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1-DODECANOL
CAS N°: 112-53-8

SIDS INITIAL ASSESSMENT PROFILE

CAS No.	112-53-8
CHEMICAL NAME	1-Dodecanol
STRUCTURAL FORMULA	CH ₃ CH ₂ CH ₂ CH ₂ CH ₂ CH ₂ CH ₂ CH ₂ CH ₂ CH ₂ CH ₂ CH ₂ (OH)
<u>CONCLUSIONS</u>	
<p>Only minor releases of Dodecanol are expected during production. The major use of this substance is as a chemical intermediate for the production of Dodecyl sulfates and ethoxylates. Consumers will be exposed directly due to presence in foods and cosmetics.</p> <p><u>Environment:</u></p> <p>Although Dodecanol exhibits non-polar narcotic toxicity to aquatic organisms of about 1 mg/l, the substance is readily degradable and releases during production, or through diffuse uses of the free alcohol do not give rise to environmental concerns.</p> <p><u>Human Health:</u></p> <p>No risks were identified as a result of animal testing or experience with human use. The substance is practically non-toxic, and is a permitted food additive (GRAS) in both the U.S. and the EU.</p>	
<u>RECOMMENDATIONS</u>	
1-Dodecanol is presently of low concern.	

SIDS Initial Assessment Report

1. Identity: 1-Dodecanol,
Cas. no. 112-53-8,
 $\text{CH}_3(\text{CH}_2)_{10}\text{CH}_2\text{OH}$

2. Exposure

2.1 General Discussion

The production of fatty alcohols of this type range between 1000 and 10,000 tons per year in Denmark. In 1993 the European production of Dodecanol was estimated as being max. 60,000 tons. In the U.S.A. output of plasticizer type alcohols including Dodecanol was estimated at 110,000 tons in 1975. Domestic consumption of detergent alcohols in the U.S. in 1992 included about 24,000 tons as free alcohols.

1-Dodecanol is used primarily as a chemical intermediate for the production of n-Dodecyl sulfate salts, and in the manufacture of n-Dodecyl ethoxylates. It also finds use in synthetic detergents, lube additives, pharmaceuticals, cosmetics, rubber, textiles, perfumes, and as a flavouring agent.

According to the Danish products registry, the substance is found in 23 different products, including:

1. solvent in fillers/insulating materials for the building industry.
2. part of foaming/surface-active agents for cleaning purposes (including rinses for textiles).
3. as an ingredient in products used in
 - agricultural industry
 - foodstuff industry
 - metal refining and processing industry
 - public areas
 - personal and household (including toiletry formulations for personal use.)

Use in the top 4 of these products exceeds two tons per year in Denmark. The total volume of products registered as containing 1-dodecanol is approximately 225 tons. Percentage content ranged from trace amounts to 100%

In the U.S.A. approximately 20,000 lbs/year are used in fragrances, and some typical concentrations reported in personal care products include soaps (0.01 - 0.09%), detergents (0.002 - 0.018%), lotions and creams (0.005 - 0.02%) and perfumes (0.09 - 0.25%).

1-Dodecanol has been reported in non-alcoholic beverages at 2.0 ppm, ice cream 1 ppm, candy 2.8 ppm, baked goods 1.7 ppm, chewing gum 16-27 ppm and syrups at 7.0 ppm. The substance has been identified in the saliva of male and female volunteers by GC-MS analysis (concentration not determined).

It has also been detected at concentrations of 5 ppm in sediments of the Niagara River Watershed (U.S.A.), identified in waste water from a poultry processing plant in Maryland, U.S.A. (concentration not given), in river water near Barcelona, Spain (concentration not given) and in industrial effluent discharged into the Illinois River, U.S.A. at concentrations of 24.5 ppm.

One additional possible source in the environment would be the occurrence as the result of the breakdown of dodecyl sulphates or ethoxylates.

2.2 Environmental exposure

The Mackay I model predicts initial partitioning to air and soil/sediments (Air 67.43%, Water 1.51%, soil 16.07% and sediment 15.00%). In fact, some volatilization from open water can be expected. The exact vapour pressure is however, critical for this chemical in the Mackay model, and long-term models (such as Neely 100-day) indicate that binding to sediments will limit the amount lost to volatilization.

A rough estimate of aquatic exposure in Europe from production and processing can be calculated as follows:

Total production:	(W)	60000 t/year
Emission rate:	(E)	1%
Removal in WWTP (P)	92% (SIMPLETREAT)	
Number of working days:	(N)	300
Flow rate of river:	(V)	60m ³ /s
Number of sites:	(A)	20

$$PEC = \frac{W \times (100 - P) \times E}{N \times V \times A \times 1000 \times 24 \times 360} = 1.6 \text{ ug/l}$$

For exposure from diffuse releases, data from use of free alcohol in the U.S. leads to the following estimate:

Tons of free alcohol:	(W)	24000 t/year
Population:	(I)	253x10 ⁶ (USA)
Removal in WWTP:	(P)	92% (SIMPLETREAT)
Amount of waste water per inhabitant:	(V)	0.15 m ³ /d
Dilution factor	(D)	10

$$PEC = \frac{W \times (100 - P)}{N \times V \times I \times 100 \times D} = 13.8 \text{ ug/l}$$

This would result in a realistic worst case safety factor of 730/13.8, or ca. 55 for the most sensitive environmental endpoint (EC₁₀ *Scenedesmus subspicatus*).

2.3 Consumer exposure:

Use as a fragrance material, and in soaps and personal care products can be assumed to result in significant exposure. Likewise, oral uptake via content in foods will constitute a major source of exposure. The data received in the SIDS dossier does not allow this amount to be accurately determined, but some rough estimates may be made.

At a concentration of 2.0 ppm in non-alcoholic beverages, it would seem logical to assume that some persons will absorb as much as 4 mg/day from this route.

Using the U.S. E.P.A.'s Dermal model for exposure via a bar soap containing 1% dodecanol indicates a potential exposure of 756 mg/year, of which perhaps 50% is absorbed, giving a total load of about 1 mg/day.

The U.S. E.P.A. SCIES model for inhalation exposure, assuming content in a cleaning preparation of 100 mg, used every second day gives a potential inhalation exposure of 257 mg/year (using a vapour pressure of 0.01 mm Hg), or 0.7 mg/day.

This results in a not entirely unrealistic worst case of 5.7 mg/day, or for an average body weight of 70 kg, about 0.08 mg/kg/bw/day. For children consuming large quantities of non-alcoholic beverages, this figure could be four or five times higher.

2.4 Occupational exposure:

No specific information was found on occupational exposure, including occupational exposure standards. With a vapour pressure of 0.01 mm Hg, a maximum saturation concentration in air at 25°C of about 0.1 mg/l is obtained (12 ppm). Assuming proper hygienic conditions, exposure would probably not be high during manufacture - although exposure as a result of working with products containing 1-dodecanol cannot be ruled out, and might exceed consumer exposure, but for a much smaller number of persons.

3. Toxicity

a) Acute toxicity:

The acute oral toxicity of 1-Dodecanol appears to be very low (>12.8 ml/kg in the rat, and >36 ml/kg in the rabbit. It was not possible to obtain the original documentation of these results, but there seems little reason to doubt them: In the combined OECD reproductive/developmental toxicity study, there was no mortality in male rats receiving 2,000 mg/kg in the feed for 37 days.

No LD₅₀ was available for the inhalation route, but in one experiment there were no deaths among rats exposed to concentrations of 1 mg/l for up to 18 hours. There were, however some signs of lung irritation at autopsy in this study.

Upon repeated exposure to this substance, extreme skin irritation is observed, but the substance induced only mild, reversible eye irritation in rabbits exposed to 0.1 ml of an alcohol mixture containing over 60% 1-dodecanol.

b) Repeated dose toxicity: OECD Combined Repeat Dose and Reproductive/Developmental Toxicity Screening Test. No gross pathological or histopathological effects at doses of 0, 100, 500 or 2000 mg/kg in the feed. The total number of white blood cells was slightly reduced, from 7.0 in controls, 5.9 at 100 mg/kg, 4.3 at 500 mg/kg (P<0.001) and 4.7 at 2000 mg/kg (P<0.01). No differences in the differential counts of WBC types was seen, and the toxicological significance of this finding is difficult to assess.

In addition, plasma free cholesterol was reduced from a mean of 0.18 in controls to 0.11 in the 500 mg/kg group (P<0.05), and triglycerides were reduced from 0.58 in controls to 0.31 in the 2000 mg/kg group (P<0.01).

c) Reproductive toxicity; as under b). The test substance did not cause any reproductive or developmental toxicity. Fertility was reduced from 92% in controls to 75% in animals receiving 2000 mg/kg, but this was not statistically significant.

d) Genetic toxicity: 1-Dodecanol was not mutagenic in the Ames test with or without metabolic activation. However, it was rather cytotoxic, and the maximum concentration that could be tested was 50 µg/plate.

In the Russian literature, Lauryl alcohol was reported to diminish cell mitotic activity and cause structural changes to chromosomes and the mitotic apparatus in *Vicia faba* after 14 hours exposure. It was not possible to further evaluate the significance of this finding

Another Russian article reports chromosomal aberrations in 3.6% of 500 cells examined in rats exposed orally to 1/5 of the LD₅₀ dose of n-Dodecanol (versus None in 600 cells from non-exposed animals). It was not possible to further evaluate the significance of this experiment.

In the only GLP test for *in vivo* genetic toxicity (OECD 474) no statistically significant effects were noted in mice which had received oral doses of 5000 mg/kg. This study is assumed to be the most reliable, and is taken as evidence that 1-Dodecanol is not mutagenic *in vivo*.

e) Carcinogenicity: Mice receiving i.p. injections of 1-dodecanol for eight weeks at total doses of up to 12.0 gm/kg showed no statistically significant increase in lung tumour rate relative to controls. It must be stated that the predictive value of this experiment falls far short of a modern carcinogenesis bioassay.

In two experiments designed to investigate the effects of 1-dodecanol as a cocarcinogen (one employing B[a]p, and one using Dimethylbenz[a]anthracene) repeated topical application of 1-dodecanol appeared to have a slight cocarcinogenic effect. The unconventional design of these experiments, as well as the fact that differences between tumour rates in treated and untreated groups were small, make conclusions somewhat questionable. In addition, the fact that repeated skin application of 1-Dodecanol causes marked irritation needs to be taken into account.

f) Any other human health related information: Occasional allergic reactions to 1-Dodecanol following skin contact have been reported, but appear to be rare (of 1,664 eczema patients patch tested with 5% lauryl alcohol in vaseline, 4 reacted; at a 10% concentration 15 reactions are reported - it is difficult to rule out the possibility that some of these were, in fact, irritative responses).

3.2 Ecotoxicity

a) Acute toxicity to fish: In the Fathead minnow (*Pimphales promelas*) the 96 hour LC₅₀ is 1.01 mg/l (flowthrough test). In Bluegill sunfish (*Lepomis macrochiris*) a 96 hour LC₅₀ of 894 mg/l is reported (static) for an alcohol mixture containing 66% dodecanol.

b) Toxicity to Daphnids: DIN 38412 part 11 (approximates OECD 202, part 1)

EC₅₀ 48 hour = 320 mg/l

Toxicity to daphnids: 21 day life-cycle test NOEC = 1.0 mg/l, LOEC (reproduction) = 3.0 mg/l

c) Toxicity to algae: EC₀ = 0.30 mg/l, EC₁₀ = 0.73 mg/l, EC₅₀ = 0.97 mg/l (*Senedesmus subspicatus* DIN 38412, part 9).

d) Any other ecotoxicological information available: In a Harpticoïd (*Nitrocras spinipes*) a 96 hour LC₅₀'s of 0.9 mg/l and 1.0 mg/l were seen. In tadpoles (*Rana pipiens*, early pre-limb bud) loss of righting reflex was recorded at 0.88 mg/l and 1.0 mg/l in two experiments. 50% of Mosquito larva exposed to dodecanol floating on the water surface died at concentrations as low as 0.4 ml/m².

It should be emphasized that due to the low solubility/high logP of this substance, steady-state is unlikely to have been reached in the acute tests. In general, toxicities of 1 mg/l and less are as predicted by QSARS for

non-polar narcosis, and this is assumed to be the primary mechanism. 1-Dodecanol may also have weak surface-active properties.

4. Initial assessment

Exposure to 1-Dodecanol via foods and use of consumer products is widespread. Toxicological effects as determined at the SIDS level appear slight, being confined to minor effects on blood chemistry in rats after 37-days of administration of > 100 mg/kg in feed. The substance is not genotoxic. There is limited evidence that 1-Dodecanol can act as a cocarcinogen after repeated dermal application, but this effect appears to be weak, and may be associated with irritative effects which would not be anticipated to occur under normal conditions of exposure.

1-Dodecanol is acutely toxic to a number of aquatic organisms, in many cases at concentrations of 1 mg/l or lower. A 21-day daphnia test established a NOEC of 1.0 mg/l. It is difficult to estimate actual release to the environment, although a small percentage will certainly reach the environment through use in various products. Limited older monitoring data indicate the presence of 1-Dodecanol in effluent and river water sediments at concentrations which could cause local environmental concern.

The substance appears to be fairly rapidly degraded under aerobic conditions as seen in a number of experiments. Limited information was found on anaerobic degradation, although similar alcohols, both higher and lower appear also to be subject to substantial anaerobic degradation.

5. Conclusions and recommendations

5.1 Conclusions

All the SIDS endpoints have been met for 1-Dodecanol. The substance is practically non-toxic to mammals, and is an allowed food-additive (GRAS) in both the EU and the U.S. The substance exhibits a non-specific toxicity for aquatic organisms of around 1 mg/l, but is expected to degrade fairly rapidly in the environment.

5.2 Recommendations

1-Dodecanol is presently of low concern.

SIDS Dossier on 1-Dodecanol
Cas. No. 112-53-8

0. General Information

Name of Sponsor country Denmark
Contact point (name, address, telephone and telefax)

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National Agency of Environmental Protection
Strandgade 29
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Name of Lead organisation: National Agency of Environmental Protection

1. Chemical Identity

* **1.1 CAS_number** 112-53-8

* **1.2 Name** (give the name supplied by the OECD) 1-Dodecanol

1.3 Common Synonyms Dodecyl alcohol, Lauryl alcohol, Alcohol C-12

1.4 Empirical formula C₁₂H₂₆O

* **1.5 Structural formula** CH₃(CH₂)₁₀CH₂OH

1.6 Purity of industrial product

1.6.1 Degree of purity (percentage by weight/volume)

The actual composition of commercially available products can vary widely, depending on intended use and manufacturing process. "Dodecanols" are listed as containing 40-99% C-12 alcohol, other major components being C-14 and C-16 alcohols.

Reference: (1.)

Kirk-Othmer, Encyclopedia of Chemical Technology, 3rd. ed., Vol. 1, John Wiley & sons, New York, 1978, p. 723

1.6.2 Identity of major impurities

For a 99% C₁₂ product major impurity is reported as being Tetradecanol (about 1%) (**ref. ibid.**)
For a 98.6% C₁₂ alcohol major impurities are stated as being 0.1% Decanol and 0.7% 1-Tetradecanol.

Reference: (2.)

U.S. Environmental Protection Agency, *OHMTADS (Hazardous Materials Technical Assistance Data System)*, SilverPlatter version 1.6, 1987 ed., Accession number ACC:7216699.

1.6.3 Essential additives (stabilizing agents, inhibitors, other additives), if applicable

No information was found on additives.

2. Physical-Chemical Data

* 2.1 Melting or Decomposition Point

24 Centigrade

Method (e.g., OECD, others): Method not stated.

GLP: YES [?]
NO []

Comments: Melting point given for product obtained as leaflets from dilute ethyl alcohol.

Reference: (3.)

Windholz, M., (edit.), *The Merck Index, (An Encyclopedia of Chemicals, Drugs and Biologicals)*, Merck & Co., Inc., Rahway, N.J., U.S.A., 1983, p. 496.

* 2.2 Boiling Point (including temperature of decomposition, if relevant).

259 °C at 760 mm Hg = 101.3 kPa

Method (e.g., OECD, others): Method not stated.

GLP: YES [?]
NO []

Comments:

Reference: (3.)

Windholz, M., (edit.), *The Merck Index*, p. 496.

* 2.3 Vapour pressure

<0.0013 kPa at 24 °C (= ca. 0.01 mm Hg)

----- kPa at 25 °C (calculated)

Method (e.g., OECD, others): Method not stated.

GLP: YES [?]
NO []

Comments: Vapour pressure of 20 mm Hg (ca. 2.7 Kpa) at 150°C. A calculated vapour pressure of 0.026 mm Hg at 25°C is obtained using the Watson method.

Reference: (2.)

U.S. Environmental Protection Agency, *OHMTADS*, 1987 ed., Accession number ACC 7216699.

* **2.4 Partition coefficient n-Octanol/water**

log Pow = 5.13 at --- °C (Temperature not stated.)

Method: calculated []
 measured []

GLP: YES []
 NO []

Analytical Method: Not stated.

Comments (e.g., is the compound surface active or dissociative?): No.

Reference: (4.)

Verschueren, K., *Handbook of Environmental Data on Organic Chemicals*, Second ed., Van Nostrand Reinhold Company, New York, 1983, p. 596.

Note: Various sources indicate Log Pow in ranges from 5.06 to 5.36.

* **2.5 Water solubility**

1.9 mg/l at 25°C

Method (e.g., OECD, others):

Chemical added to water in a 25 ± 1°C water bath and shaken until constant concentration. Samples of saturated water centrifuged for 30 min.

GLP: YES []
 NO []

Analytical Method: GC analysis.

Comments (e.g., the detection limit for insoluble substances):

Most sources simply state that the substance is insoluble in water, but do not mention the detection limit.

Reference: (18.)

Veith, G., "Structure-Toxicity Relationships for the Fathead Minnow, *Pimphales promelas*: Narcotic Industrial Chemicals," *Can. J. Fish Aquat. Sci.*, vol. 40, 1983, pp. 743-758.

2.6 Flash point (liquids)

121°C closed cup [] open cup []

Method (e.g., OECD, others including reference to the standard test used):

DIN-ISO 2592.

GLP: YES [
NO [

Comments:

Reference: (6.)

Henkel KGaA, Datablatt für Altstoffe: CAS-Nummer 112-53-8, 05.07.1988.

2.7 Flammability (solid/gases)

Method (e.g., OECD, others):

GLP: YES [
NO [

Test results:

Comments: The material is flammable and is said to present a slight fire hazard when exposed to heat or flame.

Reference: (5.)

National Library of Medicine, HSDB, (Hazardous Substances Data Bank), 19.03.1990, Cas. No. 112-53-8.

2.8 pH in water

pH at mg/l (water)
pKa

Method (e.g., OECD, others):

GLP: YES [
NO [

Comments: No information was found. QSAR calculations indicate a pKa of 16.00 at 25°C (ref. 13. Veith, U.S. EPA QSAR system, ERL-Duluth, 1985.

Reference:

2.9 Other data e.g., relative density, surface tension (of aqueous solution), fat solubility, explosivity, oxidising properties and particle size distribution

Comments: Relative density D_4^{24} 0.8309. Soluble in alcohol and ether.

Reference: (3.)

Windholz, M., (edit.), The Merck Index, 1983, p. 496.

3. Source of exposure

* 3.1 Production levels expressed as tonnes per annum

Information on production levels should be provided in ranges (e.g., 100-1000 tonnes, etc.) per responder or country and the date for which those ranges apply should be given.

According to Danish trade statistics, national use and manufacture of lauryl, stearyl and cetyl alcohols was in the range of 1000 to 10 000 tons in 1986 (**ref. 7. Danmarks Statistik, Manufacturers' Sales of Commodities in the year 1986, Copenhagen, 1987**). In the U.S., production in 1975 (including higher alcohols) was estimated at 110,000 tons (**ref. 5. HSDB, 1990, Cas. No. 112-53-8**). The IUCLID database reported a total European production of max. 60,000 tons per year in 1993. According to a U.S. survey (Preliminary Exposure to Lauryl Alcohol and Sodium Lauryl Sulfate, EPA contract no. 68-D1-0156, 1994) about 24,000 tons of free detergent alcohols, including dodecanol were consumed in 1992.

3.2 Processes

Describe sources of potential human or environmental exposure including workplace concentrations and emission data (in % release), if available, for both manufacturing and user areas.

No detailed information was found on emission of Dodecanol; however, use patterns (see below) would seem to indicate a wide range of potential human and environmental exposure.

Reference:

* 3.3 Information concerning Uses (including categories and types of uses expressed in percentage terms)

Examples of use categories are dyestuffs, intermediates, solvents, adhesives, building material agents, detergents, cleaning agents, fertilisers, plastic agents, surface treatment agents, etc.

Types of uses are divided into three: industrial use (open system and closed system), public use and export. The greatest single use category is as a chemical intermediate for the production of n-Dodecyl sulphate salts, followed by use as an intermediate for the manufacture of n-Dodecyl ethoxylates. 1-Dodecanol is also used in synthetic detergents, lube additives, pharmaceuticals, cosmetics, rubber, textiles, perfumes, and as a flavouring agent. Ca. 20,000 lbs/year used in fragrances in the U.S. Found in non-alcoholic beverages at 2.0 ppm, ice cream 1 ppm, candy 2.8 ppm, baked goods 1.7 ppm, chewing gum 16-27 ppm and syrups at 7.0 ppm (**ref. 5. HSDB, 1990, Cas. No. 112-53-8**).

Used in soaps at concentrations of 0.01-0.09%, detergents 0.002-0.018%, lotions and creams 0.005-0.02% and perfumes 0.09-0.25% (**ref. 8. Opdyke, D., Fd. Cosmet. Toxicol., vol. 11, 1973, p. 109.**)

3.4 Options for disposal

Mode of disposal (e.g., incineration, release to sewage system) for each category and type of use, if appropriate; recycling possibility.

No detailed information was found. With the exception of use as an intermediate, ultimate release into the environment must be assumed. One source recommends incineration as a method of disposal (**ref. 5. U.S. Environmental Protection Agency, OHMTADS, 1987 ed. Accession number ACC 7216699**).

3.5 Other remarks**Reference:****4. Environmental Fate and Pathways**

Reporting of studies should give the test method, test conditions (lab versus field studies), test results (e.g., % degradation in specified time period) and reference. Information on breakdown products (transient and stable) should be provided when available.

*** 4.1 Degradability (biotic and abiotic)****4.1.1 Biodegradability****Test substance:** n-Dodecanol, analytic grade**Test type, aerobic [X] , anaerobic []**

Test medium: water, water-sediment, soil, sewage treatment

Activated sludge.

In the case of poorly soluble chemicals, treatment given (nature, concentration, etc.):

Test method (e.g., OECD, ISO, others):

Activated sludge suspension adjusted to 2,500 mg/l suspended solids. Substrate concentration 500 mg/l. Temperature maintained at 20°C, measurements on Warburg respirometer.

GLP YES [?]

NO []

Test results:

BOD 13.4% of TOD at conclusion of test period (24 hrs.)

Comments:

Reference: (9.)

Gerhold, R., "Structural Determinants in the Oxidation of Aliphatic Compounds by Activated Sludge," J. Water Pollut. Control Fed., Vol. 38, 1966, pp. 562-579.

4.1.1.a Biodegradability**Test substance:** Dodecyl alcohol, chemically pure, C₁₂**Test type, aerobic [X], anaerobic []****Test medium: Water, water-sediment, soil. sewage treatment**

Activated acclimated sludge (I.) and domestic sewage (II.)

Test method (e.g. OECD ISO, others):

Warburg apparatus, standard dilution technique, 20°C.

GLP YES [?]
NO []

Test results:

BOD 5-day 29.7% of TOD for activated sludge (I.)
BOD 5-day 27.0% of TOD for domestic sewage (II:)

Comments:

Reference: (10.)

Bogan, R., "Biochemical Degradation of Synthetic Detergents", Sewage and Industrial Wastes, Vol 27, 1955, pp. 917-928.

4.1.1.b Biodegradability

Test substance: 1-Dodecanol, analytical grade

Test type, aerobic [X], anaerobic []

Test medium: Water, water-sediment, soil, sewage treatment

Acclimated domestic sewage.

Test method (e.g. OECD, ISO, others):

Standard BOD technique, 21°C (plus-minus 3°C).

GLP YES [?]
NO []

Test results:

BOD 5-day 23.2% of ThOD.

Comments:

Reference: (11.)

Vaishnav, D., et. al., "Quantitative Structure - Biodegradability Relationships for Alcohols, Ketones and Alicyclic Compounds", Chemosphere, Vol. 16, No. 4, 1987, pp. 695-703.

4.1.1.c Biodegradability

Test Substance: Lorol C12 - 99, 100% pure.

Test type, aerobic [x], anaerobic []

Test medium: water inoculated with mixed bacteria.

Test method: (e.g. OECD ISO, others):

GLP: YES NO

BODIS: Biological oxygen demand test for insoluble substances. Synonym: Modified RDA/Blok-test. The method represents a modification of the closed bottle test especially suited for poorly soluble compounds.

Test procedure:

A mineral medium is inoculated with a mixed bacterial inoculum, stabilized under laboratory conditions for one week and then spiked with a predetermined amount of test chemical.

The test vessels are closed glass bottles with a known volume of aqueous test mixture (2/3) and air (1/3). They are shaken continuously to assure steady state oxygen partitioning between liquid and gas phase. The degradation is followed by weekly measurements of BOD in the aqueous phase for a 28 d period. The total oxygen uptake in the flasks is calculated from the measured dissolved oxygen concentration divided by the saturation value at normal conditions and multiplied with the total oxygen content originally present in the liquid and gas phase.

Results:

at test conc. 100 mg COD/l:

% BOD/COD 7 days= 72%, 14 days= 89%, 21 days= 93%, 28 days = 100%

BOD = biological oxygen demand

COD = chemical oxygen demand = 2.97 mgO₂/mg

Reference:

Henkel KGaA, TFB-ökologi, "Lorol C12 - 99, Bewertung der biologischen Abbaubarkeit im BODIS-test," Abschlussbericht 5. März 1992, Börner, RE 920025.

4.1.2 Sewage Treatment

Information on treatability of the substance

No information was found on sewage treatment.

4.1.3 Stability in air (e.g., photodegradability) and in water (e.g., hydrolysis)

Test substance:

Test method or estimation method (e.g., OECD, others):

If available, information on degradation products, dissociation constants and half-life should be given.

GLP YES
NO

Test results:

Percentage of degradation after certain period:

Comments:

Does not react with water, and has a low general reactivity (**ref. 12.** U.S. Coast Guard, CHRIS (Chemical Hazard Response Information System), SilverPlatter 1.6, Jan. 1988 edition, Cas no. 112-53-8).

Estimated hydrolysis half life of 1000 days (**ref. 13., Veith**, U.S. EPA QSAR system, ERL-Duluth, 1985).

Although stable under normal conditions of storage for long periods of time, exposure of hot [detergent alcohols] to air will result in increased carbonyl content particularly in presence of iron and rust (**ref. 1.** Kirk-Othmer, Encyclopedia of Chemical Technology, 3rd. ed., Vol. 1, 1978, p. 726).

Reference:

4.1.4 Identification of main mode of degradability in actual use

No information.

Reference:

4.2 Bioaccumulation

Test substance:

Test method (e.g., OECD, others):

- . Type of test: static [], semi-static [], flow-through []
- . Other (e.g., field test) []

GLP YES []
NO []

Test results:

Bioaccumulation factor:

Calculated results: BCF 3801.0

Method of Calculation: Veith, et. al., 1980

Comments:

Reference: **(13.)**
U.S. EPA, QSAR system, ERL-Duluth, 1985.

* **4.3 Transport and distribution between environmental compartments including estimated environmental concentrations and distribution pathways**

This information may be provided by industry or by public authorities. It should be indicated whether the calculation is on a global basis or is site-specific, and whether it is based on laboratory measurements or field observations.

Type of transport and distribution processes between compartments (e.g., air, water, soil):

Estimation of environmental concentrations:

. results of the estimation

$$\text{Log}_{10}(\text{Henry's Constant}) = -3.42 \text{ atm}\cdot\text{m}^3/\text{mole}$$

Partitioning pattern, Air = 0.27%; Water = 3.82%; Ground = 49.61%;
Hydrosoil = 46.30%

. summary of the method (or model) used

Neely 100 day partitioning pattern.

Reference: (13.)

U.S. EPA, QSAR system, ERL-Duluth, 1985.

4.4 Monitoring data (environment)

Test substance:

Indicate whether the data are measurements of background concentrations or measurements at contaminated sites:

- air:(ug/m³) in as of 19..
- surface water:(ug/l) in as of 19..
- ground water:(ug/l) in as of 19..
- soil/sediment:(ug/g) in as of 19..
- biota*:(ug/g) inas of 19..
- *(specify species)
- food:(ug/g) in as of 19..

Comments:

Detected in sediment of Niagara River Watershed at concentration of 5 ppm (**ref. 14.** Proctor, B., et. al., "Industrial Organic Compounds in the Niagara River Watershed", Adv. Ident. Anal. Org. Pollut. Water, Vol 2, 1981, pp. 1017-1036.

Tentatively identified by GC-MS in waste water from poultry processing plant in Maryland, U.S.A., no quantitative data (**ref. 15.** Wachter, J., et. al., Organic Chemicals and Other Factors in Water Reuse at a Poultry Processing Plant, PB-82-223660, 1982, pp. 862-880.

Detected in river water near Barcelona, Spain by GC-MS. Concentration not given. (**ref. 16.** Rivera, J., et. al., "GC/MS, HPLC and FAB Mass Spectrometric Analysis of Organic Micropollutants in Barcelona's Water Supply", Intern. J. Environ. Anal. Chem., Vol. 29, 1987, pp. 15-35.)

Found in industrial effluent discharged into the Illinois River at concentration of 24,500 ppb (ref. 17. Satu, M., et. al., "Identification of Cocarcinogens and Promoters in Industrial Discharges into and in the Illinois River", Journal of Toxicology and Environmental Health, Vol. 6, 1980, pp. 315-331).

Reference:

5. Ecotoxicological Data

5.1 Toxicity to fish

* 5.1.1 Results of acute tests

Test substance: 1-dodecanol, purity not stated.

Test species: *Pimephales promelas* (Fathead minnow).

Test method (e.g., OECD, others):

- . Type of test static [], semi-static [], flow-through [X]
- . Other (e.g., field observation) []

GLP YES [?]
NO []

Test results:

96-hour LC₅₀ 1.01 mg/l

LC₅₀ or EC₅₀ - values after 24,48,72 and 96 hours and method used to calculate these values

Comments:

Twenty to twenty-five 30-day old fish weighing ca. 0.12 g used in each experiment, test tanks consisting of control and five different concentrations. Fish were not fed during the test.

Concentrations of test chemical analyzed daily by GC. Deaths recorded at 1,3,6,12,24,48,72 and 96 hours. LD₅₀'s computed using trimmed Spearman-Kärber method.

Reference: (18.)

Veith, G., "Structure-Toxicity Relationships for the Fathead Minnow, *Pimephales promelas*: Narcotic Industrial Chemicals," Can. J. Fish Aquat. Sci., Vol. 40, 1983, pp 743-748.

5.1.1.a Results of acute tests

Test substance: 1-Dodecanol (purity not specified)

Test species: Golden orf (Goldorfen)

Test method (e.g. OECD, others): Test method and conditions not specified.

GLP YES [?]

NO []

Test results: LC₀ 3000 mg/l, LC₁₀₀ > 10000 mg/l

Comments:

It is not possible to evaluate the results of this study on the basis of the very limited information provided in the data sheet. It should be pointed out that the test concentrations indicated are between 1000 and 5000 times the estimated solubility of the substance in water.

Reference: (6.)

Henkel KGaA, Datablatt für Altstoffe : CAS-Nummer 112-53-8, 05.07.1988.

5.1.1.b Results of acute tests

Test substance: CO-1214 N Fatty Alcohol; C-10 0.6%, C-12 66.0%, C-14 25.7%, C-16 7.1%, C-18 0.5%

Test species: *Lepomis macrochirus* (Bluegill sunfish).

Test method: (e.g., OECD, others):

Fish Toxicity Standard Protocol Modification " Vigorous Mixing Before Adding Test Organism " Recommended bioassay practices (U.S. EPA 1975) with the exception that replicate concentrations were not used.

Type of test static [x], semi-static [], flow-through []

GLP YES [] NO [x]

test results:

96- Hour LC₅₀ 894.5 mg/l (95% conf. 750.1-1066.8 mg/l)

No Observed Effect Level 320.0 mg/l

Comments:

5 month old Bluegill sunfish (average weight 0.63 grams, length 37 mm) acclimatized to test water for 24 hours prior to testing. 48 hours before initiating the test the fish were taken off feed. 10 fish placed in each test vessel at concentrations of 0, 100, 180, 320, 560 and 1000 mg/l. No mortality was observed at 24, 48, or 96 hour intervals, except in the high dose fish at 96 h, where mortality was 70%. Behavioral observations made during the test indicated that Bluegill sunfish exposed to 560 mg/l and higher exhibited abnormal surfacing behaviour and became quiescent.

Reference:

*The Acute Toxicity of WIS-77.010 (100% Active Ingredient) to the Bluegill Sunfish, *Lepomis macrochirus*, Rafinesque. Prepared for The Procter and Gamble Company, Ivorydale Technical Centre, Cincinnati, Ohio. Prepared by Union Carbide Environmental Services, Union Carbide Corporation, Tarrytown, New York, 10591, December 29, 1977. UCES Proj. #: 11506-25-53.*

5.1.2 Results of long-term tests e.g., prolonged toxicity, early life-stage

(No information was found on long-term tests.)

Test substance:

Test species:

Test method (e.g., OECD, others):

- . Type of test: static , semi-static , flow-through
- . Other (e.g., field observation)

GLP YES

NO

Test results:

Maximum concentration at which no effect was observed within the period of the test

Minimum concentration at which effect was observed within the period of the test

Comments:

Reference:

* **5.2 Toxicity to daphnids**

5.2.1 Results of acute tests

Test substance: Loral C 12 - 99 (Dodecanol)

Test species: Daphnia magna, BGA/WaBoLu

DIN 38412 part 11. (approximates OECD 202, part 1.)

Test method (e.g., OECD, others):

GLP YES

NO

Test results:

EC₅₀ - values after 24 and 48 hours, and method used to calculate these values

24 hours: EC₀ = 300 mg/l, EC₅₀ = 1700 mg/l, EC₁₀₀ = 10000 mg/l

48 hours: EC₀ = 100 mg/l, EC₅₀ = 320 mg/l, EC₁₀₀ = 1000 mg/l

Comments:

Slight precipitation occurred at doses of 100, 300, 1000 and 3000 mg/l, while the amount of precipitation was moderate at 10,000 mg/l. No observations were reported indicating physical effects on the test organisms (surface floating, etc.). Measured concentrations of the test substance (DOC) in the 1000 mg/l dose solution were 0.3 mg/l on day 0, 1.1 mg/l on day 1, and

0.8/0.9 mg/l on day 2. Measured concentrations in the 10,000 mg/l dose solution were 0.9 mg/l on day 0, 1.6 mg/l on day 1 and 1.4/1.3 mg/l on day 2. The very low solubility of the test substance in water make results somewhat difficult to interpret.

Reference:

Henkel KgaA, Ökologie, Dodecanol (lorol C 12 - 99), Bestimmung der akuten Daphnientoxizität im Daphnientest nach DIN 38412, Teil 11, abschlussbericht 24.04.1992, Dr.

5.2.2 Results of long-term tests e.g., reproduction

Test substance: Lorol C 12 - 99 (Dodecanol)

Test species: *Daphnia magna*, BGA/WaBoLu

Test method (e.g., OECD, others):

- . Type of test: static , semi-static [], flow-through []
- . Other (e.g., field observation) []

GLP YES

NO []

Subacute/chronic toxicity: *Daphnia* 21 day life cycle test. Draft method of the working group of the Umweltbundesamt for the development of ecotoxicological test methods in aquatic systems: Prolonged toxicity test with *Daphnia magna* (Determination of the NOEC for reproduction rate, mortality and the moment of the first appearance of descendants; 21 d). This method is in line with OECD test guideline 202, part 2.

Test results:

Maximum concentration at which no effect was observed within the period of the test

NOEC = 1.0 mg/l

Minimum concentration at which effect was observed within the period of the test

FOEC = 3.0 mg/l

Comments:

Daphnia were exposed for 21 days to solutions of the test substance at 1, 3, 10, 30, and 100 mg/l. Test solutions were changed three times per week. For each concentration 20 female *daphnia* (5 per test vessel) are used. The test vessels are controlled regularly and the time of first appearance of decedents and the number of juvenile organisms is determined. At (nominal) concentrations of 1 mg/l no effects were noted, while at concentrations of 3 mg/l and above, fertility was significantly effected. There were no effects on the adults in any group including controls on day 2. On day 5, 1/(20) died in the control group, and 8/(20) in the 10 mg/l group, 4/(20) in the 30 mg/l group, and 1/(20) in the 100 mg/l group. By day 21, adult mortality reached or exceed 50% in all test groups above 3 mg/l, while being 10% in the control and low dose groups.

Measured (DOC) concentrations were 0.6/0.5 mg/l at 0 hours, 1.3/1.2 mg/l at 48 hours, and 1.9/1.8 mg/l at 120 hours for the 10 mg/l group. Similar measured concentrations were obtained

in the 30 mg/l and 100 mg/l groups. No information was given on possible physical effects on the Daphnia (surface floating, etc.).

Reference:

Henkel KGaA, Ökology, Dodecanol (Lorol C 12 - 99), Bestimmung der chronischen Daphnientoxizität im verlängerten Daphnientest, 21 Tage, Abschlussbericht 03.06.1992., Dr. Guhl/Mühlberg, RE 920095.

* **5.3 Toxicity to algae**

Test substance: 1-Dodecanol, 99.7%: The substance was handled as an ethanol solution.

Test species: *Senedesmus subspicatus* SAG 8681.

Test method (e.g., OECD, others):

DIN 38412 part 9.

GLP YES
NO

Test results:

EC₀ = 0.30 mg/l EC₁₀ = 0.73 mg/l EC₅₀ = 0.97 mg/l

EC₅₀ (duration, e.g. 24,48,72 hours)

96 hours

Maximum concentration at which no effect was observed within the period of the test

EC₀ = 0.30 mg/l

Minimum concentration at which effect was observed within the period of the test

EC₁₀ = 0.73 mg/l

Comments:

It was found difficult to obtain reproducible results in the algae test.

Reference:

Henkel KGaA, Forshung Biologie, Ökologi, 1-Dodecanol, Algen-Zellvermehrungshemmtest, Abschlussbericht, November 1992, Dr. Guhl/Mühlberg, RE 920200.

5.4 Toxicity to other aquatic organisms

Test substance: 1-Dodecanol, E. G. Merck, 97%.

Test species: Harpacticoid (*Nitocra spinipes*)

Test method (e.g., OECD, others):

- . Type of test: static , semi-static , flow-through
- . Other (e.g., field observation)

N. spinipes was tested in standard 15 ml laboratory test tubes containing 10 ml of brackish water, filtered through folded filter paper. Water temperature 20-22°C. Only adult animals harvested from 3-6 week old cultures were used. Tests were carried out in at least six concentrations and with one control. 2 x 10 *N. spinipes* exposed to each concentration. No control analyses of the test solutions was made, and animals were not fed during the test period. Substances with low solubility in water were first dissolved in acetone (p.a. quality) and then added to the test vessels. The concentration of acetone never exceeded 500 µl/l, which was far below the LC₅₀ for the species. Mortality was recorded after 96 hours under a low power microscope.

GLP YES [
NO [

Test results:

LC₅₀ or EC₅₀ values (acute)

96 hour LC₅₀ 0.9 mg/l (0.8-1.2)

Maximum concentration at which no effect was observed within the period of the test (prolonged test)

Minimum concentration at which effect was observed within the period of the test (prolonged test)

Comments:

Reference: (19.)

*Linden, E. et. al., "The Acute Toxicity of 78 Chemicals and Pesticide Formulations Against Two Brackish Water Organisms, the Bleak (*Alburnus alburnus*) and the Harpacticoid *Nitocra spinipes*," Chemosphere, Nos. 11/12, 1973, pp. 843-851.*

5.4a Toxicity to other aquatic organisms

Test substance: 1-dodecanol, p.a. quality

Test species: *Nitocra spinipes*

Test method: As above, see 5.4.

Test results: 96 hour LC₅₀ 1.0 mg/l

Comments:

100 ppm of EtOH/Tween-80 added to test solution to increase solubility (acute toxicity of this emulsion exceeded 5000 ppm in test organisms).

Reference: (20.)

Bengtsson, B., et. al., "Molecular Structure and Aquatic Toxicity - an Example with C₁ - C₁₃ Aliphatic Alcohols," Chemosphere, Vol. 13, No. 5/6, 1984, pp. 613-622.

5.4.b. Toxicity to other aquatic organisms

Test substance: [¹⁴C]-dodecanol (56 ci mol⁻¹) (ICN Biomedicals, Irvine, Ca., radiochemical purity > 98.5%)

Test species: *Rana pipiens*, early pre-limb bud tadpoles, 1-1.5 cm.

Test method:

Anaesthetic concentration-response curves determined by loss of righting reflex. Tadpoles placed in beakers of neutral, oxygenated aqueous solutions of alcohol prepared in twice-distilled water. After 15-240 minutes allowed for equilibration, tadpoles tipped manually with flame polished glass pipette. Unresponsiveness of > 5 sec. was recorded, and test repeated at 15 min. intervals.

Minimum of 10 animals at each of 5 different concentrations, studies repeated and data pooled. Solutions prepared by diluting stock solutions in ethanol, final concentration of EtOH always being lower than 25 mM. EC₅₀s and slopes obtained using logistic method for quantal responses. 15% depletion of dodecanol in test solution measured as function of [¹⁴C] after 2 hours.

Test results: EC₅₀ after 2 hrs. exposure 4.7 uM (0.88 mg/l)

Comments:

An earlier experiment (**ref. 22.**, Pringle, M., et. al., "Can the Lipid Theories of Anaesthesia Account for the Cutoff in Anaesthetic Potency in Homologous Series of Alcohols?," Molecular Pharmacology, Vol. 19, 1979, pp. 49-55.) using an unspecified species of tadpole obtained similar results with ED₅₀ of 5.4 x 10⁻⁹ M dodecanol (1.0 mg/l).

Reference: (21.)

Alifimoff, J., et. al., "Anaesthetic Potencies of Primary Alkanols: Implications for the Molecular Dimensions of the Anaesthetic Site," Br. J. Pharmacol., Vol. 96, 1989, pp. 9-16.

5.4.c. Toxicity to other aquatic organisms

Test substance: 1-dodecanol, purity not specified.

Test species: Mosquito, *Aedes aegypti* and *Aedes scutellaris*.

Test Method:

I. Eggs of both species aged 2 to 14 days immersed in 150 ml of hay infusion in jars of 51 cm² surface area. 150-250 embryonated eggs per jar. Each trial carried out in triplicate at ten different concentrations. Each series of tests repeated ten times. Eggs allowed to remain in jars for 24-72 hours at 25-27°C. Mortality based on difference between larval count between control and study group.

II. Larvae and pupae of both species, 25 of each treated as above with minimum of five different concentrations of test substance, each series of test repeated ten times. Mortality interpreted as failure of larvae to move.

Test results:

Eggs, *Ae. aegypti* and *Ae. scutellaris*, LD₅₀ 4 l/hectare = ca. 0.4 ml/m². LD₉₀ 7 l/hectare = ca. 0.7 ml/m².

First, second, third and fourth instar larvae and pupae of *Ae. aegypti*, LD₅₀ 3-4 l/hectare = ca. 0.3-0.4 ml/m² ; LD₉₀ 6-7 l/hectare = ca. 0.6-0.7 ml/m².

First, second, third and fourth instar larvae and pupae of *Ae. scutellaris*, LD₅₀ 4 l/hectare = ca. 0.4 ml/m² ; LD₉₀ 6-7 l/hectare = 0.6-0.7 ml/m².

Comments:

According to authors, the alcohols tested initially acted as irritants, finally causing death of the larvae by breaking down some components of cellular structures, presumably of lipid composition, leading to death of the test organisms.

Reference: (23.)

Sinniah, B., "Insecticidal Effect of Aliphatic Alcohols Against Aquatic Stages of Aedes Mosquitoes," Transactions of the Royal Society of Tropical Medicine and Hygiene, Vol. 77, No. 1, 1983, pp. 35-38.

5.5 Toxicity to bacteria

Test substance: Lorol C12 chemically pure

Test species: *Ps. putida*

Single species tests such as "Microtox Photobacterium luminescence test" and tests on overall processes such as nitrification or soil respiration are included in this item.

Test method (e.g., OECD, others):

- . Type of test
- . Other (e.g., field observation) []

02-Consumption test, OECD

GLP YES [?]

NO []

Test results: Acute bacterial toxicity, EC₅₀ > 100 mg Prod./l

Comments:

No additional information supplied.

Reference: (6.)

Henkel KGaA, Datablatt für Altstoffe: CAS-nummer 112-53-8, 05.07.1988 - DIN-Sicherheitsdatenblatt 003838, folge 01 vom 23.06.1988, page 1.

* 5.6 Toxicity to terrestrial organisms

5.6.1 Toxicity to soil dwelling organisms

No information found on toxicity to soil dwelling organisms.

Test substance:

Test species:

Test method (e.g., OECD, others):

GLP YES

NO

Test results:

LC₅₀ (at 7 and 14 days for earthworms)

Comments:

Reference:

5.6.2 Toxicity to plants

Test substance: Dodecane-1-ol, purity not stated.

Test species: Tomato plants, cultivar 'Sonato,' 5-6 weeks after sowing.

Test method (e.g., OECD, others):

Application of a spray containing an aqueous emulsion of test substance at concentrations of 1% or 2%, with observation 1,2,6 and 10 days after treatment.

GLP YES

NO

Test results:

Both concentrations resulted in death of leaves within 6-10 days, with moderate damage to stems and severe damage to side shoots.

EC₅₀ for 7 and 14 days or LC₅₀

Maximum concentration at which no effect was observed within the period of the test

Minimum concentration at which effect was observed within the period of the test

Comments:

Reference: (24.)

Maw, G., "Aliphatic Alcohols as Pruning-Agents for Tomato Side Shoots," *Scientia Horticulturae*, Vol. 7, 1977, pp. 43-55.

5.6.3 Toxicity to birds

No information found on toxicity to birds.

Test substance:

Test species:

Test method (e.g., OECD, others):

GLP YES []

NO []

Test results:

LD₅₀ (acute), LC₅₀ (subacute)

Maximum concentration at which no effect was observed within the period of the test (semi-chronic or chronic)

Minimum concentration at which effect was observed within the period of the test (semi-chronic or chronic)

Comments:

Reference:

5.7 Biological Effects Monitoring (including biomagnification)

No information found on Biological Effects Monitoring.

Studies on variation of predominant species in certain ecosystems and monitoring of biological effects (e.g., thinning of eggshell) etc. are included.

Test substance:

Organism or ecosystem studied:

Effects monitored:

Information on monitoring conditions (water characteristics: suspended matter, pH, temperature, hardness) (Soil/sediment characteristics: % organic matter, clay content)

Test results:

Chemical analysis:

Comments:

Reference:

5.8 Biotransformation and kinetics in environmental species

No information found on Biotransformation.

Under this item, studies on absorption, distribution, metabolism and excretion etc. should be given.

6. Toxicological Data (oral, dermal and inhalation, as appropriate)

Where observations on humans are available, e.g., irritation, these should be entered in the appropriate "Comments" section.

*** 6.1 Acute toxicity**

6.1.1 Acute oral toxicity

Test substance: Dodecanol, no further details on purity.

Test species/strain: Rat, strain not identified.

Test method (e.g., OECD, limit test, fixed dose test):

GLP YES []
NO [x]

Test results:

LD₅₀ reported as > 12.8 ml/kg and > 36 ml/kg.

LD₅₀ or other measure of acute toxicity (e.g. in case of fixed-dose test)

Discriminating dose (for fixed dose only):

Comments:

An oral LD₅₀ in the rabbit of > 36 ml/kg is also reported, as well as an i.p. LD₅₀ for rats of 0.8-1.6 g/kg. All of these acute studies stem from unpublished results, or personal communications. They are extensively quoted in other secondary or tertiary literature sources.

Reference: (25.)

Clayton, G., et. al., ed., "Alcohols," *Patty's Industrial Hygiene and Toxicology*, 3rd. Ed., Vol. 2C, John Wiley & Sons, New York, 1982, p. 4632-4633.

6.1.2 Acute inhalation toxicity

Test substance: Dodecyl alcohol, purity not specified.

Test species/strain: Rat, male Sprague-Dawley (Charles River).

Test method (e.g., OECD, EC, limit test):

42 animals exposed in stainless steel and glass exposure chamber to aerosol pumped at a constant rate. Concentrations measured during exposure by standard gravimetric techniques at 1.05 plus-minus 0.06 mg/liter. Particle size analysis indicated mean aerodynamic diameter of 2.98 u. Total length of exposure time for subgroups of animals, 1, 6 or 18 hours.

GLP YES [?]

NO

Test results:

LC₅₀: Not determined.

Comments:

No deaths occurred in any of the exposed animals. Decreased general activity : Mild dyspnea in some animals. At necropsy a few animals showed a mild degree of scattered haemorrhagic areas in the lungs.

Reference: (26.)

Ulrich, C., et. al., "Pulmonary Deposition of Aerosols in Individual and Group Caged Rats," American Industrial Hygiene Journal, Vol. 40, 1979, pp. 633-636.

6.1.2.a Acute inhalation Toxicity

Test substance: n-Dodecanol, purity not specified.

Test species/strain: Rat, male Sprague-Dawley, 225-300 gm.

Test method:

Ten animals exposed by aspiration to 0.2 ml dodecanol, and observed for max. 24 hours prior to sacrifice.

Test results:

Nine of ten rats died during observation period, seven deaths occurring within 7-30 minutes. Cause of death reported as massive, extensive, severe pulmonary haemorrhage.

Comments:

Reference:

Gerard, H., et. al., "The Aspiration Hazard and Toxicity of a Homologous Series of Alcohols," Arch. Environ. Health, Vol. 13, 1966, pp. 457-461.

6.1.3 Acute dermal toxicity

Test substance: Dodecanol, purity not specified.

Test species/strain: Guinea pig.

Test method (e.g., OECD, limit test):

GLP YES

NO

Test results:

LD₅₀: LD₅₀ > 10 ml/kg

Comments:

Results of unpublished study. No further details.

Reference: (25.)

Clayton, G., et. al., ed., "Alcohols," *Patty's Industrial Hygiene and Toxicology*, 3rd. Ed., Vol. 2C, John Wiley & Sons, New York, 1982, p. 4632-4633.

6.2 Corrosiveness/Irritation

6.2.1 Skin Irritation

Test substance: Dodecanol, about 97% pure.

Test species/strain: Female Swiss mice.

Test method (e.g., OECD, others):

GLP YES [?]
NO []

50 animals exposed by dermal application to ca. 20 ul 20% dodecanol in cyclohexane three times weekly for 60 weeks.

Test results: give maximum scores after hrs

Comments:

Severe cutaneous irritation. Depilation and erythema most intense between sixth and twelfth week, slowly decreasing to leave grossly normal looking skin after 20 weeks.

A brief statement in *Patty's Industrial Hygiene and Toxicology* (ref. 25) referring to an unpublished study states that there was practically no irritation when applied to the skin of Guinea pigs.

In human beings tested by the chamber-scarification method, non-occlusive exposure to a 25% solution in mineral oil produced marked irritation (ref. 29., Frosch, P., "The Chamber-Scarification Test for Irritancy," *Contact Dermatitis*, Vol. 2, 1976, pp. 313-324.)

Severe skin irritation was observed in rats following repeat application of 1-Dodecanol during range-finding studies in preparation for the OECD Combined repeat dose and reproductive/developmental toxicity screening test, causing this exposure rout to be abandoned. (ref. Hansen)

Reference: (28.)

Sice, J., "Tumor-Promoting Activity of n-Alkanes and 1-Alkanols," *Toxicology and Applied Pharmacology*, Vol. 9, 1966, pp. 70-74.

6.2.2 Eye Irritation

Test substance: A. Commercial Lauryl alcohol (natural source) containing C10 0.3%, C12 68.9%, C14 25.1%, C16 5.1%, C18 0.3% and 0.3% unidentified. B. Commercial Lauryl alcohol (synthetic source) containing C10 0.1%, C12 63.3%, C14 24.1%, C16 8.3%, C18 0.4% and 3.8% unidentified.

Test species/strain: New Zealand White rabbit.

Test method (e.g., OECD, others):

Rabbit eye irritation, scored according to Draize criteria.

GLP YES [?]

NO []

(Reviewed by International Research and Development Corporation Quality Assurance Department.)

Test results: give maximum scores after hrs

Product A, 3 animals dosed with 0.1 ml/unwashed and 3 animals with 0.1 ml/washed. Product B, 3 animals dosed with 0.1 ml/unwashed and 3 with 0.1 ml/washed. The undiluted test substance was introduced into the conjunctival sac of the right eye of each rabbit, after which the eyelids were held closed for approximately 1 second. Rabbits in the washed group received washout about 4 seconds following installation with 20 ml lukewarm tap water. The left eye served as a control for each rabbit.

Maximum average irritation scores for product A were 9.3 (unwashed) at 1 hour, and 8.7 (washed) at 1 hour. For product B maximum scores (unwashed) of 10, and 8.4 (washed) at 1 hour. Most scores returned to zero within 3-4 days, but in one animal 14 days were required.

All animals appeared normal during the course of the study, except for one female in group A. (washed) which exhibited hair loss around the right eye on days 17 to 21, and one male in group B. (unwashed) which exhibited clear nasal discharge on days 3 to 9.

Comments:

The results indicate mild, mainly conjunctival irritation under the conditions of this study. An additional study of the same two product batches, using a low volume procedure (10 ul test substance per eye), gave Draize scores of zero for substance A., and 2.8 for substance B.

Reference:

The Procter and Gamble Company, Test articles J0171.01 and J0172.01, Rabbit Eye Irritation, May 7, 1980, 191-566.

The Procter and Gamble Company, Test articles J0171.01 and J0172.01, Rabbit Eye Irritation (Low Volume Procedure), April 8, 1980, 191-567.

6.3 Skin sensitisation

(No animal experiments were found for skin sensitization.)

Test substance:

Test species/strain:

Test method (e.g., OECD, others):

GLP YES []
NO []

Test results:

Number of animals with skin reaction at challenge

Number of animals with skin reaction in control group at challenge

Comments:

Reference:

* **6.4 Repeated dose toxicity**

Test substance: 1-Dodecanol, Sigma L 5375, 99% purity

Test species/strain: Rats, Mol/WIST SPF, 8 weeks of age.

Test method (e.g., OECD, others):

OECD Combined repeat dose and reproductive/developmental toxicity screening test.

GLP YES [x]
NO []

Test results:

No effect was seen in the macroscopic and histological examinations. The total number of white blood cells was reduced dose dependently, but no differences in differential count of the white blood cells could explain this effect. Mean white blood cell counts were 7.0 in the control group, 5.9 at 100 mg/kg, 4.3 (P<0.001) at 500 mg/kg and 4.7 (P<0.01) in the 2000 mg/kg groups. A statistically significant reduction was observed in plasma free cholesterol in the 500 mg/kg/bw/day group (from a mean of 0.18 in controls to 0.11 (P<0.05), and in triglyceride in the 2000 mg/kg/bw/day group (from a mean of 0.58 in controls to 0.31 (P<0.01). The reduction in free cholesterol seen in the 500 mg/kg group may be explained by two outliers with much lower concentrations than the remainder of that group.

Dose or concentration at which no toxic effects were observed:

NOEL = 100 mg/kg for reduction in mean white blood cell counts.

Comments:

24 rats (12 male and 12 female) were used in each dose group, which received 1-Dodecanol in the diet in concentrations of 0, 1500, 7500, and 30000 ppm (ca. 0, 100, 500 and 2000 mg/kg/bw/day) for a period of 37 days. 1-Dodecanol had no influence on body weight, weight gain, food consumption and food efficiency in either sex at the doses employed. All pathological and histopathological findings were considered incidental, and not related to the dosing. With the exception of the small effect on white blood cells and biological parameters mentioned above, no toxic effects were observed.

Reference:

Ernst Hansen, "Combined Repeat Dose and Reproductive/Developmental Toxicity Screening Test on 1-Dodecanol in Rats," Institute of Toxicology, Danish National Food Agency, IT 921105, July 30, 1992.

6.4.a. Repeated dose toxicity

Test substance: n-Lauryl alcohol, reagent grade.

Test species/strain: Chicken, male white Leghorn.

Test method:

Groups of 15-16 1-day-old chicks fed 8-13% dodecanol in standard laboratory diet for three weeks.

Test results:

Mortality during the experimental period was about 20%. 23/94 chicks exhibited signs of encephalomalacia. Five of the animals showing symptoms were examined histopathologically, and in all cases necrotic lesions of the brain typical of nutritional encephalomalacia were observed.

Comments:

The mean lethal dietary level of dodecanol for male Leghorn was determined as being 17.6%. There were no deaths, and no cases of encephalomalacia in 15 chicks receiving 10% dodecanol in the diet, supplemented with 200 mg/kg feed of dl- α -tocopheryl acetate.

Reference: (31.)

Yoshida, M., et. al., "Effects of Alcohols, Aldehydes and their Derivatives to Induce Nutritional Encephalomalacia in Starting Chicks," Agr. Biol. Chem., Vol. 35, No. 10, 1971, pp. 1610-1616.

* **6.5 Genetic toxicity**

6.5.1 Bacterial test

Test substance: 1-Dodecanol, 90% purity, Wako Pure Chemicals Ltd.

Test species/strain:

Salmonella typhimurium TA98, TA100, TA1535, TA1537, TA1538 and E. coli WP2uvrA.

Test method (e.g., OECD, others):

Modified Ames test. With and without metabolic activation with rat liver S9 mix.

GLP YES [?]

NO []

Test results:

Non-mutagenic in all test systems at doses ranging from 0.01-50 ug/plate.

Minimum concentration of test substance at which toxicity to bacteria was observed:

with metabolic activation:

without metabolic activation:

Toxic to strain TA1535 at dose of 10 ug/plate, and to TA100, TA1535, TA98, TA1537 and TA1538 at 50 ug/plate.

Concentration of the test compound resulting in precipitation:

Genotoxic effects:

	+	?	-
with metabolic activation:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
without metabolic activation:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Comments:

The fact that no tests were performed at doses of > 50ug/plate makes the predictive value of the results difficult to interpret.

Reference: (32.)

Shimizu, H., et. al., "The Results of Microbial Mutation Test for Forty-Three Industrial Chemicals," Jpn. J. Ind. Health, Vol 27, 1985, pp. 400-419.

6.5.2 Non-bacterial in vitro test

Test substance: Lauryl alcohol

Type of cell used: Vicia faba

Test method (e.g., OECD, others):

GLP: YES
NO

Test results:

"Lauryl alcohol was established to diminish the cell mitotic activity, after 14 hours' treatment causing different structural changes of chromosomes and of the mitotic apparatus. Following 48 hours' treatment some multipolar figures were observed."

Lowest Concentration producing cell toxicity:

with metabolic activation:

without metabolic activation:

Genotoxic effects:

	+	?	-
with metabolic activation:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
without metabolic activation:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:

(Only the brief English abstract concerning this experiment was consulted. The original article, in Russian, has not been translated.)

Reference: (33.)

Bobak, M., "Effect of Lauril Alcohol on the Mitosis of *Vicia Faba*," *Tsitologiya*, Vol. 9, iss. 2, 1967, pp. 229-231.

6.5.3 Non-bacterial test in vivo

Test substance: 1-Dodecanol (lorol C12-99, batch no. A 06502:91)

Test species/strain: Albino mice, CFW 1

Test method (e.g. OECD, others):

OECD no. 474

GLP yes no

Test results:

No statistically significant enhanced mean values of micronucleated cells in polychromatic erythrocytes were seen following oral doses of 5000 mg/kg. No reduction in the ratio of polychromatic to normochromatic erythrocytes was seen.

Lowest dose producing toxicity:

No toxicity was observed.

Effects on Mitotic Index or P/N Ratio:

No effect.

Genotoxic effects: + ? -
 [] [] [x]

Comments:

Six male and six female mice were used per group. Test substance administered once by oral gavage in arachis oil at a dosage of 5000 mg/kg. Six males and six females per group sacrificed at intervals of 24, 48 and 72 hours after administration. Bone marrow smears from both femurs of each animal prepared, and smears from first five animals of each group examined for micronuclei in 1000 polychromatic erythrocytes of each animal.

The negative control consisted of administration of arachis oil alone, and a positive control received 20 mg/kg Cyclophosphamide.

Reference:

Henkel KGaA, *Toxikologie, 1_dodecanol (Lorol C12-99), Micronucleus Test in vivo in Bone Marrow Cells of the Mouse, Report, May 1992, Dr. N. Banduhn, RT 920162.*

6.5.3.a Non-bacterial test in vivo

Test substance: n-Dodecanol

Test species/strain: Rat

Test method (e.g., OECD, others):

GLP: YES

NO

8 animals received 1/5 of LD₅₀ by stomach tube as 40% suspension in water.

Test results:

Increase in chromosomal aberrations to 3.6% of 500 cells examined, versus none in 600 cells from 10 control animals.

Lowest dose producing toxicity:

Effect on Mitotic Index or P/N Ratio:

Genotoxic effects: + ? -

Comments:

(Original article in Russian. Formal translation would be necessary to evaluate the significance of these results.)

Reference: (34.)

Barilyak, I., Tsitol. Genet., vol. 22, iss 2, 1988, pp. 49-52.

6.6 Carcinogenicity

Test substance: 1-Dodecanol, J.T. Baker, lot 1-3669.

Test species/strain: Mouse, A/He

Test method (e.g., OECD, others):

GLP: YES

NO

Male and female animals, 6-8 weeks old received i.p. injections of dodecanol in 0.1 ml tricapyrin 3 times weekly for eight weeks. Total amount administered 12.0 gm/kg to 30 animals in high dose group, and 2.4 gm/kg to 28 animals in low dose group. The animals were observed for an additional 16 weeks prior to sacrifice.

Test results:

Lung tumours were observed in 2/15 female mice in the high dose group, and in 2/15 males and 3/13 females in the low dose group. The lung tumour rate was not statistically significant relative to either untreated or vehicle controls. No tumours were found in other organs examined.

Comments:

Reference: (30.)

Stoner, G., et. al., "Test for Carcinogenicity of Food Additives and Chemotherapeutic Agents by Pulmonary Tumor Response in Strain A mice," *Cancer Research*, Vol. 33, 1973, pp. 3069-3085.

6.6.a. Carcinogenicity

Test substance: Lauryl alcohol, purified by distillation; bp. 99-100°C/2.5 mm, Eastman Organic Chemicals.

Test species/strain: Mouse, female ICR/Ha Swiss (ARS/Sprague-Dawley).

Test method (e.g. OECD, others):

GLP YES [?]

NO []

50 mice aged 6-8 weeks treated 3 times weekly by skin application with 10 mg Dodecanol in acetone, 0.1 ml for 440 days. Another group of 50 animals received the same dose of dodecanol, but were also exposed to B[a]P, 5 ug/0.1 ml in acetone 3 times weekly. During the experimental period animals bearing tumours appearing grossly to be carcinomas were killed 2 months after the tumor was classified as malignant, or when animals were moribund. All animals were autopsied.

Test results:

No tumours were observed in the 50 mice receiving dodecanol. Of the animals receiving dodecanol and B[a]P, 27 papillomas occurred in a total of 21 animals, 13 mice with squamous cell carcinoma. In a control group also consisting of 50 mice and being treated with B[a]P (5 ug) alone, 26 papillomas were observed in 16 animals, 12 of these tumours being squamous cell carcinoma. The authors conclude that these results suggest a weak to moderate cocarcinogenic effect.

Comments:

It is difficult to interpret the results of this test regarding cocarcinogenicity: while 21/50 animals in the dodecanol-B[a]P exhibited tumours versus 16/50 in the B[a]P group, the total number of tumours was almost the same in each experimental group (27/50 dodecanol-B[a]P, 26/50 B[a]P alone), and there was also little difference in the number of carcinomas (13/50 in the dodecanol-B[a]P group, v. 12/50 for B[a]P alone. Additionally, the number of days to first papilloma in the Dodecanol-B[a]P group was somewhat longer (226 days) than in the group receiving B[a]P alone (210 days).

Reference (45.)

Van Duuren, B., et. al., "Cocarcinogenic and Tumor-Promoting Agents in Tobacco Carcinogenesis," *Journal of the National Cancer Institute*, Vol. 56, 1976, pp. 1237-1242.

6.6.b. Carcinogenicity

Test substance: Dodecanol, 97%, purified by repeated freezing and distillation under nitrogen at reduced pressure.

Test species/strain: Mouse, female Swiss.

Test method:

GLP YES [?]
NO []

30 animals initiated by skin treatment with 7,12-Dimethylbenz[a]anthracene, thereafter treated with 20 ul of dodecanol in cyclohexane 3 x weekly for 60 weeks. (ca. 0.4 mg dodecanol per application).

Test results:

2 of the 20 surviving mice developed local papillomas (at weeks 39 and 49). No papillomas were seen in 34 of 50 surviving non-initiated mice treated with the same dose of dodecanol. The authors state the initiation dose alone is non-carcinogenic.

Comments:

Reference: (28.)

Sice, J., "Tumor-Promoting Activity of n-Alkanes and 1-Alkanols," *Toxicology and Applied Pharmacology*, Vol. 9, 1966, pp. 70-73.

6.6.c. Carcinogenicity

Test substance: 1-Dodecanol (PAH-free by UV spectra)

Test species/strain: Mice, C3H/He

Test method (e.g. OECD, others):

GLP YES [?]
NO []

Groups of 20 animals each were exposed by skin application to 50 mg of a solution of 0.05%, or 0.2% Benzo[a]pyrene in decalin twice weekly, which had been adulterated with 0, 10, 20, 30, 40, 50, 75 or 100% dodecanol.

Test results:

Malignant tumours occurred in 65-100% of all 16 groups. In the animals exposed to 0.05% B[a]P, the tumor latency period decreased steadily from 63 weeks for mice receiving no dodecanol, to 26 weeks for mice exposed to the solution containing 100% dodecanol. In the groups exposed to 0.2% B[a]P, average latency decreased from 42 weeks in the group receiving no dodecanol, to 22 weeks in the 100% dodecanol group. There were no skin tumours seen in 50 control animals receiving 50% dodecanol in decalin alone.

Comments:

Reference: (35.)

Bingham, E., "Environmental Carcinogens: The Modifying Effect of Cocarcinogens on the Threshold Response," *Arch. Environ. Health*, Vol. 19, 1969, pp. 779-783.

6.6.d. Carcinogenicity

Test substance: Lauryl alcohol, from Tokyo Kasei, Ltd.

Test species/strain: Mouse, Swiss albino ddY.

Test method (e.g. OECD, others)

GLP YES

NO

Groups of four or six 5-week old animals were implanted i.p. with Ehrlich ascites tumor cells (1×10^6 cells per mouse). After 24 hours the mice were exposed i.p. to doses of 2, 2.5, 4, 8 or 10 mg/mouse/day of dodecanol once daily for 5 consecutive days.

Test results:

Survival time was increased to > 30 days in the 2.5 mg/mouse group and to > 26 days in the 8 mg/mouse group, relative to 18.3 days for 20 controls not treated with dodecanol. Survival time was decreased in the mice receiving 10 mg/mouse (to 5 days) and in those receiving 2 mg/mouse (13 days).

Comments:

The small number of animals used make these conflicting results difficult to interpret.

Reference: (36.)

Ando, K., et. al, "Antitumor Activity of Glyceryl Ethers," *Cancer Research*, Vol. 32, 1972, pp. 125-129.

6.7 Reproductive and Developmental toxicity

6.7.1 Reproductive toxicity

Test substance: 1-Dodecanol (Sigma L 5375, 99% purity)

Test species/strain: Rats (Mol/WIST) SPF, aged 8 weeks.

Test method (e.g., OECD, others):

OECD Combined repeat dose and reproductive/developmental toxicity screening test.

GLP: YES

NO

Test results:

No effect was seen of reproductive or developmental parameters up to and including the maximum dose of 2000 mg/kg/by.

NOEL for P generation

NOEL for F1 generation

NOEL for F2 generation

Maternal and Paternal general toxicity:

1-Dodecanol in the doses administered had no influence on body weight, weight gain, food consumption and food efficiency in males or females. No general toxicity was noted.

Reproductive toxicity observed in parental animals (fertility, gestation, reproductive organ toxicity, etc.):

Pregnancy rates were slightly reduced (92% in controls v. 75% in the high dose group) but this was not statistically significant. There were no differences in the lengths of the gestation periods. There was no indication for effects on results from the observations of corporae luteae, implantations, resorptions and the number of fetuses at birth. No organ toxicity was observed.

Reproductive toxicity observed in offspring (weights of litter, postnatal growth, viability, etc.):

There were no effects on the number of pups per litter, weight, sex distribution or mortality rate from days 1-5. Macroscopic findings at autopsy indicated no effect from 1-Dodecanol under the conditions of this experiment.

Comments:

Groups of 24 animals each (12 males 12 females) were exposed to 1-Dodecanol in the feed at concentrations of 0, 1500, 7500 and 30000 ppm, corresponding to ca. 0, 100, 500 and 2000 mg/kg/by/day. After 14 days of dosing, females were placed together with the males. Females in which no mating was recorded were kept together with the same male for a 14 day period. If no plug and no indication of pregnancy was found after a 14-day period, the female rat was placed together with another male for an 8-day period.

Pups were autopsied and macroscopically examined on day 5. Haematology and clinical biochemistry were performed on the males. Both males and females were examined macroscopically. Histology was performed on selected organs of the control and highest dose group.

Reference:

Ernst Hansen, "Combined Repeat Dose and Reproductive/Developmental Toxicity Screening Test on 1-Dodecanol in Rats," Institute of Toxicology, Danish National Food Agency, July 30, 1992, IT 921105.

6.7.2 Teratogenicity/Developmental toxicity

(No information was found on Teratogenicity/Developmental tox.)

Test substance:

Test species/strain:

Test method (e.g., OECD, others):

GLP: YES []
NO []

Test results:

NOEL for maternal animals

NOEL for offspring

Maternal general toxicity

Pregnancy and litter data

Foetal data (live/dead, sex, external defects, soft tissue and skeletal defects)

Comments:

Reference:

6.8 Specific toxicities (Neurotoxicity, immunotoxicity etc.)

(See 6.4, encephalomalacia in Leghorn chickens.)

6.9 Toxicodynamics, toxico-kinetics

[1-¹⁴C] lauryl alcohol from New England Nuclear Corp. purified by silica gel chromatography. 1.38 umole in 25 ul EtOH applied to 2.9 cm² of the dorsal skin of 10 week old female hairless mouse using a silicon resin enclosure. The mouse was immediately placed in a chamber to measure expiratory excretion. After 4 hours the experiment was terminated and the animal sacrificed.

A total of 46.1% plus-minus 0.9% of the dodecanol was absorbed: 17.7% ± 1.9% was found intravitaly, 1.2% ± 0.2% was recovered in faecal and urinary excreta. 27.2% ± 1.0% was excreted via respiration. 52.9% ± 2% retained on excised skin (total recovery 98.5% ± 1.5%).

Of the percutaneously absorbed dodecanol, 60% was excreted in the expired air, presumably after metabolism, while only 2.6% was excreted in faeces and urine.

Reference: (37.)

Nishiyama, T., et. al., "In Vivo Percutaneous Absorption of Polyoxyethylene Lauryl Ether Surfactants in Hairless Mice," J. Soc. Cosmet. Chem., Vol. 34, 1983, pp. 263-271.

An additional source reports somewhat conflicting results with a 100 ul dose of 0.5% dodecanol in triethyl citrate in occluded contact with the skin of mice for 24 hours. 95% of the dose was reported to remain in the skin layer, with only 0.1% recovered in faeces and urine, 0.13% recovered from the body and 2.61% excreted in the air.

Reference: (44.)

Walker, A., "1-Dodecanol," unpublished manuscript, March 1990 - referring to: Iwata, Y., et. al., Cosmet. Toilet, Vol 102, 1987, p. 53 - (The journal article is not available at this time.)

7. Experience with Human Exposure (give full description of study design, effects of Accidental or Occupational Exposure, epidemiology)

Patch testing on a group of 1,664 eczema patients yielded 4 cases with positive reactions to 5% lauryl alcohol in vaseline, 15 reactions to 10% in vaseline.

Reference: (39.)

Hjorth, N., "Skin Reactions to Ointment Bases," *Trans. a. Rep. St. John's Hosp. Derm. Soc.*, Vol. 49, 1963, pp. 127-140.

Of 51 patients allergic to wool wax alcohols, 22 reacted to 30% Lauryl alcohol in vaseline. Combined scores at 24, 48 and 72 hours showed nine persons with reactions graded as 2+ or 3+(erythema, papules or infiltration; erythema, infiltration and papulovesicles).

Reference: (40.)

Auth, R., et. al., "Ein Beitrag zur Wollwachsalkohol-Allergie," *Akt. Dermatol*, Vol 10, 1984, pp. 215-220.

A maximization test carried out on 25 human volunteers using 4% 1-dodecanol in petrolatum produced no cases of sensitization.

Reference: (8.)

Opdyke, D., "Alcohol C-12," *Fd. Cosmet Toxicol.*, Vol. 11, 1973, p. 109. (reference to 1972 unpublished study by RIFM.)

When tested by chamber-scarification test in human volunteers, 25% dodecyl alcohol in mineral oil produced marked irritation.

Reference: (41.)

Drill, V., et. al., ed., "The chamber-Scarification test for Assessing Irritancy of Topically Applied Substances," *Cutaneous Toxicity*, Academic Press Inc., New York, 1977, pp. 127-154.

7.1 Biological Monitoring (including clinical studies, case reports, etc.)

Found in saliva of male and female human volunteers as determined by GC-MS analysis (concentration not determined).

Reference: (42.)

Kostelc, J., et. al., "Volatiles of Exogenous Origin from the Human Oral Cavity," *Journal of Chromatography*, Vol. 226, 1981, pp. 315-323.

8. Recommended Precautions, Classification (use and/or transportation) and Safety Data Sheets.

Not classified as a dangerous or harmful substance in the European Communities.

Transport: IATA, Flammable liquid, 1 liter (passenger), 40 liters (cargo). U.S. ICC; Flammable liquid, 10 gallons. U.S. CGC; Flammable liquid (ref. 5. HSDB, 1990, Cas. No. 112-53-8).

Recommended precautions: Handling and storage - Chemical safety goggles. Rubber gloves. Mechanical exhaust required. Safety shower and eye bath. Do not breath vapour. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Irritant. Keep tightly closed. Store in a cool dry place. May be harmful by inhalation, ingestion or skin absorbtion. Vapour or mist is irritating to eyes, mucus membranes and upper respiratory tract. Causes skin irritation. (Ref. 43., Lenga, R., "1-Dodecanol," *The Sigma-Aldrich Library of Chemical Safety Data*, 2nd. Ed., Vol 1., 1988, p. 1490.)

9. Availability and reference(s) for existing review(s)

No comprehensive reviews were found in the published literature.

10. Name of responder

Jay Niemelä
Ministry of the Environment
National Agency of Environmental Protection
Strandgade 29
DK-1401 Copenhagen K
Denmark

EXTRACT FROM IRPTC LEGAL FILE

File: 17.01 LEGAL

rn : 303211

systematic name:1-Dodecanol
 common name :lauryl alcohol
 reported name :LAURYL ALCOHOL
 cas no :112-53-8
 area : CAN
 rtecs no :JR5775000
 type : REG

subject	specification	descriptor
USE	OCC	RQR
STORE		
LABEL		

Ingredient Disclosure List - Concentration: 1% weight/weight. The Workplace Hazardous Materials Information System (WHMIS) is a national system providing information on hazardous materials used in the workplace. WHMIS is implemented by the Hazardous Products Act and the Controlled Products Regulations (administered by the Department of Consumer and Corporate Affairs). The regulations impose standards on employers for the use, storage and handling of controlled products. The regulations also address labelling and identification, employee instruction and training, as well as the upkeep of a Materials Safety Data Sheet(MSDS). The presence in a controlled product of an ingredient in a concentration equal to or greater than specified in the Ingredient Disclosure List must be disclosed in the Safety Data Sheet.
 entry date: APR 1991 effective date: 31DEC1987

amendment: CAGAAK, CANADA GAZETTE PART II, 122 , 2 , 551 , 1988

File: 17.01 LEGAL

rn : 401224

systematic name:1-Dodecanol
 common name :lauryl alcohol
 reported name :LAURYL ALCOHOL
 cas no :112-53-8
 area : CZE
 rtecs no :JR5775000
 type : REG

subject	specification	descriptor
FOOD		PRMT
GOODS		MXL

COMPONENT OF PLASTIC PRODUCTS PERMITTED FOR CONTACT WITH FOOD. MAXIMUM LIMIT FOR THE PLASTIC MATERIALS: 20MG/G.
 entry date: DEC 1991 effective date: 1JUL1978

title: DIRECTIVE NO.49 ON HYGIENIC REQUIREMENTS ON PLASTICS AND PLASTIC GOODS COMING IN CONTACT WITH FOODSTUFFS
 original : HPMZC*, HYGIENICKE PREDPISY MINISTERSTVA ZDRAVOTNICTVI CSR(HYGIENIC REGULATIONS OF MINISTRY OF HEALTH OF CSR), 42 , , 1978

File: 17.01 LEGAL

rn : 402136

systematic name:1-Dodecanol
 common name :lauryl alcohol
 reported name :dodecanol
 cas no :112-53-8
 area : CZE
 rtecs no :JR5775000
 type : REG

subject	specification	descriptor
USE	PESTI	PRMT

SUBSTANCE IS APPROVED AS PESTICIDE. SPECIFIC USES, LIMITATIONS AND SAFETY PRECAUTIONS ARE GIVEN. (APPLIES TO MIXTURE OF ALCOHOLS C6-C12).
 entry date: JUL 1994 effective date: JAN1994

title: LIST OF PERMITTED CHEMICALS FOR PLANT PROTECTION
 original : SPPOR*, SEZNAM POVOLENYCH PRIPRAVKU NA OCHRANU ROSTLIN(LIST OF PERMITTED CHEMICALS FOR PLANT PROTECTION), , , 271 , 1993

File: 17.01 LEGAL

rn : 502344

systematic name:1-Dodecanol
 common name :lauryl alcohol
 reported name :1-DODECANOL
 cas no :112-53-8 rtecs no :JR5775000
 area : DEU type : REC

subject	specification	descriptor
AQ		CLASS
USE	INDST	RQR

SATURATED FATTY ALCOHOLS WITH AN EVEN-NUMBERED C CHAIN, C NUMBER >= 12, AND A TERMINAL OH GROUP ARE CLASSIFIED AS IN GENERAL NOT HAZARDOUS TO WATER (WATER-HAZARD CLASS: WGK 0). (THE DIFFERENT CLASSES ARE: WGK 3 = VERY HAZARDOUS; WGK 2 = HAZARDOUS; WGK 1 = SLIGHTLY HAZARDOUS; WGK 0 = IN GENERAL NOT HAZARDOUS.) THE CLASSIFICATION FORMS THE BASIS FOR WATER-PROTECTION REQUIREMENTS FOR INDUSTRIAL PLANTS IN WHICH WATER-HAZARDOUS SUBSTANCES ARE HANDLED.
 entry date: JAN 1995

title: Administrative Rules concerning Substances Hazardous to Water (Verwaltungsvorschrift wassergefaehrdende Stoffe)
 original : GMSMA6, Gemeinsames Ministerialblatt, , 8 , 114 , 1990

File: 17.01 LEGAL

rn : 606543

systematic name:1-Dodecanol
 common name :lauryl alcohol
 reported name :dodecyl alcohol
 cas no :112-53-8 rtecs no :JR5775000
 area : GBR type : REG

subject	specification	descriptor
TRNSP	MARIN	RQR
AQ	MARIN	RSTR
AQ	EMI	RSTR

CATEGORY B SUBSTANCE: DISCHARGE INTO THE SEA IS PROHIBITED;DISCHARGE OF TANK WASHINGS AND RESIDUAL MIXTURES IS SUBJECT TO RESTRICTIONS.
 entry date: 1992 effective date: 06APR1987

title: THE MERCHANT SHIPPING (CONTROL OF POLLUTION BY NOXIOUS LIQUID SUBSTANCES IN BULK) REGULATIONS 1987, SCHEDULE 1
 original : GBR SI*, STATUTORY INSTRUMENTS, 551 , , 15 , 1987
 amendment: GBR SI*, STATUTORY INSTRUMENTS, 2604 , , 2 , 1990

File: 17.01 LEGAL

rn : 1142598

systematic name:1-Dodecanol
 common name :lauryl alcohol
 reported name :Dodecyl alcohol
 cas no :112-53-8 rtecs no :JR5775000
 area : RUS type : REG

subject	specification	descriptor
AIR	OCC	MAC CLASS

CLV: 10MG/M3 (VAPOUR, AEROSOL) HAZ. CLASS: III
 entry date: MAY 1990 effective date: 1JAN1989

amendment: GOSTS*, GOSUDARSTVENNYI STANDART SSSR(STATE STANDARD OF
 USSR), 12.1.005 , , , 1988

File: 17.01 LEGAL

rn : 1302357

systematic name:1-Dodecanol
 common name :lauryl alcohol
 reported name :LAURYL ALCOHOL
 cas no :112-53-8 rtecs no :JR5775000
 area : USA type : REG

subject	specification	descriptor
FOOD	ADDIT	RSTR
TRANS		RSTR
STORE		RSTR
PACK		RSTR

; Summary - THIS SUBSTANCE IS INCLUDED ON A LIST OF SUBSTANCES USED TO
 PREPARE ADHESIVES WHICH MAY BE SAFELY USED AS COMPONENTS OF ARTICLES
 INTENDED FOR USE IN PACKAGING, TRANSPORTATION, OR HOLDING FOOD IN
 ACCORDANCE WITH THE FOLLOWING PRESCRIBED CONDITIONS: SUBSTA NCE MUST BE
 SEPARATED FROM THE FOOD BY A FUNCTIONAL BARRIER, MUST NOT EXCEED LIMITS
 OF GOOD MANUFACTURING PRACTICE USED WITH DRY FOODS, OR NOT EXCEED TRACE
 AMOUNTS AT SEAMS AND EDGE EXPOSURES WHEN USED WITH FATTY AND AQUEOUS
 FOODS. ALSO REGULATED BY SEA M INTEGRITY, LABELING STANDARDS, AND ANY
 PROVISION UNDER 21 CFR 175
 entry date: NOV 1991 effective date: 1977

title: SUBSTANCES FOR USE ONLY AS COMPONENTS OF ADHESIVES
 original : FEREAC, FEDERAL REGISTER, 42 , , 14534 , 1977
 amendment: CFRUS*, CODE OF FEDERAL REGULATIONS, 21 , 175 , 105 , 1988

File: 17.01 LEGAL

rn : 1323012

systematic name:1-Dodecanol
 common name :lauryl alcohol
 reported name :1-DODECANOL
 cas no :112-53-8 rtecs no :JR5775000
 area : USA type : REG

subject	specification	descriptor
CLASS	PESTI	RQR
MANUF	PESTI	PRMT
FOOD	ADDIT	RQR

CASE NAME ALIPHATIC ALCOHOLS, C6-C16; Summary - THIS SUBSTANCE IS INCLUDED ON A LIST OF ACTIVE INGREDIENTS CONTAINED IN A PRODUCT FIRST REGISTERED BEFORE NOVEMBER 1, 1984, FOR WHICH A REGISTRATION STANDARD HAS NOT BEEN ISSUED. PUBLICATION OF THIS LIST INITIATES AN ACCELERATED REREGISTRATION AND DATA C ALL-IN FOR PRODUCTS CONTAINING THE LISTED ACTIVE INGREDIENTS.
 entry date: JAN 1992 effective date: 1989

title: FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT PESTICIDES REQUIRED TO BE REREGISTERED; LIST D
 original : FEREAC, FEDERAL REGISTER, 54 , 204 , 43388 , 1989
 amendment: FEREAC, FEDERAL REGISTER, 54 , 204 , 43388 , 1989

File: 17.01 LEGAL

rn : 1346076

systematic name:1-Dodecanol
 common name :lauryl alcohol
 reported name :LAURYL ALCOHOL
 cas no :112-53-8 rtecs no :JR5775000
 area : USA type : REG

subject	specification	descriptor
FOOD	ADDIT	RSTR
PACK	ADDIT	RSTR
MANUF	ADDIT	GL
USE		RSTR

Summary - THIS SUBSTANCE INCLUDED ON A LIST OF SUBSTANCES USED TO PREPARE BASE SHEET OR COATING SUBSTANCES FOR CELLOPHANE MUST BE OF A GRADE OF PURITY SUITABLE FOR USE IN FOOD PACKAGING TO IMPART THE DESIRED TECHNOLOGICAL PROPERTIES.ACRYLONITRILE COPOLYMER SUBST ANCES MUST ABIDE UNDER THE CONDITIONS GIVEN IN 21 CFR 180.22 1988.
 entry date: NOV 1991 effective date: 1977

title: INDIRECT FOOD ADDITIVES; POLYMERS-CELLOPHANE.
 original : FEREAC, FEDERAL REGISTER, 42 , , 14572 , 1977
 amendment: CFRUS*, CODE OF FEDERAL REGULATIONS, 21 , 177 , 1200 , 1988

File: 17.01 LEGAL

rn : 1408334

systematic name:1-Dodecanol
 common name :lauryl alcohol
 reported name :1-DODECANOL
 cas no :112-53-8 rtecs no :JR5775000
 area : EEC type : REG

subject	specification	descriptor
FOOD		RQR
GOODS		MXL
GOODS		PRMT

THE SUBSTANCE IS INCLUDED IN THE LIST OF AUTHORIZED MONOMERS AND OTHER STARTING SUBSTANCES, WHICH SHALL BE USED FOR THE MANUFACTURE OF PLASTICS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS. THE USE OF THE SUBSTANCE IS SUBJECT TO THE RESTRICTIONS SPECIFIED THEREIN. PLASTIC MATERIALS AND ARTICLES SHALL NOT TRANSFER THEIR CONSTITUENTS TO FOODSTUFFS IN QUANTITIES EXCEEDING 10MG/DM2 OF SURFACE AREA OF MATERIAL OR ARTICLE OR 60 MG/KG OF FOODSTUFFS IN THE SPECIFIED CASES. VERIFICATION OF COMPLIANCE WITH THE MIGRATION LIMITS SHALL BE CARRIED OUT IN ACCORDANCE WITH DIRECTIVES 82/711/EEC AND 85/572/EEC. (IT APPLIES TO ALIPHATIC SATURATED LINEAR PRIMARY ALCOHOLS WITH 4-22 C-ATOMS).
 entry date: SEP 1995 effective date: 01JAN1991

title: COMMISSION DIRECTIVE OF 23 FEBRUARY 1990 RELATING TO PLASTICS MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS (90/128/EEC)
 original : OJEC**, OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES, L75 , , 19 , 1990
 amendment: OJEC**, OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES, L90 , , 26 , 1993

File: 17.01 LEGAL

rn : 1604062

systematic name: 1-Dodecanol
 common name : lauryl alcohol
 reported name : dodecyl alcohol
 cas no : 112-53-8 rtecs no : JR5775000
 area : IMO type : REG

subject	specification	descriptor
TRNSP	MARIN	RQR
AQ	EMI	RQR

Category B substance (substance which is bioaccumulated with a short retention of the order of one week or less, or which is liable to produce a tainting of sea food, or which is moderately toxic to aquatic life): discharge into the sea of this substance, of ballast water, tank washings or other residues or mixtures containing such a substance shall be prohibited except where specified conditions are satisfied. Technological requirements prescribe equipments and designs that must be present on the tankers as well as port facilities for receiving residues or mixtures containing the regulated substance. Technical assistance for training of scientific and technical personnel shall be promoted where requested by the Parties to the Convention.
 entry date: SEP 1994

title: International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto (MARPOL 73/78)
 original : IMODC*, , , , , 1992