

VARISOFT BTMS

CERTIFICADOS

Summary of Product Data with Reference to Toxicology and Ecotoxicology

Test	Method	Result	Date
Acute Eye Irritation/Corrosion (in-vitro)	Hen's Egg Test ¹⁾	not irritating ²⁾	06/2009
Skin Sensitisation (guinea pig)	OECD 406	not sensitising ³⁾	07/1992
Biodegradation aerobic	OECD 301 F	76 – 80 %, 28 d ⁴⁾	05/2007

- ¹⁾ Evaluated in-vitro alternative methodology; The Hen's Egg Test on the Chorioallantois Membrane, HET-CAM
- ²⁾ Does not result in labelling according to EEC Regulations or German Dangerous Goods Regulation, respectively
- ³⁾ VARISOFT® EQ 65 MB has not been tested for acute effects. However, there are test results available for comparable representatives of the Ester Quat family (REWOQUAT® WE 18; TEA based). The results may be safely applied to VARISOFT® EQ 65 MB.
- ⁴⁾ The criteria of the 10 day window are fulfilled

For further assessment of toxicological properties of components contained in the product mixture it is referred to existing data on such components or relevant literature.

The results are summarized in the documents

DISTEAROYLETHYL DIMONIUM CHLORIDE
CETYL ALCOHOL
STEARYL ALCOHOL

(Internal marking "distearethdimchl_zs")
(Internal marking "cetal_zs")
(Internal marking "stearyl_zs")

Summary of Product Data with Reference to Toxicology and Ecotoxicology*

Toxicological information for Distearoylethyl Dimonium Chloride (INCI); chemical substance name: Dimethylbis[2-[(1-oxooctadecyl)oxy]ethyl]ammonium chloride; CAS No. 67846-68-8; EC No. 267-382-0

Test	Method	Result	Date
Basic toxicokinetics	Similar to OECD 417	Low bioaccumulation potential ¹⁾	1993
Dermal absorption	Similar to OECD 427	A total of < 1.4 % (normalised for 100 % recovery) of the administered dose was absorbed over the 72-hour test period. Most of the test substance remained on the skin. Following dermal administration of radiolabelled test substance, the principal route for the elimination of radioactivity was via the urine. Low amounts of radioactivity were sporadically detected in expired carbon dioxide and faeces. ¹⁾	1993
Acute Toxicity: oral	OECD 423	LD50 > 2,000 mg/kg bw	2009
Acute Toxicity: dermal	Similar to OECD 402	LD50 > 2,000 mg/kg bw ²⁾	1986
Skin irritation / corrosion	OECD 404	Not irritating ²⁾	1993
Eye irritation	Similar to OECD 405	Not irritating ²⁾	1993
Skin sensitisation	OECD 406	Not sensitising ²⁾	1986
Repeated dose toxicity: oral	OECD 407	NOEL = 1,000 mg/kg bw/day	2010
Repeated dose toxicity: oral	OECD 408	NOAEL > 500 mg/kg bw/day ³⁾	1994
Genetic toxicity: in vitro	OECD 473	Negative with and without metabolic activation	2009
Genetic toxicity: in vitro	OECD 476	Negative with and without metabolic activation ³⁾	1996
Genetic toxicity: in vitro	OECD 471	Negative with and without metabolic activation ²⁾	2008
Genetic toxicity: in vivo	OECD 474	Negative ³⁾	2013

Summary of Product Data with Reference to Toxicology and Ecotoxicology*

Toxicity to reproduction	OECD 407	NOEL = 1,000 mg/kg bw/day	2010
Developmental toxicity / teratogenicity	OECD 414	NOAEL = 1,000 mg/kg bw/day ³⁾	1997
Sensitisation data (human)	No Guideline	In this study, MDEA-Esterquat C16-18 and C18 unsatd. is not a dermal sensitizer. (Human Repeat Insult Patch method; 95 volunteers) ³⁾	1993
Sensitisation data (human)	No Guideline	In this study, MDEA-Esterquat C16-18 and C18 unsatd. is not a dermal sensitizer. (Human Repeat Insult Patch method; 104 volunteers) ³⁾	1992
Sensitisation data (human)	No Guideline	In this study, MDEA-Esterquat C16-18 and C18 unsatd. is not a dermal sensitizer. (Human Repeat Insult Patch method; 90 volunteers) ³⁾	1986
Biodegradation in water: screening tests	OECD 301 B	Readily biodegradable ³⁾	1993
Biodegradation in water: screening tests	ECETOC Anaerobic Biodegr. ⁴⁾	Highly biodegradable under anaerobic conditions ³⁾	1994
Biodegradation in water and sediment: simulation tests	OECD 303 A	On average >99% parent MDEA-Esterquat C16-18 and C18 unsatd. was removed during the three weeks removal period. ³⁾	1994
Short-term toxicity to fish	OECD 203	LC50 (96 h) = 5.2 mg/L ³⁾	1985
Long-term toxicity to fish	US EPA TSCA, 40 CFR, Part 797.1600	NOEC (35 d) = 0.686 mg/L ³⁾	1996
Short-term toxicity to aquatic invertebrates	OECD 202	EC50 (24 h) = 14.8 mg/L ³⁾	1985
Long-term toxicity to aquatic invertebrates	EPA OTS 797.1330	EC50 (21 d) = 1.7 mg/L ³⁾ NOEC (21 d) = 1.0 mg/L	1996
Toxicity to aquatic algae and cyanobacteria	OECD 201	NOEC (72 h) = 2.7 mg/L (growth rate) ⁵⁾ EC50 (72 h) = 8.1 mg/L (growth rate)	2014
Toxicity to microorganisms	OECD 209	NOEC (3 h) > 47.4 mg/L ³⁾	1993

Summary of Product Data with Reference to Toxicology and Ecotoxicology*

Toxicity to soil macroorganisms except arthropods	OECD 207	LC50 (14 d) > 47.4 mg/kg soil dw ³⁾	1993
Toxicity to terrestrial plants	OECD 208	NOEC (17 d) > 47.4 mg/kg soil dw ³⁾ EC50 (17 d) > 47.4 mg/kg soil dw	1993

- 1) Read-across from N-Bis (Talloxyloxyethyl)-N-Dimethyl Ammonium Chloride
- 2) Read-across from Diethylester dimethyl ammonium chloride (DEEDMAC)
- 3) Read-across from N,N-dimethyl-2-(stearoyloxy)-N-[2-(stearoyloxy)ethyl]ethanaminium chloride (MDEA-Esterquat C16-18 and C18 unsatd)
- 4) (Technical Report No. 28)
- 5) Read-across from 1-Propanaminium, 2-hydroxy-N-(2-hydroxypropyl)-N,N-dimethyl-, esters with fatty acids, C16-18 (even numbered), C18 (unsatd.), Me sulfates (salts) (MDIPA-Esterquat C16-18 and C18 unsatd)

* Full robust Study Summaries can be checked under the ECHA Registered Substance website and with the following registration number: 01-2120121302-78

Zusammenfassung der Produktdaten zur Toxikologie und Ökologie Summary of Product Data with Reference to Toxicology and Ecology

Toxicological information for Cetyl

Alcohol (INCI), representing the C16-alcohol of the mixture with the INCI name Cetearyl Alcohol; chemical substance name: Hexadecan-1-ol; CAS No. 36653-82-4; EC No. 253-149-0

Test	Method	Result	Date
Basic toxicokinetics	¹⁾	Following skin application of lauryl alcohol about 2.84 % of the administered dose was absorbed. Of this absorbed dose > 90% was excreted in expired air (CO ₂)	1987
Basic toxicokinetics	²⁾	Substance was incompletely absorbed with 20% of the dose recovered unchanged from the faeces. Faecal excretion was complete within 48 h. About 6% of the dose was in the form of glucuronic acid conjugate in the urine	1958
Acute dermal toxicity (rat)	OECD 401	LD ₅₀ > 2,000 mg/kg bw	04/1996
Acute inhalation toxicity	No guideline followed	EL (1 h) > 1.5 mg/L air ³⁾	
Acute dermal toxicity	No guideline followed	LD ₅₀ = 8,000 mg/kg bw ³⁾	
Acute dermal irritation/corrosion (rabbit)	OECD 404	not irritating	03/1996
Acute eye irritation (rabbit)	OECD 405	not irritating	04/1996
Skin sensitisation (guinea pig)	OECD 406	not sensitising	06/1996
90 day repeated dose toxicity (rat)	No guideline followed	NOAEL > 4,257 mg/kg bw based on highest dose tested	1973
90 day repeated dose toxicity (rat)	No guideline followed	NOAEL = 1,127 mg/kg bw/day (males) NOAEL = 1,243 mg/kg bw/day (females) (highest doses tested) ⁴⁾	
Gene toxicity (Ames)	OECD 471	not mutagenic	06/1996
<i>In vitro</i> mammalian cell gene mutation test	OECD 476	not mutagenic ⁵⁾	
Chromosomal aberration	OECD 473	non clastogenic ⁵⁾	
Toxicity to reproduction (rat)	No guideline followed	A repeated oral dose NOAEL of 1,822 mg/kg/day for males and 4,567	1966

Zusammenfassung der Produktdaten zur Toxikologie und Ökologie Summary of Product Data with Reference to Toxicology and Ecology

		mg/kg/day (the highest dose tested) in females was determined for effects on reproductive organs in the rat	
Toxicity to reproduction (repeated dose 28-day oral toxicity in rats)	OECD 407	NOAEL for effects on reproductive organs = 1,000 mg/kg bw/day	1985
Biodegradation aerobic	OECD 301 B	82.4 % (28 d) readily biodegradable	1993
Bioaccumulation aquatic / sediment	QSAR	BCF = 45.300 L/kg	2005
Absorption/desorption	QSAR	Log K _{oc} (TGD hydrophobics method) = 5.487	2005
Acute fish toxicity	OECD 203	LC ₅₀ (96h) is greater than limit of solubility	03/1996
Acute daphnia immobilisation	QSAR	EC ₅₀ (48h) > 100 mg/L	2009
Algae growth inhibition test	DIN 38412 part 9	EL50 (96h) is > 0.01 mg/L (> limit of solubility)	02/1992
Long-term toxicity to fish	OECD 210	EC ₁₀ (33 d) 0.43 mg/l NOEC (33 d) 0.26 mg/l	2015 ⁶⁾

¹⁾ Publication: Percutaneous absorption of aliphatic compounds. Iwata Y, Moriya Y, Kobayashi T. 1987, Cosmet. Toiletries 102(2): 53-68

²⁾ Publication: The metabolism of spermaceti W.A., McIsaac W M, Williams R T, 1958, Journal Biol. Chem. 2(2): 42-44

³⁾ Read-across from myristyl alcohol

⁴⁾ Read-across from 1-hexanol

⁵⁾ Read-across from behenyl alcohol

⁶⁾ Read-across from decan-1-ol

* Full Robust Study Summaries can be checked under the ECHA Registered Substance website and with the following registration number: 01-2119485905-24

Zusammenfassung der Produktdaten zur Toxikologie und Ökologie
Summary of Product Data with Reference to Toxicology and Ecology



Zusammenfassung der Produktdaten zur Toxikologie und Ökologie Summary of Product Data with Reference to Toxicology and Ecology

Toxicological information for Stearyl Alcohol (INCI), representing the C18-alcohol of the mixture with the INCI name Cetearyl Alcohol; chemical substance name: Octadecan-1-ol; CAS No. 112-92-5; EC No. 204-017-6

Test	Method	Result	Date
Basic toxicokinetics	¹⁾	All the primary alcohols investigated form glucuronic acid conjugates which are excreted in the urine. However this was generally <10% of the dose. Interpretation of results: no bioaccumulation potential based on study results	1953
Dermal absorption	²⁾	Of a dose of 1-14C-cetyl alcohol (5%) in squalene applied to the skin of nude mice for 24 hours under occlusive conditions, 1 % was absorbed.	
Acute dermal toxicity (rat)	OECD 401	LD ₅₀ > 2,000 mg/kg bw	1996
Acute dermal toxicity	No guideline followed	LD ₅₀ = 8,000 mg/kg bw ³⁾	
Acute dermal irritation/corrosion (rabbit)	OECD 404	not irritating	03/1996
Acute eye irritation (rabbit)	OECD 405	not irritating	04/1996
Skin sensitisation (guinea pig)	OECD 406	not sensitising	06/1996
28 day repeated dose toxicity (rat)	OECD 407	NOAEL = 1,000 mg/kg bw	1999
Gene toxicity (Ames)	OECD 471	not mutagenic	06/1996
In vitro mammalian cell gene mutation test	OECD 476	not mutagenic ⁴⁾	
Chromosomal aberration	OECD 473	non clastogenic ⁴⁾	
Toxicity to reproduction (rat)	No guideline followed	A repeated oral dose NOAEL of > 1,243 mg/kg bw/day in females and > 1,127 mg/kg bw/day for males was determined for effects on reproductive organs ⁵⁾	1966
Developmental toxicity / teratogenicity	OECD 422	NOAEL maternal toxicity and teratogenicity = 1,000 mg/kg bw/day	1992
Biodegradation aerobic	EPA OPPTS 835.3100	67 % (31d) readily biodegradable	1994
Biodegradation aerobic	OECD 301 D	38 - 69 % (29d) biodegradable	1992

Zusammenfassung der Produktdaten zur Toxikologie und Ökologie Summary of Product Data with Reference to Toxicology and Ecology

Biodegradation aerobic	ISO 10708 (BODIS)	67 % (28d) readily biodegradable	1992
Biodegradation aerobic	OECD 301 B	43 % (28d) inherently biodegradable	1997
Biodegradation aerobic	OECD 301 B	95.6 % (28d) readily biodegradable	04/2009
Biodegradation in water and sediment	ISO 11733	Over the last 30 days of the study the substance was 98% mineralised, with 0.05% remaining in the effluent, and 0.4% of the radioactivity adsorbed to the sludge. The overall removal from influent was > 99.9%, and removal from the total system was 99.5%. ⁶⁾	
Bioaccumulation aquatic / sediment	SIDS Dossier on 1-Octadecanol	BCF = 100.000 L/kg	1993
Absorption/desorption	batch equilibrium method	Log K _{oc} = 5.67	2006
Acute fish toxicity	OECD 203	LC ₅₀ (96h) is greater than limit of solubility	03/1996
Acute daphnia immobilisation	DIN 38412, Part 11	EC ₅₀ (48h) = 1,700 mg/L	02/1992
Long-term toxicity to aquatic invertebrates	EPA OPPTS 850.1300	EC ₅₀ (21d) > 47.6 µg/L ⁷⁾ NOEC (21d) = 20.6 µg/L	
Long-term toxicity to fish	OECD 210	EC ₁₀ (33 d) 0.43 mg/l NOEC (33 d) 0.26 mg/l	2015 ⁸⁾
Algae growth inhibition test	DIN 38412, Part 9	EL ₅₀ and NOEC > 0.0011 mg/L (> limit of solubility)	04/1992
Toxicity to microorganisms	OECD Oxygen Consumption Test	EC ₀ (30 min) > 10,000 mg/L	1994

¹⁾ Publication: Studies in detoxication 46, The metabolism of aliphatic alcohols. The glucuronic acid conjugation of acyclic aliphatic alcohols.

²⁾ Read-across from cetyl alcohol: Publication: Percutaneous absorption of aliphatic compounds, Iwata Y, Moriya Y, Kobayashi T, 1987, Cosmet. Toiletries 102(2): 53-68.

³⁾ Read-across from myristyl alcohol

⁴⁾ Read-across from behenyl alcohol

⁵⁾ Read-across from 1-hexanol

⁶⁾ Read-across branched pentadecanol

⁷⁾ Read-across from octadecanol, branched

STEARYL ALCOHOL

Zusammenfassung der Produktdaten zur Toxikologie und Ökologie Summary of Product Data with Reference to Toxicology and Ecology

⁸⁾ Read-across from decan-1-ol

* Full Robust Study Summaries can be checked under the ECHA Registered Substance website and with the following registration number: 01-2119485907-20