FOREWORD

**INTRODUCTION** 

**<u>1-OCTADECANOL</u>** CAS N°: 112-92-5

#### Substance

End Point	:	<b>IDENTIFIERS, PHYSICAL AND CHEMICAL PROPERTIES</b>
Chemical Name	:	1-Octadecanol
Common Name	:	Stearyl alcohol
CAS Number	:	112-92-5
RTECS Number	:	RG2010000

#### Synonyms

Aldol 62	Alfol 18
Atalco S	Cachalot S 43
CO 1895F	Conol 1675
Conol 30F	Crodacol S
1-Hydroxyoctadecane	Kalcohl 80
Lanol S	Lorol 28
Octadecanol	n-Octadecanol
Octadecyl alcohol	Sipol S
Siponol S	Siponol SC
Stearol	Steraffine

#### **Properties & Definitions**

Molecular Formula	:	C18H38O
Molecular Weight	:	270.50
Melting Point	:	59.8C
Boiling Point	:	336C
Flash Point	:	170C
Density	:	0.8124 at 59C
Vapour Pressure	:	0.133kPa (1mmHg) at 150.3C
Octanol/Water Partition Coefficient	:	log Pow = 8.22 (calculated)
Water Solubility	:	1.1E-3mg/l at 34C
Solubility in other Solvents	:	Soluble in alcohol, acetone, ether, benzene, chloroform
Impurities	:	Up to 10% of impurities. Variable amounts of n-hexadecanol, n-tetradecanol, n-eicosanol and n-dodecanol. Maximum 2% stearyl stearate, 1% octadecane, 0.5% stearic acid and total hydrocarbons at about 1.8%.
General Comments	:	MP of commercial product = $56-60C$ and calculated VP= $1.93E-6mmHg$ are also reported. Presents a moderate fire hazard when exposed to heat or flame. Autoignition temperature = $450C$ . Adsorption coef. (Log Koc = $5.81$ calculated)

#### **Overall Evaluation**

SIDS INITIAL ASSESSMENT

There is need for further work.

#### SHORT SUMMARY OF THE REASONS WHICH SUPPORT THE RECOMMENDATION

The substance is firmly bound to sediments, and therefore anaerobic biodegradation can be an important factor. A 21-day test in daphnids indicated that the substance may be toxic at a range of between 1 and 3mg/l.

#### FURTHER WORK RECOMMENDED:

Determination of anaerobic biodegradability. Depending on the results of this test, it may be considered whether or not long-term fish toxicity testing is required.

### Production-Trade

Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Geographic Area	:	USA
General Comments	:	In the United States production of detergent range alcohols including octadecanol was 354000 tonnes in 1987.

#### References

#### **!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 7, (1993)

### Production-Trade

Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Geographic Area	:	DNK
General Comments	:	According to Danish trade statistics, national use and manufacture of lauryl, stearyl and cetyl alcohols was in the range of 1000 to 10000 tonnes in 1986.

#### References

#### **!SIDSP\***

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 6, (1993)

Uses			
Chemical Name CAS Number	: :	1-Octadecanol 112-92-5	
Geographic Area	:	USA	
Use			
<u>Quantity</u>		<u>Year</u>	<u>Comments</u>
		1981	Reported as being used in 425 cosmetic formulations at the above range of 0.5 to 50%.
References			
Primary References	:	<b>JACTDZ</b> ANON. Journal of the (1985)	American College of Toxicology, Part A, 4(5), 1-29,
Secondary References	:	<b>!SIDSP*</b> OECD/SIDS. Screenin Production Volume Cl	ng Information Data Set (SIDS) of OECD High hemicals Programme, 7, (1993)
Uses			
Chemical Name CAS Number	: :	1-Octadecanol 112-92-5	
Geographic Area	:	DNK	
Use			
<u>Quantity</u>		<u>Year</u>	<u>Comments</u>
		1992	Registered in 47 non-cosmetic products on the Danish market.
References			
Secondary References	:	! <b>SIDSP*</b> OECD/SIDS. Screenin Production Volume Cl	ng Information Data Set (SIDS) of OECD High hemicals Programme, 6, (1993)
Uses			
Chemical Name	:	1-Octadecanol	
CAS Number	:	112-92-5	
Geographic Area	:	USA 1981	Unspecified amount used in pharmaceutical dispensing, cosmetic creams, emulsions, textile oils and finishes, antifoam agent and as a chemical raw material.

# References : 12VXA5 Merck Index: An Encyclopedia of Chemicals, Drugs and Biologicals, 10, 1259, (1983) Secondary References : ISIDSP\* OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 7, (1993)

End Point Chemical Name CAS Number	: : :	Pathway into the Environment and Environmental Fate. 1-Octadecanol 112-92-5
Pathway and Trans	por	t
Pathway Pathway description	: :	<b>NATUR</b> Persumably of natural origin, has been isolated from plants and insects, from human sebaceous lipids, and has been found in mammalian glands and organs.
References		
Primary Reference	:	<b>JACTDZ</b> ANON. Journal of the American College of Toxicology, Part A, 4(5), 1-29, (1985)
Secondary Reference	:	<b>!SIDSP*</b> Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 10, (1993)
Study		
End Point	:	Pathway into the Environment and Environmental Fate.

Ena Point		Pathway into the Environment and Environmental Fat
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5

#### Test Method and Conditions

Оц	Test method description Temperature antity Transpo	: : rted	Mackay level 1 I 25 C	Environmental Partitionir	ng Model		
20	Medium	to Med	ium	Quantitv	Time	Year	to Year
	AIR Into air according to M	ackay lev	rel 1 model (ML1E	<b>0.45 %</b> EP)		<u></u>	
	SOIL Into soil (according to ML1EP)			51.43 %			
	AQ Into water (according t	o ML1EP	)	0.00 %			
	AQ Into suspended solids	(accordin	g to ML1EP)	0.08 %			
	<b>AQ</b> Aquatic biota (accordir	ng to ML1	EP)	0.03 %			
	SED Sediment (according to General Comments	o ML1EP) <i>:</i>	Above values ar exclusively onto	<b>48.00 %</b> re all calculated. Environ soils and sediments.	mental partitionin	g will be a	almost

### References

Secondary Reference

#### : !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

End Point	:	CONCENTRATION
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Geographic Area	:	ESP

#### Test Subject

Organism Medium Specification Lifestage Sex

#### AQ FRESH

Species/strain/system : River water entering water works near Barcelona, Spain.

#### Test Method and Conditions

Test method	:	FAB mass spectrometry
description		

#### **Test Results**

<u>Matrix</u>	Concentrations	<u>Spec.</u>	<u>Date</u>	

1-Octadecanol has been identified but the concentration was not determined.

#### References

Primary Reference	:	WRERAQ Ventura, F. et al. Water Resources Research, 23(9), 1191, (1989)
Secondary Reference	:	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 10, (1993)

### Study

End Point	:	CONCENTRATION
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5

:

#### **Test Results**

General Comments

Environmental partitioning will be almost exclusively onto soils and sediments. Stearyl alcohol (presumably of natural origin) has been isolated from plants and insects, from human sebaceous lipids and has been found in mammalian glands and organs. (ref. Journal of the American College of Toxicology. vol.4, no.5, 1985. pp.1-29)

#### References

Secondary Reference :	<b>ISIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 10, (1993)
Study	
End Point : Chemical Name : CAS Number : Geographic Area :	CONCENTRATION 1-Octadecanol 112-92-5 USA
Test Subject	
<u>Organism Medium</u> <u>Specificati</u>	on Lifestage Sex
AQ INDST	
Species/strain/system :	Industrial effluent discharged into the Illinois river.
Test Results	
Matrix Concentrations	<u>Spec.</u> <u>Date</u>
1-Octadecanol has been identified l	but the concentration was not determined.
References	
Primary Reference :	<b>JTEHD6</b> Somani, S. et al. Journal of Toxicology and Environmental Health, 6, 315-331, (1980)
Secondary Reference :	ISIDSP* Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 10, (1993)
Study	
End Point : Chemical Name : CAS Number :	CONCENTRATION 1-Octadecanol 112-92-5

### Test Subject

Geographic Area

Organism Medium Specification Lifestage Sex

:

USA

#### AIR

Species/strain/system :

Indoor aerosol samples from large building in U.S.A. Particle sizes from 1.1 to 2um.

### Test Method and Conditions

Test method : GC-MS description

#### Test Results

Matrix Concentrations

<u>Spec.</u> <u>Date</u>

1-Octadecanol has been identified but the concentration was not determined.

#### References

Primary Reference	:	<b>ESTHAG</b> Weschler, C. Environmental Science and Technology, 14(4), 428-431, (1980)
Secondary Reference	:	<b>!SIDSP*</b> Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 10, (1993)

End Point	:	HUMAN INTAKE AND EXPOSURE
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5

#### Test Subject

<u>Organism</u>	<u>Medium</u>	Specification Route	<u>Lifestage</u>	<u>Sex</u>
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#### HUMAN

#### **Test Results**

<u>Intake</u>

Spec. Date

# 1-5 mg/d

Expected daily exposure through use of consumer products (cosmetics)

#### 0.015-0.075 mg/kg

BW

Expected daily exposure for a person weighing 70kg.

#### <1 mg/d

Ingested per day as 1-octadecanol as an ingredient in lipsticks

#### 3782 mg/y

An annual dermal potential dose with 5% content in a bar of soap used daily (according to the U.S. EPA dermal model, worst case scenario).

*General Comments* : There are many sources of potential consumer exposure. The most intense probably being through the use of creams and cosmetics. Inhalation is unlikely to be a significant exposure route. (See evaluation of the health aspects of stearyl alcohol as a food ingredient, FDA 223-78-2100, 1980).

#### References

Secondary Reference :

#### !SIDSP\*

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

End Point	:	BIODEGRADATION
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB

### Exposure

	Exposure Period	:	2-16 d
Tes	st Results		
	<u>Quantity</u>	<u>Time</u>	Comments on result
			BOD: T/2 ranges from 2 to 16 days. (Painter 1974)
	100 mg/l		COD
	67 %	28 d	BOD/COD
	General Comments	:	The manufacture considers this as evidence of "ready" biodegradability. However, this test requires continuous shaking, and, as only 67% of the substance had been degraded at the conclusion of the test, the result may better be thought of as an indication of "inherent" biodegradability. Possibly the very low solubility of the test substance (0.0011g/l at 34C) limits bioavailability and thus ready degradation. The test result can perhaps best be interpreted as being near the bordeline between ready and inherent biodegradation.
Re	ferences		
	Secondary Reference	ce :	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

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:	HYDROLYSIS
:	1-Octadecanol
:	112-92-5
:	LAB
:	AQ
:	FRESH
	:

### Test Results

<u>Quantity</u>	<u>Time</u>	Comments on result
50 %		Hydrolysis T/2 estimated at 1000 days (practically inert).

### References

Primary Reference	:	HKBAD* Henkel. Bestimmung der Akuten Daphientoxizitat von Octadecanol im Daphnietest nach DIN 38412 (Test of Octadecanol on Acute Toxicity to Daphnia according to DIN 38412), 01(2), (1988)
Secondary Reference	:	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 4, (1993)

End Point Chemical Name CAS Number	:	SORPTION 1-Octadecanol 112-92-5
Test Results		
General Comments	:	The water solubility of this substance is too low to allow a reliable estimate of partitioning. Can be expected to bind strongly to soils, sediments and particles.
References		
Primary Reference	:	XQSAR* Veith, G. et al. EPA QSR System, Environmental Research Lab (ERL), (1985)
Secondary Reference	:	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 9, (1993)

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End Point	:	ABSORPTION
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB

## Test Subject

	<u>Organism</u> <u>Medium</u>	Specification	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Number exposed	Number controls
	BIRD		ORL	ADULT			
	Species/strain/system	n :	White Legl	horn chicken	S		
Exp	oosure						
	Exposure Type Dose / Concentration Exposure comments	: : :	SHORT 10 % DIE Feeding st digestibility	E <b>T</b> udies with 1- ∕	octad	ecanol at 10% in the	diet, to determine
Tes	t Results						
	Quantity Absorbed	<u>Time</u>	<u>Comment</u>	<u>ts on result</u>			
			Digestibilit	y was detern	nined	as 0%	
Ref	ferences						
	Primary Reference	:	<b>JAFCAU</b> ANON. Joi (1971)	urnal of Agric	cultura	I and Food Chemistr	y, 35(10), 1610-16,
	Secondary Reference	9 :	<b>!SIDSP*</b> OECD/SID Production	9S. Screening Volume Che	g Infor emical	mation Data Set (SID s Programme, 27, (1	9S) of OECD High 993)
Stu	dy						
	End Point	:	ABSORP	TION			-

	ABSURPTION
:	1-Octadecanol
:	112-92-5
:	LAB
	: : :

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<u>Organism</u> <u>Medium</u>	Specification	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Number exposed	Number controls
RAT		ORL PAR				
Species/strain/systen	n :	Sprague-D	awley rats			
Test Substance						
Labelled Compound	: '	1-Octadeca	nol labelled w	vith C14	l I	

### Exposure

Exposure Type : Exposure comments :	<b>SHORT</b> Test substance was labelled with C14 and administered via duodenal or aortic cannula. Blood and lymph were monitored at intervals up to 24h. Distribution of radioactive substance and biochemical analyses were examined.
Test Results	
Quantity Absorbed Time	Comments on result
	Absorption of the compound appeared to be a function of its lipid solubility. 56.6% (+/- 14%) was in the lymph. Of this more than half was found in the triglycerides, 6-13% in phospholipids, 2-8% in cholesterol esters, 4-10% unchanged as octadecanol. 90% of the octadecanol was carried in the chylomicron fraction of blood.
References	
Primary Reference :	<b>JACTDZ</b> ANON. Journal of the American College of Toxicology, Part A, 4(5), 1- 29, (1985)
Secondary Reference :	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 27, (1993)

End Point	:	DISTRIBUTION
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB

## Test Subject

	<u>Organism</u> <u>Medium</u>	Specification	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Number exposed	Number controls
	BIRD		ORL PAR	ADULT			
	Species/strain/syster	n :	White legh	orn chickens			
Tes	t Substance						
	Labelled Compound	:	1-Octadeca	nol. C14			
Ехр	osure						
	Exposure Type Exposure comments	:	SHORT C14 labelle cannula, b Distribution	ed test substa lood and lym n of radioactiv	ance v ph we ve sub	vas administered thro re monitored at interv stance was measure	ugh duodenal or aortal /als up to 24h. d.
Tes	t Results						
Oi	rgan Quantity		Time	Com	ments	s on result	
IN	т			Analy (+/-14 syste	sis of I%) of m of tl	homogenated intestir the substance presence the intestine.	nal wall showed 56.6% nt in the lymphatic
BL	OOD			Analy subst	sis of ance i	blood compartments n the chylomicron fra	showed 90% of test ction.
Ref	erences						
	Primary Reference	:	<b>JACTDZ</b> ANON. Joi 29, (1985)	urnal of the A	meric	an College of Toxicol	ogy, Part A, 4(5), 1-
	Secondary Referenc	e :	<b>!SIDSP*</b> OECD/SID Production	0S. Screening Nolume Che	g Infor emical	mation Data Set (SID s Programme, 27, (19	S) of OECD High 993)

End Point	:	BIOCONCENTRATION
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5

### Test Results

Organ	Bioconcent. Factor	Calc Basis	Time	State	Comments on result
	100000				Calculated results based on method of Veith, G. et al. (1980).
Gene	eral Comments	:	The wa estimat	ter solubi e of partit	lity of this substance is too low to allow a reliable ioning.
Refere	nces				
Prin	ary Reference	:	<b>XQSAF</b> Veith, C (1985)	<b>₹</b> * 6. et al. E	PA QSR System, Environmental Research Lab (ERL),
Seco	ondary Reference	e :	<b>!SIDSP</b> OECD/ Produc	* SIDS. Sci tion Volur	reening Information Data Set (SIDS) of OECD High ne Chemicals Programme, 9, (1993)

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End Point	:	METABOLISM
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB
Geographic Area	:	DNK

<u>Organism</u> <u>Medium</u>	Specification	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Number exposed	Number controls
RAT		ORL PAR				
Species/strain/syster	m :	Sprague-D	awley rats			
Test Substance						
Labelled Compound	:	C14 labellee	d 1-octadecan	ol		
Exposure						
Exposure Type Exposure comments	: :	SHORT C14 labelle cannula. B administra	ed 1-octadec lood and lym tion. Distribu	anol w ph we tion ar	vas administered via are monitored at inter ad biochemical analy	duodenal or aortal vals up to 24h post sis were assessed.
Test Results						
Organ Quantity		Time	Com	ments	s on result	
			From metal 8% to uncha	the al polized chole anged	osorbed fraction mor d to triglycerides, 6-1 esterol esters, and 4- octadecanol after 24	e than half was 3% to phospholipids, 2- 10% remained as h period, from dosing.
References						
Primary Reference	:	<b>JACTDZ</b> ANON. Joi 29, (1985)	urnal of the A	meric	an College of Toxico	logy, Part A, 4(5), 1-
Secondary Referenc	e :	<b>!SIDSP*</b> OECD/SID Production	S. Screening	g Infor emical	mation Data Set (SID s Programme, 27, (1	9S) of OECD High 993)

End Point	:	MAMMALIAN ACUTE TOXICITY
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Species/strain/system	:	Wistar rats
Dose / Concentration	:	<b>5.0 g/kg</b>

### Test Method and Conditions

Test method	:	OECD No. 401, Limit test.
description		

#### Test Results

<u>Organism</u> <u>Medium</u> <u>Sp</u>	<u>ec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	Effect Comments
RAT		ORL			LD50	Oral LD50 for wistar rats was estimated as >5.0g/kg/body weight.
General Comments	:	No mortali weight.	ty among the	exper	imental	animals at the dose up to 5.0g/kg/body
References						
Secondary Reference	:	<b>!SIDSP*</b> OECD/SID Productior	0S. Screening 1 Volume Che	Inforr	nation D s Progra	ata Set (SIDS) of OECD High mme, 17, (1993)

End Point	:	MAMMALIAN TOXICITY
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5

	<u>Organism</u> <u>Medium</u>	Specific	cation	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Number exposed	Number controls
	RAT			IHL				
	Species/strain/system	:	Strain n	ot indicat	ed			
Test	Method and C	Conc	ditions	6				
	Test method description	:	The rats 2-hours.	were ex . OECD f	posed by inlived dose te	nalatio st guio	n of 10% 1-octadecar lelines for variable du	nol in 55% ethanol for iration of testing.
Ехр	osure							
	Exposure Period Dose / Concentration	: :	2 h 10 %					
Test	Results							
	LC50 for acute inhalatior General Comments	toxicit	y was not The exp provideo	t establis osure wa d.	hed under th as reported t	ne exp o be w	erimental conditions. ithout effect. No furth	er details were
Ref	erences							
	Secondary Reference	:	<b>!SIDSP</b> * OECD/S Producti	SIDS. Sci ion Volur	reening Infor ne Chemica	matior Is Proo	n Data Set (SIDS) of g gramme, 17-18, (1993	OECD High 3)

End Point	:	MAMMALIAN TOXICITY
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB
Geographic Area	:	DNK

### Test Subject

<u>Organism</u> <u>Mediur</u>	<u>n</u> <u>Specif</u>	ication <u>Route</u>	<u>Lifestage</u> <u>Sex</u>	Number exposed	Number controls					
RAT		ORL	M F	10/DOSE 10/DOSE	10 10					
Species/strain/sys	stem :	Sprague-Dawley	y rats strain							
Test Substance										
Vehicle - Solvent	:	Olive oil								
Test Method an	nd Con	ditions								
Test method description	Test method:OECD Guideline No. 407; a 28-day oral Toxicity Test (Repeated Dose ToxicitdescriptionTest).									
Exposure										
Exposure Period Dose / Concentra Exposure comme	Exposure Period       :       28 d         Dose / Concentration       :       100-1000 mg/kg BW         Exposure comments       :       Ten animals per each sex per dose received: 0 (negative control), 100, 500 or 1000mg/kg/body weight per day in oral gavage, preparation of 1-octadecanol in olive oil for 28 days.									
Test Results										
Organ Eff	ect F	Rev. OnS	Set Se	Affected i ex Exposed - C	n Controls 					
NEF         Dose at which no toxic effects were observed was concluded to be >1000mg/kg/body weight per day.         General Comments       :         There was no substance related effects: no effects noted on biochemical anatomical or histopathological parameters. No cummulative effects were observed after 28 days of daily oral administration of 1-octadecanol up to 1000mg/kg/body weight per day.										
References										
Secondary Refer	ence :	!SIDSP*								

OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 20, (1993)

End Point	:	MAMMALIAN TOXICITY
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB
Geographic Area	:	DNK

	<u>Organism</u> <u>Me</u>	edium_	<u>Specit</u>	<i>lication</i>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Number expos	ed _	Number controls			
	RBT				SKN			10/DOSE		10			
	Species/strain/system : Rabbit, strain unspecified												
Tes	Test Substance												
	Description of the test : Cream containing 8% of tested substance. substance												
Tes	Test Method and Conditions												
	Test method : OECD Guidelines for Repeated Dose Toxicity-Dermal description												
Exp	osure												
	Dose / Concentration       :       8.8-13.2 mg/cm2         Exposure comments       :       2 groups of 10 animals each received topical applications of the cream containing 8% 1-octadecanol 3d/wk for 3 months. One group received a dose of 8.8mg/cm2 on 8.4% of body surface, the other group received 13.2mg/cm2 on 11.2% of body surface. 10 animals served as untreated control												
Tes	t Results												
	Organ	Effect	F	Rev.	OnS	et	Sex	Affecte x Exposed -	d in - Cc	ontrols			
	SKIN	CIRC STRUC											
	The product ca	aused sli	ght to w	ell define	ed eryther	na and mild o	desqua	amation during the	e first	t month of treatment.			
	SKINSTRUCAt necropsy symptoms of mild inflammation at the application site were reported.General Comments:Apart from local changes there was no evidence of systemic toxicity attributable to topical exposure of 1-octadecanol. No treatment related effects were found in hematological and blood chemistry determinations, urinanalysis, organ weight measurements at necropsy.												
Ref	erences												
	Primary Refe	erence	:	JACTE ANON	<b>)Z</b> . Journal (	of the Americ	an Co	llege of Toxicolog	ıy, Pa	art A, 4(5), 14, (1985)			
	Secondary Reference : ISIDSP* OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme. 20-21. (1993)												

End Point	:	CARCINOGENICITY
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB
Geographic Area	:	DNK

	<u>Organism</u> <u>Me</u>	<u>edium</u>	<u>Specific</u>	<u>cation</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Numbe</u>	<u>r exposed</u>	Number controls
	MOUSE				SKN		F		30	
	Species/straii	n/syster	m :	Swiss ı	mouse str	ain				
Tes	t Substan	се								
	Purity Grade	<b>;</b>	:	97%						
Exp	osure									
	Dose / Conce Exposure con	entration mments	n : :	<b>0.4 mg</b> 30 fem octade thereaf weeks	ale mice v canol. Ski ter treated (about 0.4	were treated in was pretre d with 20ul o 4mg of octac	to test ated w f octac lecano	t dermal o vith dimet decanol in bl/applicat	carcinogenic hylbenz(a)aı ı cyclohexan ion).	ity potential of hthracene and e, 3x week for 60
Tes	t Results									
	Organ	Effect	R	ev.	OnS	et	Se	x Ex	Affected ir (posed - C	n ontrols
	SKIN       STRUC       F         1 local papilloma was observed among 23 surviving animals, (appearing at week 30).         General Comments       :         The authors state that the initiation dose alone is non-carcinogenic, an conclude that octadecanol is probably a weak tumor-promoter. OECD/ comment: "The unconventional design of the test, and small number o animals involved make the results difficult to interpret".									
Ref	erences									
	Primary Refe	erence	:	<b>TXAPA</b> Sice, J	<b>\9</b> . Toxicolo	gy and Appli	ied Ph	armacolo	gy, 8, 70-74	, (1966)
	Secondary Reference : ISIDSP* OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 24-25, (1993)								DECD High 3)	

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End Point	:	CARCINOGENICITY
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Geographic Area	:	DNK

	<u>Organism</u> <u>Me</u>	edium <u>Spe</u>	ecifica	ation	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Numb	per exposed	Number controls			
	MOUSE				PAR				56	42/GROUP			
	Species/strail	n/system	: 9	Strain u	nspecifie	d							
Tes	Test Method and Conditions												
	Test method : OECD Guideline for Carcinogenicity Testing description												
Exp	osure												
	<i>Exposure comments</i> : The test substance was pressed into spheroidal pellets 5/32 inch in diameter, weighting 24-27mg. Pellets were inserted into bladders of 56 mice. 330 days after surgery all surviving animals were sacrificed and examined for the evidence of carcinoma. Animals surviving more than 175 days but less than 330 days were also evaluated.												
Tes	t Results												
	Organ	Effect	Re	V.	OnS	et	Se	x I	Affected ir Exposed - C	า controls			
	STRUC CAR         In a total of 39 mice surviving more than 175 days, 7 benign tumors and 2 carcinomas of the bladder (5%) were observed (1 stage II and 1 stage III tumor). There were no tumors, benign or malignant among the 3 control groups of 42 animals each which had not received bladder implants.         General Comments       :         A number of other substances tested in this series also produced bladder carcinomas. These included cholesterol, 8% tumor incidence and paraffin with 3% incidence of carcinoma.												
Ref	erences												
	Primary Refe	erence	: ( E	<b>CNREA</b> Bryan, (	. <b>8</b> G. Cance	r Research,	26, 10	5-109,	(1966)				
	Secondary Reference : ISIDSP* OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 25, (1993)												

End Point	:	CARCINOGENICITY
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB
Geographic Area	:	DNK

	<u>Organism</u> <u>Medium</u> <u>S</u>	pecific	ation <u>Route</u>	<u>Lifestage</u> Se.	x <u>Number exposed</u>	Number controls		
	MOUSE		IPR		4/GROUP	4		
	Species/strain/system	:	Swiss albino ddy	/ strain				
Exp	osure							
	Exposure Period Dose / Concentration Exposure comments	: : :	<b>5 d</b> <b>2.5-10 mg/kg/ d</b> Groups of four 5-week old mice were implanted intra-peritonealy with Erlich Ascites Tumor cells (1 million cells per mouse). After 24h, the mice were exposed I.P. to doses of 2.5 or 10mg/mouse/day of octadecanol for 5 consecutive days.					
Tes	t Results							
	Survival time was increas group relative to untreated <i>General Comments</i>	ed to > d contr <i>:</i>	25.5 days in the ols (18.0 days ar "The small numb antitumor activit	2.5mg group. Th d 18.3 days resp per of animals us y of octadecanol	e survival time was und ectively). ed makes assessment difficult".	changed in the 10mg of the possible		
Ref	erences							
	Primary Reference	:	<b>CNREA8</b> Ando, K. et al. C	ancer Research,	32, 125-129, (1972)			
	Secondary Reference	:	<b>!SIDSP</b> * OECD/SIDS. Sc Production Volu	reening Informati me Chemicals Pr	on Data Set (SIDS) of ogramme, 25-26, (199	OECD High 3)		

End Point	:	MUTAGENICITY
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB
Geographic Area	:	DNK

### Test Subject

<u>Organism</u> <u>Medium</u>	<u>Specifi</u>	<u>cation</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Number exposed	Number controls
BACT			VTR				
Species/strain/system	n :	Bacteri TA153	ia, Salmor 7	nella typhimu	irium,	strains: TA98, TA100	), TA1535,

### Test Method and Conditions

Test method description	:	Ames test
Exposure		
Dose / Concentration Exposure comments	: :	<b>3umol</b> Ames test. The substance was spot tested at one concentration 3umol/plate = total of 815ug/plate in all strains, both with and without metabolic activation with S-9.
Toot Dooulto		

Affected in

### Test Results

Organ	Effect	Rev.	OnSet	Sex	Exposed -	Controls
	NEF					
No evidenc	e of mutagenici	ty was seen	in this test system.			
General C	Comments	: There (below interpr	was a precipitation the original concer etation of the result	of the substar ntration of the is rather difficu	ice at concent substance) ma ilt.	ration <3umol/plate aking a valid
Reference	S					
Primary R	Reference	: TXCY/ Florin,	<b>AC</b> I. Toxicology, 18, 2	219-232, (1980	))	
Secondary	y Reference	: <b>!SIDSI</b> OECD Produc	⊐* /SIDS. Screening Ii ction Volume Cherr	nformation Dat nicals Program	a Set (SIDS) me, 22, (1993	of OECD High

End Point	:	MUTAGENICITY
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB
Geographic Area	:	DNK

### Test Subject

<u>Organism</u> <u>Medium</u>	Specification	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Number exposed	Number controls
BACT		VTR				
Species/strain/syster	<i>m :</i> Bacter TA153	ia, Salmoı 7, TA100,	nella typhimu TA98	ırium,	strains: TA1538, TA	1535
t Substanco						

### Test Substance

Description of the test	:	Stearyl alcohol from SIGMA chemical company
substance		

### Test Method and Conditions

Test method description	:	Ames test
Exposure		
Exposure comments	:	Ames test for spot testing of 1-octadecanol at concentration of 50mg/plate in all strains both with and without metabolic activation with S-9.

### Test Results

Organ	Effect	Rev.	OnSet	Sex	Affected in Exposed - Controls
	NEF				
There was r either with c <i>General C</i>	no mutagenic a or without metal comments	ctivity observ bolic activatio : The co substa	ved under the cond on. There was no p onclusion drawn by nce tested was so	ition of this tes precipitation ob the authors wa low that the va	t. There was no toxic effect reported served at the concentration used. as that the concentration of the alue of the test was not fully predictive.
Reference	S				
Primary R	eference	: JEHSI Blevins Enviro	<b>)H</b> s, R. et al. Journal nmental Health Sc	of Environmen iences, A17(2)	tal Sciences and Health, Part C, , 217-239, (1982)
Secondary	Reference	: <b>!SIDSI</b> OECD Produc	<b>⊳</b> ∗ /SIDS. Screening I ction Volume Chen	nformation Dat nicals Program	ta Set (SIDS) of OECD High me, 22-23, (1993)

End Point	:	MUTAGENICITY
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB
Geographic Area	:	DNK

### Test Subject

<u>Organism</u> <u>Medium</u>	<u>Specifi</u>	cation	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Number exposed	Number controls
BACT			VTR				
Species/strain/system	n :	Salmor TA100	nella typhi	murium strai	ns: TA	1535, TA1537, TA15	538, TA98

### Test Method and Conditions

Test method description	:	Ames test.
Exposure		
Dose / Concentration Exposure comments	:	<b>0.63-20.0 ug/ PLATE</b> Concentrations of 0, 0.63, 1.25, 2.5, 5.0, 10.0 and 20.0 microgram/plate, were used with and without metabolic activation by S9. All experiments were performed twice, and results were averaged.
Test Results		

Organ	Effect	Rev.	OnSet	Sex	Affected in Exposed - Controls
	NEF				

No significant increase in the number of histidine + revertants/plate relative to controls was observed at any concentrations tested, with and without metabolic activation.

#### References

Primary Reference	:	NKEZA4 Hacmiya, N. Japanese Journal of Public Health, 29(5), 236-239, (1982)
Secondary Reference	:	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 21-22, (1993)

Study		
End Point	:	MUTAGENICITY
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB
Geographic Area	:	DNK

### Test Subject

	<u>Organism</u> <u>Medium</u>	<u>Specifi</u>	<u>cation</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Number exposed	Number controls
	MOUSE			ORL			6/DOSE	6
	Species/strain/syste	<i>m</i> :	Strain	not specif	ied			
Tes	t Substance							
	Vehicle - Solvent	:	Olive c	bil				
Tes	t Method and	Cond	dition	IS				
	Test method description	:	Micron	ucleus tes	st. Japanese	Guide	lines of testing.	
Ехр	osure							
Dose / Concentration:0.36-1.45 g/kg BExposure comments:Groups of six mic body weight. An a 0.73g/kg body we				BW ce each rece additional gr eight of test	eived s roup of ed sub	ingle oral dose of 0.3 f five mice received fo ostance.	6, 0.73 or 1.45g/kg our doses (oral) of	
Tes	t Results		-		-			
	Organ Effec	t R	ev.	OnS	et	Se.	Affected in x Exposed - C	n Controls
	<b>NEF</b> There was no evidenc	e of geno	toxic eff	ect accord	ding to the au	uthors.		
Ref	erences							
	Primary Reference	:	<b>NKEZ/</b> Hacmi <u>y</u>	<b>44</b> ya, N. Jap	anese Jourr	nal of F	Public Health, 29(5), 2	236-239, (1982)
	Secondary Referen	ce :	ISIDSF	<b>)</b> *				

•	
	OECD/SIDS. Screening Information Data Set (SIDS) of OECD High
	Production Volume Chemicals Programme, 24, (1993)

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End Point	:	SENSITIZATION
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Geographic Area	:	DNK

### Test Subject

<u>Organis</u>	<u>m Medium</u>	<u>Specifi</u>	ication	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Number exposed	Number controls
GPIG				SKN			25	5/GROUP
Species	s/strain/syste	em :	Guinea	a pigs, stra	ain not speci	fied		
Test Subs	tance							
Descrip substar	tion of the te	est :	Deodo	rant conta	aining 24% o	f 1-oct	adecanol	
Vehicle	e - Solvent	:	Petrola	itum				
Exposure	2							
Dose / Exposu	Concentratio re comments	n : s :	<b>12 %</b> Draize applica applica untreat	repeated tions, 14- tions for o red anima	topical appli day period v determinatio ls.	ication vithout n of sk	method consisting o treatment followed b in sensitization. Con	of 9 induction by the challenge trols for petrolatum and
Test Resu	ilts							

Organ	Effect	Rev.	OnSet	Sex	Affecte Exposed	ed in - Controls	
SKIN	ALLER INC				1/25	1/5	•

One of 25 treated animals exhibited an equivocal score 24 hours post application to intact skin sites.

One of 5 petrolatum control animals showed an equivocal reaction score 24 hours post application to intact skin sites.

:	The authors concluded that 1-octadecanol was not a contact sensitizer at
	concentration of 12% in petroleum from an unidentified deodorant (containing
	24% of the tested substance) preparation as a source of 1-octadecanol.
	:

### References

Primary Reference	:	<b>JACTDZ</b> ANON. Journal of the American College of Toxicology, Part A, 4(5), 18, (1985)
Secondary Reference	:	ISIDSP* OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 19-20, (1993)

	End Point Chemical Na CAS Numbo Geographic A	: me : er : Area :		SENSIT 1-Octad 112-92-{ DNK	IZATIO ecanol 5	N			
Tes	t Subject								
	<u>Organism</u> <u>Me</u>	edium <u>Spec</u>	cific	ation <u>F</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u> <u>Nı</u>	umber exposed	Number controls
	HUMAN				SKN			172-824	
Tes	t Substan	се							
	Vehicle - Sol	lvent :		Petrolatu	m				
Tes	t Method	and Co	nd	litions					
	<i>Test method :</i> According to North American Contact Dermatitis Group Study Designs. <i>description</i>						Study Designs.		
Exp	osure								
	Exposure Pe Exposure cor	riod : mments :	Ţ	<b>1-4 y</b> Patch tes 96 hours numbers	at with 30 The tes of huma	)% stearyl al it was condu in subjects.	cohol in p cted durir	petrolatum was a ng several one-y	assessed after 48 and ear periods on large
Tes	st Results								
	Organ	Effect	Re	₽V.	OnSe	et	Sex	Affected Exposed -	in Controls
	 <b>sĸɪn</b> In 1975-1976 c	ALLER	out	 t of 172 te		showed aller	gic reacti	<b>2/172</b> ion (1.2%)	
	<b>sĸɪn</b> In 1976-1977 c	ALLER	out	of 446 te	ested. 1 s	showed aller	gic reactio	<b>1/446</b> on (0.22%)	
SKIN       ALLER       6/634         In 1978-1979 one year study out of 824 tested. 6 showed allergic reaction (0.73%). In 1979-1980 one year study out of 634 tested. 6 showed allergic reaction (0.95%)       In 1978-1979 one year study out of 824 tested. 6 showed allergic reaction (0.95%)         General Comments       :       There were several other studies performed testing skin sensitization pote of stearyl alcohol (1-octadecanol). The results were negative for skin sensitization. According to the authors, the positive results above indicate very mild sensitization potential.						979-1980 one year n sensitization potential gative for skin ults above indicate a			
Ref	ferences								
	Primary Refe	erence	:	<b>JACTDZ</b> ANON. J (1985)	ournal of	f the America	an Colleg	e of Toxicology,	Part A, 4(5), 1-29,
	Secondary R	eference	:	<b>!SIDSP</b> * OECD/SI Productic	DS. Scroon Volum	eening Inforr ne Chemicals	nation Da s Progran	ata Set (SIDS) of nme, 27-28, (199	f OECD High 93)

End Point	:	IRRITATION
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB
Geographic Area	:	DNK

### Test Subject

<u>Organisr</u>	<u>m</u> <u>Medium</u>	<u>Specifica</u>	ation <u>Route</u>	<u>Lifestage</u>	<u>Sex</u> <u>N</u>	umber exposed	Number controls
HUMAN			SKN			80	
Exposure							
Exposur Dose / C Exposur	e Type Concentration e comments	: 1 n : * s : \$	ACUTE 100 % Single insult occ 24 hours.	culsive patch t	est using	g 100% stearyl alco	ohol. Assessment after
Test Resu	lts						

Organ	Effect	Rev.	OnSet	Sex	Affected in Exposed - Controls	
SKIN	IRRIT				1/80	

A mild irritation was found in one out of 80 human subjects.

### References

Primary Reference	:	<b>JACTDZ</b> ANON. Journal of the American College of Toxicology, Part A, 4(5), 1-29, (1985)
Secondary Reference	:	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 27, (1993)

### Study

End Point	:	IRRITATION
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB
Geographic Area	:	DNK

<u>Organism</u> <u>Medium</u>	<u>Specifica</u>	tion <u>Route</u>	<u>Lifestage</u> S	<u>ex</u> <u>Number exp</u>	oosed Number controls
RBT		EYE		6	
Species/strain/system	n : F	Rabbit, strain no	ot specified		

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#### Exposure

	Exposure Type : Exposure comments :			<b>ACUTE</b> Undiluted 1-octadecanol from four separate commercial sources was instilled full strength into one eye of each of the experimental animals. The irritation was scored on the scale of 0-110.					
Tes	st Results								
	Organ	Effect	Rev.	Ons	Set	Sex	Affected in Exposed - C	า Controls	
	EYE Minimal irritat was reported General Co	IRRIT tion was note . There was note omments	ed on day no irritatio <i>:</i> Th	<b>1 d</b> one for three on reported fo ne results wer	of the sample r the remaining e classified by	s tested. I sample. the autho	Maximum score Scores decrease rs as minimal ey	of 5 (scale 0 - 110) ed to 0 by day 4. e irritation.	
Re	ferences								
	Primary Re	ference	: <b>J</b> A Al (1	<b>ACTDZ</b> NON. Journal 985)	of the America	an College	of Toxicology, F	Part A, 4(5), 14-15,	
	Secondary	Reference	: <b>!S</b> Ol Pr	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 19, (1993)					
Stu	idy								
	End Point Chemical N CAS Num Study type Geographic	lame ber Area	: IR : 1- : 11 : L/ : DI	RITATION Octadecand 12-92-5 AB NK	ы				
Tes	st Subject	t							
	<u>Organism</u> <u>N</u>	<u>/ledium_S</u>	pecificat	ion <u>Route</u>	Lifestage	<u>Sex Nui</u>	mber exposed	Number controls	
	RBT			SKN	ADULT		9		
Exp	<i>Species/stra</i> DOSUIE	ain/system	; Ra	abbit, strain no	ot specified				
	Exposure T Exposure co	ype omments	: A( : Ea 24	<b>CUTE</b> ach sample wa 4 hours.	as applied in fu	ull strength	n under occlusio	n to the clipped skin for	
Tes	st Results								
	Organ 	Effect	Rev.	OnS	Set	Sex	Affected in Exposed - C	n Pontrols	
	SKIN Irritation scor General Co	IRRIT es of 0.4, 0.5 omments	5, 1.42 an <i>:</i> Th pr	nd 1.5 (scale 0 ne results wer imary skin irri	- 4) were reco e interpreted b tation.	orded after y the auth	24 hours of full fors as indicating	strength exposure. g minimal to mild	

### References

Primary Reference	:	<b>JACTDZ</b> ANON. Journal of the American College of Toxicology, Part A, 4(5), 15, (1985)
Secondary Reference	:	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 18-19, (1993)

End Point	:	REPRODUCTION
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Geographic Area	:	DNK

#### Test Subject

<u>Organism</u> <u>Medium</u>	<u>Specifi</u>	<u>cation</u> Rout	<u>e Lifestage</u>	<u>Sex</u>	Number exposed	Number controls
RAT		ORL		M F		
Species/strain/syster	m :	Wistar (Mol/W	/IST) SPF strai	in		

### Test Substance

Description of the test	:	1-Octadecanol (Sigma L 5751)
substance		
Purity Grade	:	99%

### Test Method and Conditions

Test method description	:	OECD - Combined Repeated Dose and Reproductive/Developmental Toxicity Screening. GLP: YES.
Exposure		

Exposure Type	:	SHORT
Dose / Concentration	:	100-2000 mg/kg BW
Exposure comments	:	The doses of 0, 100, 500 or 2000mg/kg body weight/day was administered in the diet.

#### Test Results

	NEF				
Organ	Effect	Rev.	OnSet	Sex	Exposed - Controls
					Affected in

No observed effect level for parental animals was determined to be more than the highest dose tested >2000mg/kg body weight/day.

OFSPR NEF

NOEL for F1 generation was established as >2000mg/kg body weight/day

*General Comments* : 1-Octadecanol administered orally in the diet at dosages up to 2000mg/kg body weight/day did not cause any toxic effect on reproduction or on the haematological and pathological parameters investigated under the test conditions.

#### References

Secondary Reference	:	!SIDSP*
		OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 26, (1993)

End Point	:	AQUATIC ACUTE TOXICITY
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Species/strain/system	:	Mosquito (Aedes aegypti) age: 2-14 days
Exposure Period	:	24-72 h
Dose / Concentration	:	8.2-101 ml/m2

### Test Method and Conditions

Test method description	:	Hexane was used as solvent in both tests. The solvent itself showed no harmful effects on the larvae. See under general comments for details.
Temperature	:	25-27 C

### Test Results

	<u>Organism</u>	<u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	Effect Comments
	INSEC	AQ	FRESH		EGG LARVA		LD50	LD50 eggs = 8.2ml/m2; LD90 eggs = 14.5ml/m2; LD50 juvenile,(1-4th instar larvae, pupae) = 23.4-77.1ml/m2; LD90 juvenile,(1-4th instar larvae, pupae) = 28.1-101.0ml/m2
	General C	Comments	÷	Mortality ba group. LD5 150ml of ha eggs per ja Each series as above w series of te move.	PUPA ased on diffe to based on ay infusion ir r. Each trial s of tests rep vith minimum sts repeated	erence t field ap n jars o carried peated n of 5 d 1 10 tim	Detween oplication f 51cm2 l out in ti 10 times ifferent o les. Mor	larval count, between control and study n of litre/hectar. Eggs were immersed in surface area. 150-250 embryonated riplicate at 10 different concentrations. Larvae and pupae, 25 of each treated concentrations of test substance, each tality interpreted as failure of larvae to
Ref	erence	S						
	Primary R	Reference	:	<b>TRSTAZ</b> Transactior 38, (1983)	ns of the Ro	yal Soc	iety of T	ropical Medicine and Hygiene, 77(1), 35-
	Secondary	y Referenc	e :	<b>!SIDSP*</b> OECD/SID Production	S. Screening Volume Ch	g Inform emicals	nation D s Progra	ata Set (SIDS) of OECD High mme, 14, (1993)
Stu	dy							
	End Poin Chemical CAS Nur	t Name mber	:	AQUATIC 1-Octadeo 112-92-5	ACUTE T canol	OXICI	ТҮ	
	Species/st Exposure	train/syster Period	n : :	Golden Orf <b>96 h</b>	(Leuciscus	idus)		

### Test Results

<u>Organ</u>	ism <u>Medium</u>	<u>Spec.</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	<u>Effect</u>	Effect Comments
FISH	AQ	FRESH				LC50	LC0 >10000 and LC50 >10000 mg/l. (Purity of test substance questionable)
Gene	ral Comments	:	No further estimated (Water sole substance containing	details were water solubil ubility = 2.05 tested was n other alcoho	provide ity of th E-04 (o not pure ols.	ed. The he subst calculate e 1-octa	stated concentration exceeds the tance by a factor of about 50 million. ed)). It is possible that the actual decanol, but a commercial mixture also
Referen	ces						
Secon	dary Referend	ce :	<b>!SIDSP*</b> OECD/SID Production	S. Screening Volume Che	g Inforr emicals	mation D s Progra	Data Set (SIDS) of OECD High amme, 14, (1993)

End Point	:	AQUATIC TOXICITY
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB

### Test Subject

	<u>Organism</u>	<u>Medium</u>	<u>Specifi</u>	cation	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Number exposed	Number controls
	ALGAE	AQ	FRESH						
	Species/s	strain/syste	<i>m</i> :	Green	algae (Sc	enedesmus	subspi	catus)	
Tes	t Metho	od and	Cond	ditior	IS				
	Test meth descriptio	hod on	:	DIN 38	3412 part 9	9. (Approxim	ates C	ECD Guideline 201)	. GLP: yes.
Tes	t Result	S							
	Organ	Effec	t R	ev.	OnS	et	Se.	Affected i x Exposed - C	n Controls
	Effect cond	EC10 centration E	C10 = 21	mg/l					
	EC50 = 24	<b>EC50</b> 0 mg/l							
Ref	ference	es							
	Primary I	Reference	:	HKAV Algenz RE920	<b>T*</b> zellvermeh )040(9), (1	rungshemm 992)	test na	ch (Cell Inhibition Te	est on Algae),
	Secondary Reference :			<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 13, (1993)					
Stu	dy								
	End Poil Chemical CAS Nu Study typ	nt I Name Imber De	:	AQUA 1-Oct 112-92 LAB	ATIC TO) adecano 2-5	KICITY I			
Tes	t Subje	ct							
	, <u>Organism</u>	<u>Medium</u>	<u>Specifi</u>	cation	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Number exposed	Number controls

CRUS AQ FRESH

Species/strain/system : Water flea (Daphnia magna)

### Test Method and Conditions

Test method	:	DIN 38412 part 2, corresponds approximately with OECD Guideline 202 part
description		1. No information given regarding the use of solvents or emulsifiers, the test
1		substance apparently having been added directly.

#### Exposure

Exposure Type	:	ACUTE
Exposure Period	:	48 h
Dose / Concentration	:	980-2900 mg/l
Exposure comments	:	Doses of 1700mg/l were also tested.

#### Test Results

					Affected in
Organ	Effect	Rev.	OnSet	Sex	Exposed - Controls
	EC0				

Effect concentration EC0 = 980mg/l for 48h.

#### EC50

EC50 = 1700 mg/l for 48h.

#### EC100

EC100 = 2900 mg/l for 48h.

#### LOEC

The concentration of test substance producing any effect are about 1000000 times the water solubility (water solubility = 1.1E-3mg/l)

#### References

Primary Reference	:	HKBAD* Bestimmung der Akuten Daphientoxizitat von Octadecanol im Daphnietest nach DIN 38412 (Test of Octadecanol on Acute Toxicity to Daphnia according to DIN 38412), 11 RE920029, (1992)
Secondary Reference	:	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 12, (1993)

#### Study

:	AQUATIC TOXICITY
:	1-Octadecanol
:	112-92-5
:	LAB
	: : : :

#### **Test Subject**

Organism Medium Specification Route Lifestage Sex Number exposed Number controls

#### CRUS AQ FRESH

Water flea (Daphnia magna) Species/strain/system :

60

Tes	t Substan	се						
	Purity Grade	e	:	98%				
Tes	t Method	and C	Cond	ditions	i			
Test method:OECD Guidelines 202, part 2. Statdescriptiondirectly without using solvents or e reproduction rate, mortality and time					art 2. Static tes vents or emulsi ity and time of t	t. GLP: yes. Octadecanol wa fier. Observations made with irst appearance of decendar	is added i regard to nts.	
Ехр	osure							
	Exposure Ty Exposure Pe	pe eriod	: :	LONG 21 d				
Tes	t Results							
	Organ	Effect	R	ev.	OnSet	Sex	Affected in Exposed - Controls	
	No observed e 0.98 mg/l <i>General Cor</i>	NOEC offect conce	entratio	on NOEC No detai etc.).	is approx. 100 tir Is were given abo	mes the water s	solubility = (1,1 E-3mg/l). No	DEC = ∋ floating
Ref	erences							
Primary Reference :				HKBCD* Bestimmung der Chronischen Daphnientoxizitat von Octadecanol im Verlanerten Daphnientest (Prolonged Test on Chronic Toxicity of Octadecanol to Daphnia), 920096, (1992)				
	Secondary R	eference?	:	<b>!SIDSP</b> * OECD/S Producti	IDS. Screening I on Volume Chen	nformation Dat hicals Program	a Set (SIDS) of OECD High me, 13, (1993)	
Stu	dy							<i></i>
	- End Point		:	AQUAT				

End Point	:	AQUATIC TOXICI
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB

### Test Subject

IRPTC Data Profile

<u>Organism</u>	<u>Medium</u>	<u>Specific</u>	<u>cation</u>	<u>Route</u>	<u>Lifestage</u>	<u>Sex</u>	Number exposed	Number controls
FISH	AQ	ESTUA					48	
Species/s	train/syster	n :	Rainbo	w trout (C	ncorhynchu	s myki:	ss) weight: 30-40g	

### Test Method and Conditions

Test method	:	Static test
description		

#### Exposure

Exposure Exposure Dose / Col Exposure	Type Period ncentration comments	: : : :	ACUTE 96 h 1-1000 Doses	<b>=</b> ) <b>mg/l</b> of 10 and 100mg/l	were also tes	sted
Test Results	8					
Organ	Effect	R	ev.	OnSet	Sex	Affected in Exposed - Controls
No toxicity v	<b>NEF</b> was observed.	There	e were tv	vo deaths which w	ere not dose-r	elated
Reference	S					
Primary R	Reference	:	<b>BFPIA</b> Gorin,	<b>B</b> J. et al. Bulletin Fr	ancais de Pis	cisculture, 277, 163-185, (1980)
Secondary	/ Reference	:	<b>!SIDSF</b> OECD/ Produc	o∗ /SIDS. Screening I ction Volume Chen	nformation Da nicals Prograr	ata Set (SIDS) of OECD High nme, (1993)
Study						
End Poin	t	:	AQUA			

End Point		AQUATIC TOXICI
Chemical Name	:	1-Octadecanol
CAS Number	:	112-92-5
Study type	:	LAB

### Test Subject

<u>Organism Medium</u> <u>Specification</u> <u>Route</u> <u>Lifestage</u> <u>Sex</u> <u>Number exposed</u> <u>Number controls</u>

FISH	AQ	ESTUA
------	----	-------

Species/strain/system : Rainbow trout (Oncorhynchus mykiss)

#### Exposure

Exposure Period	:	20-40 mo
Dose / Concentration	:	1-1000 mg/l
Exposure comments	:	Doses of 10 and 100mg/l were also tested for fertilizing ability of sperm of rainbow trout

#### Test Results

					Affected in
Organ	Effect	Rev.	OnSet	Sex	Exposed - Controls
	DEAD				

#### RESP

At concentration of 1000mg/l (reported as ppm), a statistically significant drop in oxygeno-dependence level occurred both during the exposure period and after 2h recuperation in pure water.

#### METAB NEF

Concentrations of 2-3mg/l (reported as ppm) seemed to have no effect on the rest of the metabolism.

#### EGG REPRO

The fertility of eggs was significantly reduced (p<0.01) following 40 minutes exposure to 100mg/l.

#### SPERM REPRO

Induced significant drop in fertilizing ability of sperm following exposure for 20 or 40 minutes and concentrations of 1, 10, 100 or 1000mg/l.

#### References

Primary Reference	:	<b>BFPIAB</b> Billard, R. Bulletin Francais de Piscisculture, 271, 3-8, (1978)
Secondary Reference	:	<b>!SIDSP*</b> OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, 10, (1993)

End Point : Chemical Name : CAS Number : Study type :	TERRESTRIAL TOXICITY 1-Octadecanol 112-92-5 LAB
Test Subject	
<u>Organism Medium</u> <u>Specit</u>	ication Route Lifestage Sex Number exposed Number controls
BACT	
Species/strain/system :	Bacteria (Pseudumonas putida)
Test Substance	
Description of the test : substance	Lorol C18
Test Method and Con	ditions
Test method : description	Oxygen consumption test
Exposure	
Exposure Type :	ACUTE
Test Results	
Organ Effect F	Affected in Rev. OnSet Sex Exposed - Controls
Effect concentration EC0 > 100	) mg/l
References	
Primary Reference :	HKDBA* Datenblatt fur Altstoffe (Datasheet for Existing Chemical (1-Octadecanol)), 1, 2, (1988)
Secondary Reference :	ISIDSP* OECD/SIDS. Screening Information Data Set (SIDS) of OECD High Production Volume Chemicals Programme, (1993)

Sub	osta	nce							
	Che Rep CA	mical Na orted Na S Numb	ame ame oer	:	stearyl a 112-92-5	alcohol j			
<u>Area</u>	<u> </u>	<u>Subject</u>	<u>Spec.</u>	<b>Description</b>	Level / Sumr	nary Infor	mation :		
CSK	REG	FOOD GOODS	-	PRMT MXL	COMPONENT MAXIMUM LII <u>Title</u> : DIRE GOOI	OF PLAS MIT FOR ' CTIVE N( DS COMII	TIC PRODUCTS PERMIT THE PLASTIC MATERIA D.49 ON HYGIENIC REQ IG IN CONTACT WITH F	ITED FOR CONTACT WITH LLS: 20MG/G. DUIREMENTS ON PLASTIC: FOODSTUFFS	FOOD. 5 AND PLASTIC
					Reference	:	HPMZC*, 42, 1978	Effective Date :	1JUL1978
							HYGIENICKE PREDPISY (HYGIENIC REGULATIO	Y MINISTERSTVA ZDRAVOTI DNS OF MINISTRY OF HEALT	NICTVI CSR H OF CSR)
					Last Amendm	<u>ent :</u>		Entry / Update	DEC1991
<b>C</b> 1									
Sub	osta	nce							

	Che Rep CA	mical Na orted Na S Numb	ame ame oer	: : :	1-0 11:	OCTADECA 2-92-5	ANC	L				
<u>Area</u>	<u>Type</u>	<u>Subject</u>	<u>Spec.</u>	<b>Description</b>	Level .	/ Summary In	nform	nation :				
DEU	REC	AQ USE	- INDST	CLASS RQR	SATURA 12, ANE TO WAT VERY H IN GEN WATER HAZARJ <u>Title</u> : <u>Referen</u> Last An	ATED FATTY ) A TERMINA FER (WATER- IAZARDOUS; IERAL NOT H 2-PROTECTIO DOUS SUBST ADMINISTR (VERWALTU nce: mendment :	ALC L OF HAZ WGI IAZA N RI CANC RATI UNG	OHOLS WITH A I GROUP ARE C ARD CLASS: WG (2 = HAZARDO RDOUS.) THE C EQUIREMENTS ES ARE HANDI VE RULES CON SVORSCHRIFT GMSMA6, 8, 114 Gemeinsames M	AN EVEN- N ZLASSIFIEI GK 0). (THE US; WGK 1 ZLASSIFICA FOR INDU LED. (CERNING ' WASSERGI J, 1990 Aninisterialbla	JUMBERE ) AS IN GE ) DIFFERE = SLIGHT \TION FOR STRIAL PI WATER- H EFAEHRDI <u>Ei</u> att. Joint M <u>E</u>	D C CHAIN, C NI ENERAL NOT HA INT CLASSES AR LY HAZARDOUS MS THE BASIS LANTS IN WHICH IAZARDOUS SUF ENDE STOFFE) <u>ffective Date :</u> linisterial Papers ntry / Update :	UMBER >= \ZARDOUS \E: WGK 3 = S; WGK 0 = FOR H WATER- 3STANCES DEC1991
Suk	osta	nce										
	Che	mical Na	ame	:			- 1					

	Rep CAS	orted Na 5 Numb	ame ber	: :	stearyl alcohol 112-92-5			
<u>Area</u>	<u> </u>	<u>Subject</u>	<u>Spec.</u>	Description	Level / Summary Inform	nation :		
GBR	REG	TRNSP AQ AQ	MARIN MARIN EMI	RQR RQR RQR	CLASSIFIED AS A NON- OF ASSESSMENT AND A SEA IS NOT PROHIBITE <u>Title</u> : THE MERCHAM SUBSTANCES I	POLLUTING LIQUID SUBSTANCE APPROVAL REQUIRED BY A CARR D. IT SHIPPING (CONTROL OF POLL N BULK) REGULATIONS 1987, SC	2. DOCUMENTARY 21ER. DISCHARGE UTION BY NOXIO HEDULE 2	( EVIDENCE INTO THE US LIQUID
					<u>Reference :</u>	GBRSI*, 551, 15, 1987	Effective Date :	06APR1987
					l ast Amendment ·	STATUTORY INSTRUMENTS	Entry / Undate ·	1992
					<u>Lact / mondment .</u>	STATUTORY INSTRUMENTS	<u>Liniy / Spuare .</u>	1002

### Substance

	Che Rep CA	mical Na orted Na S Numb	ame ame per	: : :	stearyl alcoho 112-92-5	I		
<u>Area</u>	<u> </u>	<u>Subject</u>	<u>Spec.</u>	Description	Level / Summary Info	ormation :		
USA	REG	FOOD PACK MANUF USE	addit Addit Addit	RSTR RSTR GL RSTR	; SUMMARY - THIS SUBSTANCE INCLUDED ON A LIST OF SUBSTANCES USED TO PREPARE BASE SHEET OR COATING SUBSTANCES FOR CELLOPHANE MUST BE 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. <u>Title</u> : INDIRECT FOOD ADDITIVES; POLYMERS-CELLOPHANE.			
					<u>Reference :</u>	FEREAC, 42, 14572, 1977	Effective Date :	1977
					<u>Last Amendment :</u>	Federal Register CFRUS*, 21, 177, 1200, 1988 Code of Federal Regulations	<u>Entry / Update :</u>	NOV1991
Suk	osta	nce						
Chemical Name : Reported Name : CAS Number :		1-OCTADECAN 112-92-5	NOL					

<u>Area</u>	<u>Туре</u>	<u>Subject</u>	<u>Spec.</u>	Description	Level / Summary Information :
EEC	REG	FOOD FOOD FOOD	-	RQR MXL RSTR	THE SUBSTANCE MAY BE USED FOR THE MANUFACTURE OF REGENERATED CELLULOSE FILM WHICH IS INTENDED TO OR DOES COME INTO CONTACT WITH FOODSTUFFS. THE MAXIMUM QUANTITY OF THE SUM OF 1-HEXADECANOL AND 1- OCTADECANOL: 2MG/DM2 ON THE SIDE IN CONTACT WITH FOODSTUFFS.
					Title :       COUNCIL DIRECTIVE OF 25 APRIL 1983 ON THE APPROXIMATION OF THE         LAWS OF THE MEMBER STATES RELATING TO MATERIALS AND ARTICLES         MADE OF REGENERATED CELLULOSE FILM INTENDED TO COME INTO         CONTACT WITH FOODSTUFFS. (83/229/EEC).

<u>Reference</u> :	OJEC**, L123, 31, 1983	Effective Date :	01APR1987
	Official Journal of the European	Communities	
Last Amendment :	OJEC**, L228, 32, 1986	<u>Entry / Update :</u>	OCT1987
	Official Journal of the European		