiated from other organisms examined by the virtual absence of 18:2 and 18:3 and 18:4; the *Cryptophyta* are

distinguished by their high content of 20:. The fatty acid arrays of species belonging to the same genus are frequently very similar e.g *Dunaliella primolecta* and *D. tertiolecta*.

Report: Schlenk, H and Gellerman, J.L . 1965 Annex point/reference 7.2.1.3/06

Abstract: Arachidonic and related fatty acids which normally are found only in animals or microorganisms have been isolated and identified from several moses and ferns. Fatty acids with double bond in position 5, separated by more than one methylene group from other double groups, have been found in *Ginko biloba* and *Equisetum*. Analyses of fatty acids from numerous plants, in particular their chlorophyll containing parts, are listed according to componenets. The experimental part gives details on structure determination of the usual of the methylene-interrupted fatty acids by ozonization-hydrogenation-GLC. Alkaline isomerization combined with these procedures was applied to determine the unsusal double bond structures. The method permits positional identification of an internal double bond.

Report: Erwin, J. and Boloch, K. 1963 Annex point/reference 7.2.1.3/07

Abstract: *Euglena gracilis* was grown in the light and in the dark and the fatty acid composition of the extracted lipids determined. Cells grown in the light procedure large amount of *alpha*- linolenic acid and contain only small quantities of other polyunsaturated fatty acids. The chloroplast lipids account for over 35% of the *alpha*-linolenic acid content of the green cells. In dark-grown cells and various cololress mutants of *Euglena alpha*-linolenic acid is a minor component whereas the content of C_{20}, C_{22} and C_{24} polyunsaturated acids is greatly increased. The fatty acid composition of some phytomonads, of *Scenedesmus*, and of some of their mutants was also determined.

B.8.4.1.3.1 Ready biodegradability

Report: Hertl, J. (2002): Report No. 14737160. Annex point /reference IIA, 7.2.1.3.1/01
Guideline: Directive 92/69/EEC, C.4-D, 1992 and OECD 301 F, 1992
GLP: Y

Test substance: Pelargonic Acid (Cas nº 112-05-0). Lot number 950144 Analyzed content of a.i. 930 g/kg.

The degradation of Pelargonic Acid by sludge was investigated in a climatic chamber at 21°C for 28 days in the darkness at a pH of 7.6. The consumption of oxygen was determined daily over a period of 28 days.

The activated sludge supplied by the sewage plant Groß-Zimmern, Germany was washed by centrifugation and the supernatant liquid phase was decanted. The solid material was resuspended in tap water and again centrifuged. This procedure was repeated twice. An aliquot of the final sludge suspension was weighed, dried and the ratio of wet sludge to its dry weight was determined. Based on this ratio, calculated aliquots of washed sludge suspension, corresponding to 1.5 g dry material per liter were mixed with test water and then aerated until use.

Findings: The percentage biodegradation (BOD/ThODNH$_4$) of test item, of aniline and of the toxicity control is summarised in Table 8.4.1.3.1. After correction of the mean biochemical oxygen demand of the inoculum controls on day 1 of exposure 9% and 11% biodegradation were determined.

The oxygen demand of the inoculum control (medium and inoculum) was 30 mg O_2/L and thus not greater than 60 mg O_2/L within the 28 d

At the end of the 10-day window on day 11, 64% and 67% biodegradation were found. At the end of the 28-day exposure period degradation rates of 77% and 76% were found. The percentage biodegradation exceeded 60% within the 10-day window.

The reference item aniline was sufficiently degraded to 82% after 14 days, and to 94% after 28 days of incubation.

In the toxicity control containing both, the test item and the reference item aniline at least 49% biodegradation was noted within 14 days and at least 47% biodegradation was determined after 28 days of incubation. Thus, the test item can be assumed to be not inhibitory on the activated sludge microorganisms.

After correction of the mean biochemical oxygen demand of the inoculum controls in the abiotic control the oxygen demand was 195 mg =2/L at the end of the exposure period. This indicates an abiotic degradation rate of 62%.

Table 8.4.1.3.1-1: Percentage biodegradation (BOD/ThODNH$_4$) of test item, of aniline and of the toxicity control

Time (days)	Percentage BOD				
	Pelargonic acid		Aniline	Abiotic control	Toxicity control
1	11	9	-1	-1	5
2	20	20	-2	-2	27
3	28	28	-3	-3	40
4	37	44	6	-4	51*
5	47	52	58	0	51
6	50	54	61	9	51
7	52	56	65	14	51
8	57	62	71	24	51
9	59	63	74	29	50

Time (days)	Percentage BOD				
	Pelargonic acid		Aniline	Abiotic control	Toxicity control
10	60	65	78	33	50
11	64	67	80	41	50
12	67	69	82	45	50
13	67	70	81	48	50
14	69	71	82	50	49
15	70	73	82	54	49
16	71	73	84	54	49
17	73	74	84	56	49
18	73	74	84	57	49
19	73	74	85	57	49
20	74	75	84	57	48
21	75	75	86	59	48
22	76	76	86	61	48
23	77	77	90	61	48
24	78	77	92	63	48
25	77	77	93	63	48
26	77	76	92	62	47
27	77	77	94	62	47
28	77	76	94	62	47

$ThODNH_4$ of Pelargonic acid: 2.53 mg O2/mg test item
$ThODNH_4$ of aniline: 2.41 mg O2/mg Aniline
* calculation of toxicity control from day 4 until test end was done with 275 mg O2/L, biodegradation may be higher, but could not be calculated due to overflow

Assessment: The study is considered valid.

The percentage biodegradation exceeded 60% within the 10-day window. The test item can therefore be considered as ready biodegradable. The percentage biodegradation of the reference item confirms the suitability of the used activated sludge inoculum. According to the test guidelines the test item can be assumed to be not inhibitory on the activated sludge micro organisms because degradation was > 25% within 14 days.
The test substance (C10:0) does not corresponds to the active substance (trygliceride of fatty acids).

According to the notifier, the study on Pelargonic acid (C10:0) may be extrapolated to Rapeseed oil but with the available information on the fate and behaviour in water this statement cannot be confirmed by RMS.

B.8.4.1.3.2 Water/sediment study Circumstances

No data submitted.

According to the notifier, the degradation of fatty acids in water is similar in almost all respects to the degradation in soil. Thus, the DT50 value obtained for soil (refer to point 8.1.2) may be extrapolated to surface water.

owever, with the information available it is not possible to extrapolate the information on the fate and behaviour to soil to the water compartment.

B.8.4.1.4 Degradation in the saturated zone Circumstances

No study on the degradation in the saturated zone was conducted due to the rapid microbial degradation of Rapeseed oil and the natural occurrence of fatty acids in the environment.

B.8.5 Impact on water treatment procedures

No information submitted

B.8.6 Predicted environmental concentrations in surface water and in ground water (PEC_{SW} , PEC_{GW})

B.8.6.1 Estimation of concentrations in groundwater

No calculation of PEC (ground water) was done. According to the notifier, it is unlikely that Rapeseed oil will contaminate the ground water based on the natural occurrence of fatty acids in soil. Since fatty acids degrade rapidly in soil leaching into groundwater is unlikely to occur.

B.8.6.2 Estimation of concentrations in surface water

B.8.6.2.1 Prediction of environmental concentration of Rapeseed oil in surface water (PECSW ini, PECSW actual) for <u>greenhouse uses</u>

The maximum initial PECSW (PECSW ini) was calculated for this use as follows.

Realistic worst-case scenarios for greenhouse uses of Rapeseed oil are 3 applications at 70.64 kg a.s./ha with an interval of 7 days between successive applications. The application rate corresponds to the maximum rate for the maximum plant height of > 125 cm (80 L NEU 1160 I/ha).

The initial PECsw value was calculated based on a loading of 0.1 % of application rate and for a water depth of 30 cm in a lentic water body, according to the following equation:

$$PEC_{SWini} = \frac{A \cdot dr}{V_{sw} \cdot 100}$$

where

A = application rate in [µg/m²]

dr = loading to the water body [%] and

Vsw = water volume per m² [L/m²]

The loading is based on recommendations for greenhouse applications by the Dutch CTB1.

The predicted environmental concentrations are calculated for several time points using the formula:

$$actualPEC_{SW} = PEC_{SWini} \cdot e^{-t \cdot \frac{\ln(2)}{DT_{50}}}$$

where

PECSWini = initial PECSW after one application

DT50 = DT50 of the water phase

In addition, the time-weighted average concentrations are calculated using the formula:

$$twaPEC_{SW} = PEC_{SWini} \cdot \frac{DT_{50}}{t \cdot \ln(2)} \cdot (1 - e^{-t \cdot \frac{\ln(2)}{DT_{50}}})$$

Where

twaPECSW = time-weighted average concentration at time t

PECSWini = initial PECSW after the last application

DT50 = DT50 of the water phase

This twa concentration considers the initial concentration (after the last application) and also the fate of the substance in water. Assuming first order kinetics for the degradation, long-term PEC values were calculated. The degradation of fatty acids in water is similar in almost all respects to the degradation in soil. Thus, the DT50 value obtained for soil (AII, 7.1.1.2.1/01) of 2.8 days (maximum recalculated value) was extrapolated to the degradation behaviour of Rapeseed oil in surface water. This approach represents the worst-case situation.

Predicted actual concentrations and time-weighted average (twa) PECSW values for Rapeseed oil are presented in Table 8.6.2.1-1

Table 8.6.2.1-1: Actual concentration and time-weighted average (twa) PECSW of Rapeseed oil after three applications of NEU 1160 I at a rate of 70.64 kg a.s./ha

Day	Appl. No.	Days post final appl.	Rapeseed oil	
			PECSW actual (µg a.s./L)	PECSW twa (µg a.s./L)
0	1	-	23.52	-
7	2	-	27.68	-
14	3	0	**28.42**	28.42
15	-	1	22.19	25.17
16	-	2	17.32	22.41
18	-	4	10.56	18.04
21	-	7	5.02	13.50

[1] CTB: Authorisation manual, Appendix A: Drift percentages, version 0.2, 2004.

Day	Appl. No.	Days post final appl.	Rapeseed oil	
			PECSW actual (µg a.s./L)	PECSW twa (µg a.s./L)
28	-	14	0.89	7.94
35	-	21	0.16	5.44
42	-	28	0.03	4.10
56	-	42	0.00	2.73
64	-	50	0.00	2.30
114	-	100	0.00	1.15
164	-	150	0.00	0.77
214	-	200	0.00	0.57
374	-	360	0.00	0.32

Assessment: The calculation is considered valid.

B.8.6.2.2 Prediction of environmental concentration of Rapeseed oil in surface water (PECSW ini, PECSW actual) for field uses

Report: Häusler, A.2005. Report Nº 105276-A3-0907-01 Annex point /reference, IIIA 9.2.3/01

To calculate concentrations in surface water (PECSW ini, PECSW actual and TWA) for the active substance after outdoor applications, the tiered approach as recommended in the guidance document SANCO/4802/20011 was used.

Steps 1 and 2 enable a first evaluation of the fate of substances in surface waters and sediment in order to identify potential risks for aquatic and sediment dwelling organisms and to provide PEC values for a risk assessment for aquatic species. If a risk cannot be excluded, a calculation of PEC values based on step 3 modelling software follows.

Input parameters

The application rates were 21.192 kg Rapeseed oil/ha for woody ornamental and 26.490 kg Rapeseed oil/ha for orchards. Following the GAP table (Table 8.3-1) NEU 1160 I was assumed to be applied once in the same crop.

For ornamentals the FOCUS crop scenario “Vines, late applications” was selected corresponding to the worst case use in woody ornamentals with a plant height > 125 cm.

The key application data used in the FOCUS_SW calculations are summarised in Table 8.6.2.2-1

Table 8.6.2.2-1: Key application data used in the FOCUS_SW calculations

Parameter	Orchards	Ornamentals
Application rate	26.490 kg a.s./ha* 30 L NEU 1160 I/ha	21.192 kg a.s./ha** 24 L NEU 1160 I/ha
Number of applications	1/year	1/year
Region of use	North- and South-EU	North- and South-EU
FOCUS Crop scenario	Pome/stone fruit, early	Vines, late application
Plant interception (applicability depends on the model software used)	Step 1: not relevant Step 2: minimal crop cover (20%) Step 3: interception depending on growth stage	Step 1: not relevant Step 2: minimal crop cover (40%) Step 3: interception depending on growth stage
Application method	Drainage scenarios: air blast Runoff scenarios: air blast, CAM2	Drainage scenarios: air blast Runoff scenarios: air blast, CAM2
Application timing	Step 1: not relevant Step 2: March to May Step 3***: beginning of emergence to 30 days after emergence	Step 1: not relevant Step 2: March to May Step 3***: beginning of emergence to 30 days after emergence

* application rate corresponds to 3 m crown height
** application rate corresponds to plant height > 125 cm
*** time period for first and last possible application

The DT50 value obtained for soil of 2.8 days was extrapolated to the degradation behaviour of Rapeseed oil in water. Likewise the DT50 value obtained for soil of 2.0 days (maximum value, moisture corrected) was extrapolated to the degradation behaviour of Rapeseed oil in sediment.

A main characteristic of step 1 calculation is that an application leads to inputs via spray drift, runoff, erosion and drainage which are evaluated as a single loading to the water body. All inputs are assumed to occur at the same time. Considering multiple applications, this loading to surface water is based upon the maximum single use rate multiplied by the number of applications.

In contrast to this, at step 2, one application causes a series of individual loadings, i.e. firstly substance inputs entering the water body via drift directly after application, followed by a runoff, erosion and/or drainage event occurring 4 days after the application.

The key substance parameters for FOCUS evaluation steps 1, 2 and 3 are summarised in Table 8.6.2.2-2.

Table 8.6.2.2-2: Key substance parameters used in the FOCUS_SW calculations

Parameter	**FOCUS evaluation steps**			**Rapeseed oil**	
	1	**2**	**3**	**input value**	**range**
Vapour pressure (Pa) (calculated for 25 °C)			x	1.33×10^{-18}	n.r.
Solubility in water (mg/L)	x	x	x	0.000001*	n.r.
K_{OC} (mL/g)	x	x	x	1724000**	n.r.

Parameter	FOCUS evaluation steps			Rapeseed oil	
	1	2	3	input value	range
Freundlich sorption exponent			x	0.9***	n.r.
Plant uptake			x	0.0	n.r.
$DT_{50\ soil}$[a] (days)		x	x	2.0****	1.9 to 2.0 (n = 2)
$DT_{50\ water}$[b] (days)		x	x	2.8	n.r.
$DT_{50\ sediment}$[c] (days)		x	x	2.0	n.r.
$DT_{50\ system}$[d] (days)	x			2.8	n.r.

n.r. not relevant
* corresponds to the minimum input value for step 3 modelling software, calculated value: 2.551 x 10^{-20} mg/L at 25 °C and the neutral range
** corresponds to the maximum input value for step 3 modelling software, calculated value: 1 x 1010 mL/g
*** default value
**** maximum value
a following 1st order kinetics, soil moisture adjusted to field capacity
b no water/sediment study available, maximum value (not moisture corrected) from laboratory soil degradation study
c no water/sediment study available, mean value from laboratory soil degradation study
d no water/sediment study available, maximum value (not moisture corrected) from laboratory soil degradation study

Findings: For orchards and ornamentals the predicted actual concentrations of Rapeseed oil in surface water resulting from simultaneous loadings by spray drift, runoff and drainage (Step 1) are predicted to be 2580.000 and 570.170 µg a.s./L, respectively.

When considering sequential loadings to surface water (Step 2), the Rapeseed oil concentrations in surface water were calculated to be 2580.000 and 567.098 µg a.s./L, respectively. The maximum PECSW value was determined for orchards.

Table 8.6.2.2-3: Maximum predicted actual concentrations of Rapeseed oil in surface water (PECSW actual) after one application of NEU 1160 I (FOCUS evaluation steps 1 and 2)

Crop (FOCUS crop scenario)	Step	No. appl.	Appl. rate	Region and season of appl.	Drift	Maximum PEC_{SW} actual
			(kg a.s./ha)		(%)*	(µg a.s./L)
Orchards (Pome/stone fruit, early)	1**	1	26.490	n.r.	29.197	2580.000
	2**	1	26.490	N, March-May	29.197	2580.000
	2**	1	26.490	S, March-May	29.197	2580.000
Ornamentals (Vines, late)	1**	1	21.192	n.r.	8.028	570.170
	2**	1	21.192	N, March-May	8.028	567.098
	2**	1	21.192	S, March-May	8.028	567.098

n.r. not relevant
N Northern Europe
S Southern Europe
* % of application rate
** concentration in water layer exceeds water solubility of Rapeseed oil

As the aforementioned values of steps 1 and 2 were above the water solubility of Rapeseed oil, a calculation of PECSW values based on step 3 modelling software is necessary.

For every main entry route different software were used as recommended, including Drift calculator 1 (spray drift), MACRO 4.4.2 (drainage) and PRZM 1.5.6 (runoff). Based on the different pesticide inputs calculated, TOXSWA 2.4.2 simulates the fate of pesticide entries in typical surface water bodies and finally calculates maximum as well as actual and time-weighted average concentrations in water layer and sediment for different dates or periods, respectively, needed in the registration procedure.

All FOCUS_SW site scenarios were used without any change. The concentrations presented are the maximum concentrations in the given simulation period. Table 8.6.2.1-4 summarises the predicted environmental concentrations of Rapeseed oil in surface water for all relevant FOCUS SW scenarios corresponding to the representative uses chosen.

The water concentrations presented generally exceed the water solubility of Rapeseed oil. The assumed higher water solubility can partly be justified by the emulsifying agent of the formulation which increases the water solubility of Rapeseed oil. Thus, the concentrations calculated were taken as a worst case though overestimating the concentrations of Rapeseed oil in water

The concentrations of Rapeseed oil related to suspended solids in surface waters are also summarised in

Table 8.6.2.2-4. These concentrations can be attributed to the extremely high K_{OC} value of Rapeseed oil. Assuming a considerable inhibition of the adsorption of Rapeseed oil to suspended solids by the emulsifier, it can be concluded that significantly lower concentrations are reached under more realistic circumstances than predicted by standard simulation runs. Therefore, concentrations of Rapeseed oil related to suspended solids were not further considered since they represent unrealistic worst case conditions.

Table 8.6.2.2-5: Maximum predicted actual concentrations of Rapeseed oil in surface water ($PEC_{SW\ actua}$) after one application of NEU 1160 I at recommended application rates in orchards and ornamentals (FOCUS evaluation step 3)

Crop (FOCUS crop scenario)	Step	Scenario	Water body	No. appl.	Drift (%)*	PECsw global max. act. conc. (µg a.s./L)	
						dissolved in water	adsorbed to suspended solids
Orchards (Pome/stone fruit, early)	3	D3**	Ditch	1	23.599	867.773 a	1188.226
		D4**	Pond	1	4.730	43.961 a	81.113
		D4**	Stream	1	25.899	842.798 a	1157.405
		D5**	Pond	1	4.730	43.949 a	81.094
		D5**	Stream	1	25.899	839.754 a	1153.642
		R1**	Pond	1	4.730	43.953 a	81.101

Crop (FOCUS crop scenario)	Step	Scenario	Water body	No. appl.	Drift (%)*	PECsw global max. act. conc. (µg a.s./L)	
						dissolved in water	adsorbed to suspended solids
		R1**	Stream	1	25.899	693.076 a	970.593
		R2**	Stream	1	25.899	934.169 a	1269.745
		R3**	Stream	1	25.899	**1001.670 a**	1352.03
		R4**	Stream	1	25.899	693.248 a	970.809
Ornamentals (Vines, late)	3	D6**	Ditch	1	5.173	134.161 a	221.411
		R1**	Pond	1	0.612	3.861 a	9.086
		R1**	Stream	1	5.152	97.760 a	166.524
		R2**	Stream	1	5.152	132.058 a	218.285
		R3**	Stream	1	5.152	**141.543 a**	232.344
		R4**	Stream	1	5.152	97.728 a	166.476

a peak occurs at time of spray drift event
* % of application rate
** error message: concentration in water layer exceeds water solubility of Rapeseed oil in all segments considered

Predicted actual concentrations of Rapeseed oil in surface waters ranged from 3.861 to 1001.670 µg a.s./L considering both uses. Peak concentrations can generally be attributed to spray drift events. The lowest PECSW values were calculated for R1-pond and ornamentals. Maximum PECSW values were calculated for the use orchards and the Southern European scenarios.

The predicted actual concentrations of Rapeseed oil in sediment resulting from simultaneous loadings by spray drift, runoff and drainage (Step 1) are predicted to be 66.20 x 103 and 53.00 x 103 µg a.s./kg dry sediment for the uses orchards and ornamentals, respectively (Table 8.6.2.1-6).

When considering sequential loadings to surface water (Step 2), the Rapeseed oil concentrations in sediment ranged from 2.69 x 103 to 10.30 x 103 µg a.s./kg dry sediment (Table 8.6.2.2-6). The maximum PECSED value was calculated for the use in orchards.

Table 8.6.2.2-6: Maximum predicted actual concentrations of Rapeseed oil in aquatic sediment (PECSED actual) after one application of NEU 1160 I (FOCUS evaluation steps 1 and 2)

Crop (FOCUS crop scenario)	Step	No. appl.	Appl. rate	Region and season of appl.	Drift	*Maximum $PEC_{SED\ actual}$*
			(kg a.s./ha)		(%)*	*(µg a.s./kg dry sediment)*
Orchards (Pome/stone fruit, early)	1**	1	26.490	n.r.	29.197	*66.20 x 10^3*
	2**	1	26.490	N, March-May	29.197	*9.11 x 10^3*
	2**	1	26.490	S, March-May	29.197	*10.30 x 10^3*
Ornamentals (Vines, late)	1**	1	21.192	n.r.	8.028	*53.00 x 10^3*
	2**	1	21.192	N, March-May	8.028	*2.69 x 10^3*
	2**	1	21.192	S, March-May	8.028	*4.28 x 10^3*

n.r. not relevant
N Northern Europe
S Southern Europe
* % of application rate
** concentration in water layer exceeds water solubility of Rapeseed oil

Maximum predicted actual concentrations of Rapeseed oil in sediment are summarised in Table 8.6.2.2-7. Sediment concentrations of Rapeseed oil ranged from 103.299 to 7560.024 µg a.s./kg dry sediment.

Table 8.6.2.2-7: Maximum predicted actual concentrations of Rapeseed oil in aquatic sediment (PECSED actual) after one application of NEU 1160 I at recommended application rates in orchards and ornamentals (FOCUS evaluation step 3)

Crop (FOCUS crop scenario)	Step	Scenario	Water body	No. appl.	Drift	*Maximum $PEC_{SED\ actual}$*
					(%)*	*(µg a.s./kg dry sediment)*
Orchards (Pome/stone fruit, early)	3	D3**	Ditch	1	23.599	*7560.024*
		D4**	Pond	1	4.730	*1160.845*
		D4**	Stream	1	25.899	*1204.636*
		D5**	Pond	1	4.730	*1037.681*
		D5**	Stream	1	25.899	*695.807*
		R1**	Pond	1	4.730	*1047.716*
		R1**	Stream	1	25.899	*2456.252*
		R2**	Stream	1	25.899	*1686.545*
		R3**	Stream	1	25.899	*5227.238*
		R4**	Stream	1	25.899	*2470.354*
Ornamentals (Vines, late)	3	D6**	Ditch	1	5.173	*803.355*
		R1**	Pond	1	0.612	*103.299*
		R1**	Stream	1	5.152	*340.265*
		R2**	Stream	1	5.152	*238.421*
		R3**	Stream	1	5.152	*736.448*
		R4**	Stream	1	5.152	*338.177*

* % of application rate

** error message: concentration in water layer exceeds water solubility of Rapeseed oil in all segments considered

The high concentrations of Rapeseed oil in sediment of FOCUS evaluation steps 1, 2 and 3 can be attributed to the extremely high KOC value of Rapeseed oil. Since the emulsifier being part of the formulation NEU 1160 I modifies the adsorption behaviour of Rapeseed oil to a large extent, these predicted concentrations do not represent the conditions of use. Assuming a considerable inhibition of the adsorption of Rapeseed oil to sediment by the emulsifier, it can be concluded that significantly lower concentrations are reached under more realistic circumstances than predicted by standard simulation runs. For these reasons the predicted sediment concentrations of Rapeseed oil are considered to represent unrealistic worst case conditions.

Details of the PECsw TWA at 2 and 4 days after the global maximum are summarised in table

Table 8.6.2.2-8: 1, 2 and 4 time weighted average (twa) PECSW of Rapeseed oil (dissolved)

Orchards (Pone/stone fruits, early).			
scenarios	1d TWA (µg/L)	2d TWA (µg/L)	4d TWA (µg/L)
D3- ditch	389.937	231.764	128.739
D4-pond	35.435	30.043	23.524
D4-stream	51.476	25.829	12.958
D5-pond	34.905	29.243	22.372
D5-stream	30.514	15.283	7.654
R1-pond	34.959	29.319	22.472
R1-stream	107.382	54.174	27.289
R2-stream	73.159	36.75	18.442
R3-stream	250.125	128.812	65.893
R4-stream	108.017	54.5	27.456
Ornamentals (Vine, late)			
scenarios	1d TWA (µg/L)	2d TWA (µg/L)	4d TWA (µg/L)
D6-ditch	38.858	20.232	10.5
R1-pond	3.137	2.654	2.046
R1-stream	14.631	7.363	3.704
R2-stream	10.246	5.141	2.578
R3-stream	34.198	17.468	8.893
R4-stream	14.529	7.312	3.678

B.8.7 Fate and behaviour in air

B.8.7.1 Route and rate of degradation in air

Due to the low vapour pressure of oleic acid, one of the main fatty acids in rapeseed oil (1.33 * 10-18 Pa), it is unlikely that the fatty acid will occur in the atmosphere.

B.8.9 Definition of residue

Rapeseed oil is a mixture of triglycerides of fatty acids, therefore the degradation, transformation and metabolism follows the same principle as they are generally described for fatty acids and lipids. **No definition of residue was proposed by the notifier;** The residues would be present in the form of CO_2 and H_2O, all of which occur naturally in the soil and do not represent a risk to human or environmental health. **RMS considers that at least environmental risk assessment should be made to the exposure to rapeseed oil.**

B.8.10 Monitoring Data

No monitoring data is necessary, because of the natural occurrence of fatty acids; the well-known, rapid degradation pathways for the active ingredient; the lack of toxicity to mammals; and the fact that it is accepted as food grade.

B.8.11 References relied on

Annex point/ reference no.	Author(s)	Year	Title Source (where different from company) Company, report no. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
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