

## Decalact deo

(INCI: Sodium Caproyl/Lauroyl Lactylate, Triethyl Citrate, Salvia Officinalis (Sage) Oil)

### Summary of Product Data with Reference to Toxicology and Ecology

#### Sodium Caproyl/Lauroyl Lactylate

#### Toxicological information

Study	Method	Results	Source
Acute Oral Toxicity	Rat	LD <sub>50</sub> 4880 mg/kg	Bibliographical data, Expert statement Dr. Knoell Consult, 2012
Skin Irritation/Corrosion	OECD 431 (EpiDerm™) OECD 439 (EPISKIN)  HRIPT  Rabbit	Not corrosive  Non irritant  Non-primary irritant (25% (w/w) in glycerol)  Not irritating (10% w/w)	Laus Report No. 11090502G820; 2011 TOXI-COOP Report No: 691.554.3352; 2012  AMA Lab. Report MS12.RIPT.M6370SO.50:DSG, 2012  Conclusion based on analogy; Lit.: L. Osipow, D. Marra, N. Resnansky <i>Drug Cosmetic Ind.</i> 104(3), (1969), 56-64 and L. Murphy, F. Baiocchi <i>Drug Cosmetic Ind.</i> 122(5), (1978), 35-45
Eye Irritation	HET-CAM (Method Steiling et al., 1999)  OECD 437 (BCOP)  Rabbit	Slightly irritating (10%(w/w) in glycerin)  Non – corrosive, No severe irritant (10% (w/w) in 0.9% NaOH)  Not irritating (10% w/w)	L+S AG Report No. 11763281, 2011  Laus Report No: 12012701G850, 2012  Conclusion based on analogy; Lit.: L. Osipow, D. Marra, N. Resnansky <i>Drug Cosmetic Ind.</i> 104(3), (1969), 56-64 and b) L. Murphy, F. Baiocchi <i>Drug Cosmetic Ind.</i> 122(5), (1978), 35-45

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Study	Method	Results	Source
Sensibilization	OECD 429 (LLNA)	Weak-moderate sensitizing (50% (w/w) in acetone/olive oil 4:1 (v/v))	TOXI-COOP Report No: 691.553.3353; 2012
	HRIPT	Non primary sensitizer (25% (w/w) in glycerol)	AMA Lab. Report MS12.RIPT.M6370SO.50:DSG, 2012
Mutagenicity	OECD 471 (AMES)	Not mutagenic	Laus Report No. 09021801G803, 2011

### Ecotoxicological information

Study	Method	Results	Source
Biodegradability (Aerobic)	OECD 301 B (CO <sub>2</sub> Evolution (Sturm)Test) OECD 301 D (Closed Bottle Test)	Readily biodegradable  Readily biodegradable	Laus Report No: 12080801G605, 2012  Ibacon Report: Project No. 76951161, 2012
Aquatic Toxicity  Algae Growth Inhibition Test <i>(Pseudokirchneriella subcapitata)</i>	OECD 201	EC 50/72h: > 22.8 mg/l EC 10/72h: 6.0 mg/l NOEC/72h: 2.0 mg/l	DHI Report: Study No. 001-0947, 2013
Daphnia Immobilization Test <i>(Daphnia magna)</i>	OECD 202	EC 10/24h: 33 mg/l EC 50/24h: 40 mg/l EC 10/48h: 29 mg/l EC 50/48h: 34 mg/l	DHI report: Study No. 011-0947, 2013
Bioaccumulation		No bioaccumulation is expected since the substance is proven to be readily biodegradable	
Water Endangering Class (WEC)	Self classification	WEC=1	German Federal Institute of the Environment, Nature Conservation and Nuclear safety VwVwS (Sodium Stearoyl Lactylate No 2872)

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#### Triethyl Citrate Toxicological information

Study	Method	Results	Source
Acute Toxicity - Oral	Single dose administration [Rat, cat, guinea pig]	LD50: 5900 mg/ kg bw [rat] 3500 mg/ kg bw [cat] 25 ml/ kg bw [guinea pig]	RTECS GE8050000*
	Single dose administration [Rabbit]	LD50:> 5000 mg/kg	RTECS GE8050000*
	Single dose administration [Rat]	LC50 (6h): 1300 ppm	RTECS GE8050000*
Skin Irritation	OECD 404 [Rabbit]	Not irritating	IUCLID file CAS 77-93-0, (Read across from 2 study reports on <i>Acetyl tributyl citrate</i> and <i>acetyl-tri-(2-ethylhexyl)-citrate</i> )
Eye Irritation	OECD 405 [Rabbit]	Not irritating	IUCLID file CAS 77-93-0, (Read across from a study report on <i>Acetyl-tri-(2-ethylhexyl)-citrate</i> )
Skin Sensitization	HRIPT	Not sensitizing (20%TEC in petrolatum)	IUCLID file CAS 77-93-0 (Based on bibliographical data: Epstein , 1975)
Mutagenicity	OECD 471 [AMES]	Not mutagenic	IUCLID file CAS 77-93-0, (Read across from <i>Acetyl tributyl citrate</i> )
	OECD 476 [In-vitro mammalian cell gene mutation]	Not mutagenic	IUCLID file CAS 77-93-0, (Read across from a study report on <i>Acetyl tributyl citrate</i> )
	OECD 475 [Rat]	Not mutagenic (2000mg/kg bw)	IUCLID file CAS 77-93-0, (Read across from a study report on <i>o-Acetyl tributyl citrate</i> )

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### Summary of Product Data with Reference to Toxicology and Ecology

<b>Study</b>	<b>Method</b>	<b>Results</b>	<b>Source</b>
Carcinogenicity	2 Year feeding study [rat]	No signs of carcinogenicity at 1.5 g/kg bw	IUCLID file CAS 77-93-0 (Bibliographical data)
Teratogenicity	1 Year feeding study [rat]	Maternal toxicity: NOEL: 50 mg/kg bw Developmental toxicity: NOEL: 250 mg/kg bw	IUCLID file 77-93-0 (Read across from bibliographical data on <i>Acetyl tributyl citrate</i> )

\*): RTECS: The Registry of Toxic Effects of Chemical Substances; GE8050000, 1997

### Ecotoxicological information

<b>Study</b>	<b>Method</b>	<b>Results</b>	<b>Source</b>
Biodegradability			
- Water	OECD 301 F	Readily biodegradable	IUCLID file 77-93-0
- Soil	EPA OPPTS 835.3300 or ASTM D 5988	Readily biodegradable	IUCLID file 77-93-0
Aquatic Toxicity			
- Toxicity to Algae	OECD 201 [Pseudokirchnerella subcapitatus]	NOEC (72h): >= 100 mg/L  LOEC (72h): > 100 mg/L	IUCLID file 77-93-0
- Short term toxicity to Invertebrates	OECD 202/ EU C.2 [Daphnia magna]	EC50 (48h): > 100 mg/L  NOEC (48h): >= 100 mg/L	IUCLID file 77-93-0
- Short term toxicity to Fish	REACH Guidance R.6: QSAR	LC50 (96h): 112.02 mg/L	IUCLID file 77-93-0
Water Endangering Class (WEC)		WEC = 1	German Federal Institute of the Environment, Nature Conservation and Nuclear safety VwVws Annex III, No: 5227

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#### Salvia Officinalis (Sage) Oil

#### Toxicological information

Study	Method	Results	Source
Acute Toxicity - Oral - Dermal	Single administration [rat] [rabbit]	LD 50: 2600 mg/ kg bw LD50: > 5000mg/ kg bw	RTECS VN 3015000*
Skin Irritation	Draize [rabbit]	Moderately irritant	RTECS VN 3015000*
Eye Irritation		Irritating	Supplier information
Skin Sensitization		May cause sensitization by skin contact	Supplier information
Inhalation		Inhalation of high doses narcotic effects/ intoxication may be induced	Supplier information
Mutagenicity, Cancerogeneity, Teratogenity		No experimental indications of mutagenicity in-vitro exist	Supplier information

\*): RTECS: The Registry of Toxic Effects of Chemical Substances; VN3015000, 1997

#### Ecotoxicological information

Study	Method	Results	Source
Biodegradability		No information	Supplier information
Aquatic Toxicity - <i>Bacteria</i> - <i>Algae</i> - <i>Daphnia</i> - <i>Fish</i>		No information No information No information Toxic to fish	Supplier information
Water Endangering Class (WEC)	Self classification (Supplier)	WEC = 2	German Federal Institute of the Environment, Nature Conservation and Nuclear safety VwVws Annex III