I U C L I D

D a t a s e t

Existing Chemical	Substance ID: 73398–61–5
CAS No.	73398–61–5
EINECS Name	Glycerides, mixed decanoyl and octanoyl
EINECS No.	277–452–2
Molecular Weight	498
Molecular Formula	approximately C29 H54 O6

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.

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1.0.1 OECD and Company Information

Name: Croda Universal Ltd
Street: Cowick Hall, Snaith
Town: DN14 9AA Goole, North Humberside
Country: United Kingdom
Phone: 0405 860551
Telefax: 0405 860205
Telex: 57601
Cedex: DN14 9AA

Name: Huels AG
Street: Postfach
Town: D–45764 Marl
Country: Germany

1.0.2 Location of Production Site

–

1.0.3 Identity of Recipients

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1.1 General Substance Information

Substance type: organic
Physical status: liquid

1.1.1 Spectra

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1.2 Synonyms

C8 und C10–Fettsaeureglycerinester
Source: Huels AG Marl

caprylic/capric triglyceride
Source: Croda Universal Ltd Goole, North Humberside

Decanoyl–octanoyl–triglyceridgemisch
Source: Huels AG Marl

fractionated coconut oil
Source: Croda Universal Ltd Goole, North Humberside

Glyceride, gemischte Decanoyl und Octanoyl
Source: Huels AG Marl

glyceryl tricaprylate/caprate
Source: Croda Universal Ltd Goole, North Humberside

glyceryl trioctanoate/decanoate
Source: Croda Universal Ltd Goole, North Humberside

MCT Oil (Ph. Eur.)
Source: Huels AG Marl

medium chain triglycerides
Source: Croda Universal Ltd Goole, North Humberside

MIGLYOL 812
Source: Huels AG Marl

Mittelkettige Triglyceride
Source: Huels AG Marl

octanoic/decanoic acid triglyceride
Source: Croda Universal Ltd Goole, North Humberside

Softenol 3108
Source: Huels AG Marl

Triglyceride von Capryl- und Caprinsaeure
Source: Huels AG Marl

1.3 Impurities
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1.4 Additives
-

1.5 Quantity
-

1.6.1 Labelling
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1.6.2 Classification
-

1.7 Use Pattern
-

1.7.1 Technology Production/Use
-

1.8 Occupational Exposure Limit Values

Type of limit: MAK (DE)
Limit value:
Country: Germany
Remark: value not established
Source: Huels AG Marl

(1)

1.9 Source of Exposure

Memo: Release into the atmosphere at production site
Remark: Release into the atmosphere on production site in 1994: No release
Source: Huels AG Marl

(2)

Remark: Manufactured at one site only by esterification reaction
Source: Croda Universal Ltd Goole, North Humberside

1.10.1 Recommendations/Precautionary Measures

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1.10.2 Emergency Measures

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1.11 Packaging

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1.12 Possib. of Rendering Subst. Harmless

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1.13 Statements Concerning Waste

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1.14.1 Water Pollution

Classified by: KBwS (DE)
Labelled by: KBwS (DE)
Class of danger: 0 (generally not water polluting)
Country: Germany
Remark: No. 760 in catalogue
Source: Huels AG Marl

(1)

1.14.2 Major Accident Hazards

Legislation: Stoerfallverordnung (DE)
Substance listed: no
Country: Germany
Remark: Stoerfallverordnung 1991
Source: Huels AG Marl

(1)

1.14.3 Air Pollution

Classified by: other: Huels AG
Labelled by: other: Huels AG
Number: 3.1.7 (organic substances)
Class of danger: III
Country: Germany
Source: Huels AG Marl

1.15 Additional Remarks

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1.16 Last Literature Search

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1.17 Reviews

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1.18 Listings e.g. Chemical Inventories

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2.1 Melting Point

Value: ca. 0 - 10 degree C
Decomposition: no
Sublimation: no
GLP: no
Source: Huels AG Marl

(3)

Value: < 0 degree C
Decomposition: no
Sublimation: no
GLP: no
Remark: cloud point
Source: Huels AG Marl

(4)

2.2 Boiling Point

-

2.3 Density

Type: density
Value: ca. .95 g/cm3 at 20 degree C
GLP: no
Source: Huels AG Marl

(5) (4)

2.3.1 Granulometry

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2.4 Vapour Pressure

Value: < .01 hPa at 20 degree C
GLP: no
Source: Huels AG Marl

(4)

2.5 Partition Coefficient

log Pow: > 3 at 23 degree C
Method: OECD Guide-line 107 "Partition Coefficient (n-octanol/water), Flask-shaking Method"
Year: 1981
GLP: no
Source: Huels AG Marl

(6)

2.6.1 Water Solubility

Value: < 10 mg/l at 20 degree C
Qualitative: of very low solubility
Source: Huels AG Marl

(4)

2.6.2 Surface Tension

-

2.7 Flash Point

Value: ca. 220 degree C
Type: open cup
Method: other: DIN ISO 2592
Year:
GLP: no
Source: Huels AG Marl

(5) (4)

2.8 Auto Flammability

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2.9 Flammability

-

2.10 Explosive Properties

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2.11 Oxidizing Properties

-

2.12 Additional Remarks

-

3.1.1 Photodegradation

Type: air
INDIRECT PHOTOLYSIS
Sensitizer: OH
Conc. of sens.: 500000 molecule/cm3
Rate constant: = .0000000000294998 cm3/(molecule * sec)
Degradation: = 50 % after .5 day
Method: other (calculated): AOP Computer Program, Vers. 1.53, Syracuse Research Center (basedon Reference)
Year: 1994 **GLP:**
Test substance:
Remark: The OH concentration represents 24 hour average, thus the half-life refers to 24 hour-days.
A triester with two n-octyl and one n-decyl alcohol components was chosen for the calculation.
Source: Huels AG Marl

(7)

3.1.2 Stability in Water

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3.1.3 Stability in Soil

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3.2 Monitoring Data (Environment)

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3.3.1 Transport between Environmental Compartments

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3.3.2 Distribution

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3.4 Mode of Degradation in Actual Use

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3.5 Biodegradation

Type: aerobic
Inoculum: activated sludge, domestic, non-adapted
Concentration: 36.5 mg/l related to Test substance
Degradation: = 93 % after 28 day
Result: readily biodegradable
Method: other: ISO 10708 (draft): BODIS (Blok) Test
Year: 1993 **GLP:** yes
Test substance: as prescribed by 1.1 - 1.4
Source: Huels AG Marl

(8)

3.6 BOD5, COD or BOD5/COD Ratio

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3.7 Bioaccumulation

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3.8 Additional Remarks

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AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

Type: semistatic
Species: Brachydanio rerio (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** yes
LC0: >= 53
Method: other: Directive 92/69/EEC, C.1
Year: 1992 **GLP:** yes
Test substance: as prescribed by 1.1 – 1.4
Remark: No toxic effects were observed below the water solubility (under test conditions).
Source: Huels AG Marl
Test substance: MIGLYOL 812

(9)

Type: static
Species: Leuciscus idus (Fish, fresh water)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no
LC0: >= 1000
Method: other: Bestimmung der Wirkung von Wasserinhaltsstoffen auf Fische, DIN38412 Teil 15
Year: **GLP:** no
Test substance: as prescribed by 1.1 – 1.4
Remark: An emulsifier (MARLOWET EF) was added.
Source: Huels AG Marl

(10)

4.2 Acute Toxicity to Aquatic Invertebrates

Species: Daphnia magna (Crustacea)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no
EC0: >= 2.2
EC50: > 2.2
Method: other: DIN 38412 part 11
Year: **GLP:** no
Test substance: as prescribed by 1.1 – 1.4
Source: Huels AG Marl

(11)

4.3 Toxicity to Aquatic Plants e.g. Algae

Species: Scenedesmus subspicatus (Algae)
Endpoint: biomass
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:** no
Method: other: Directive 92/69/EEC, part C
Year: 1992 **GLP:** yes
Test substance: as prescribed by 1.1 – 1.4
Remark: EC50 > water solubility (under test conditions)
Source: Huels AG Marl
Test substance: MIGLYOL 812

(12)

4.4 Toxicity to Microorganisms e.g. Bacteria

Type: aquatic
Species: Pseudomonas putida (Bacteria)
Exposure period: 5 hour(s)
Unit: mg/l **Analytical monitoring:** no
EC10: > 1900
Method: other: Oxygen consumption test (Huels method)
Year: **GLP:** yes
Test substance: as prescribed by 1.1 – 1.4
Remark: Nonylphenol–10EO–5PO was used as solubilizer
Source: Huels AG Marl

(13)

4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish

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4.5.2 Chronic Toxicity to Aquatic Invertebrates

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TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Soil Dwelling Organisms

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4.6.2 Toxicity to Terrestrial Plants

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4.6.3 Toxicity to other Non–Mamm. Terrestrial Species

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4.7 Biological Effects Monitoring

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4.8 Biotransformation and Kinetics

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4.9 Additional Remarks

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5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: > 34000 mg/kg bw
Method:
Year: **GLP:** no
Test substance: as prescribed by 1.1 – 1.4
Remark: Groups of 10 rats (Wistar, male) received 4.5, 9.0, 18.0 or 36.0 ml/kg of undiluted test substance per gavage; no animal died during the study; 10 days after dosing all animals were sacrificed and submitted to autopsy; no pathological changes were observed.
Source: Huels AG Marl

(14)

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: > 5000 mg/kg bw
Method:
Year: **GLP:** no data
Test substance: no data
Remark: Test material produced no mortality in male or female rats; all animals showed no changes in appearance or behavior and presented no abnormalities at necropsy 14 days after treatment; no further details reported.
Source: Huels AG Marl

(15)

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: > 5000 mg/kg bw
Method:
Year: **GLP:** no data
Test substance: no data
Remark: Test material produced no mortality in male or female rats; all animals showed no changes in appearance or behavior and presented no abnormalities at necropsy 14 days after treatment; no further details reported.
Source: Huels AG Marl

(16)

Type: LD50
Species: mouse
Sex:
Number of Animals:
Vehicle:
Value: > 23750 mg/kg bw
Method:
Year: **GLP:** no
Test substance: as prescribed by 1.1 – 1.4
Remark: Groups of 10 female mice of Tyler’’s Original Strain each were dosed with undiluted test material per gavage (12.5, 20.0 or 25.0 ml/kg); lethargy, ataxia and dyspnea occurred within 15 minutes after dosing in the highest dosage group; 1 animal of the highest dosage group and 2 animals of the mid dosage group died 24–48 hours after dosing; all symptoms disappeared in the survivors by the end of the third day.
Source: Huels AG Marl

(17)

5.1.2 Acute Inhalation Toxicity

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5.1.3 Acute Dermal Toxicity

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5.1.4 Acute Toxicity, other Routes

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Route of admin.: i.p.
Value: > 22800 mg/kg bw
Method:
Year: **GLP:** no
Test substance: as prescribed by 1.1 – 1.4
Remark: Animals were injected intraperitoneally with single doses of the test substance ranging from 1 to 24 ml/kg (1.0, 2.0, 4.0, 8.0, 16.0 or 24.0 ml/kg; 5 male rats/dose); all animals were sacrificed 14 days after dosing and submitted to autopsy; no death occurred during the study; no signs of toxicity or treatment related effects were observed.
Source: Huels AG Marl

(14)

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.:
Method: other: EPA guidelines, (FIFRA, TSCA)
Year: **GLP:**
Test substance: as prescribed by 1.1 – 1.4
Remark: irritation index: 0/8
Source: Huels AG Marl

(18)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.:
Method:
Year: **GLP:** no
Test substance: as prescribed by 1.1 – 1.4
Remark: 3 male animals; the test substance was applied for 24, 48, and 72 hours; no irritating effects were observed.
Source: Huels AG Marl

(14)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.:
Method: other: Performed by an official French method (Journal Official de laRepublique Francaise)
Year: **GLP:**
Test substance: as prescribed by 1.1 – 1.4
Remark: irritation index: 0,21/8
Source: Huels AG Marl

(19)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: irritation index: 0/8
3 rabbits/sex, 0.5 ml of undiluted test material was applied to abraded and non–abraded skin, occluded patch; observation period: 24 and 72 hours after treatment; no further details reported.
Source: Huels AG Marl

(16)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: irritation index: 0.25/8
6 rabbits (sex unspec.), 0.5 ml of undiluted test material was applied to abraded and non–abraded skin, occluded patch; observations were made 24 and 72 hours after treatment; no further details reported.
Source: Huels AG Marl

(16)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: irritation index: 0.05/8
3 rabbits/sex, no further details reported.

Source: Huels AG Marl
(15)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.:
Method:
Year: **GLP:** no
Test substance: no data
Remark: irritation index: 0.92/8
6 rabbits (sex unspec.), no further details reported.
Source: Huels AG Marl
(20)

5.2.2 Eye Irritation

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: not irritating
EC classificat.:
Method: other: EPA guidelines, (FIFRA, TSCA)
Year: **GLP:**
Test substance: as prescribed by 1.1 – 1.4
Remark: irritation index: 2,04/110 (according to Draize)
cornea : x = 0
iris : x = 0
––––––––––––––
conjunctiva:
–redness : x = 0,16
–chemosis: x = 0,16
the treated eye of one rabbit showed transient inflammation one hour after treatment; all treated eyes appeared normal 24 to 48 hours after treatment.
Source: Huels AG Marl
(21)

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: not irritating
EC classificat.:
Method: Draize Test
Year: **GLP:** no
Test substance: as prescribed by 1.1 – 1.4
Remark: No corneal nor iris damage was seen during the study; conjunctival irritation was very slight.
Source: Huels AG Marl

(22)

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: not irritating
EC classificat.:
Method:
Year: **GLP:** no
Test substance: as prescribed by 1.1 – 1.4
Remark: 0.5 ml of the test substance were applied once daily to 3 male rabbits on 6 consecutive days; no irritating effects were observed.
Source: Huels AG Marl

(14)

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: not irritating
EC classificat.:
Method: other: Performed by an official French method (Journal Official de laRepublique Francaise)
Year: **GLP:**
Test substance: as prescribed by 1.1 – 1.4
Remark: irritation index: 2/110
Source: Huels AG Marl

(19)

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: not irritating
EC classificat.:
Method: Draize Test
Year: **GLP:** no data
Test substance: no data
Remark: irritation index: 0/110
6 rabbits, observations were made after 24, 48 and 72 hours, no further details reported.
Source: Huels AG Marl

(16)

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: not irritating
EC classificat.:
Method: Draize Test
Year: **GLP:** no data
Test substance: no data
Remark: irritation index: 0/110
6 rabbits, observation were made 24, 48, 96 and 108 hours after treatment; no further details reported.
Source: Huels AG Marl

(16)

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: not irritating
EC classificat.:
Method: Draize Test
Year: **GLP:** no data
Test substance: no data
Remark: 6 rabbits, observations were made 24, 48, 72 and 96 hours after treatment; a very mild, transient conjunctival redness and discharge was reported, resulting in scores of 0.7/110 (24 hours) and 0.3/110 (48 and 96 hours); no further details reported.
Source: Huels AG Marl

(15)

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: not irritating
EC classificat.:
Method: Draize Test
Year: **GLP:** no
Test substance: no data
Remark: irritation index: 0/110
6 rabbits, observations were made 24, 48 and 72 hours after treatment; no further details reported.
Source: Huels AG Marl

(20)

5.3 Sensitization

Type: other: skin sensitisation
Species: guinea pig
Number of Animals:
Vehicle:
Result: not sensitizing
Classification:
Method:
Year: **GLP:** no
Test substance: as prescribed by 1.1 – 1.4
Remark: The test substance was applied as a 4% solution in ethanol to closely clipped areas on the backs and flanks every other day for 10 days; 24 hours after each application erythema and edema readings were zero in all cases; the challenge application was made 2 weeks after the last priming dose; 0/6 animals showed sensitization 24 hours after the challenge application.
Source: Huels AG Marl

(23)

5.4 Repeated Dose Toxicity

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: oral feed
Exposure period: 3 months
Frequency of treatment: daily
Post. obs. period: –
Doses: 10000 ppm, 50000 ppm
Control Group: yes
Method:
Year: **GLP:** no
Test substance: as prescribed by 1.1 – 1.4
Remark: 20 male rats/dose; 20 male and 20 female rats/control; urine analysis and blood counts were done in the middle and at the end of the feeding period; serum GOT and GPT transaminases and free and esterified fatty acids were measured when the animals were sacrificed; no death occured during the study; no treatment related effects on behavior, food intake, weight gain, relative organ weights or on histological findings were observed.
Source: Huels AG Marl

(14)

Species: rat **Sex:** male/female
Strain: Wistar
Route of admin.: oral feed
Exposure period: 47 weeks
Frequency of treatment: daily
Post. obs. period: none
Doses: –
Control Group: no
Method:
Year: **GLP:** no
Test substance: no data
Remark: Rats were fed a diet containing 19,6 % of a triglyceride composed of 75 % caprylic acid and 25 % of capric acid (MCT); controls were fed a diet which differed only in the source of dietary fat (oleo oil, butter fat, coconut oil, corn oil); safflower oil was added to all diets containing MCT to insure adequacy of the essential fatty acids; the MCT containing diet supported normal growth and development, though growth rate was slightly less than that of rats fed the other diets; mortality was not markedly different between the groups; at autopsy, the carcass protein, ash levels and organ weights of test rats were similar to those of control rats, but there was less carcass fat and smaller epididymal fat pads in the test group; histological study revealed no abnormalities in intestine and liver.
Source: Huels AG Marl

(24)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: gavage
Exposure period: 30 days
Frequency of treatment: daily (7 days/week)
Post. obs. period: –
Doses: 1,0 or 3,0 ml/rat
Control Group: yes
Method:
Year: **GLP:** no
Test substance: as prescribed by 1.1 – 1.4
Remark: 10 rats/dose or control group;
the average doses were 7200 or 20200 mg/kg; weight gains of the treatment groups and the control group did not differ significantly; no signs of toxicity and no treatment related death was observed; animals of the lower dosage group showed no abnormal appearance or behavior and no urinary changes throughout the test; animals of the higher dosage group exhibited a decrease in appetite, fatty feces and a shaggy coat in the first five to seven days; all animals were submitted to autopsy at the end of the study and showed no pathological changes.
Source: Huels AG Marl

(14)

5.5 Genetic Toxicity 'in Vitro'

Type: Ames test
System of testing: Salmonella typhimurium TA 97, TA 98, TA 100
Concentration: 0 – 1000 ug/plate
0 – 1000 ug/plate
0 – 1000 ug/plate
Metabolic activation: with and without
Result: negative
Method:
Year: **GLP:**
Test substance: as prescribed by 1.1 – 1.4
Remark: Only one test with three strains was performed;
solvent: DMSO
test was performed in presence and absence of liver S–9 of aroclor treated rats; the test substance did not induce mutations in this test system.
Source: Huels AG Marl

(25)

5.6 Genetic Toxicity 'in Vivo'

–

5.7 Carcinogenicity

–

5.8 Toxicity to Reproduction

-

5.9 Developmental Toxicity/Teratogenicity

-

5.10 Other Relevant Information

Type: Biochemical or cellular interactions
Remark: 5 rabbits received a single injection of 0.5 ml of test material in both thigh muscles; another group of 5 animals received 0.2 ml of test material 3 times/week for 2 weeks by the same way; all animals were sacrificed 48 hours after the last application; no signs of topical reactions were observed.
Source: Huels AG Marl

(26)

Type: Biochemical or cellular interactions
Remark: 3 rabbits received a single injection of 0.5 ml of test material in both thigh muscles; another group of 3 animals received the test substance (0.5 ml) 3 times/week for 2 weeks by the same way; all animals were sacrificed 48 hours after the last application; no signs of topical reactions and no pathological abnormalities at the injection site were observed.
Source: Huels AG Marl

(27)

Type: Biochemical or cellular interactions
Remark: 4 rabbits received a single injection of 0.5 ml test material in both thigh muscles; 2 animales were sacrificed 5 days after application, the remaining animals 14 days after application; 4 other animals were treated in the same way with olive oil; no treatment related adverse effects were observed; microscopic examination revealed no pathological changes.
Source: Huels AG Marl

(28)

Type: Biochemical or cellular interactions
Remark: 5 rabbits received 0.5 ml of test material 2 times/week for 90 days by injection in both thigh muscles; the animals were sacrificed 48 hours after the last application; blood samples taken before treatment started and before its termination showed no effects on total lipids or cholesterol levels, nor on hemoglobin, red and white cell counts and the differential blood picture; there were no indications of pathological effects in the large parenchymatous organs and no fatty degeneration of pulmonary fatty embolism.
Source: Huels AG Marl

(28)

Type: other: acute i.v. toxicity
Remark: The acute toxicity by intravenous injection of emulsions of triglycerides of fatty acids (C2–C11) to mice was determined. Triglycerides were injected as 10 % or 25 % emulsions in glucose solution, containing phosphatides and polyglycerol mono–oleate; each type of emulsion was administered to at least 6 groups of 10 mice each.
LD50 of C8–triglycerid : 3700 +–194 mg/kg
LD50 of C10–triglycerid : >10000 mg/kg
Source: Huels AG Marl

(29)

Type: other: acute inhalation toxicity
Remark: 10 male rats (Sprague–Dawley) and 10 guinea pigs (Birbright White/W 58) were exposed for six hours to an aerosol of the test substance at a concentration of 28,1 ug/l of air; the fraction with particles small enough to be inhaled into the lung (<5 um) represented 1,97 ug/l of air; three animals of each species were exposed to air and served as control.
One hour after the exposure three animals and one control of each species were sacrificed for pathological examination, the remaining animals were sacrificed 14 days after exposure; no death occurred throughout the study; observation during the exposure and for 14 days thereafter revealed no symptoms, abnormal behavior or effects on body weight; no treatment related gross or microscopic defects were detected.
Source: Huels AG Marl

(30)

Type: other: repeated dose toxicity study with chicken
Remark: A three week feeding study (16 % of test material in the diet) was conducted with 12 male chicken (White Leghorn), 12 male chicken served as control;
the control and test diet were not palatable to the animals, resulting in reduced feed consumption (control group – 954 g, test group – 786 g) and reduced body weight gain for both groups; all mortalities (3 animals of the control group, 4 animals of the test group) seemed to reflect diet rejection and did not appear related to the test material; gross autopsy did not reveal any abnormal liver or kidney changes.
Source: Huels AG Marl

(31)

Type: other: reproductive toxicity
Remark: In a reproduction study young adult male and female rats (Mc Collum–Wisconsin Strain) were fed a diet containing 19.6 % of a triglyceride of 75 % caprylic and 25 % capric acid for three weeks before mating; litter size and birth weight of the test animals were similar to those of rats on conventional or low fat diets, but mortality during lactation was somewhat higher and there was less weight gain due to a smaller volume of milk secreted; after weaning the F1 generation was fed as the F0 generation had been and showed a weight gain comparable to that of control rats on an oleo oil diet.
Source: Huels AG Marl

(24)

Type:
Remark: The test material (10, 20 and 50% solutions of caprylic/capric triglycerides in paraffin liquid DAB6) was dropped into one eye each of two test persons at four– to six–day intervals; an additional five male subjects were tested with the undiluted substance; no incompatibility reactions occurred; no further details reported.
Source: Huels AG Marl

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5.11 Experience with Human Exposure

Remark: The test substance was applied to human skin (n=20) for 30 min; after removal of the test substance the skin was exposed to UV light for up to 11,2 min; 8–methoxy–psoralene served as a positive control substance; no erythema was observed 24 or 48 hours after exposure; whereas at the areas of psoralene treatment, erythema were observed.
Source: Huels AG Marl

(33)

Remark: 100 patients were tested with patches of tissue paper saturated with the test material (caprylic/capric triglycerides) for 48 hours; no positive reactions occurred; no further details reported.
Source: Huels AG Marl

(34)

Remark: 128 adult males and females were tested with the test material using a modification of the Draize repeated insult patch test; all subjects had little or no irritation and none was sensi– tized; one subject had barely perceptible erythema at the first reading immediately following the removal of the first patch which had been applied for 48 hours; no further details reported
Source: Huels AG Marl

(35)

Remark: 12 women were tested with 0.4 ml of the test material on each patch; patches were applied daily to the same site for 21 consecutive days; they were removed 23 hours after application and read at 24 hours; one subject had a score of 1/3 on day 16; all other scores were reported to be 0; no further details reported.
Source: Huels AG Marl

(35)

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7.1 Risk Assessment

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