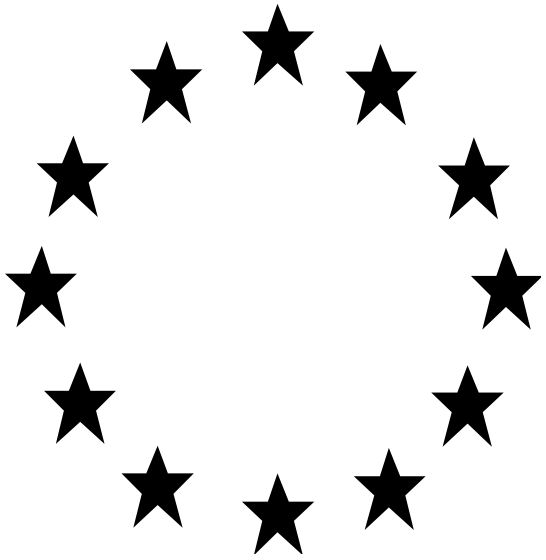

Draft Assessment Report (DAR)

- 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 1, B.1 – B.5

September 2008

MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACIÓN

INSTITUTO NACIONAL DE INVESTIGACIÓN Y TECNOLOGÍA AGRARIA Y ALIMENTARIA (I.N.I.A.)

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Monograph prepared in the context of the inclusion of the following active substance in Annex I of the Council Directive 91/414/EEC

RAPESEED OIL

Volume III

Summary, Scientific Evaluation and Assessments

July 2007

B.1 Identity

B.2 Physical and chemical properties

B.3 Data on application and further information

B.4 Proposals for classification and labelling

B.5 Methods of analysis

B.6 Toxicology and metabolism

B.7 Residue data

B.8 Environmental fate and Behaviour

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ANNEX B

RAPESEED OIL

B - 1 : IDENTITY

B.1 Identity

B.1.1 Identity of the active substance (IIA, 1 and 3.1)

All the information regarding the identity of the active substance has been included in the level 1 of this monograph.

B.1.2 Identity of the plant protection products (IIIA 1)

All the information regarding the identity of the plant protection product has been included in the level 1 of this monograph.

B.1.3 References relied on

See Annex C of this monograph

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ANNEX B

RAPESEED OIL

B - 2: PHYSICAL AND CHEMICAL PROPERTIES

B.2 Physical and chemical properties

B.2.1 Physical and chemical properties of the active substance

Study	Method	Material/ Purity	Results	Conclusion/ Comments	Reference
B.2.1.1 Melting point, freezing point or solidification point (IIA 2.1.1)	92/69/EEC A.1 OECD 102 DIN ISO 313 GLP:Yes	Batch No. 765103 content: Rapeseed oil: 100%	Melting/ Freezing range -12.0 – -30.6 °C	**Acceptable** **Remarks:** Point of crystallization is the temperature at which the test substance begins to crystallize during cooling: -30.6 °C Freezing temperature is the temperature at which the crystallized test substance changes completely from the solid to the liquid state at atmospheric pressure: -12.0 °C	Wilfinger, 2003a Report: 20031238/01-PCFP IIA, 2.1.1/01
B.2.1.2 Boiling point (IIA 2.1.2) **B.2.1.3 Temperature of decomposition or sublimation (IIA 2.1.3)**	92/69/EEC A.2 OECD 103 OECD 113 (DSC method) GLP:Yes	Batch No. 765103 content: Rapeseed oil: 100%	Boiling point > 350 °C with decomposition	**Acceptable**	Smeykal, 2003 Report: 20030778.01 IIA, 2.1.2/01 and IIA, 2.1.3/01
B.2.1.4 Relative density (IIA 2.2)	92/69/EEC A.3. OECD 109 (pycnometer method) GLP: Yes	NEU 1160 I Batch No. 018070 content: 96%	$D_4^{20} = 0.92$	**Acceptable** **Remarks:** The notifier assumed that the results of studies conducted with the formulation NEU 1160 I (for the determination of physical and chemical properties) will not differ from studies conducted with rapeseed oil considering the small amount of [redacted] in NEU 1160 I.	Krips, 2000a NOTOX Project 300364 IIA, 2.2 /01

Study	Method	Material/ Purity	Results	Conclusion/ Comments	Reference
B.2.1.5 Vapour pressure (IIA 2.3.1)	Calculation method (SAR determination MPBPWIN Model) GLP : No	1,2,4-Trioctadec-9-en-oyl-glycerol Experimental results will not be reliable for rapeseed oil and therefore calculations from the chemical structure of the main molecule (oleic acid glycerol ester) were obtained.	$1.33*10^{-18}$ Pa **RMS proposal**: < 10^{-5} Pa	**Acceptable as additional information** **RMS Remarks:** The result can only be considered as a rough estimation of the vapour pressure of the active substance. The active substance is a mixture of glycerides of different fatty acids with the oleic acid being the major component. RMS considers that an exact numerical value can not be given in this case and a value as **< 10^{-5} Pa** would be more adequate.	Tiemann, 2003a Report 105159-A2-020301-01 IIA, 2.3.1/01
B.2.1.6 Volatility, Henry's law constant (IIA 2.3.2)	Calculation method (SAR determination HENRYWIN Model) GLP: No	1,2,4-Trioctadec-9-en-oyl-glycerol Experimental results will not be reliable for rapeseed oil. Calculations from the chemical structure of the main molecule (oleic acid glycerol ester) were obtained.	1.49 Pa m^3/mole	**Acceptable as additional information** **RMS Remarks:** The result can only be considered as a rough estimation of the vapour pressure of the active substance. The active substance is a mixture of glycerides of different fatty acids with the oleic acid being the major component.	Tiemann, 2003b Report 105159-A2-020302-01 IIA, 2.3.2/01
B.2.1.7 Appearance: physical state (IIA 2.4.1)	--	Rapeseed oil	Clear light yellow liquid	**Acceptable** **Remarks:** The information was taken from the safety data	Anonymous, 2000 Product health and safety data IIA, 2.4.1/01

Study	Method	Material/ Purity	Results	Conclusion/ Comments	Reference
B.2.1.8 Appearance: colour (IIA 2.4.1)				of the product manufactured by [redacted] RMS considers that for these kinds of substances (SANCO/10472/2003) this information is acceptable.	
B.2.1.9 Appearance: odour (IIA 2.4.2)	--	Rapeseed oil	Characteristic odour	**Acceptable** **Remarks:** The information was taken from the safety data of the product manufactured by [redacted] RMS considers that for these kinds of substances (SANCO/10472/2003) this information on the appearance is acceptable.	Anonymous, 2000 Product health and safety data. IIA, 2.4.2/01

Study	Method	Material/ Purity	Results	Conclusion/ Comments	Reference
B.2.1.10 Spectra of the active substance (IIA 2.5.1) IIA 2.5.1.1	**UV-VIS**			**Not acceptable** **RMS remarks**: The notifier has only sent a copy of a spectrum of Canola without labelling. A correct report with the identification of the test substance and interpretation of the spectrum is necessary.	Anonymous IIA, 2.5.1.1
IIA 2.5.1.2	**FT-IR** (4000-400 cm^{-1}) Film between windows of sodium chloride	Batch No 245902 Content: Rapeseed oil 100%	The data acquisition of an infrared spectrum was carried out. No interpretation was necessary and no IR spectrum for comparison was available.	**Acceptable as additional information only** **RMS remarks:** The interpretation of the spectrum is necessary.	Mekelburger, 2004 Report: AN-ASB 0314 IIA, 2.5.1.2/01
IIA, 2.5.1.3	**^{1}H-NMR and ^{13}C-NMR**		Not applicable. Rapeseed oil is a mixture of triglyceride	**Acceptable**	--
IIA 2.5.1.4	**MS**		Not applicable. Rapeseed oil is a mixture of triglyceride	**Acceptable**	--
B.2.1.10 Optical purity (IIA 2.5.1.6)			Not relevant. No optical isomers	**Acceptable**	--
B.2.1.11 Spectra of relevant impurities (IIA 2.5.2)			Not applicable as no impurities are included according to Deutscher Arzneimittel-Codex 1986, 6. Erg. 1994.	**Not Acceptable.** **RMS remarks:** The notifier was required to address the possible relevance of one of the components of Rapessed Oil and depending of the answer spectra of this component may be required.	

Study	Method	Material/ Purity	Results	Conclusion/ Comments	Reference
B.2.1.12 Solubility in water (IIA 2.6)	Calculation method (SAR determination WSKOWWIN Model v 1.40, Meylan, W. 2000) GLP: No	1,2,4-Trioctadec-9-en-oyl-glycerol Experimental results will not be reliable for rapeseed oil. Calculations from the chemical structure of the main molecule (oleic acid glycerol ester) were obtained.	Neutral range: 2.551 * 10^{-20} mg/L **RMS proposal:** negligible or < 10^{-3} mg/L Effect of pH: Not required, because rapeseed oil does not contain or build any salts.	**Acceptable as additional information** **RMS Remarks:** The result can only be considered as a rough estimation of the water solubility of the active substance. The active substance is a mixture of glycerides of different fatty acids with the oleic acid being the major component. RMS considers that an exact numerical value can not be given in this case and a result as: **negligible or < 10^{-3} mg/L** would be more adequate.	Tiemann, 2003c Report: 105159-A2-0206-01 IIA, 2.6/01
B.2.1.13 Solubility in organic solvents (technical active substance) (IIA 2.7)	CIPAC MT 181 GLP: Yes	Rapeseed oil, Batch No 765103 content 100%	Solubility at 20 ºC: ıne > 250 g/L p-xylene > 250 g/L 1,2-Dichloroethane > 250 g/L Methanol <10 g/L Acetone > 250 g/L Ethyl acetate > 250 g/L	**Acceptable**	Wilfinger, 2003b Report: 20031238/01-PSBO IIA, 2.7/01

Study	Method	Material/ Purity	Results	Conclusion/ Comments	Reference
B.2.1.14 Partition coefficient n-octanol/water (IIA 2.8)	Calculation method (SAR determination HENRYWIN Model v 1.66, Meylan, W., 2000) GLP: No	1,2,4-Trioctadec-9-en-oyl-glycerol Calculations from the chemical structure of the main molecule (oleic acid glycerol ester) were obtained.	log Kow = 23.2908 **RMS proposal**: log Kow (estimated) = 23.2908 Effect of pH: Not required, because rapeseed oil is neither an acid with a pKa value <2 nor a base with a pKa value >2	**Acceptable as additional information** **RMS Remarks:** The result can only be considered as a rough estimation of the n-octanol/water partition coefficient of the active substance. The active substance is a mixture of glycerides of different fatty acids with the oleic acid being the major component.	Tiemann, 2003d Report: 105159-A2-0208-01 IIA, 2.8.1/01
B.2.1.15 Hydrolysis rate at pH 4, 7 and 9 under sterile conditions in the absence of light (IIA 2.9.1)			Not applicable. Rapeseed oil is practically not soluble in water	**Acceptable.**	
B.2.1.16 Direct phototrans-formation of purified a.i. in water using artificial light under sterile conditions (IIA 2.9.2)			Not applicable. Rapeseed oil is practically not soluble in water	**Acceptable**	
B.2.1.17 Quantum yield (IIA 2.9.3)			Not applicable. Rapeseed oil is practically not soluble in water	**Acceptable**	
B.2.1.18 Dissociation constant (pKa) (IIA 2.9.4)			Not applicable. Rapeseed oil is practically not soluble in water	**Acceptable**	

Study	Method	Material/ Purity	Results	Conclusion/ Comments	Reference
B.2.1.19 Stability in air, photochemical oxidative degradation (IIA 2.10)			Not applicable. Rapeseed oil is practically not soluble in water	**RMS remarks:** RMS considers that the estimated photochemical oxidative degradation is not required because the low volatility of the substance but not the water solubility.	
B.2.1.20 Flammability (technical active substance) (IIA 2.11)			Not relevant, because rapeseed oil is a liquid	**Acceptable**	
B.2.1.21 Auto-flammability (technical active substance) (IIA 2.11.2)	92/69/EEC A.15 DIN 51794 GLP: Yes	NEU 1160 I Batch No. 018070 content: 96%	Auto-ignition at 405°C	**Acceptable** **Remarks:** The notifier assumed that the results of studies conducted with the formulation NEU 1160 I (for the determination of physical and chemical properties) will not differ from studies conducted with rapeseed oil considering the small amount of [redacted] in NEU 1160 I.	Krips, 2000b NOTOX Project 300329 IIA, 2.11.2/01
B.2.1.22 Flash point (technical active substance) (IIA 2.12)	92/69/EEC A.9 DIN EN 22719 Pensky-Martens closed cup GLP: Yes	NEU 1160 I Batch No. 018070 content: 96%	flash point 187.5 °C	**Acceptable** **Remarks:** The notifier assumed that the results of studies conducted with the formulation NEU 1160 I (for the determination of physical and chemical properties) will not differ from studies conducted with rapeseed oil considering the small amount of [redacted] in NEU 1160 I.	Krips, 2000c NOTOX Project 300318 IIA, 2.12/01

Study	Method	Material/ Purity	Results	Conclusion/ Comments	Reference
B.2.1.23 Explosive properties (technical active substance) (IIA 2.13)	--	--	**Notifier statement:** Rapeseed oil does not contain explosive ingredients. In addition it is neither flammable nor autoflammable.	**The statement is Acceptable.**	--
B.2.1.24 Surface tension (IIA 2.14)	92/69/EEC A.5 OECD 115 GLP: Yes	NEU 1160 I Batch No. 018070 content: 96%	44.6 mN/m at 20 °C, (90% saturated solution in pure water) NEU 1160 I is surface active.	**Not Acceptable.** **RMS remarks:** The notifier assumed that the results of studies conducted with the formulation NEU 1160 I (for the determination of physical and chemical properties) will not differ from studies conducted with rapeseed oil considering the small amount of [redacted] in NEU 1160 I but for this property RMS considers that the emulsifying co-formulant would affect this property.	Krips, 2000d NOTOX Project 300353 IIA, 2.14/01
B.2.1.25 Oxidizing properties (technical active substance) (IIA 2.15)			**Notifier statement:** Rapeseed oil does not include oxidizing ingredients.	**The statement is Acceptable.**	

B.2.2 Physical, chemical and technical properties of the plant protection product (Annex IIIA 2)

Trade name and manufacturer's code number: NEU 1160 I (883 g Rapeseed oil/L; 96% w/w). NEU-01160-AI-0-EC

Study	Method	Results	Conclusion	Reference
B.2.2.1 Appearance: physical state (IIIA 2.1)	Visual assessment GLP: Yes	Clear homogenous liquid	Acceptable	Parker, 1996 IIIA, 2.1/01
B.2.2.2 Appearance: colour (IIIA 2.1)	Visual assessment GLP: Yes	pale yellow liquid	Acceptable	Parker, 1996 IIIA, 2.1/01
B.2.2.3 Appearance: odour (IIIA 2.1)	smelling GLP: Yes	a typical odour	Acceptable	Parker, 1996 IIIA, 2.1/01
B.2.2.4 Explosive properties (IIIA 2.2.1)		Notifier statement: Based on the fact that Rapeseed oil and the other ingredient do not include explosive ingredients, NEU 1160 I does not possess explosive properties	Acceptable	
B.2.2.5 Oxidising properties (IIIA 2.2.2)		Statement: Based on the fact that Rapeseed oil and the other ingredient do not include oxidizing agents, NEU 1160 I does not possess oxidizing properties	Acceptable	
B.2.2.6 Flash point (IIIA 2.3)	92/69/EEC A.9 DIN EN 22719 Pensky-Martens closed cup GLP: Yes	flash point 187.5 °C	Acceptable	Krips, 2000c NOTOX Project 300318 IIIA, 2.3.1/01
B.2.2.7 Flammability (IIIA 2.3)		Statement: Not required, because NEU 1160 I is neither a solid nor a gaseous formulation.	Acceptable	

Study	Method	Results	Conclusion	Reference
B.2.2.8 Auto-flammability (IIIA 2.3)	92/69/EEC A.15 DIN 51794 GLP: Yes	Auto-ignition at 405°C	Acceptable	Krips, 2000b NOTOX Project 300329 IIIA, 2.3.3/01
B.2.2.9 Acidity or alkalinity and pH value (IIIA 2.4.1)		Not required, because the pH of NEU 1160 I is higher than 4 and lower than 10.	Acceptable	
B.2.2.10 pH of 1 % aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	CIPAC MT 75 GLP: Yes	pH of 1% emulsion: 5.26 (20 °C)	Acceptable.	Krips, 2000 NOTOX Project 300331 IIIA, 2.4.2/01
B.2.2.11 Kinematics Viscosity (III 2.5.1)		Not required, because NEU 1160 I is no preparation for ultra low volume (ULV) use.	Acceptable.	
B.2.2.11 Dynamic Viscosity (III 2.5.2)	OECD 114 DIN 53019 GLP: Yes	76 to 84 mPa s at 20 °C and D = 127 to 1227 s^{-1} 25 to 32 mPa s at 40 °C and D = 394 to 1231 s^{-1}	Acceptable	Krips, 2000 NOTOX Project 300342 IIIA, 2.5.2/01
B.2.2.12 Surface tension (III 2.5.3)	92/69/EEC A.5 OECD 115 Ring tensiometer GLP: Yes	Mean surface tension of a 90% saturated solution at 20 °C: 44.6 mN/m (surface active)	Acceptable	Krips, 2000 NOTOX Project 300353 IIIA, 2.5.3/01
B.2.2.13 Relative density (III 2.6.1)	92/69/EEC A.3 OECD 109 pycnometer method GLP: Yes	Relative density at 20 °C: D_4^{20} = 0.92	Acceptable	Krips, 2000 NOTOX Project 300364 IIIA, 2.6.1/01

<table>
<tr><th>Study</th><th>Method</th><th>Results</th><th>Conclusion</th><th>Reference</th></tr>
<tr><td>B.2.2.14
Bulk or tap density
(IIIA 2.6.2)</td><td></td><td>Not required, because NEU 1160 I is not a powder or granules.</td><td>Acceptable</td><td></td></tr>
<tr><td rowspan="2">B.2.2.15
Stability after storage for 14 days at 54°C
(IIIA 2.7.1)</td><td>CIPAC MT 46
The formulation was storage into plastic bottles.
Quantification of canola oil: extraction with petroleum ether, drying and weighting of the extract.
Quantification of erucic acid: conversion to methyl esters of the fatty acids (boron trifluoride method) and GC.

GLP: Yes</td><td>The canola oil content in NEU 1160 I remained stable for one month when stored at 54 °C (initial 95.4 ± 0.7 %, after 1 month 96.31 ± 0.1 %)
The erucic acid content in NEU 1160 I remained stable for one month when stored at 54 °C (initial 0.30 ± 0.01 %, after 1 month 0.32 ± 0.02 %)</td><td>Not Acceptable
Only the composition was determined before and after storage and the method for the determination of a.s. content is not considered acceptable.</td><td>Parker, 1996
IIIA, 2.7.1/01</td></tr>
<tr><td>CIPAC MT 46
The formulation was storage into plastic bottles with polyethylene-lined caps (commercial)
Testing was performed according to methods:
Saponification value: DFG standard method C-V 3(02)</td><td>No significant change in physical properties following accelerated storage:
<table>
<tr><th></th><th>Before storage</th><th>After storage</th></tr>
<tr><td>Saponification value</td><td>182.4 ± 0.55</td><td>181.6 ± 0.67</td></tr>
<tr><td>Acid value</td><td>0.25 ± 0.02</td><td>0.24 ± 0.01</td></tr>
<tr><td>Iodine value</td><td>109.0 ± 0.76</td><td>110.7 ± 1.10</td></tr>
<tr><td>Appearance</td><td colspan="2">clear, pale yellow and homogeneous</td></tr>
<tr><td>pH (1% in water)</td><td>4.94 ± 0.09</td><td>4.84 ± 0.10</td></tr>
<tr><td rowspan="2">Emulsion stability</td><td colspan="2">1:20 = 5% emulsion in CIPAC water D and 30ºC</td></tr>
<tr><td>Started emulsifying,</td><td>Started emulsifying,</td></tr>
</table></td><td>Acceptable as additional information
Remarks: The stability of the composition must be assessed.</td><td>Parker, 2006
Study number: Neu1160-060821-2 wk 54
IIIA, 2.7.1/03</td></tr>
</table>

Study	Method	Results			Conclusion	Reference
	Acid value: DFG standard method C-V 2(81) Iodine value: DFG standard method C-V 11a(02) Appearance by visual estimation And the CIPAC methods: MT 75.3 and MT 36. GLP: Yes		with a cream layer on top	with a thin cream layer on top		
			After 30 min standing: no froth, no oil, 4 mL cream	After 30 min standing: no froth, no oil, 4.5 mL cream		
			After 24 h standing: no froth, thin layer oil (<0.1 mL), 4 mL cream	After 24 h standing: no froth, no oil, 4.5 mL cream		
			Re-emulsification after 24 h: sample is homogeneous	Re-emulsification after 24 h: sample is homogeneous		
			After 24.5 h: no froth, no oil, 4 mL cream	After 24.5 h: no froth, no oil, 4.5 mL cream		
			1:50 = 2% emulsion in CIPAC water D and 30ºC			
			Started emulsifying, with a thin cream layer on top	Started emulsifying, with a thin cream layer on top		
			After 30 min standing: no froth, no oil, 1 mL cream	After 30 min standing: no froth, no oil, 1.5 mL cream		
			After 24 h standing: no froth, barely visible oil, 2 mL cream	After 24 h standing: no froth, no oil, 1.5 mL cream		
			Re-emulsification after 24 h: sample is homogeneous	Re-emulsification after 24 h: sample is homogeneous		
			After 24.5 h: no froth, no oil, 1.5 mL cream	After 24.5 h: no froth, no oil, 1.5 mL cream		
		Stability of the container		Packaging remains unchanged		
B.2.2.16 Effect of low temperature on stability (IIIA 2.7.2)	CIPAC MT 39.2 7 days at 0 ± 1 °C GLP: Yes	Initial observations: clear, homogeneous, pale yellow liquid After 7 days at 0 ± 1 °C: No solid or oily matter present			Acceptable	Parker, 1996 IIIA, 2.7.4/01

<table>
<tr><th>Study</th><th>Method</th><th>Results</th><th>Conclusion</th><th>Reference</th></tr>
<tr>
<td>B.2.2.17
Shelf life
(IIIA 2.7.3)</td>
<td>Guidelines not stated
The formulation was storage for 2 years at room temperature into plastic bottles with polyethylene-lined caps.
Quantification of canola oil: extraction with petroleum ether, drying and weighting of the extract
Emulsion stability: MT 36

GLP: Yes</td>
<td>The canola oil content in NEU 1160 I remained stable when stored 2 years at room temperature (initial 95.4 ± 0.7 %, after 2 years 95.8 ± 0.2 %)
<table>
<tr><th></th><th>Before storage</th><th>After storage</th></tr>
<tr><td rowspan="6">Emulsion stability</td><td colspan="2">5% emulsion in CIPAC water D</td></tr>
<tr><td>Started emulsifying, no froth, white opaque, 1.5 mL on top</td><td>Started emulsifying, no froth, 1 mL oil layer on top, opaque</td></tr>
<tr><td>After 30 min standing: 5 mL cream on surface</td><td>After 30 min standing: 5 mL cream, opaque to translucent solution</td></tr>
<tr><td>After 24 h standing: 2 mL oil, 3 mL cream on surface, solution translucent-nearly clear</td><td>After 24 h standing: no 7 mL cream, opaque to translucent solution</td></tr>
<tr><td>Re-emulsification after 24 h: 1-1.5 mL froth and cream, few drops of oil on surface, white/opaque solution</td><td>Re-emulsification after 24 h: 2 mL foam, 2 mL cream, opaque</td></tr>
<tr><td>After 24.5 h: 1 mL oil, 4 mL cream on the surface</td><td>After 24.5 h: 2 mL foam, 3 mL cream, opaque to translucent solution</td></tr>
</table>
</td>
<td>Acceptable as additional information
The method for the determination of a.s. content is not considered acceptable.</td>
<td>Parker, 2001
Study number: NEU1160-990410

IIIA, 2.7.5/01</td>
</tr>
<tr>
<td>B.2.2.18
Wettability
(IIIA 2.8.1)</td>
<td></td>
<td>Not required, because NEU 1160 I is not a solid preparation.</td>
<td>Acceptable</td>
<td></td>
</tr>
<tr>
<td>B.2.2.19
Persistent foaming
(IIIA 2.8.2)</td>
<td>CIPAC MT 47.2

GLP: Yes</td>
<td>- Concentration not specified in CIPAC water C
After 0 19 ± 1.2 mL
After 1 min 13 ± 0.6 mL</td>
<td>Acceptable as additional information
RMS remarks:
Persistent foaming should be performed in CIPAC water D. The concentration was not specified</td>
<td>Parker, 1996
IIIA, 2.8.2/01</td>
</tr>
</table>

Study	Method	Results	Conclusion	Reference
B.2.2.20 Suspensibility (IIIA 2.8.3)	--	Not required, because NEU 1160 I is not a water dispersible product.	Acceptable	--
B.2.2.21 Spontaneity of dispersion (IIIA 2.8.3)	--	Not required, because NEU 1160 I is not a water dispersible product.	Acceptable	--
B.2.2.22 Dilution stability (IIIA 2.8.4)	--	Not required, because NEU 1160 I is an emulsifiable concentrate and not water soluble concentrate.	Acceptable	--
B.2.2.23 Dry sieve test (IIIA 2.8.5)	--	Not required, because NEU 1160 I is not a dustable powder.	Acceptable	--
B.2.2.24 Wet sieve test (IIIA 2.8.5)	--	Not required, because NEU 1160 I is not a water dispersible formulation.	Acceptable	--
B.2.2.25 Size distribution of particles - Nominal size range of granules (IIIA 2.8.6.1)	--	Not required, because NEU 1160 I is not a powder.	Acceptable	--
B.2.2.26 Dust content/particle size (IIIA 2.8.6.2)	--	Not required, because NEU 1160 I is no granular preparation.	Acceptable	--
B.2.2.27 Attrition resistance and friability (IIIA 2.8.6.3)	--	Not required, because NEU 1160 I is no granular preparation.	Acceptable.	--

Study	Method	Results	Conclusion	Reference
B.2.2.28 Emulsifiability, re-emulsifiability and emulsion stability (IIIA 2.8.7.1)	CIPAC MT 36 GLP: Yes	<table><tr><th></th><th>Before storage</th><th>After storage</th></tr><tr><td rowspan="5">Emulsion stability</td><td colspan="2">5% emulsion in CIPAC water D</td></tr><tr><td>Started emulsifying, no froth, white opaque, 1.5 mL on top</td><td>Started emulsifying, no froth, 1 mL oil layer on top, opaque</td></tr><tr><td>After 30 min standing: 5 mL cream on surface</td><td>After 30 min standing: 5 mL cream, opaque to translucent solution</td></tr><tr><td>After 24 h standing: 2 mL oil, 3 mL cream on surface, solution translucent-nearly clear</td><td>After 24 h standing: no 7 mL cream, opaque to translucent solution</td></tr><tr><td>Re-emulsification after 24 h: 1-1.5 mL froth and cream, few drops of oil on surface, white/opaque solution</td><td>Re-emulsification after 24 h: 2 mL foam, 2 mL cream, opaque</td></tr></table>	Acceptable	Parker, 2001 Study number: NEU1160-990410 IIIA, 2.8.7.1/01
B.2.2.29 Stability of dilute emulsions (IIIA 2.8.7.2)	CIPAC MT 36 GLP: Yes	<table><tr><th></th><th>Before storage</th><th>After storage</th></tr><tr><td rowspan="3">Emulsion stability</td><td colspan="2">5% emulsion in CIPAC water D</td></tr><tr><td>Re-emulsification after 24 h: 1-1.5 mL froth and cream, few drops of oil on surface, white/opaque solution</td><td>Re-emulsification after 24 h: 2 mL foam, 2 mL cream, opaque</td></tr><tr><td>After 24.5 h: 1 mL oil, 4 mL cream on the surface</td><td>After 24.5 h: 2 mL foam, 3 mL cream, opaque to translucent solution</td></tr></table>	Acceptable	Parker, 2001 Study number: NEU1160-990410 IIIA, 2.8.7.2/01
B.2.2.30 Flowability (IIIA 2.8.8.1)		Not required, because NEU 1160 I is not a granular preparation.	Acceptable	
B.2.2.31 Pourability (rinsibility) (IIIA 2.8.8.2)		Not required, because NEU 1160 I is not a suspension.	Acceptable	

Study	Method	Results	Conclusion	Reference
B.2.2.32 Dustability (IIIA 2.8.8.3)	--	Only required for dustable powders.	Acceptable	--
B.2.2.33 Physical and chemical compatibility of tank mixes (IIIA 2.9)	--	No mixture mentioned on product label.	Acceptable	--
B.2.2.34 Adherence and distribution to seeds (IIIA 2.10)	--	Not used for seed treatment.	Acceptable	--

B.2.3 Summary and evaluation

Rapeseed oil is a blend of different fatty acids. The formulation NEU 1160 I contains [redacted] and 96% technical rapeseed oil. Considering the composition of the two products and the small amount of emulgator in NEU 1160 I, the notifier concluded that physical and chemical properties will be determined by the major ingredient i.e. Rapeseed oil. The other ingredient might contribute negligibly to these properties. As conclusion, it was assumed that the results of studies conducted with NEU 1160 I (for the determination of physical and chemical properties) will not differ from studies conducted with rapeseed oil. Thus, values found from studies conducted on the preparation NEU 1160 I were used for the properties: relative density, auto-flammability, flash point and surface tension. RMS considers that the study for the determination of the surface tension can not been accepted because the emulsifying co-formulant would affect this property.

Rapeseed oil is a clear light yellow liquid with a characteristic odour. The melting/ freezing range is -12.0 – -30.6 °C and decomposes before boiling (> 350 °C). The vapour pressure and Henry's Law Constant were estimated by calculations from the chemical structure of the main molecule (oleic acid glycerol ester). These results are considered as rouge estimation but give information about the no volatility of this compound. A correct UV-VIS report with the identification of the test substance and interpretation of the spectrum is necessary. The interpretation of the FT-IR spectrum is also necessary. The notifier was required to address the possible relevance of one of the components of Rapessed Oil and depending of the answer spectra of this component may be required. The water solubility in the neutral range was estimated to be 2.551 * 10^{-20} mg/L (negligible). Rapeseed oil is very soluble in organic solvents. Its log Pow was estimated by calculations from the chemical structure of the main molecule (oleic acid glycerol ester). These results are considered as a rouge estimation but give information about its high particion to fat (log Kow = 23.2908). Its flammability is not critical, it does not present any risk for explosion and does not have oxidising properties. A study for the determination of surface tension is required.

One formulation is proposed for Annex I (Directive 91/414/EEC) inclusion: NEU 1160 I (883 g Rapeseed oil/L; 96% w/w). The formulation is an emulsifiable concentrate (EC)

NEU 1160 I is not explosive. The product is not oxidizing, and not flammable. Its pH is within the range which naturally occurs e.g. in soil. It is a surface active substance with a relative density of 0.92 at 20°C. Its physical stability allows storage under practical and commercial conditions but the stability of the composition when it is storage for 14 days at 54°C and 2 years at ambient temperature must be determined with an accuracy method. Its technical properties indicate that no particular problems are to be expected, when it is used as recommended. The persistent foaming should be performed in CIPAC water D and the concentration used for the performance of the test should be specified.

B.2.4 References relied on.

Annex point/ reference number	Author(s)	Year	Title **Source** (where different from company) **Company name,** **Report No.,** **GLP status** (where relevant) **published or not**	Data protect. claimed	Owner
Annex II, 2.1.1/01	Wilfinger, W.	2003a	Melting/Freezing Temperature of Rapeseed oil GAB Biotechn. GmbH & IFU Umweltanalytik GmbH, Germany Neudorff GmbH KG Report-no. 20031238/01-PCFP GLP: yes published: no	Yes	NEU
Annex II, 2.1.2/01 2.1.3/01	Smeykal, H.	2003	Boiling point /Boiling range Sicherheitstechnik Siemens Axiva GmbH & Co. KG, Frankfurt Neudorff GmbH KG Report-no. 20030778.01 GLP: yes published: no	Yes	NEU
Annex II, 2.2/01	Krips, H.J.	2000a	Determination of the density (liquid) of NEU 1160 I Notox B.V, 5231 DD 's-Hertogenbosch, The Netherlands W. Neudorff GmbH KG Report-no. NOTOX Project 300364 GLP: yes published: no	Yes	NEU
Annex II, 2.3.1/01	Tiemann, J.	2003a	Vapour Pressure Determination GAB Consulting GmbH, 21769 Lamstedt, Germany W. Neudorff GmbH KG Report-no. 105159-A2-020301-01 GLP: no published: no	Yes	NEU
Annex II, 2.3.2/01	Tiemann, J.	2003b	Rape seed oil (Oleic Acid Ester) Reg-Nr.:20020479 TG. Point 2.3.2 Henry's law constant GAB Consulting GmbH, Lamstedt, Germany W. Neudorff GmbH KG Report-no. 105159-A2-020302-01 GLP: no published: no	Yes	NEU
Annex II, 2.4.1/01 2.4.2/01	Anonymous	2002	Product health and safety data [redacted] W. Neudorff GmbH KG Report-no. not stated GLP: no published: no	Yes	NEU
IIA 2.5.1.2/01	Mekelburguer H.B.	2004	Performance of infrared spectroscopy on rapeseed oil Aqura GmbH, Gebäude 145. Marl. Germany Neudorff GmbH KG Report-no. AN-ASB 0314 GLP: yes published: no	Yes	NEU
IIA 2.6/01	Tiemann, J.	2003c	Solubility in water GAB Consulting GmbH, 21769 Lamstedt, Germany W. Neudorff GmbH KG Report-no. 105159-A2-0206-01 GLP: no published: no	Yes	NEU

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source** (where different from company) **Company name,** **Report No.,** **GLP status** (where relevant) **published or not**	**Data protect. claimed**	**Owner**
Annex II, 2.7/01	Wilfinger, W.	2003b	Solubility of rapeseed oil in organic solvents GAB Biotechn. GmbH & GAB Analytik GmbH, Niefern-Öschelbron W. Neudorff GmbH KG Report-no. 20031238/01-PSBO GLP: yes published: no	Yes	NEU
IIA 2.8.1/01	Tiemann, J.	2003d	n-octanol/water partition coefficient GAB Consulting GmbH, Lamstedt, Germany W. Neudorff GmbH KG Report-no. 105159-A2-0208-01 GLP: no published: no	Yes	NEU
IIA 2.11.2/01	Krips, H.J.	2000b	Determination of the auto-ignition temperature of NEU 1160 I Notox B.V, 5231 DD 's-Hertogenbosch, The Netherlands W. Neudorff GmbH KG Report-no. NOTOX Project 300329 GLP: yes published: no	Yes	NEU
IIA 2.12/01	Krips, H.J.	2000c	Determination of the flash-point of NEU 1160 I Notox B.V, 5231 DD 's-Hertogenbosch, The Netherlands W. Neudorff GmbH KG Report-no. NOTOX Project 300318 GLP: yes published: no	Yes	NEU
Annex III Data and Information					
IIIA 2.1/01 IIIA 2.7.4/01	Parker D.L.	1996	Low temperature stability of NEU 1160 I Eco-Care Technologies Inc., Sidney, BC V8L 5L6, Canada W. Neudorff GmbH KG Report-no. not stated GLP: yes published: no	Yes	NEU
IIIA 2.3.1/01	Krips, H.J.	2000	Determination of the flash-point of NEU 1160 I Notox B.V, 5231 DD 's-Hertogenbosch, The Netherlands W. Neudorff GmbH KG Report-no. NOTOX Project 300318 GLP: yes published: no	Yes	NEU
IIIA 2.3.3/01	Krips, H.J.	2000	Determination of the auto-ignition temperature of NEU 1160 I Notox B.V, 5231 DD 's-Hertogenbosch, The Netherlands W. Neudorff GmbH KG Report-no. NOTOX Project 300329 GLP: yes published: no	Yes	NEU
IIIA 2.4.2/01	Krips, H.J.	2000	Determination of the pH of an aqueous dispersion of NEU 1160 I Notox B.V, 's-Hertogenbosch, The Netherlands W. Neudorff GmbH KG Report-no. 300331 GLP: yes published: no	Yes	NEU
IIIA 2.5.2/01	Krips, H.J.	2000	Determination of the viscosity of NEU 1160 I Notox B.V, 's-Hertogenbosch, The Netherlands W. Neudorff GmbH KG Report-no. 300342 GLP: yes published: no	Yes	NEU

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source** (where different from company) **Company name,** **Report No.,** **GLP status** (where relevant) **published or not**	**Data protect. claimed**	**Owner**
IIIA 2.5.3/01	Krips, H.J.	2000	Determination of the surface tension of an aqueous solution of NEU 1160 I Notox B.V, 's-Hertogenbosch, The Netherlands W. Neudorff GmbH KG Report-no. 300353 GLP: yes published: no	Yes	NEU
IIIA 2.6.1/01	Krips, H.J.	2000	Determination of the density (liquid) of NEU 1160 I Notox B.V, 's-Hertogenbosch, The Netherlands W. Neudorff GmbH KG Report-no. 300364 GLP: yes published: no	Yes	NEU
IIIA, 2.7.1/03	Parker D.L.	2006	Storage stability of NEU 1160 2 week Eco-Care Technologies Inc.,Canada W. Neudorff GmbH KG Study number: Neu1160-060821-2 wk 54 GLP: yes published: no	Yes	NEU
IIIA 2.7.4/01	Parker D.L.	1996	Low temperature stability of NEU 1160 I Eco-Care Technologies Inc., Sidney, BC V8L 5L6, Canada W. Neudorff GmbH KG Report-no. not stated GLP: yes published: no	Yes	NEU
IIIA 2.7.5/01 IIIA 2.8.7.1/01 IIIA 2.8.7.2/01	Parker D.L.	2001	Storage stability of NEU 1160 I Eco-Care Technologies Inc., Sidney, BC V8L 5L6, Canada W. Neudorff GmbH KG Report-no. NEU1160-990410 GLP: yes published: no	Yes	NEU
IIIA 2.8.2/01	Parker D.L.	1996	Foaming of NEU 1161 I Eco-Care Technologies Inc., Sidney, BC V8L 5L6, Canada W. Neudorff GmbH KG Report-no. not stated GLP: yes published: no	Yes	NEU

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ANNEX B

Rapeseed oil

B - 3 : DATA ON APPLICATION AND FURTHER INFORMATION

B.3 Data on application and further information

B.3.1 Data on application relevant to the active substance (Annex IIA 3.1 to 3.6)

B.3.1.1 Function

Insecticide and acaricide

B.3.1.2 Effects on harmful organisms

B.3.1.2.1 The nature of the effects on harmful organisms

Contact action

B.3.1.2.2 Translocation in plants

Non-systemic, not translocated in plants

B.3.1.3 Field of use envisaged

Ornamental horticulture, orchards.

RMS assessment: The use "*orchards*" is very wide and the notifier should specify the use in the table of intended uses under GAPs in order to make the evaluation.

B.3.1.4 Harmful organisms controlled and crops or product protected or treated

B.3.1.4.1 Details of existing and the intended use

Rapeseed oil is intended for the use in ornamentals in greenhouses and in woody ornamentals and fruit crops (except strawberry).

RMS: The notifier should clarify the intended use and specify the use in the table of intended uses under GAPs ("*orchards*" is very wide).

B.3.1.4.2 Details of harmful organisms.

Rapeseed oil is an insecticide/acaricide e.g. for the use against spider mites, scales, and mealy bugs. The target pests cause damage to the plants by sucking plant juices.

B.3.1.4.3 Effects achieved

In orchards and woody ornamentals, Rapeseed oil is used for the suppression of winter stages, whereas all developmental stages are affected with higher application amounts in ornamentals in greenhouses.

B.3.1.5 Mode of action

B.3.1.5.1 Mode of action of the active substance

Rapeseed oil suffocates insects and mites by blocking the spiracles. In addition, the oil also blocks the body pores, which are used by the mite to take in moisture in order to maintain the levels of water in the body.

B.3.1.5.2 Details of active metabolites or degradation products

No active metabolites or degradation products are formed.

B.3.1.5.3 Available information relating to the formation of active metabolites and degradation products

No active metabolites or degradation products are formed.

B.3.1.6 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies

When it is sprayed onto target species or their winter eggs, the thin, air-tight oil layer blocks the permeation of air so that target animals and their eggs die. Since this mode of action is mechanical rather that chemical, insect resistance or tolerance to oils is not expected. There is no information available on insects or mites developing resistance to this active substance.

B.3.2 Data on application relevant to the plant protection product (IIIA, 3)

B.3.2.1 Field of use

Ornamental horticulture, orchards.

B.3.2.2 Effects on harmful organisms

Contact action

B.3.2.3 Details of intended use

B.3.2.3.1 Details of existing and intended uses

NEU 1160 I is intended for the use in ornamentals in greenhouses and in woody ornamentals and fruit crops (except strawberry).

RMS: The notifier should clarify the intended use and specify the use in the table of intended uses under GAPs ("*orchards*" is very wide).

B.3.2.3.2 Details of harmful organisms against which protection is afforded

NEU 1160 I is an acaricide/insecticide for the use against spider mites, scales, and mealy bugs. The target pests cause damage to the plants by sucking plant juices.

Spider mites are tiny arachnids of less than 0.4 mm length when mature. Most spider mites spend the winter in the egg stage. The life cycle comprises the egg stage, one larval stage, 4 nymph stages and the adult stage. Spider mites are usually found on the underside of leaves. The sucking of plant juices from individual plant cells causes a speckled appearance. When plants are heavily infested, they may be discoloured and stunted, fine webbing may be seen on the plants, and leaves may drop prematurely.
Scale species secrete a characteristic waxy protective covering over their bodies. They can be divided into armoured scales and soft scales. In contrast to soft scales, armoured scales have a dense cover which is usually separated from the scale's body. Most armoured scales have several generations a year, whereas soft scales often have only a single generation. Eggs of both groups are often hidden under the adult female. Eggs hatch into tiny crawlers which settle down at permanent feeding sites after a few days. Adult females are immobile and have a characteristic scale cover, whereas adult males are tiny winged insects that live only a few hours. Scales may be found on either side of the leaves, on branches or stems. Damage symptoms caused by scales are reduced growth and premature leaf drop, as well as yellow spots on leaf tips. Furthermore, soft scales may produce large quantities of honeydew, which may serve as substrate for black sooty mould fungi.

Mealy bugs are soft-bodies insects covered with a white powder material. They are common pests of greenhouses. Reproduction under greenhouse conditions is year-round. Mealy bugs may form dense colonies. Some species produce "waxy wool" in which they lay their eggs. Young crawlers disperse rapidly on the plant to find suitable feeding sites. The complete life cycle takes approximately 50 days at 20 °C. They damage the plants by sucking the juices from leaves. Leaf yellowing, leaf curling, leaf drop, and reduced plant growth are common symptoms of high infestations with mealy bugs. Furthermore, they also produce honeydew, which may serve as substrate for black sooty mould fungi.

B.3.2.3.3 Effects achieved e.g. sprout suppression

With an early application of NEU 1160 I in orchards and woody ornamentals in the field, infestation levels with winter eggs of spider mites are suppressed, so that populations of the target species are reduced to a low level during the year.

Applications in glasshouses are intended to kill also the adult stages of spider mites, scales, and mealy bugs. Higher application amounts are necessary to achieve this effect.

B.3.2.4 Application rate

In orchards, NEU 1160 I is applied at amounts of 10 L/ha and m crown height (corresponding to 8.83 kg Rapeseed oil/ha and m crown height). In woody ornamentals, the application amounts are also dependent on plants height with recommendations between 12 and 24 L/ha (10.6-21.2 g Rapeseed oil/ha).

For the application in ornamentals in greenhouses, recommended application amounts vary between 40-80 L/ha (35.3-70.6 g Rapeseed oil/ha).

RMS assessment: The use "*orchards*" is very wide and the notifier should specify the use in the table of intended uses under GAPs. In addition, the application rate for orchards of 8.83 kg as/ha and m crown height is not accepted. A range of the application per ha must be specified, independently of the height of the plant.

B.3.2.5 Concentration of active substance in material used

The product should be used in spray solutions of 2% product in water (v/v), corresponding to 1.77 kg Rapeseed oil/hL.

B.3.2.6 Method of application

NEU 1160 I is to be sprayed. Dependent on the size of the area to be treated, this may be done by motor sprayers, knapsack sprayers or hand sprayers. In orchards, a water amount of 500 L/ha and m crown height is recommended, whereas amounts in woody ornamentals vary between 600 and 1200 L/ha. In ornamentals in greenhouses, the product should be applied in 2000 to 4000 L/ha.

RMS assessment: The use "*orchards*" is very wide and the notifier should specify the use in the table of intended uses under GAPs. In addition, a water amount of 500 L/ha and m crown height is not accepted. A range of the application per ha must be specified, independently of the height of the plant.

B.3.2.7 Number and timing of applications and duration of protection

B 3.2.7.1 Maximum number of applications and their timing

In orchards and woody ornamentals, the product is used with 1 application in spring, shortly after the start of vegetation. In contrast to this, up to 3 applications with an interval of 7 days are intended in greenhouses. These applications should be timed at the beginning of infestation.

B 3.2.7.2 Growth stages of the crop or plants to be protected

In orchards and woody ornamentals, the application should be performed in the period between the start of vegetation (bud swelling) up to mouse ear stage or bud break.

B 3.2.7.3 Development stages of the harmful organism concerned

In orchards and woody ornamentals, the treatment is intended against winter eggs of spider mites. In contrast to this, all developmental stages of target species will be affected by applications in the greenhouse, however, as NEU 1160 I is a contact insecticide/acaricide, hidden stages of the target species may be less affected, so that the treatment has to be repeated after about 7 days.

B 3.2.7.4 Duration of protection afforded by each application

NEU 1160 I is a contact acaricide/insecticide. Thus duration of protection is dependent on the period of population recovery or re-infestations and cannot be estimated. A single application is recommended against winter stages of spider mites in orchards and woody ornamentals. In greenhouses, it is recommended to repeat the treatment after about 7 days to interfere with the recovery of pest populations from hidden stages.

B 3.2.7.5 Duration of protection afforded by the maximum number of applications

A single application is recommended against winter stages of spider mites in orchards and woody ornamentals. This treatment should reduce the population of mites so far that protection should last for the next months to come. Up to 3 treatments are required to achieve an optimal control of all stages of spider mites, scales and mealy bugs in ornamentals under glass. Protection then should last until a new population begins to develop. This re-infestation risk is highly dependent on conditions which are not connected with the effectiveness of NEU 1160 I.

B.3.2.8 Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops

B 3.2.8.1 Minimum waiting periods

Succeeding crops will normally not occur in orchards or woody ornamentals. Furthermore, the active substance Rapeseed oil degrades rather rapidly in the soil. Thus, no adverse effects on succeeding crops are to be expected e.g. in greenhouses.

B 3.2.8.2 Limitations on choice of succeeding crops

Since no relevant residues are to be expected at planting or sowing of succeeding crops, there are no limitations in the choice of crops.

B 3.2.8.3 Description of damage to rotational crops

Since no relevant residues are to be expected at planting or sowing of succeeding crops, there are no limitations in the choice of crops.

B.3.2.9 Proposed instructions for use

As it is included in the proposed label

B.3.3 Summary of data on application

Rapeseed oil is an insecticide/acaricide e.g. for the use against spider mites, scales, and mealy bugs. The target pests cause damage to the plants by sucking plant juices. The action is by contact; Rapeseed oil suffocates insects and mites by blocking the spiracles and the body pores. It is intended to be used in ornamental horticulture and orchards. In orchards, the formulation NEU 1160 I is applied at amounts of 10 L/ha and m crown height (corresponding to 8.83 kg Rapeseed oil/ha and m crown height). In woody

ornamentals, the application amounts are also dependent on plants height with recommendations between 12 and 24 L/ha (10.6-21.2 g Rapeseed oil/ha). In orchards and woody ornamentals, the product is used with 1 application in spring, shortly after the start of vegetation. For the application in ornamentals in greenhouses, recommended application amounts vary between 40-80 L/ha (35.3-70.6 g Rapeseed oil/ha) and up to 3 applications with an interval of 7 days. These applications should be timed at the beginning of infestation. NEU 1160 I is to be sprayed.

RMS considers that the use "*orchards*" is very wide and the notifier should specify the use in the table of intended uses under GAPs. In addition, the application rate for orchards of 8.83 kg as/ha and m crown height is not accepted. A range of the application per ha must be specified, independently of the height of the plant.

B.3.4 Further information on the active substance (IIA 3.7 to 3.9)

B.3.4.1 Recommended methods and precautions concerning handling, storage, transport, fire

The recommended precautions concerning handling, storage, transport and fire are collected in the safety data sheet (**IIA 3.7/01**).

B.3.4.2 Procedures for destruction or decontamination

B.3.4.2.1 Controlled incineration

Rapeseed oil is an active substance without any halogens. A study on pyrolytic behaviour, therefore, is not required.

Disposal should be done according to the EEC Directives on the disposal of waste oil.

B.3.4.2.2 Others

Other methods are of no relevance

B.3.4.3 Emergency measures in case of an accident

Procedures for the decontamination of water

Dike spill: Prevent from entering sewers, waterways, or low areas. Sweep up and place in suitable containers for later disposal.

RMS: Information to cover this annex point has not been provided.

B.3.5 Further information on the plant protection product (Annex IIIA 4)

B.3.5.1 Packaging (type, material, size etc.), compatibility of the preparation with proposed packaging material

B.3.5.1.1 Packaging specification

250 mL flask

Material	HDPE
Shape/size	Round / 155 x 73 x 42 mm (h/b/d)
Opening	32 mm diameter
Closure	Measuring screw cap with sealing disk

500 mL flask

Material	HDPE
Shape/size	Round / 196 x 90 x 52 mm (h/b/d)
Opening	32 mm diameter
Closure	Measuring screw cap with sealing disk

1 L flask

Material	HDPE
Shape/size	Round / 271 x 109 x 63 mm (h/b/d)
Opening	32 mm diameter
Closure	Measuring screw cap with sealing disk

5 L can

Material	PE can
Shape/size	250 x 180 x 140 mm (h/b/d)
Opening	45 mm diameter
Closure	PE screw cap with sealing disk

10 L can

Material	PE can
Shape/size	300 x 220 x 180 mm (h/b/d)
Opening	45 mm diameter
Closure	PE screw cap with sealing disk

B.3.5.1.2 Packaging suitability

The above mentioned packaging and closures are suitable for containing, handling and transport of the emulsion concentrate NEU 1160 I.

RMS: Information to cover this annex point has not been provided.

B.3.5.1.3 Packaging resistance

High density polyethylene is known from experience to be very resistant to influences of chemicals. NEU 1160 I is an emulsion concentrate (EC) on a plant oily basis. Plant oil based formulations are not expected to react with the packaging materials (linerless cap and polyethylene container). NEU 1160 I does not contain any strong acidic, alkaline components or organic solvents and also its other physical and chemical properties do not give reason to expect particular problems.

B.3.5.2 Procedures for cleaning equipment

B.3.5.2.1 Procedures for cleaning application equipment and protective clothing

Remainder of spray in the tank of sprayer shall be diluted and sprayed over already treated areas. Empty as thoroughly as possible all the equipment. Double rinse with water and recover contaminated effluents. After use, containers and nozzles are thoroughly rinsed with water and cleaning agent. Contaminated water should be disposed off in agreement with local regulations.

Protective clothing shall be washed in the usual way.

B.3.5.2.2 Effectiveness of the cleaning procedure

Due to its good water emulsifiability, the expected effectiveness of the cleaning procedure of contaminated equipment and clothing is accepted to be very high.

B.3.5.3 Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment

B.3.5.3.1 Pre-harvest interval (in days) for each relevant crop

Notifier statement: The waiting period is not relevant in ornamentals as they are not harvested for food or feed (waiting period proposal "N"). Furthermore, it is also not relevant in orchards, since Rapeseed oil is a natural food commodity composed of natural fatty acids, which are indistinguishable from the plants own fatty acids at harvest.

RMS assessment: Rapeseed oil is intended to be applied long before the development of fruits in orchards and therefore residues is not likely to be present at time of harvest in the fruit, nevertheless more information about the residue definition for plant material and clarification on the intended uses are needed before a conclusion can be achieved.

B.3.5.3.2 Re-entry period (in days) for livestock, to areas to be grazed

A re-entry period is considered not relevant, since Rapeseed oil is a natural oil which is also used as a food commodity.

B.3.5.3.3 Re-entry period (in hours or days) for man to crop, buildings or spaces treated

A re-entry period is considered not relevant, since Rapeseed oil is a natural oil which is also used as a food commodity. There is no toxicological concern of man getting in contact with this oil.

B.3.5.3.4 Withholding period (in days) for animal feedingstuffs

A withholding period for animal feeding stuffs is considered not relevant, since Rapeseed oil is a natural oil which is also used as a food commodity.

B.3.5.3.5 Waiting periods (in days) between application and handling treated products

Rapeseed oil is a natural oil which is also used as a food commodity. There is no toxicological concern of man getting in contact with this oil.

B.3.5.3.6 Waiting period (in days) between last application and sowing or planting succeeding crops

Rapeseed oil is intended for application in permanent cultures which are normally not followed by succeeding crops. Furthermore, the fatty acids contained in Rapeseed oil degrade rapidly (refer to **B.8**) and are natural components of the soil. Thus, a waiting period between application and sowing or planting succeeding crops is considered not relevant.

B.3.5.3.7 Information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used

There are no specific conditions under which the preparation may or may not be used. The product is suitable for professional and home garden use.

RMS: Information to cover this annex point has not been provided.

B.3.5.4 Recommended methods and precautions concerning handling, storage, transport or fire

B.3.5.4.1 Warehouse storage

B.3.5.4.2 User level storage

Read the entire label. Use in accordance with label precaution statements and directions. General hygiene measures for the handling of chemicals are applicable. Avoid contact with eyes or skin. Eating, drinking, smoking as well as food storage is prohibited in working areas.

B.3.5.4.3 Transport

No regulation for land, sea and air shipment.

B.3.5.4.4 Fire

Combustible material, low hazard. The product can form flammable mixtures or can burn only on heating above the flash point. However, minor contamination by hydrocarbons of higher volatility may increase the hazard. Leakage or conditions resulting in impregnation of this oil some porous material such as rags, paper, insulation or clay may cause spontaneous combustion.

Recommended fire-fighting media: foam, carbon dioxide, dry powders.

Avoid the escape of fire-fighting water to the environment.

Wear a self-contained breathing apparatus.

B.3.5.4.5 Protective clothing and equipment proposed for use in storage, transport or in the event of fire-nature

B.3.5.4.6 Protective clothing and equipment proposed for use in storage, transport or in the event of fire-characteristics

Wear fitting goggles for handling and storage of the product. Additional, skin contact should be avoided during handling by means of universal protective gloves resistant to penetration, water leak test according to EN 374, part 3 and air leak test, EN 374, part 4. Moreover, resistance to permeation by chemicals tested according to EN 374 part 5.

B.3.5.4.7 Sufficient data to evaluate suitability and effectiveness of protective clothing and equipment under realistic conditions of use

The tests mentioned above provide enough information on the suitability of the protective clothing under realistic conditions of use.

B.3.5.4.8 Procedures to minimize the generation of waste

Product containers must be cleaned during loading of the tank by means of standard devices at the sprayer.

Remainder of spray in the tank of sprayer shall be diluted and sprayed over already treated areas; totally cleaned packages can be given to the waste disposal.

B.3.5.4.9 Information on combustion products likely to be generated in the event of fire

In the case of fire following substances can be formed: toxic gases, oxides of carbon, oxides of nitrogen.

B.3.5.5 Emergency measures in case of an accident

B.3.5.5.1 Containment of spillages

If leakage occurs, dam up. Prevent from entering drainage system. Prevent surface and ground-water infiltration, as well as ground penetration. If accidental entry into drainage system occurs, inform responsible authorities.

Recover the product by pumping, suction or absorption using a dry and inert absorbent like clay, dry sand or earth. Shovel up and place into a labelled tightly closed container.

All contaminated material should be placed in closable receptacles and submitted to controlled incineration.

B.3.5.5.2 Decontamination of areas, vehicles, buildings

Spillages must be collected by scoop or vacuum. Use absorbent material (e.g. Universal binding medium) to collect spillage.

To clean contaminated floors and objects, wipe with a damp cloth. All contaminated cleaning material should be placed in closable receptacles

B.3.5.5.3 Disposal of damaged packaging, adsorbents and other material

The diluted spray remainders e.g. from cleaning of application techniques must not be disposed over drains or in drainage channels, gullies or similar structures.

Remainders of the product, contaminated cleaning material and absorbents shall be given to the local waste disposal for controlled incineration.

B.3.5.5.4 Protection of emergency workers and bystanders

In open systems where contact is likely, wear safety glasses with side shields. When concentration in air may exceed the occupational exposure limit of 5 mg/m³, and where engineering, work practices, or other means of exposure reduction are not adequate, approved respirators may be required.

B.3.5.5.5 First aid measures

Inhalation: At ambient/normal handling temperatures (0-38 °C) no adverse effects due to inhalation of vapour are expected. Ensure availability of fresh air.

Ingestion: No adverse effects due to ingestion are expected.

Skin contact: No adverse effects due to skin contact are expected. Clean with water and soap. Remove contaminated clothing, launder before re-use.

Eye contact: No adverse effects are expected. Rinse with water. In case of irritation seek medical attention

B.3.5.6 Procedures for the destruction or decontamination of the plant protection product and its packaging

B.3.5.6.1 Possibility of neutralisation

NEU 1160 I is neither acidic nor alkaline. Neutralization procedures are therefore not applicable.

B.3.5.6.2 Controlled incineration. Pyrolytic behaviour of the active substance under controlled conditions at 800°C:

Not applicable. NEU 1160 I is a preparation with a halogen content below 25 %.

B.3.5.6.3 Others

Only empty and clean packages shall be given to the municipal waste disposal collection.

No other methods are currently available.

B.3.6 References relied on.

Annex point / reference number	Author(s)	Year	Title Source Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
Annex II Data and Information					
Annex II, 3.7/01	Anonymous	2002	Product health and safety data [redacted] W. Neudorff GmbH KG Report-no. not stated GLP: no published: no	Yes	NEU

NEU: W. Neudorff GmbH KG

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ANNEX B

Rapeseed Oil

B - 4: PROPOSALS FOR CLASSIFICATION AND LABELLING

B.4 Proposals for classification and labelling

B.4.1 Proposals for the classification and labelling of the active substance (IIA, 10)

Notifier proposal: No proposal for the classification and labelling of the active substance. This product is a pure edible vegetable oil which is not considered to present any hazard during normal use. Therefore no risk or safety phrases are stated.

RMS proposal: According to EU Council Directive 2001/59/EEC (for dangerous substances) the following classifications and labelling are proposed for the active substance

Hazard symbol			**Justification**
Indication of danger	N		
Risk phrases:	R52	Harmful to aquatic organism	
Safety phrases	S61	Avoid release to the environment. Refer to special instructions / Safety data sheets	
Hazardous components	Parent compound		

B.4.2 Proposal for the classification and labelling of preparations (IIIA, 12.3 and 12.4)

Notifier proposal: No proposal for the classification and labelling of preparation.. This product is nearly a pure edible vegetable oil which is not considered to present any hazard during normal use. Therefore no risk or safety phrases are stated.

RMS proposal: classification and labelling of the plant protection product according to Directive 67/548/EEC and Directive 1999/45/EC

NAME OF PREPARATION: NEU 1160 I

Hazard symbol			**Justification**
Indication of danger	N		
Risk phrases:	R52	Harmful to aquatic organism	
Safety phrases	S61	Avoid release to the environment. Refer to special instructions / Safety data sheets	
Hazardous components	Parent compound		

B.4.3 References relied on

The applicant has not submitted any reference concerning this point.

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ANNEX B

RAPESEED OIL

B - 5 : METHODS OF ANALYSIS

B.5 Methods of analysis

B.5.1 Analytical methods for technical active substance and formulation analysis (IIA 4.1; IIIA 5.1)

B.5.1.1 Analytical Methods, for the determination of pure active substance in the active substance as manufactured (IIA 4.1.1 and 4.1.3)

See **Annex C**,C.1.2.4.1, confidential information.

No applicable existing CIPAC methods.

B.5.1.2 Analytical Methods for the determination of significant and/or relevant impurities and additives (e.g. stabilizers) in the active substance as manufactured (IIA 4.1.2 and 4.1.3).

See **Annex C,** C.1.2.4.2, confidential information for significant impurities.

B.5.1.3 Analytical methods for the determination of the active substance in plant protection products (IIIA 5.1.1 and 5.1.3)

References: Anonymous; "2.301 Preparation of the fatty acid methyl esters." IUPAC methods. **IIIA 5.2.1/01.**

References: Anonymous; "2.302 Gas-liquid chromatography of fatty acid methyl esters." IUPAC methods. **IIIA 5.2.1/02.**

The notifier proposed already established IUPAC methods (2.301 and 2.302) for the determination of components of Rapeseed oil. These methods have been used during years in laboratories all over the world to analyse rapeseed oil acceptability for food uses, being included also in the FAO Codex Alimentarius 210/1999 as methods for the determination of fatty acids.

Also, a full protocol is submitted specifically for the determination of erucic acid as attach document to the 2.302 method (IUPAC method 2.311).

Principle of the method for the determination of fatty acids

To determine the composition of a mixture of fatty acids such as the rapeseed oil, the vegetable oil [redacted] (IUPAC method 2.301). Alternative methods not involving [redacted] in the

[redacted]

Fatty acid methyl esters are analyzed by mean of gas-liquid chromatography to determine the composition of the mixture (IUPAC method 2.302).

GC parameters	
Detector	Ordinary equipment such as flame-ionization detector (FID). It should be capable of being heated to a temperature above that of the column
Column	1 to 3 m length , glass or stainless steel, 2 to 4 mm diameter
Carrier gas	Inert gas containing less than 10 mg/kg of oxygen
Injection	Maximum capacity 10 µL graduated in 0.1µL

Principle of the method for the determination of erucic acid

The method involves [redacted] (IUPAC method 2.301), followed by [redacted] chromatography (IUPAC method 2.311).

Evaluation and conclusion: The dossier only includes a copy of the standard IUPAC methods without a clear reference to the manual where they were published. The notifier states that validation is not needed because they have been used for many years to determine the composition of rapeseed oil and acceptability for food uses in countries all over the world but the validation of the notifier is not provided. **So, it is required a validation for the three IUPAC methods** (2.301, 2.302 and 2.311 methods) according to the SANCO 825/00-rev 6 (20/06/00) guideline.

B.5.1.4 Analytical methods for the determination of relevant impurities and formulants in plant protection products (IIIA 5.1.2 and 5.1.3)

Not relevant impurities.

B.5.2 Analytical methods (residue) for plants, plant products, foodstuffs of plant and animals origin, feeding stuffs. (IIA 4.2.1, IIIA 5.2)

B.5.2.1 Plant material

The notifier indicates that no information regarding method of analysis for plant residues is required when the exposure, due to the use of the plant extract as a plant protection product, is not relevant in relation to the exposure due to consumption of the plant itself (**IIA 4.3/02**). RMS agrees with the notifier however according with the assessment of the metabolism in plant (Chapter B7 Residue Data), some additional data is needed to confirm that "not naturally occurrence fatty acids" or undesirable compounds are not found in the plant as a consequence of the application of rapeseed oil.

B.5.2.2 Animal material

There is no residue definition in animal material. So, it is no necessary analytical methods.

B.5.3 Analytical methods (residue) soil, water, air (IIA 4.2.2 to 4.2.4; IIIA 5.2)

B.5.3.1 Soil

The notifier has not submitted analytical method for soil because considered that the natural occurrence in plants, animals and soils, together with the rapid microbial degradation eliminate the need to quantify rapeseed oil residue from applications as an insecticide or acaricide. For it contributes with three articles of Goring & Hamaker, 1972; Moucawi et al., 1981 and Smith, 1974. (IIA 4.4/01, IIA 4.4/02 and IIA 4.4/04). The public literature reveals that the degradation of fatty acids in soil is biologically mediated. Fatty acids are excellent substrate for microbial growth, serving both as carbon source and as energy source. 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. The decomposition of typical lipids is influenced by soils properties to which they were added. 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. One of the conclusions of these articles is that although all the fatty acids follow the same metabolism process, differences can be quantitatively but no qualitatively. According to the SANCO/10472/2003 rev.5, a validated method for analysing the active substance in water, soil and air can be judged necessary if exposure of the concerning compartment is likely and the contribution compared to natural background levels is substantial. RMS considers that according to data in the environmental fate and behaviour section and the ecotoxicology risk assessment the exposure of soil organism to rapeseed oil, due to an application as insecticide, is likely, furthermore the estimated the DT_{90} is 9.3 days. Therefore, analytical methods for soil is required

B.5.3.2 Water

The notifier has not submitted analytical method because considered that any contamination of this substance to drinking water or ground water is unlikely to occur. Even if the oil may be washed off treated plants by rain, it will rapidly degrade in the environment. There is no degradation studies in water. RMS can not confirm this assumptions. In addition the US EPA considers that, since people are exposed to this substance from food or other sources, the incremental exposure derived from non-dietary exposure such as drinking water or ground water should be minimal (US EPA 1998). Thus, a method to quantify rapeseed oil residue in waters from applications as an insecticide or acaricide, is considered not necessary. **RMS considers that there are not enough data to confirm it.** The notifier concludes that the conclusions on the fate and behaviour in soil can be extrapolated to the water compartment. RMS considers that according to data in the environmental fate and behaviour section and the ecotoxicology risk assessment the exposure of water organism to rapeseed oil, due to an application as insecticide, is likely, furthermore the estimated DT_{90} is 9.3 days. **Therefore, analytical method for water is required**

B.5.3.3 Air (where worker or bystander exposure likely)

As the Rapeseed oil does not volatize, analytical method for the determination of the metabolites in air is not required.

B.5.4 Analytical methods (residue) for body fluids an tissues. (IIA 4.2.5; IIIA 5.2)

A method for body fluids and tissues is not required, because Rapeseed oil is not classified as toxic or highly toxic.

B.5.5 Overall Evaluation and assessment

B.5.5.1 Analytical methods for technical active substance and formulation analysis

See **Annex C**,C.1.2.4.1 and **Annex C,** C.1.2.4.2, confidential information for active substance as manufactured.

The notifier proposed already established IUPAC methods (2.301 and 2.302) for the determination of components of Rapeseed oil. Also, a full protocol is submitted specifically for the determination of erucic acid as attach document to the 2.302 method (IUPAC method 2.311). The dossier only includes a copy of the standard IUPAC methods without a clear reference to the manual where they were published. The notifier states that validation is not needed because they have been used for many years to determine the composition of rapeseed oil and acceptability for food uses in countries all over the world but the validation of the notifier is not provided and it is necessary as established the analysis

methods guidelines. **So, it is required a validation for the three IUPAC methods** (2.301, 2.302 and 2.311 methods) according to the SANCO 825/00-rev 6 (20/06/00) guideline in the NEU 1160 I formulation.

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B.5.5.2 Analytical methods for residues

The notifier indicates that no method of analysis for plant residues is required. RMS agrees with the notifier however according with the assessment of the metabolism in plant (Chapter B7 Residue Data), some additional data is needed to confirm that "not naturally occurrence fatty acids" or undesirable compounds are not found in the plant as a consequence of the application of rapeseed oil.

The notifier considered that methods to quantify rapeseed oil residue in soil and water are not necessary because the natural occurrence in environment together the rapid microbial degradation eliminate the need to quantify rapeseed oil residue when it is applies as an insecticide or acaricide. However, **RMS considers that exposure in soil and water is likely and analytical methods in soil and water are required**.

There is no residue definition in animal material. So, it is no necessary analytical methods.

As the Rapeseed oil does not volatize, analytical method for the determination of the metabolites in air is not required.

A method for body fluids and tissues is not required, because Rapeseed oil is not classified as toxic or highly toxic.

B.5.6 References relied on

Annex point/ reference number	Author(s)	Year	Title **Source** (where different from company) **Company name,** **Report No.,** **GLP status** (where relevant) **published or not**	Data protect. claimed	Owner
IIA 4.3/01	Anonymous	2004	Concerning the data requirements for active substances of plant protection products made from plants or plant extracts not stated European commission Report-no. SANCO/10472/2003-rev.5 GLP: no published: yes	no	-
IIA 4.3/02	Anonymous	1998	Canola oil;exemption from the requirement of a tolerance not stated USEPA Report-no. not stated GLP: no published: yes	no	-
IIA 4.4/01	Cleve, A.; Goring, C.A.I.; Hamaker; J.W.	1972	Organic chemicals in the soil environment not applicable Marcel Dekker Inc. New York Report-no. not applicable GLP: no published: yes	no	
IIA 4.4/02	Moucawi J. et al.	1981	Decomposition of lipids in soils: free and esterrified fatty acids, alcohols and ketones not stated not stated Report-no. not stated GLP: no published: yes	no	-
IIA 4.4/03	Smith J.H.	1974	Decomposition in soil of waste cooking oils used in potato processing not stated J.Environ.Quality, Vol. 3, no. 3, 1974 Report-no. not stated GLP: no published: yes	no	-
IIA 4.4/04	Anonymous	1992	Reregistration eligibility document: Soap salts not stated USEPA Report-no. 540/RS-93-231 GLP: no published: yes	no	-
IIA 4.5/01	Anonymous	1998	Canola oil;exemption from the requirement of a tolerance not stated USEPA Report-no. not stated GLP: no published: yes Submitted in: KIIA 4.3/02	no	-

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source** (where different from company) **Company name,** **Report No.,** **GLP status** (where relevant) **published or not**	**Data protect. claimed**	**Owner**
IIIA 5.2.1/01	Anonymous	1900	2.301 Preparation of the fatty acid methyl esters not stated IUPAC Report-no. not stated GLP: no published: yes	no	-
IIIA 5.2.1/02	Anonymous	1900	2.302 Gas-liquid chromatography of fatty acid methyl esters not stated IUPAC Report-no. not stated GLP: no published: yes	no	-

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