Survey of Chemical Substances in Consumer Products

Survey No 12, 2002

Mapping of Chemical Substances from Tampons

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1 Content

2 Introduction

September 2001 MILJØ-KEMI, Dansk Miljø Center A/S was assigned to carry out a project from the Danish Environmental Protection Agency titled:

3 Mapping of Chemical Substances in Tampons

The project is part of a larger investigation of different consumer products titled:

4 Mapping of Chemical Substances in Consumer Products

The Danish Environmental Protection Agency had prepared a project proposal (8 August 2001, HSHA/12) that formed the background for contents and scope of the project.

The background for the Danish Environmental Protection Agency's investigation is that tampons represent consumer products that are in direct contact with the mucous membrane. Furthermore, the exposure often occurs over a period of time.

Project leaders for the Danish Environmental Protection Agency were Henriette Seiler Hansen and Anette Ejersted.

The products included in this report have been made anonymous.

The report has been read and commented by the manufacturers of the investigated products. They assess that the using their products does not imply a health risk for the consumer.

Based on the investigation and the detected chemical compounds and low concentrations of the single compounds the Danish Environmental Protection Agency supports this assessment.

5 Scope

5.1 Selection of tampons

5.1.1 Purchase of products

A wide selection of groceries, supermarkets, discounts chains, perfumeries, and pharmacies have been visited. Their selection of different brands of tampons were purchased with a view to further investigation.

5.1.2 Selection of hygiene products for the project

The selection of the products was made in co-operation with the Danish Environmental Protection Agency. As there were only five different tampons available on the Danish market, all products were included in the project.

5.2 Chemical analyses

The chemical analyses performed on tampons include the following compounds:

- Colophony
- Selected pesticides
- Selected acrylates
- GC/MS screening

According to the information from the supplier no optical brightener or chloric bleach have been added at production of the tampons. A chemical analysis for bleaching agents has therefore been assessed to be unnecessary. Furthermore, the presence of optical brightener has been evaluated by a visual assessment of the UV illumination.

5.3 Toxicological profile

From the analysis results performed by MILJØ-KEMI, Dansk Miljø Center A/S Dansk Toksikologi Center (DTC) has suggested single components where a toxicological profile could be prepared.

The final selection was carried out in co-operation with Anette Ejersted from EPA. A total of two components were selected - glycerol tricaprylate and oleyl alcohol.

6 Methods

6.1 Sample preparation

All tampons were wrapped in foil or plastic. Some were accordingly packed in an injection cover of cardboard or plastic. All wrapping material was removed, where after the entire product including the string was cut into pieces of approximately 0.5 x 0.5 cm.

6.2 GC/MS screening (acrylates and other extractable organic compounds)

A number of tampons corresponding to approximately 5 g, is extracted with dichloromethane added internal standard by Soxhlet extraction for 16 hours. A part sample of the extract is taken, concentrated, and analysed at combined gas chromatography and mass spectrometry (GC/MS) by scanning over a larger mass area. The content is calculated to relevant standards (acrylates and phenols) or semi-quantitative to internal standards (others).

The table specifically states with results which components are calculated to internal standard. The quantification is semi-qualitative for these components corresponding to a larger uncertainty (estimated 50-200%).

The analysis is performed as double identification. The content is calculated to relevant standards and internal standards. The limit of detection is 1.5 mg/kg.

6.3 Pesticides

The sample is extracted with dichloromethane, the extract is derived, and analysed at gas chromatography with a mass spectrometric detector (GC/MS). Toxaphen is analysed with electron capture detector (GC/ECD) following resolution in hexane.

The analysis is carried out as double identification and includes the following pesticides:
Aldrin, atrazine, camfechloro (toxaphen), cyflurthrin, 2,4-D, DDT, diazinon, dichlorvos, dieldrin, dicofol, endosulfan, endrine, fluazifop butyl, fenvalerate, heptachloropoxide, hexachlorobenzene, captan, carbaryl, quintozen, lambda-cyhalothrine, methoxychloro, pentachlorophenol, permethrin, pirimicarb, simazine, 2,4,5-T, trifluralin.

Pesticide	Limit of detection
Atrazine, 2,4-D, DDT, diazinon, dichlorvos, dieldrin, fluazifop butyl, heptachloropoxide, hexachlorobenzene, captan, quintozen, methoxychlor, pentachlorophenol, permethrin, pirimicarb, simazine, 2,4,5-T og trifluralin	0.01 mg/kg

Aldrin, carbaryl, fenvalerat, dicofol, endosulfan	0.02 mg/kg
Lambda-cyhalothrin, cyflurthrin	0.03 mg/kg
Camfechloro (toxaphen)	0.04 mg/kg
Endrine	0.05 mg/kg

6.4 Colophony

A part sample of the Soxhlet extract (see 4.3) is evaporated to dryness, resolved in methanol and water (90:10), and analysed at combined liquid chromatography and mass spectrometry (LC-DAD-MS).

The analysis is carried out as double identification. The limit of detection is 0.4 mg/kg.

6.5 Optical brightener

All suppliers have stated that their products did not contain optical brightener. Instead of making an analysis this fact was verified by a total division of the products and an ultra-violate illumination. This method can provide false positive results as other substances may have fluorescent abilities, however, not false-negative results. In case there are fluorescent substances these will be detected at the test.

7 Results

7.1 Supplier data

All manufactures of the selected tampons have been contacted by MILJØ-KEMI, Dansk Miljø Center A/S in order to obtain information on the composition. All manufactures have answered a questionnaire and supplied data sheets on the products.

7.1.1 Selection of hygiene products for the project

The selection of hygiene products included in the project was made in co-operation with Henriette Seiler Hansen of the Danish Environmental Protection Agency. As there are only five different products on the Danish market all tampons were included in the project.

The below mentioned table states name, a brief product description, and manufacture/supplier. The description is made from the suppliers' information. A table containing additional information is enclosed as appendix A.

Table 1. Products included in the project.

Description			Manufacture/supplier
Core	**Surface**	**String**	
Cotton, rayon or mix	Rayon fibre	Cotton	A
Cotton, rayon or mix	Rayon fibre	Cotton	A
Viscose	PE/PP non woven	PP	B
Viscose and cotton	Non woven	Cotton	C
Ecological cotton	Ecological cotton	Ecological cotton	D

PE: polyethylene, PP: polypropylene. Non-woven is a collective nomination for non-woven textile.

7.2 Results

7.2.1 Optical brightener

Optical bleach could not be detected visually in the divided tampons at the UV-illumination. Chemical analyses have therefore not been made for these substances.

7.2.2 Pesticides

Table 2 states the result of the pesticide analysis. The specific limits of detection are stated in the method description.

Table 2. The results for the pesticide analyses are stated in mg/kg. The limits of detection vary from 0.01 to 0.05 mg/kg. Two results indicate double identification.

Pesticide	1		2		3		4		5	
Aldrine	-	-	-	-	-	-	-	-	-	-
Atrazine	-	-	-	-	-	-	-	-	-	-
Camfechlor (toxaphen)	-	-	-	-	-	-	-	-	-	-
Cyflurthrine	-	-	-	-	-	-	-	-	-	-
2,4-D	-	-	-	-	-	-	-	-	-	-
DDT	-	-	-	-	-	-	-	-	-	-
Diazinone	-	-	-	-	-	-	-	-	-	-
Dichlorvos	-	-	-	-	-	-	-	-	-	-
Dieldrine	-	-	-	-	-	-	-	-	-	-
Dicofol	-	-	-	-	-	-	-	-	-	-
Endosulfane	-	-	-	-	-	-	-	-	-	-
Endrine	-	-	-	-	-	-	-	-	-	-
Fluazifop butyl	-	-	-	-	-	-	-	-	-	-
Fenvalerate	-	-	-	-	-	-	-	-	-	-
Heptachloropoxide	-	-	-	-	-	-	-	-	-	-
Hexachlorobenzene	-	-	-	-	-	-	-	-	-	-
Captan	-	-	-	-	-	-	-	-	-	-
Carbaryl	-	-	-	-	-	-	-	-	-	-
Quintozene	-	-	-	-	-	-	-	-	-	-
Lambda-cyhalothrine	-	-	-	-	-	-	-	-	-	-
Methoxychlor	-	-	-	-	-	-	-	-	-	-
Pentachlorophenol	-	-	-	-	-	-	-	-	-	-
Permethrin	-	-	-	-	-	-	-	-	-	-
Pirimicarb	-	-	-	-	-	-	-	-	-	-
Simazine	-	-	-	-	-	-	-	-	-	-
2,4,5-T	-	-	-	-	-	-	-	-	-	-
Trifluraline	-	-	-	-	-	-	-	-	-	-

-: Means less than the limit of detection.

7.2.3 Colophony and Acrylates

Table 3 states the identification of colophony and selected acrylates respectively. Besides the acrylates selected for the specific identification other acrylates could be detected at the GC/MS screening. The limit of detection is given in the method description.

Table 3. Results of colophony and selected acrylates. The results are stated in mg/kg. Two results per product indicate double identification

	1		2		3		4		5	
Colophony	-	-	-	-	-	-	-	-	-	-
Methylacrylate	-	-	-	-	-	-	-	-	-	-
Ethylacrylate	-	-	-	-	-	-	-	-	-	-
Butylacrylate	-	-	-	-	-	-	-	-	-	-
Butylmethacrylate	-	-	-	-	-	-	-	-	-	-
Tert-butyl acrylate	-	-	-	-	-	-	-	-	-	-
Ethylendiacrylate	-	-	-	-	-	-	-	-	-	-
Ethylhexylmethacrylate	-	-	-	-	-	-	-	-	-	-
Hydroxypropylacrylate	-	-	-	-	-	-	-	-	-	-
1,6-hexadioldiacrylate	-	-	-	-	-	-	-	-	-	-
Diethylenglycoldiacrylate	-	-	-	-	-	-	-	-	-	-

-: Means less than the limit of detection.

No other acrylates have been detected in the screening of the samples.

7.2.4 GC/MS screening

Table 4 states the results of the GC/MS screening. Some of the components could be identified by their chemical name, while others were given a group name.

Table 4. Results of GC/MS-screening of tampons. The results are stated in mg/kg. Two results per product indicate double identification. The components detected in the screening are calculated by use of internal standard.

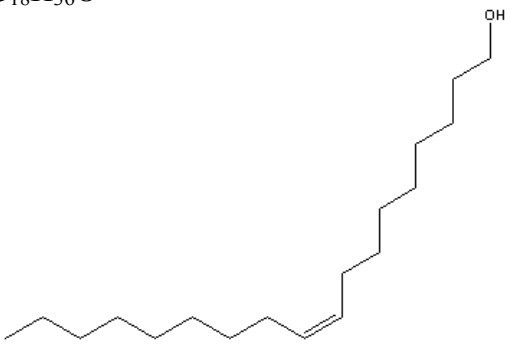
	1		2		3		4		5	
Glycerol tricaprylate#	12	5.4	21	13	15	29	14	23	14	23
Isomer compound of glycerol tricaprylate#	7.0	4.8	13	11	11	26	11	16	12	16
Aliphatic hydrocarbons#	-	-	-	-	-	-	2.6	2.7	-	-
Fatty acid ester, unknown length#	-	-	-	-	-	-	3.1	2.4	-	-
Unsaturated aliphatic alcohol (e.g. C_{16})#	-	-	-	-	-	-	-	-	48	70
Oleyl alcohol or corresponding unsaturated aliphatic alcohol#	-	-	-	-	-	-	-	-	130	170

-: Means less than the limit of detection.

#: Means that the components are quantified to internal standards.

8 Toxicological profile for oleyl alcohol

8.1 Chemical identity

6.1.1	Name:	Oleyl alcohol	
6.1.2	CAS no:	143-28-2	
6.1.3	Molecular weight:	268.48	
6.1.4	Molecular formula:	$C_{18}H_{36}O$	
6.1.5	Structure formula:		

8.2 Regulation

6.2.1	EU classification:	Not classified.	(1)
6.2.2	Limit in foods:	Not allowed in food.	(2)
6.2.3	Limit in food contact materials:	No restrictions on the provisional lists of monomers and additives notified to European Commission as substances, which may be used in the manufacture of plastics intended to come into contact with foodstuffs. Substances for which an ADI or a TDI could not be established, but where the present use could be accepted. SCF opinion: Precursor of oleic acid.	(3)
6.2.4	Limit in cosmetics:	Permitted with no restrictions.	(4)

8.3 Physico-chemical properties

6.3.1	Melting point:	13 – 19°C, -7.5°C, 0.1- 5°C	(5) (6) (7)
6.3.2	Boiling point:	205 – 210°C	(8)
6.3.3	Vapour pressure:	0.000015 mmHg at 25°C (calculated)	(9)
6.3.4	Water solubility:	Insoluble in water	(5)
6.3.5	Lipid solubility:	Soluble in alcohol, ether	(5)

6.3.6 Partition coefficient (log P_{ow}): 7.50 (calculated) (9)

8.4 Toxicological properties

8.4.1 Toxicokinetic properties

8.4.1.1 Uptake through skin or mucosae

Percutaneous toxicity studies with products containing 8% oleyl alcohol indicate low toxicity. (6)

8.4.1.2 Biotransformation

The metabolism was studied in one adult sheep. The animal received 66 g per day of oleyl alcohol in the diet for 12 days. Continuous measurements showed increased excretion of lipids (9 g/day fatty acids and 30 g/day unsaponifiables) and increased excretion of stearic and oleic acid. Oleyl alcohol had no effects on either methane or heat production. (6)

The metabolism of orally administered oleyl alcohol was studied in rats. The alcohol produced no abnormalities and did not affect the distribution of lipid classes or fatty acid composition of the phosphoglycerides in the liver. Pronounced changes did occur in both the alkyl and alkyl-1-enyl moieties of the phosphoglycerides of the liver. Metabolites of long-chain alcohols become incorporated into the phosphoglycerides of the liver. (6)

8.4.2 Acute toxicity

The results of acute oral toxicity studies indicate a very low toxicity. (6)

8.4.2.1 Oral exposure

Product formulations containing 8% or 20% oleyl alcohol administered by gastric intubation at doses up to 10 g/kg bw caused no deaths and no toxic effects in rats. (6)

8.4.2.2 Skin exposure

Unsaturated fatty alcohols such as oleyl alcohol, and 2-octyl dodecanol are moderately to severely comedogenic. (10)

8.4.2.3 Irritation

Undiluted oleyl alcohol and 10% aqueous dispersions were fixed for 24 hours under occlusion to the backs of rabbits. In this test oleyl alcohol was slightly irritating when undiluted, and nonirritating when in a 10% aqueous dispersion. (6)

When undiluted oleyl alcohol was applied on the skin of rabbits for 4 consecutive days, the result was interpreted as mild primary skin irritation. (6)

Technical grade oleyl alcohol was tested for skin irritation using rabbits, guinea pigs, rats, (each with doses of 0.1 g) miniature swine, and man (each with doses of 0.05 g). (6)

Irritation was moderate to severe in the rabbit, guinea pig and rat, but no irritation occurred in the swine or in humans. Eye rabbit: 100 mg/24 h: mild irritation. (8)

An irritation test of 100% oleyl alcohol using 6 rabbits gave an ocular irritation score of 1 (max. 110) on Day 1. All scores were 0 by the second day. (6)

8.4.3 Subchronic/chronic toxicity

8.4.3.1 Skin sensitisation

Oleyl alcohol in lipstick base was the sensitiser in three patients with lipstick dermatitis. (11)

Contact allergy to cutting fluids can less commonly come from oleyl alcohol. (12)

The frequency of contact sensitisation of oleyl alcohol is estimated to be uncommon. Cross-reactions are seen with stearyl alcohol. (13)

8.4.3.2 Mutagenic effects

No data found.

8.4.3.3 Reproduction toxicity

No data found.

8.4.3.4 Carcinogenicity

No data found.

8.4.3.5 Organ toxicity

Observations made in a subchronic skin irritation study indicated that 100% oleyl alcohol was “poorly tolerated” when applied to the skin of rabbits daily for 60 days. Dilutions of 10% were “relatively well tolerated” with only slight exfoliation. (6)

8.5 Conclusion

Based on the above information DTC concludes, that the critical acute effect is skin irritation tested on backs of rabbits.
Skin contact with 100% oleyl alcohol resulted in irritation.
NOAEL <10% in aqueous dispersions.
LOAEL is 10% in an aqueous dispersion.

Based on the information from a 60-day study on rabbits DTC concludes, that the critical effect from long-term, repeated exposure is skin irritation.
NOAEL <10% in aqueous dispersions.
LOAEL is 10% in an aqueous dispersion.

8.6 Literature

1. Miljø- og Energiministeriets bekendtgørelse nr. 733 af 31. juli 2000 (Bekendtgørelse om listen over farlige stoffer).
2. Positivlisten: fortegnelse over tilsætningsstoffer til fødevarer. Søborg: Ministeriet for Fødevarer, Landbrug og Fiskeri, Fødevaredirektoratet; 2000.
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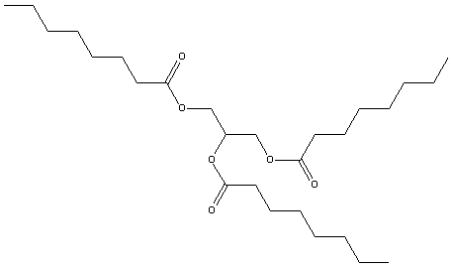
9 Toxicological profile for glycerol



tricaprylate

9.1 Chemical identity

8.1.1	Name:	Glycerol tricaprylate
8.1.2	CAS no:	538-23-8
8.1.3	Molecular weight:	470.69
8.1.4	Molecular formula:	$C_{27}H_{50}O_6$
8.1.5	Structure formula:	

9.2 Regulation

8.2.1	EU classification:	Not classified	(1)
8.2.2	Limit in foods:	Not allowed in food	(2)
8.2.3	Limit in food contact materials:	Not on the provisional lists of monomers and additives notified to European Commission as substances that may be used in the manufacture of plastics intended to come into contact with foodstuffs.	(3)
8.2.4	Limit in cosmetics:	Permitted with no restrictions.	(4)

9.3 Physico-chemical properties

8.3.1	Melting point:	6°C	(5)

8.3.2	Boiling point:	233.1 °C	(5)
8.3.3	Vapour pressure:	23.5 mmHg at 75°C	(6)
8.3.4	Water solubility:	0.4 mg/l	(7)
8.3.5	Lipid solubility:	>10% soluble in chloroform	(6)
8.3.6	Partition coefficient (log P_{ow}):	9.20	(7)

9.4 Toxicological properties

9.4.1 Toxicokinetic properties

9.4.1.1 Uptake through skin or mucosae

Glycerol tricaprylate has been shown to increase skin penetration of drugs. (8)

Log Kp is a measure for skin permeability. Using the Potts & Guy model, the Log Kp for glycerol tricaprylate can be calculated to be 0.94 cm/h. Substances with a log Kp value between –5 and 2 are categorised as having medium skin permeability. (9)

9.4.1.2 Biotransformation

Human fibroblasts and lymphoblasts (in vitro) hydrolyse glycerol tricaprylate to yield octanoic acid. Following intravenous administration of 100 or 300 mg/kg bw to fasted rabbits, ketone bodies in the blood peaked after 120-180 minutes. (10)

9.4.2 Acute toxicity

9.4.2.1 Oral exposure

Oral LD_{50} in rats: 33.3 g/kg bw. (6)

9.4.2.2 Skin exposure

No data

9.4.2.3 Irritation

No data

9.4.3 Subchronic/chronic toxicity

9.4.3.1 Skin sensitisation

No data

9.4.3.2 Mutagenic effects

Mutagenicity test of glycerol tricaprylate in Salmonella Typhimurium strains was evaluated using the following strains with and without metabolic activation: TA97, TA98, TA100 and TA 1535. Glycerol trica-prylate was only mutagenic in strain TA 1535 with metabolic activation. (8)

Glycerol tricaprylate did not induce dominant lethal mutations in female germ cells. (8)

No difference was found in the spontaneous frequency of convertants of yeasts injected intraperitoneally with or without glycerol tricaprylate as vehicle. (8)

No effects were found in chromosomal aberrations assay, micronucleus test and sister chromatoid exchanges assay. (8)

9.4.3.3 Reproduction toxicity

Female rats were dosed orally from day 7 prior to mating through to day 21 of gestation. Parameters investigated were growth statistics and weaning index. Lowest toxic dose was found to be 250 g/kg/day according to (10) and 250 g/kg as a total dose over 28 days according to (11). DTC assumes that it s a total dose over 28 days. (10) (11)

No significant maternal foetotoxic or teratogenic effects were seen in mice dosed by gavage (4,750 mg glycerol tricaprylate /kg bw/day) on days 7-15 of gestation. (10)

Glycerol tricaprylate was effective in producing fusion on the endometrial epithelium (symplasma formation) and decidualization of the stroma in pseudopregnant white rabbits. (8)

9.4.3.4 Carcinogenicity

Glycerol tricaprylate was administered to rats by gavage in volumes of 2.5, 5 or 10 ml/kg bw once daily for 5 days per week for 2 years. Glycerol tricaprylate caused hyperplasia and adenomas of the exocrine pancreas. At the highest dose level glycerol tricaprylate decreased incidences of mononuclear cell leukaemia, and reduced incidence or severity of nephropathy in male rats were found. Furthermore there was an increased incidence of squamous cell papillomas of the forestomach in rats receiving 10 ml/kg bw. (8)

Glycerol tricaprylate was injected subcutaneously into 61 newborn mice of each sex in volumes of 0.1, 0.1, 0.2, and 0.2 ml on days 1, 7, 14 and 21 after birth, respectively. Of the Glycerol tricaprylate treated mice that survived (23 males, 22 females), the percentages of males and females with tumours were 60.9% and 59.1% respectively. In untreated controls (47 male and 47 female survivors) the percentages of males and females with tumours were 51.1% and 42.6%, respectively. (8)

In another experiment with glycerol tricaprylate injected either subcutaneously or intraperitoneally (0.05 ml weekly) to mice for 502-569 days (depending on survival), no tumours were found. (8)

9.4.3.5 Organ toxicity

The following statistically significant changes in organ weight were noted in female and male rats dosed (daily dosing assumed) for 31 days: (8)

Reduction in heart weight in male rats dosed with 2, 5, or 10 ml/kg bw.

Reduction in spleen weight in male rats dosed with 5 or 10 ml/kg bw.

Reduction in kidney weight in male rats dosed with 5 or 10 ml/kg bw.

Reduction in left testis weight in male rats dosed with 2, 5, or 10 ml/kg bw and in right testis when dosed with 2 or 10 ml/kg bw.

At microscopic examination, no lesions were found in either group (male-/ female rats or control groups).
Furthermore statistically significant changes of clinical chemistry and haematological parameters were noted.

In male rats dosed for 26 weeks (10 ml/kg bw, daily dosing assumed), significant reductions in GOT (Glutamate Oxaloacetic Acid Transaminase) activity and hemoglobin concentration were noted, but increases in liver weight (2 ml/kg bw) and adrenal glands (2 or 10 ml/kg bw) were seen. In another chronic oral toxicity experiment, glycerol tricaprylate caused few lesions in the kidneys, myocardium, and aorta of rats. (8)

9.5 Conclusion

There are no reported levels of NOAEL for glycerol tricaprylate, and the oral LD_{50} value in rats is reported to be very high (33 g/kg bw), but organ toxicity is seen at low oral concentrations (2-10 ml/kg bw in rats corresponding to 1.9-9.5 g/kg bw).

Notice should also be taken to the ability of the substance to enhance skin penetration.

9.6 Literature

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10 Summary and conclusion

10.1 Analysis

A total of five different tampons were included in the project.

The tampons were tested for a total of 27 different pesticides without detecting content. Likewise colophony and a number of acrylates could not be detected in the tampons.

The GC/MS screening detected a total of six components whereof one could be identified as glycerol tricaprylate and an isomer of the component. Furthermore, oleyl alcohol was identified. The other components are stated with a chemical group name.

According to the supplier's information no optical brightener or chloric bleach have been added at the production. A UV illumination visually verified that the products did not contain optical brightener.

10.2 Toxicological profile

A toxicological profile has been prepared for glycerol tricaprylate and oleyl alcohol respectively.

10.2.1 Oleyl alcohol

DTC concludes that the critical acute effect is skin irritation tested on backs of rabbits.

Based on the above information DTC concludes,
Skin contact with 100% oleyl alcohol resulted in irritation.
NOAEL < 10% in aqueous dispersions.
LOAEL is 10% in an aqueous dispersion.

Based on the information from a 60-day study on rabbits DTC concludes, that the critical effect from long-term, repeated exposure is skin irritation.
NOAEL < 10% in aqueous dispersions.
LOAEL is 10% in an aqueous dispersion.

10.2.2 Glycerol tricaprylat

There are no reported levels of NOAEL for glycerol tricaprylate, and the oral LD_{50} value in rats is reported to be very high (33 g/kg bw), but organ toxicity is seen at low oral concentrations (2-10 ml/kg bw in rats corresponding to 1.9-9.5 g/kg bw).

Notice should also be taken to the ability of the substance to enhance skin penetration.