**IUCLID Dataset**

Existing Chemical Substance ID: 67762-38-3
CAS No. 67762-38-3
EINECS Name Fatty acids, C16-18 and C18-unsatd., Me esters
EINECS No. 267-015-4
Molecular Weight 275
Molecular Formula not applicable

Dataset created by: EUROPEAN COMMISSION - European Chemicals Bureau

This dossier is a compilation based on data reported by the European Chemicals Industry following 'Council Regulation (EEC) No. 793/93 on the Evaluation and Control of the Risks of Existing Substances'. All (non-confidential) information from the single datasets, submitted in the IUCLID/HEDSET format by individual companies, was integrated to create this document.

The data have not undergone any evaluation by the European Commission.

Creation date: 19-FEB-2000

Number of Pages: 29

Chapters: all


Flags: non-confidential

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European Chemicals Bureau
1. General Information

1.0.1 OECD and Company Information

Name: Henkel KGaA
Street: Henkelstr. 67
Town: 40589 Duesseldorf
Country: Germany

Name: Novartis Agro GmbH (formerly Ciba-Geigy Agro GmbH) Germany
Street: Postfach 110353
Town: 60038 Frankfurt/Main
Country: Germany
Phone: 49 69 7155-0
Telefax: 49 69 727 647

Name: Sidobre Sinnova
Street: Allee des Platanes
Town: 77100 Meaux
Country: France

1.0.2 Location of Production Site

1.0.3 Identity of Recipients

1.1 General Substance Information

Substance type: organic
Physical status: liquid

1.1.1 Spectra

1.2 Synonyms

Edenor ME-SU/DS 20
Source: Sidobre Sinnova Meaux

Fatty acid esters, rape-oil, Me esters
Source: Sidobre Sinnova Meaux

Fatty acids, C16-18 and C18-unsatd., Me esters
Source: Henkel KGaA Duesseldorf

Fatty acids, rape-oil, Me esters
Source: Sidobre Sinnova Meaux

Fatty acids, rapeseed-oil, Me esters
Source: Sidobre Sinnova Meaux
1. General Information

Date: 19–FEB–2000

Substance ID: 67762–38–3

1. General Information

FETTSÄUREN, RUEBOEL, METHYLESTER
Source: Sidobre Sinnova Meaux

Fettsäure C16/18 und unges. C18
Source: Henkel KGaA Duesseldorf

Fettsäure(C16/18)-methylester
Source: Henkel KGaA Duesseldorf

Fettsäuren, C16-18 und C18 ungesättigt, Methyl-Ester
Source: Henkel KGaA Duesseldorf

FS-RUEBOEL, METHYLESTER
Source: Sidobre Sinnova Meaux

Oelsäuremethylester
Source: Henkel KGaA Duesseldorf

Rape-oil fatty acids, Me esters
Source: Sidobre Sinnova Meaux

Rape-oil, Me esters fatty acids
Source: Sidobre Sinnova Meaux

Rübfettsäuremethylester, erucaarm
Source: Sidobre Sinnova Meaux

Rüböl fettsäure-Methyl-ester
Source: Henkel KGaA Duesseldorf

Rüböl fettsäure-Methyl-ester, erucaarm dest.
Source: Henkel KGaA Duesseldorf

Sojaöl fettsäure-Methyl-ester
Source: Henkel KGaA Duesseldorf

Ölsäuremethyl-ester/Linolsäuremethyl-ester-Gemisch
Source: Henkel KGaA Duesseldorf

Ölsäuremethylester
Source: Henkel KGaA Duesseldorf

1.3 Impurities

1.4 Additives

1.5 Quantity

1.6.1 Labelling

-
1. General Information

1.6.2 Classification

1.7 Use Pattern

1.7.1 Technology Production/Use

1.8 Occupational Exposure Limit Values

1.9 Source of Exposure

1.10.1 Recommendations/Precautionary Measures

1.10.2 Emergency Measures

1.11 Packaging

1.12 Possib. of Rendering Subst. Harmless

1.13 Statements Concerning Waste

1.14.1 Water Pollution

Classified by: KBwS (DE)
Labelled by: KBwS (DE)
Class of danger: 1 (weakly water polluting)
Source: Henkel KGaA Duesseldorf
Test substance: Fatty acids, methyl esters (fatty acid residue saturated or unsaturated, even-numbered unbranched C-chain >= C6)

1.14.2 Major Accident Hazards

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(1)
1. General Information

1.14.3 Air Pollution

Classified by: TA-Luft (DE)
Labelled by: 
Number: 
Class of danger: 
Remark: 150 mg/m³ 
Source: Henkel KGaA Duesseldorf

1.15 Additional Remarks

Source: Henkel KGaA Duesseldorf

1.16 Last Literature Search

-

1.17 Reviews

-

1.18 Listings e.g. Chemical Inventories

-
2. Physico-chemical Data

2.1 Melting Point

Value: ca. –6 degree C
Source: Henkel KGaA Duesseldorf

2.2 Boiling Point

Value: ca. 200 degree C
Source: Sidobre Sinnova Meaux

Value: ca. 300 degree C at 1013 hPa
Method: other: DIN 51751
Source: Henkel KGaA Duesseldorf

2.3 Density

Type: density
Value: = .875 – .885 g/cm3 at 20 degree C
Source: Henkel KGaA Duesseldorf

Type: density
Value: ca. .875 g/cm3 at 20 degree C
Source: Sidobre Sinnova Meaux

2.3.1 Granulometry

2.4 Vapour Pressure

Value: = .1798 hPa at 125.6 degree C
Source: Henkel KGaA Duesseldorf
Test substance: Octadecanoic acid methyl ester

Value: = 2.93 hPa at 148.5 degree C
Source: Henkel KGaA Duesseldorf
Test substance: Hexadecanoic acid methyl ester

2.5 Partition Coefficient

log Pow:
Method:
Year:
Source: Henkel KGaA Duesseldorf
2.6.1 Water Solubility

Qualitative: not soluble
Source: Sidobre Sinnova Meaux

Qualitative: not soluble
Source: Henkel KGaA Duesseldorf

2.6.2 Surface Tension

2.7 Flash Point

Value: = 170 degree C
Type: open cup
Method: other: DIN ISO 2592 (Cleveland)
Source: Henkel KGaA Duesseldorf

Value: = 175 degree C
Type: open cup
Method: other: DIN ISO 2592 (Cleveland)
Source: Henkel KGaA Duesseldorf

Value: ca. 184 degree C
Type: open cup
Method: other: DIN ISO 2592 (Cleveland)
Source: Sidobre Sinnova Meaux

2.8 Auto Flammability

2.9 Flammability

2.10 Explosive Properties

2.11 Oxidizing Properties
2.12 Additional Remarks

Result: ca. –3°C
Source: Sidobre Sinnova Meaux

Remark: Viscosity: 3.9 mm²/s at 40 deg C (method: DIN 51562 (Ubbelohde))
1.7 mm²/s at 100 deg C (method: DIN 51562 (Ubbelohde))
Source: Henkel KGaA Duesseldorf
3. Environmental Fate and Pathways

3.1 Photodegradation

3.1.2 Stability in Water

3.1.3 Stability in Soil

3.2 Monitoring Data (Environment)

3.3.1 Transport between Environmental Compartments

3.3.2 Distribution

3.4 Mode of Degradation in Actual Use

3.5 Biodegradation

**Type:** aerobic
**Inoculum:** other: effluent from domestic sewage treatment plant
**Concentration:** 5 mg/l related to Test substance
**Degradation:** = 54 % after 30 day
**Method:** Directive 84/449/EEC, C.6 "Biotic degradation – closed bottle test"
**Year:**
**Test substance:** as prescribed by 1.1 – 1.4
**Source:** Henkel KGaA Duesseldorf

**Type:** aerobic
**Inoculum:** other: sewage treatment plant effluent/biological stage
**Concentration:** 5 mg/l
**Degradation:** 54 % after 30 day
**Method:** Directive 84/449/EEC, C.6 "Biotic degradation – closed bottle test"
**Year:**
**Test substance:** Soybean oil fatty acids, methylesters
**Source:** Henkel KGaA Duesseldorf, Sidobre Sinnova Meaux
**Test condition:** #1: 5 mg/l referring to Active Substance: 54% with parameter % BSB/CSB
<table>
<thead>
<tr>
<th>Type</th>
<th>aerobic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inoculum</td>
<td>other: sewage treatment plant effluent/biological stage</td>
</tr>
<tr>
<td>Concentration</td>
<td>1 mg/l</td>
</tr>
<tr>
<td>Degradation</td>
<td>54 % after 30 day</td>
</tr>
<tr>
<td>Method</td>
<td>Directive 84/449/EEC, C.6 &quot;Biotic degradation - closed bottle test&quot;</td>
</tr>
<tr>
<td>Year</td>
<td>GLP:</td>
</tr>
<tr>
<td>Test substance</td>
<td>as prescribed by 1.1 - 1.4</td>
</tr>
<tr>
<td>Method</td>
<td>EG-RiLi 84/449 Anh.V C4-E</td>
</tr>
<tr>
<td>Remark</td>
<td>Stammdispersion ultrabeschallt</td>
</tr>
<tr>
<td>Source</td>
<td>Henkel KGaA Duesseldorf</td>
</tr>
<tr>
<td>Source</td>
<td>Sidobre Sinnova Meaux</td>
</tr>
<tr>
<td>Test condition</td>
<td>#1: 1 mg/l referring to Active Substance: 54% with parameter % BSB/CSB</td>
</tr>
</tbody>
</table>

(10)

<table>
<thead>
<tr>
<th>Type</th>
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<tbody>
<tr>
<td>Inoculum</td>
<td>activated sludge, domestic</td>
</tr>
<tr>
<td>Concentration</td>
<td>100 mg/l</td>
</tr>
<tr>
<td>Degradation</td>
<td>86 % after 28 day</td>
</tr>
<tr>
<td>Result</td>
<td>other: well biodegradable</td>
</tr>
<tr>
<td>Method</td>
<td>ISO Draft &quot;BOD Test for insoluble substances&quot;</td>
</tr>
<tr>
<td>Year</td>
<td>GLP:</td>
</tr>
<tr>
<td>Test substance</td>
<td>as prescribed by 1.1 - 1.4</td>
</tr>
<tr>
<td>Method</td>
<td>two phase closed bottle test</td>
</tr>
<tr>
<td>Source</td>
<td>Henkel KGaA Duesseldorf</td>
</tr>
<tr>
<td>Source</td>
<td>Sidobre Sinnova Meaux</td>
</tr>
<tr>
<td>Test condition</td>
<td>#1: 100 mg/l referring to Chemical oxygen demand: 86% with parameter % BSB/CSB</td>
</tr>
</tbody>
</table>

(11) (12) (13)

<table>
<thead>
<tr>
<th>Type</th>
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<tbody>
<tr>
<td>Inoculum</td>
<td>activated sludge, domestic</td>
</tr>
<tr>
<td>Concentration</td>
<td>100 mg/l</td>
</tr>
<tr>
<td>Degradation</td>
<td>87 % after 28 day</td>
</tr>
<tr>
<td>Result</td>
<td>other: readily degradable</td>
</tr>
<tr>
<td>Method</td>
<td>ISO Draft &quot;BOD Test for insoluble substances&quot;</td>
</tr>
<tr>
<td>Year</td>
<td>GLP:</td>
</tr>
<tr>
<td>Test substance</td>
<td>as prescribed by 1.1 - 1.4</td>
</tr>
<tr>
<td>Method</td>
<td>two phase closed bottle test</td>
</tr>
<tr>
<td>Source</td>
<td>Henkel KGaA Duesseldorf</td>
</tr>
<tr>
<td>Source</td>
<td>Sidobre Sinnova Meaux</td>
</tr>
<tr>
<td>Test condition</td>
<td>#1: 100 mg/l referring to Chemical oxygen demand: 87% with parameter % BSB/CSB</td>
</tr>
</tbody>
</table>

(14) (15) (16)
3. Environmental Fate and Pathways

Substance ID: 67762–38–3

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Type: aerobic
Inoculum: activated sludge, domestic
Concentration: 100 mg/l related to COD (Chemical Oxygen Demand)
Degradation: = 87 % after 28 day
Result: readily biodegradable
Method: ISO Draft "BOD Test for insoluble substances"
Year: GLP: no
Test substance: as prescribed by 1.1 - 1.4
Remark: Parameter: BOD28/COD
Source: Henkel KGaA Duesseldorf

---

Type: aerobic
Inoculum: activated sludge, domestic
Concentration: 100 mg/l
Degradation: 92 % after 28 day
Method: ISO Draft "BOD Test for insoluble substances"
Year: GLP: no
Test substance: as prescribed by 1.1 - 1.4
Method: two phase closed bottle test
Remark: sehr gute biochemische Sauerstoffzehrungsraten.
Source: Henkel KGaA Duesseldorf, Sidobre Sinnova Meaux
Test condition: #1: 100 mg/l referring to Chemical oxygen demand: 92% with parameter % BSB/CSB

---

3.6 BOD5, COD or BOD5/COD Ratio

3.7 Bioaccumulation

3.8 Additional Remarks
4. Ecotoxicity

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

Type: static
Species: Leuciscus idus (Fish, fresh water)
Exposure period: 48 hour(s)
Unit: mg/l
Analytical monitoring: no
LC0: = 3000
LC50: = 5500
LC100: = 10000
Method: other: DIN 38412 part 15
Year:
GLP: no
Test substance: as prescribed by 1.1 – 1.4
Remark: Test method conforms with OECD Guideline 203.
Source: Henkel KGaA Duesseldorf

Type:
Species: Leuciscus idus (Fish, fresh water)
Exposure period: 48 hour(s)
Unit: mg/l
Analytical monitoring:
LC0: 3000
LC50: 5500
LC100: 10000
Method: other: DIN 38412, Teil 15 (Golden orfe, acute toxicity test)
Year:
GLP:
Test substance: as prescribed by 1.1 – 1.4
Remark: Related to: Test substance Ultraturrax
Source: Henkel KGaA Duesseldorf
Sidobre Sinnova Meaux

4.2 Acute Toxicity to Aquatic Invertebrates

4.3 Toxicity to Aquatic Plants e.g. Algae
4.4 Toxicity to Microorganisms e.g. Bacteria

Type: aquatic  
Species: Pseudomonas putida (Bacteria)  
Exposure period: 30 minute(s)  
Unit: mg/l  
Analytical monitoring: no  
EC0: 10000  
Method: other: DIN 38412 Teil 27 (respiration inhibition test)  
Year:  
Test substance: as prescribed by 1.1 – 1.4  
Remark: 10000 mg/l was highest concentration tested. Test method conforms with OECD Guideline 209.  
Source: Henkel KGaA Duesseldorf

Type: aquatic  
Species: Pseudomonas putida (Bacteria)  
Exposure period: 16 hour(s)  
Unit: mg/l  
Analytical monitoring: no  
EC0: 1000  
Method: other: DIN 38412 Teil 8 (cell multiplication inhibition test)  
Year:  
Test substance: as prescribed by 1.1 – 1.4  
Source: Henkel KGaA Duesseldorf

Type: aquatic  
Species: Pseudomonas putida (Bacteria)  
Exposure period: 30 minute(s)  
Unit: mg/l  
Analytical monitoring:  
EC0: 1000  
Method: other: DIN 38412, Teil 27 (Bacterial oxygen consumption test)  
Year:  
Test substance: as prescribed by 1.1 – 1.4  
Source: Henkel KGaA Duesseldorf

Type:  
Species: Pseudomonas putida (Bacteria)  
Exposure period: 16 hour(s)  
Unit: mg/l  
Analytical monitoring:  
EC0: 1000  
Method: other: DIN 38412, Teil 8 (Bacterial cell growth inhibition test)  
Year:  
Test substance: as prescribed by 1.1 – 1.4  
Remark: Vorbehandlung: Nach Phasentrennung wässrige Phase für Prüfung verwendet.  
Source: Henkel KGaA Duesseldorf

Source: Henkel KGaA Duesseldorf

Sidobre Sinnova Meaux
4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish

4.5.2 Chronic Toxicity to Aquatic Invertebrates

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Soil Dwelling Organisms

4.6.2 Toxicity to Terrestrial Plants

4.6.3 Toxicity to other Non-Mamm. Terrestrial Species

4.7 Biological Effects Monitoring

4.8 Biotransformation and Kinetics

4.9 Additional Remarks
5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

| Type: | LD50             |
| Species: | rat          |
| Sex: |                      |
| Number of Animals: |                      |
| Vehicle: |                     |
| Value: | > 2000 mg/kg bw |
| Method: |                    |
| Year: |                     |
| GLP: |                      |

Test substance: Analogy! Hexadecanoic acid, methylester (22)

Remark: Limit test

Source: Henkel KGaA Duesseldorf
        Sidobre Sinnova Meaux

Test substance: octadecanoic acid, methylester (23)

Type: LD50
Species: rat
Sex:                      
Number of Animals:        
Vehicle:                   
Value: > 2000 mg/kg bw 
Method:                    
Year:                      
GLP:                      
Test substance: other TS  
Remark:                   
Source: Henkel KGaA Duesseldorf 
                          Sidobre Sinnova Meaux 
Test substance: Analogy! Hexadecanoic acid, methylester (24)
5. Toxicity

Type: LD50
Species: rat
Sex: 
Number of Animals:
Vehicle: 
Value: > 2000 mg/kg bw
Method: 
Year: 
GLP: 
Test substance: other TS
Remark: Limit test
Source: Henkel KGaA Duesseldorf
Test substance: Analogy! Octadecanoic acid, methylester

Type: LD50
Species: rat
Sex: 
Number of Animals:
Vehicle: 
Value: > 2000 mg/kg bw
Method: other: Henkel protocol "Acute oral toxicity, limit-test"
Year: 
GLP: yes
Test substance: other TS
Source: Henkel KGaA Duesseldorf
Test substance: Analogy! Featty acids, C14–18 and C16–18 unsatd. was tested.

5.1.2 Acute Inhalation Toxicity

5.1.3 Acute Dermal Toxicity

5.1.4 Acute Toxicity, other Routes

5.2 Corrosiveness and Irritation
5.2.1 Skin Irritation

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result:
slightly irritating
EC classificat.:
not irritating
Method:
OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1983
Test substance:
as prescribed by 1.1 – 1.4
Source:
Henkel KGaA Duesseldorf
Sidobre Sinnova Meaux

GlP: yes

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result:
moderately irritating
EC classificat.:
not irritating
Method:
OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1983
Test substance:
other TS
Source:
Henkel KGaA Duesseldorf
Sidobre Sinnova Meaux

GlP: yes

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result:
slightly irritating
EC classificat.:
not irritating
Method:
OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1983
Test substance:
as prescribed by 1.1 – 1.4
Source:
Henkel KGaA Duesseldorf

GlP: yes

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result:
slightly irritating
EC classificat.:
not irritating
Method:
OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1983
Test substance:
as prescribed by 1.1 – 1.4
Source:
Henkel KGaA Duesseldorf

GlP: yes

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result:
slightly irritating
EC classificat.:
not irritating
Method:
OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1983
Test substance:
as prescribed by 1.1 – 1.4
Source:
Henkel KGaA Duesseldorf

GlP: yes

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result:
slightly irritating
EC classificat.:
not irritating
Method:
OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1983
Test substance:
as prescribed by 1.1 – 1.4
Source:
Henkel KGaA Duesseldorf

GlP: yes

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result:
slightly irritating
EC classificat.:
not irritating
Method:
OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1983
Test substance:
as prescribed by 1.1 – 1.4
Source:
Henkel KGaA Duesseldorf

GlP: yes

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result:
slightly irritating
EC classificat.:
not irritating
Method:
OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1983
Test substance:
as prescribed by 1.1 – 1.4
Source:
Henkel KGaA Duesseldorf

GlP: yes

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result:
slightly irritating
EC classificat.:
not irritating
Method:
OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1983
Test substance:
as prescribed by 1.1 – 1.4
Source:
Henkel KGaA Duesseldorf

GlP: yes

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result:
slightly irritating
EC classificat.:
not irritating
Method:
OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1983
Test substance:
as prescribed by 1.1 – 1.4
Source:
Henkel KGaA Duesseldorf

GlP: yes

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result:
slightly irritating
EC classificat.:
not irritating
Method:
OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1983
Test substance:
as prescribed by 1.1 – 1.4
Source:
Henkel KGaA Duesseldorf

GlP: yes

Species: rabbit
Concentration:
5.2.2 Eye Irritation

Species: rabbit
Concentration: 
Dose: 
Exposure Time: 
Comment: 
Number of Animals: 
Result: slightly irritating
EC classification: not irritating
Method: OECD Guide-line 405 "Acute Eye Irritation/Corrosion"
Year: 
Test substance: other TS
Source: Henkel KGaA Duesseldorf
Sidobre Sinnova Meaux
Test substance: Analogy! Fatty acids, C14-18 and C16-18 unsatd. was tested. (32)

5.3 Sensitization

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals: 
Vehicle: 
Result: not sensitizing
Classification: not sensitizing
Method: OECD Guide-line 406 "Skin Sensitization"
Year: 1981
Test substance: as prescribed by 1.1 – 1.4
Source: Henkel KGaA Duesseldorf
Sidobre Sinnova Meaux

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals: 
Vehicle: 
Result: not sensitizing
Classification: 
Method: OECD Guide-line 406 "Skin Sensitization"
Year: 1981
Test substance: as prescribed by 1.1 – 1.4
Source: Henkel KGaA Duesseldorf
Sidobre Sinnova Meaux
Test substance: Tallow acids, methylesters (37)
5. Toxicity

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:  
Vehicle:  
Result: not sensitizing
Classification: not sensitizing
Method: OECD Guide-line 406 "Skin Sensitization"
Year: 1981  GLP: yes
Test substance: as prescribed by 1.1 - 1.4
Source: Henkel KGaA Duesseldorf
Test substance: Rübölfettsäuremethylester

5.4 Repeated Dose Toxicity

5.5 Genetic Toxicity 'in Vitro'

Type: Ames test
System of testing: S. typhimurium TA 98, TA 100, TA 1535, TA 1537 and TA 1538
Concentration: 8, 40, 200, 1000 and 5000 ug/plate
Metabolic activation: with and without
Result: negative
Method: OECD Guide-line 471 "Genetic Toxicology: Salmonella typhimurium Reverse Mutation Assay"
Year:  GLP: yes
Test substance: as prescribed by 1.1 - 1.4
Source: Henkel KGaA Duesseldorf
Test substance: Fatty acids tallow, methyl esters was tested.
### Toxicity

**Date:** 19–FEB–2000  
**Substance ID:** 67762–38–3

<table>
<thead>
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<th>Type:</th>
<th>Ames test</th>
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<tbody>
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<td>System of testing:</td>
<td>S. typhimurium TA 98, TA 100, TA 1535, TA 1537 and TA 1538</td>
</tr>
<tr>
<td>Concentration:</td>
<td>8, 40, 200, 1000 and 5000 ug per plate</td>
</tr>
<tr>
<td></td>
<td>in addition for strain TA 100:</td>
</tr>
<tr>
<td></td>
<td>1000, 2000, 4000, 8000 and 12000 ug per plate</td>
</tr>
<tr>
<td>Metabolic activation:</td>
<td>with and without</td>
</tr>
<tr>
<td>Result:</td>
<td>ambiguous</td>
</tr>
<tr>
<td>Method:</td>
<td>OECD Guide-line 471 &quot;Genetic Toxicology: Salmonella typhimurium Reverse Mutation Assay&quot;</td>
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<tr>
<td>Year:</td>
<td>1983</td>
</tr>
<tr>
<td>GLP:</td>
<td>yes</td>
</tr>
<tr>
<td>Test substance:</td>
<td>other TS</td>
</tr>
<tr>
<td>Source:</td>
<td>Henkel KGaA Duesseldorf</td>
</tr>
<tr>
<td></td>
<td>Sidobre Sinnova Meaux</td>
</tr>
<tr>
<td>Test substance:</td>
<td>Analogy! Linolenic acid methyl ester, pure, from sigma (L-2626) was tested.</td>
</tr>
</tbody>
</table>

In the strain TA 100 slightly, but reproducibly enhanced, dose-dependent colony counts were obtained in the absence of S9-mix. However, the mutagenic potential was low and only registered at high concentrations.

### Test substance: Analogy! Linolenic acid methyl ester, pure, from sigma (L-2626) was tested.

(40)
5.6 Genetic Toxicity 'in Vivo'

Type: Micronucleus assay
Species: Chinese hamster
Sex: male/female
Strain:
Route of admin.: gavage
Exposure period:
Doses: 100 mg/kg bw
Result:
Method: other: Schwarzacher and Wolf
Year: 1974
GLP: no data
Test substance: other TS
Remark: The author tested the anticlastogenic effect of linear fatty acid methyl esters ranging from C6 to C20 of busulfan-induced aberrations. Result: the C14–C18 methyl esters exert an anticlastogenic effect, i.e. they protect the chromosomes from chemically induced aberrations. As a side result (negative controls) it was observed that the methyl esters alone do not induce aberrations.
Source: Henkel KGaA Duesseldorf
Sidobre Sinnova Meaux
Test substance: Analogy!
Palmitic acid methyl ester (C16)
Stearic acid methyl ester (C18)
Oleic acid methyl ester (C18:1)
Linoleic acid methyl ester (C18:2)
and other fatty acid methyl esters

5.7 Carcinogenicity

Species: mouse
Sex: male/female
Strain: Strain A
Route of admin.: dermal
Exposure period: 1 year
Frequency of treatment: 3 x week
Post. obs. period: 1 year
Doses: 10 mg in aceton per treatment (= ca. 200 mg/kg bw/day)
Result:
Control Group: yes
Method: other: Arffmann et al., Acta path. microbiol. scand.
Year: 1974
GLP: no data
Test substance: other TS
Result: The questions were addressed if methyl oleate is a complete carcinogen or if it has tumor-promoting activities.

Result (complete carcinogen = negative): of 35 mice treated with methyl oleate alone 3 developed a benign skin tumor and 0 a malignant tumor, whereas no tumors appeared in the negative control. In the positive control (250 ug DMBA) 14 out of 20 animals developed benign tumors; the time to the onset of tumor was significantly reduced. With respect to lymphoma 9 out of 35 animals (26 %) developed such tumor after ca. 410 days, whereas the rate in the negative control
was 4 out of 25 animals (16 %) and 710 days. In the positive control 18 out of 20 animals developed lymphomas after 170 days on average. The authors conclude that methyl oleate is not a complete carcinogen.

Result (tumor-promotor = positive): when tested methyl oleate in presence of a sub-effective dose of 50 ug DMBA, 6 animals out of 30 developed papillomas, 2 skin carcinomas, 3 sarcomas and 2 lymphomas, whereas in the negative control (20 animals given 50 ug DMBA) only 1 sarcoma was observed. The authors conclude that methyl oleate is a tumor-promotor.

Source: Henkel KGaA Duesseldorf
Test substance: Analogy! Methyl oleate

Species: mouse  Sex: male/female
Strain: Strain A
Route of admin.: dermal
Exposure period: 1 year
Frequency of treatment: 3 x week
Post. obs. period: 1 year
Doses: 10 mg in aceton per treatment (= ca. 200 mg/kg bw/day)
Result:
Control Group: yes
Method: other: Arffmann et al., Acta path. microbiol. scand.
Year: 1974  GLP: no data
Test substance: other TS
Result: The questions were addressed if methyl oleate is a complete carcinogen or if it has tumor-promoting activities.

Result (complete carcinogen = negative): of 35 mice treated with methyl oleate alone 3 developed a benign skin tumor and 0 a malignant tumor, whereas no tumors appeared in the negative control. In the positive control (250 ug DMBA) 14 out of 20 animals developed benign tumors; the time to the onset of tumor was significantly reduced. With respect to lymphoma 9 out of 35 animals (26 %) developed such tumor after ca. 410 days, whereas the rate in the negative control was 4 out of 25 animals (16 %) and 710 days. In the positive control 18 out of 20 animals developed lymphomas after 170 days on average. The authors conclude that methyl oleate is not a complete carcinogen.

Result (tumor-promotor = positive): when tested methyl oleate in presence of a sub-effective dose of 50 ug DMBA, 6 animals out of 30 developed papillomas, 2 skin carcinomas, 3 sarcomas and 2 lymphomas, whereas in the negative control (20 animals given 50 ug DMBA) only 1 sarcoma was observed. The authors conclude that methyl oleate is a tumor-promotor.
Species: mouse  
Sex: female
Strain: Swiss Webster
Route of admin.: s.c.
Exposure period: 26 weeks
Frequency of treatment: 1 per week
Post. obs. period:
Doses: 0.5 and 5 mg/injection (= ca. 3.6 and 36 mg/kg bw/day)
Result: Control Group: yes
Method: other: Swern et al.
Year: 1970  
GLP: no data
Test substance: other TS
Remark: Similar results were found in another laboratory using ICR/Ha Swiss Millerton female mice. Reference: Van Duuren, B. L., et al., (1967)
Result: Two out of 32 treated animals developed a subcutaneous sarcoma at the site of injection. Among the 202 untreated and 104 vehicle controls, there were 2 subcutaneous sarcomas.
Source: Henkel KGaA  Duesseldorf
Test substance: Analogy! Methyl stearate

Species: mouse  
Sex: female
Strain: Swiss Webster
Route of admin.: s.c.
Exposure period: 26 weeks
Frequency of treatment: 1 per week
Post. obs. period:
Doses: 0.5 and 5 mg/injection (= ca. 3.6 and 36 mg/kg bw/day)
Result: Control Group: yes
Method: other: Swern et al.
Year: 1970  
GLP: no data
Test substance: other TS
Remark: Similar results were found in another laboratory using ICR/Ha Swiss Millerton female mice. Reference: Van Duuren, B. L., et al., (1967)
Result: Two out of 32 treated animals developed a subcutaneous sarcoma at the site of injection. Among the 202 untreated and 104 vehicle controls, there were 2 subcutaneous sarcomas.
Source: Henkel KGaA  Duesseldorf
Test substance: Analogy! Methyl stearate
Species: other: mouse lymphocytes
Strain: 
Route of admin.: 
Exposure period: 
Frequency of treatment: 
Post. obs. period: 
Doses: 
Result: 
Control Group: other: Baxter et al.
Method: other TS
Year: 1981
GLP: 
Test substance: Analogy!, Hexadecansäuremethylester

Result: Während unter diesen Bedingungen Methylhexanoat, -octanoat und -octadecanoat keinen Effekt zeigten, wurde bei einer Konzentration von 120 uM bei Methyltetradecanoat das Maximum der Aktivität gefunden. Die anderen geprüften Fettsäuremethylester (C10, C12, C16) zeigten eine geringere, aber signifikante Aktivitätserhöhung. Wird statt der höchsten, nicht toxischen Konzentration von 120 uM nur eine Konzentration von 60 uM verwendet, so zeigt sich zwar die gleiche C-Kettenabhängigkeit, jedoch ist die Aktivitätserhöhung, die durch Methyldecanoat und -hexadecanoat verursacht wird, nicht signifikant.

Da aus dieser Aktivität auf eine tumorpromovierende Wirkung geschlossen wird, kann nicht ganz ausgeschlossen werden, daß der Stoff FSME C16-C18, C18' auch eine gewisse derartige Potenz besitzt, da er einen bestimmten Anteil von Hexadecansäuremethylester enthält.

Source: Henkel KGaA Düsseldorf
Sidobre Sinnova Meaux

5.8 Toxicity to Reproduction
5.9 Developmental Toxicity/Teratogenicity

Species: other: house fly larvae  
Sex:  
Strain: other: Diptera: Muscidae  
Route of admin.:  
Exposure period:  
Frequency of treatment:  
Duration of test:  
Doses:  
Control Group:  
Method:  
Year:  
GLP:  
Test substance:  
Remark:  
Result:  
Source:  
Test substance:  

5.10 Other Relevant Information

Type: Metabolism  
Remark: The presence of hexadecanoic acid methyl ester (C 16:0) and octadecenoic acid methyl ester (C 18:1) was reported in human hepatoma tissue from a patient with hypercholesterolemia.  
Source: Henkel KGaA Duesseldorf  
Sidobre Sinnova Meaux  

Type: Metabolism  
Remark: Topically applied unsaturated fatty acid methyl esters (C 16:1 and C 18:1) can penetrate to the living cells of normal epidermis, enter into metabolism and significantly modify endogenous epidermal lipids (experiments with BALB/C mice).  
Source: Henkel KGaA Duesseldorf  
Sidobre Sinnova Meaux  

Type: Metabolism  
Remark: The presence of hexadecanoic acid methyl ester (C 16:0) and octadecenoic acid methyl ester (C 18:1) was reported in human hepatoma tissue from a patient with hypercholesterolemia.  
Source: Henkel KGaA Duesseldorf
5. Toxicity

Type: Metabolism

Remark: Topically applied unsaturated fatty acid methyl esters (C16:1 and C18:1) can penetrate to the living cells of normal epidermis, enter into metabolism and significantly modify endogenous epidermal lipids (experiments with BALB/C mice).

Source: Henkel KGaA Duesseldorf

5.11 Experience with Human Exposure
(1) Katalog wassergefährdender Stoffe, Datenblatt Nr. 834

(2) Henkel KGaA, unpublished data, LIT (7800/16)

(3) Henkel KGaA, SDS 'Edenor ME SJ' DEE 00043581 01 00

(4) Henkel KGaA, SDS, 2/1997, 'ESTER METHYLIQUE DE COLZA BT', DED 00077938

(5) Henkel KGaA, SDS 'Edenor ME SU' DEE 00043119 01 00

(6) BEILSTEIN Online

(7) Henkel KGaA, SDS 'Sovermol POL 1058/III' DEE 00041586 01 00

(8) Henkel KGaA, unpublished data, Archive-No. 2209

(9) Henkel KGaA, unpublished data, Protocol 25, Page/Assay 331

(10) Henkel KGaA, unpublished data, Protocol 26, Page/Assay 336

(11) Henkel KGaA, unpublished data, File 6, Page/Assay 61

(12) Henkel KGaA, unpublished data, Final report 1988 2711

(13) Henkel KGaA, unpublished data, Protocol 2, Page/Assay 61

(14) Henkel KGaA, unpublished data, File 6, Page/Assay 54

(15) Henkel KGaA, unpublished data, Final report R 9601959

(16) Henkel KGaA, unpublished data, Protocol 2, Page/Assay 54

(17) Henkel KGaA, unpublished data, Archive-No. 7329

(18) Henkel KGaA, unpublished data, File 401/12

(19) Henkel KGaA, unpublished data, Final Report 882626

(20) Henkel KGaA, unpublished data, File 427/1

(21) Henkel KGaA, unpublished data, File 425/1

(22) Henkel KGaA, unpublished data, Archive-No. RT 920228

(23) Henkel KGaA, unpublished data, Archive-No. RT 920229

(24) Henkel KGaA, unpublished data, Archive-No. 920228

(25) Henkel KGaA, unpublished data, Archive-No. 920229

(26) Henkel KGaA, unpublished data, Archive-No. TBD 880149
6. References

(27) Henkel KGaA, unpublished data, Archive-No. RT 920116

(28) Henkel KGaA, unpublished data, Archive-No. TBD 900018
   (Final Report)

(29) Henkel KGaA, unpublished data, Archive-No. TBD 900114

(30) Henkel KGaA, unpublished data, Archive-No. TBD 880230

(31) Henkel KGaA, unpublished data, Archive-No. TBD 900018

(32) Henkel KGaA, unpublished data, Archive-No. TBD 880250

(33) Henkel KGaA, unpublished data, Archive-No. R 9400303

(34) Henkel KGaA, unpublished data, Archive-No. R 9600345

(35) Henkel KGaA, unpublished data, Archive-No. RT 930019

(36) Henkel KGaA, unpublished data, Archive-No. RT 930065

(37) Henkel KGaA, unpublished data, Archive-No. RT 930021
   (External Report, IBR, 1/1993)

(38) IBR (1993), unpublished data, sponsored by Henkel KGaA,
   Archive-No. RT 930021

(39) Henkel KGaA, unpublished data, Archive-No. TBD 880136

(40) Henkel KGaA, unpublished data, Archive-No. RT 920317

(41) Mortelmans, K., et al., Environ. Mutagen. 8 (Suppl. 7),
    1–119 (1986) (LIT 2447 / BAR 0047 / ALT 0138)

(42) Mortelmans, K., et al., Environ. Mutagen. 8 (Suppl. 7),
    1–119 (1986)


(44) Schwarzacher, H. G., Wolf, U. (Eds.), Methods in Human

    Section A 82, 127-136 (1974) (ALT 200)

(46) Arffmann, E., Glavind, J., Experientia 17 (12), 1465-1466
    (1971) (TLK 0732 / KAS 2236)

    Section A 82, 127-136 (1974)

(48) Arffmann, E., Glavind, J., Experientia 27 (12), 1465-1466
    (1971)
6. References

(49) Swern, D., et al., Cancer Res. 30, 1037–1046 (1970) (ALT 0134 / ALT 0201)


(51) Swern, D., et al., Cancer Res. 30, 1037–1046 (1970)


(54) Quraishi, M.S., Can. Entomol. 104 (10) (1972), 1505–1510 (ALT 0189)


7. Risk Assessment

7.1 Risk Assessment

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