

MATERIAL SAFETY DATA SHEET

Acc. to Regulation (EC) No 1907/2006 of the European Parliament as amended by Regulation (EU) 2020/878

Date of issue: 5 September 2016

Page: 1 / 11

Date of revision: 31 August 2021

Previous date: 30 August 2018

Version: 4.0

Product name:

desam effekt +

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**1.1 Product identifier**Trade name: **desam® effekt +****1.2 Relevant identified uses of the substance or mixture and uses advised against**

Intended or recommended use of the mixture: liquid disinfectant used for one-step cleaning and disinfection of all washable surfaces of medical devices.

Medical device cat. II a.

Uses advised against: The mixture should not be used for any other purpose than determined.

Do not use for non-ferrous metals (copper, brass), non-alloy steels, colour-unstable materials, silicone and polycarbonates.

1.3 Details of the supplier of the safety data sheet

Manufacturer trade name:

Schulke CZ, s.r.o.

Address:

Lidická 445, 735 81 Bohumín, Czech Republic

Company ID:

24301779

Phone number:

+420 558 320 260

e-mail:

schulkecz@schuelke.com

e-mail of person responsible

for the Safety Data Sheet:

MSDS@bochemie.cz**1.4 Emergency telephone number**

Toxikologické informační středisko, Na Bojišti 1, 128 08 Praha 2, Czech Republic: +420 224 91 92 93 or +420 224 91 54 02.

SECTION 2: HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture**

Acc. to Regulation No. 1272/2008/EC

Acute Tox. 4 (oral), H302; Skin Corr. 1B, H314; Eye Dam. 1, H318; Aquatic Acute 1, H400; Aquatic Chronic 1, H410

For the full wording of hazard statements see section 16.

The most important adverse physicochemical, human health and environmental effects: The mixture is harmful if swallowed. Causes severe skin burns and eye damage. Very toxic to aquatic life with long lasting effects.**2.2 Label elements**

Hazard pictograms:



Signal word:

Danger

Hazard statements:

H302 Harmful if swallowed.**H314** Causes severe skin burns and eye damage.**H410** Very toxic to aquatic life with long lasting effects.

Precautionary statements:

P273 Avoid release to the environment.**P280** Wear protective rubber gloves/protective clothing/eye protection/face protection.**P301+P330+P331** IF SWALLOWED: rinse mouth. Do NOT induce vomiting.**P303+P361+P353** IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].**P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**P310** Immediately call a POISON CENTER/doctor.**2.3 Other hazards**

The mixture does not meet the PBT/vPvB criteria according to REACH, annex XIII. The substance does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

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3.1 Substances

Not relevant.

3.2 Mixtures

3.2.1 Substances in the mixture

The preparation contains following substances classified as hazardous:

Hazardous components	% w/w	CAS ES Index number REACH number	Classification acc. to regulation 1272/2008/EC, CLP	Notes
Alkyl (C12-16) dimethylbenzyl ammonium chloride	19	68424-85-1 270-325-2 -- 01-2119970550-39	Acute Tox. 4, H302; Skin Corr. 1B, H314; Aquatic Acute 1, H400; Aquatic Chronic 1, H410	M acute=10 M chronic=1
2-Phenoxyethanol	10	122-99-6 204-589-7 603-098-00-9 01-2119488943-21	Acute Tox. 4, H302; Eye Dam. 1, H318	
2-(2-butoxyethoxy)ethanol	< 10	112-34-5 203-961-6 603-096-00-8 01-2119475104-44	Eye Irrit. 2, H319	
N-(3-aminopropyl)-N-dodecylpropan-1,3-diamine	7,2	2372-82-9 219-145-8 -- 01-2119980592-29	Acute Tox. 3, H301; Skin Corr. 1B, H314; STOT RE 2 (Iedviny), H373; Aquatic Acute 1, H400; Aquatic Chronic 1, H410	M acute=10 M chronic=1
Propan-2-ol	≤ 6	67-63-0 200-661-7 603-117-00-0 01-2119457558-25	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	
Decan-1-ol, ethoxylated	≤ 5	26183-52-8 Polymer -- --	Acute Tox.4, H302; Eye Dam 1, H318	
2-aminoethanol	< 5	141-43-5 205-483-3 603-030-00-8 01-2119486455-28	Acute Tox.4, H302-H312-H332; Skin Corr. 1B, H314; STOT SE 3, H335; Aquatic Chronic 3, H412	STOT SE 3; c≥5 %
Didecyl dimethylammonium-chloride	3	7173-51-5 230-525-2 612-131-00-6 --	Acute Tox. 4, H302; Skin Corr. 1B, H314; Eye Dam. 1, H318; Aquatic Acute 1 (M=10), H400; Aquatic Chronic 2, H411	M acute=10 M chronic=1

For the full wording of hazard statements see section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation: Shut off the source of exposure. Move the person to the fresh air, keep at rest (avoid even walking if necessary, seek medical attention.

Skin contact: Take off contaminated clothing immediately, wash contaminated skin with water, (according to the exposure extent) overlap with sterile bandage and seek medical attention.

Eye contact: Flush immediately with large amounts of fresh water at least 10 minutes to get the water under the eyelids, seek medical attention.

Ingestion: Rinse mouth with potable water and drink 0.2-0.5 L of water. Do not induce vomiting, seek medical aid. In case of spontaneous vomiting there is a risk of suffocation by spume originated from surfactants.

4.2 Most important symptoms and effects, both acute and delayed

Nausea, vomiting, swelling, burns, respectively other unidentified symptoms.

4.3 Indication of any immediate medical attention and special treatment needed.

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In case of eyes contact, ingestion and in other health problems or should the symptoms persist, always seek medical advice and provide information contained in this MSDS.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable: according to the character of the fire, the mixture is not flammable.

Unsuitable: not known, do not use water jet flow – risk of release to the sewers and environment.

5.2 Special hazards arising from the substance or mixture

Hazardous products in case of fire: Carbon monoxide, carbon dioxide, nitrous gases.

5.3 Advice for fire fighters

In case fires wear full protective clothing, eyes protection and suitable respiratory system protection. In case of release to the sewers act upon emergency plans.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear suitable personal protective equipment. Avoid contact with skin and eyes. Do not use the substance in the closed area. Do not eat, drink and smoke when handling the product.

6.2 Environmental precautions

Avoid contamination of water and soil, inform appropriate bodies in case of spillage of bigger amount of concentrated preparation into surface, ground or waste water – fire-fighting brigade, integrated security system, water stream (or sewerage system) controller.

6.3 Methods and material for containment and cleaning up

In case spill the product, use suitable absorbents (special absorbents for aggressive materials or universal absorbents) and put into the labelled lockable container. Avoid accidental discharge into sewers or water courses. In case of accidental discharge into sewers or water courses, dilute the product with sufficient amount of water act according to local regulations and emergency plans and notify local authorities.

6.4 Reference to other sections

See section 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Concentrated disinfectant can only be handled in areas with sufficient ventilation; use personal protective aids and avoid excessive contamination of personnel with the preparation. Avoid contact with other substances, in particular with acid preparations. Do not eat, drink and smoke during handling with the preparation. Areas and objects treated with preparation which are intended for contact with foodstuff must be thoroughly (several times) flushed with drinking water. Keep and store in closed containers, avoid spillage in the environment.

7.2 Conditions for safe storage, including any incompatibilities

Keep in original, well closed containers. Store in dry areas protected against weather conditions preventing possible spillage and entry of unauthorized persons. Do not keep exposed to direct sunlight. Store away from food, beverages and feed. Storage temperature: from -10 to +25°C.

7.3 Specific and use(s)

Important information is provided by material data safety sheet, by instructions on the label or on the web pages.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Exposure limits values

In accordance Regulation of Government No. 195/2021 of Czech Act Collection:

Substance	CAS	PEL (mg/m ³)	NPK-P (mg/m ³)	Conversion factor to ppm
2-(2-butoxyethoxy)ethanol	112-34-5	70	100	-
Isopropanol*	67-63-0	500	1000	0.407
2-aminoethanol	141-43-5	2.5	7.5	0.401

*Irritating to mucous membranes.

8.1.2 Biological limit values

Decree No 107/2013 of Czech Act Collection does not set indication limits of biological exposure tests.

8.1.3 Value of DNEL and PNEC

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	local	systemic	local	systemic	local	systemic	local	systemic
Inhalation	--	--	--	500 mg/m ³	--	--	--	89 mg/m ³
Dermal	--	--	--	888 mg/kg/d	--	--	--	319 mg/kg/d
Oral	Not required				--	--	--	26 mg/kg/d

PNEC

fresh water	141 mg/l
marine water	141 mg/l
fresh water, sediment	552 mg/kg
marine water, sediment	552 mg/kg
sewerage plant	24.8 mg/l
soil	28 mg/kg
intermittent release	--

2-(2-butoxyethoxy)ethanol

Route of exposure	worker				consumer			
	Acute exposure local	Acute exposure systemic	Chronic exposure local	Chronic exposure systemic	Acute exposure local	Acute exposure systemic	Chronic exposure local	Chronic exposure systemic
Inhalation	101.2 mg/m ³	--	67.5 mg/m ³	67.5 mg/m ³	60.7 mg/m ³	--	40.5 mg/m ³	40.5 mg/m ³
Dermal	--	--	--	83 mg/kg/d	--	--	--	50 mg/kg/d
Oral	Not required				--	--	--	5 mg/kg/d

PNEC

fresh water	1.1 mg/l
marine water	0.11 mg/l
fresh water, sediment	4.4 mg/kg
marine water, sediment	0.44 mg/kg
sewerage plant	200 mg/l
soil	0.32 mg/kg
intermittent release	11 mg/l

2-aminoethanol

Route of exposure	worker				consumer			
	Acute exposure local	Acute exposure systemic	Chronic exposure local	Chronic exposure systemic	Acute exposure local	Acute exposure systemic	Chronic exposure local	Chronic exposure systemic
Inhalation	--	--	3.3 mg/m ³	--	--	--	2 mg/m ³	--
Dermal	--	--	--	1 mg/kg bw/d	--	--	--	0.24 mg/kg bw/d
Oral	Not required				--	--	--	3.75 mg/kg bw/d

PNEC

fresh water	0.085 mg/l
marine water	0.0085 mg/l
fresh water, sediment	0.434 mg/kg
marine water, sediment	0.0434 mg/kg
sewerage plant	100 mg/l
soil	1.29 mg/kg
intermittent release	0.028 mg/l

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8.2 Exposure controls

8.2.1 Appropriate engineering controls

Observe conditions of handling and storage, secure effective ventilation. Avoid contamination of personnel with the preparation and working solutions, avoid contact with skin and mucous membranes with the preparation and working solutions, observe usual work safety conditions, wash your hands thoroughly after work. Secure that only personnel using personal protective aids and acquainted with nature of the preparation, instructions for use and conditions of personal and environmental protection is allowed to work with the preparation. Wash your hands thoroughly with water and soap after work, use reparation cream.

8.2.2 Individual protection measures, such as personal protective equipment

Eye/face protection: protective goggles or face shield EN166.

Skin protection: work clothing and boots (closed), use moisturising creams after work and after washing.

Hand protection: rubber (nitrile rubber, butyl rubber, polyvinyl chloride, neoprene) gloves EN374, permeance >480 min.

Respiratory protection: during use ensure respiratory protection – respirator against organic vapours, type A.

8.2.3 Environmental exposure controls

Observe instructions for handling and storage, particularly ensure provisions preventing spill of concentrated mixture into watercourses, soil and sewerage (for further information see Handling Conditions according to Act No 254/2001 of Czech Act Coll., on Waters).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state (°C):	liquid
Colour:	yellowish
Odour:	perfumed
Melting point/Freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Flammability:	not flammable
Lower and upper explosion limit:	not determined
Flash point:	not determined
Auto-ignition temperature;	not flammable
Decomposition temperature:	not estimated
pH (at 20°C):	10.4 – 11.0 (1 % working solution)
Kinematic viscosity:	not determined
Solubility:	miscible
Partition coefficient n-octanol/water:	not determined
Vapour pressure (°C):	not determined
Density and/or relative density (20°C):	0.98-0.99
Relative vapour density:	not determined
Particle characteristics	irrelevant

9.2 Other information

A mixture was tested according to the test in Part III, subsection 37.4 of the UN RTDG, Manual of Tests and Criteria – the mixture is non-corrosive to metal.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The mixture reacts with acids and strong oxidizing and reducing agents.

10.2 Chemical stability

It is stable in common conditions of use and storage (observing the temperature ranges for storage, securing against the effects of radiating heat and intensive sunlight, eliminating fluctuating temperatures during storage).

10.3 Possibility of hazardous reactions

Reaction with acids and strong oxidizing and reducing agents, powder metals, the possibility of a hazardous chemical reaction.

10.4 Conditions to avoid

Avoid raised temperature, long-lasting direct exposure to sun and actuation of acids, strong oxidizing and reducing agents.

10.5 Incompatible materials

Strong oxidising and reducing agents and acids.

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10.6 Hazardous decomposition products

Carbon monoxide, nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

a) acute toxicity:	Calculated: ATE _{mix} oral, classified. <u>Alkyl (C12-16) dimethylbenzyl ammonium chloride</u> LD50 oral, rat = 397.5 mg/kg LD50 dermal, rat > 2,000 mg/kg <u>N-(3-aminopropyl)-N-dodecylpropan-1,3-diamine</u> LD50 oral, rat = 261 mg/kg (OECD 401) LD50 dermal, rat > 600 mg/kg (OECD 402) <u>Propan-2-ol</u> LD50, oral, rat > 2000 mg/kg LD50 dermal, rat > 2000 mg/kg LC50, inhal > 20 mg/kg/8 h <u>2-(2-butoxyethoxy)ethanol</u> LD50 dermal, oral > 2000 mg/kg <u>2-aminoethanol</u> LD50, oral, rat = 1,515 mg/kg LD50, dermal, rabbit > 2,000 mg/kg LC50, inhal, pro mist: rat > 1.3 mg/l / 6 h <u>Didecyldimethyl-ammonium chloride</u> LD50 oral, rat = 658 mg/kg LD50 dermal, rat >2,000 mg/kg <u>Decan-1-ol, ethoxylated</u> LD50, oral, rat > 2000 mg/kg LD50 dermal, rat > 2000 mg/kg LC50, inhal > 1,6 mg/kg/4 h (similar substance) <u>2-Phenoxyethanol</u> LD50, oral, rat = 1,850 mg/kg
b) skin corrosion/irritation:	The mixture causes severe skin burns.
c) serious eye damage/irritation:	The mixture causes serious eye damage.
d) respiratory or skin sensitization:	Criteria for classification are not met based on available data
e) germ cell mutagenicity:	Criteria for classification are not met based on available data.
f) carcinogenicity:	Criteria for classification are not met based on available data
g) reproductive toxicity:	Criteria for classification are not met based on available data.
h) STOT-single exposure:	Criteria for classification are not met based on available data.
i) STOT-repeated exposure:	Criteria for classification are not met based on available data
j) aspiration hazard:	Criteria for classification are not met based on available data.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not established for this mixture.

Alkyl (C12-16) dimethylbenzyl ammonium chloride

Toxicity to fish	LC50	0.515 mg/l/96 h
Toxicity to daphnia	EC50	0.0161 mg/l/48 h
Toxicity to algae	IC50	0.03 mg/l/96 h
Toxicity to bacteria	IC50	0.009 mg/l

2-(2-butoxyethoxy)ethanol

Toxicity to fish, Leuciscus idus	LC50	>100 mg/l/96 h; static test
Toxicity to Daphnia, Daphnia magna	EC50	>100 mg/l/48 h; immobilization test
Toxicity to algae, Scenedesmus subs.	EC50	>100 mg/l/96 h; static test
Toxicity to bacteria	EC50	1170 mg/l; static test

N-(3-aminopropyl)-N-dodecylpropan-1,3-diamine

Toxicity to fish, Lepomis macrochirus	LC50	0.45 mg/l/96 h (OECD 203)
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Toxicity to fish, <i>Oncorhynchus mykiss</i>	LC50	0.68 mg/l/96 h (OECD203)
Toxicity to daphnia, <i>Daphnia magna</i>	EC50	0.073 mg/l/48 h (US EPA)
Chronic toxicity to daphnia, <i>Daphnia magna</i>	NOEC	0.032 mg/l/21 days
Toxicity to algae, <i>Pseudokirchneriella subcapitata</i>	ErC50	0.054 mg/l/96 h
Chronic toxicity to algae, <i>Desmodesmus subspicatus</i>	NOEC	0.0069 mg/l/72 h (OECD201)
Toxicity to activated sludge	EC50	18 mg/l/3 h (OECD 209)

Propan-2-ol

Toxicity to fish, <i>Leuciscus idus</i>	LC50	>100 mg/l/96 h
Toxicity to daphnia, <i>Daphnia magna</i>	EC50	>100 mg/l/48 h
Toxicity to algae, <i>Scenedesmus quadricauda</i>	IC50	>100 mg/l/72 h

Ethoxylated (EO 8) alcohol C10

Toxicity to fish, <i>Pimephales promelas</i>	LC50	22.5 mg/l/96 h
Toxicity to daphnia, <i>Daphnia magna</i>	EC50	15 mg/l/48 h (OECD202)
Toxicity to algae	EC50	19.6 mg/l/72 h (OECD201)

2-aminoethanol

Toxicity to fish, <i>Carassius auratus</i>	LC50	170 mg/l/96 h
Toxicity to fish, <i>Cyprinus carpio</i>	LC50	349 mg/l/96 h
Chronic toxicity to fish, <i>Oryzias latipes</i>	NOEC	1,2 mg/l/30 days
Toxicity to daphnia, <i>Daphnia magna</i>	EC50	27,04 mg/l/48 h
Chronic toxicity to daphnia, <i>Daphnia magna</i>	NOEC	0,85 mg/l/21 days
Toxicity to algae, <i>Scenedesmus subs.</i>	EC50	2,8 mg/l/72 h
Toxicity to algae, <i>Pseudokirchneriella subcapitata</i>	NOEC	0,7 mg/l/72 h
Toxicity to microorganisms, <i>Pseudomonas putida</i>	EC50	110 mg/l/16 h

Didecyldimethyl-amonium chloride

Toxicity to fish, <i>Brachydanio rerio</i>	LC50	0.49 mg/l/96 h
Toxicity to daphnia, <i>Daphnia magna</i>	EC50	0.03 mg/l/48 h
Toxicity to algae, <i>Selenastrum capricornutum</i>	EC50	0.06 mg/l/72 h
Chronic toxicity to algae, <i>Pseudokirchneriella subcapitata</i>	NOEC	0.013 mg/l/72 h
Chronic toxicity to daphnia, <i>Daphnia magna</i>	NOEC	0.021 mg/l/21 d

2-Phenoxyethanol

Toxicity to fish, <i>Pimephales promelas</i>	LC50	> 100 mg/l/96 h
Toxicity to daphnia, <i>Daphnia magna</i>	EC50	> 100 mg/l/48 h
Toxicity to algae, <i>Scenedesmus subspicatus</i>	EC50	> 100 mg /l/96 h
Chronic toxicity to fish, <i>Pimephales promelas</i>	NOEC	> 1 mg/l/34 days
Chronic toxicity to daphnia, <i>Daphnia magna</i>	NOEC	> 1 mg/l/21 days

12.2 Persistence and degradability

Components of the preparation are gradually degradable in the environment. Used surfactants are degradable in more than 90%.

Alkyl (C12-16) dimethylbenzyl ammonium chloride

Readily biodegradable.

2-(2-butoxyethoxy)ethanol

Readily biodegradable: OECD 301E, biodegradation: 70%, 28 days.

Readily biodegradable: OECD 301C, biodegradation: 76%, 28 days.

Activated sludge, aerobic: OECD 302B, biodegradation: 100%, 28 days.

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine

Method: OECD 303 A, Biodegradability test: 96 %, testing period: 12-15 days;

Method: OECD 302 B, biodegradability: 91 %, Testing period 28 days.

Method: OECD 302 B, Culture method (test in closed bottle): 79 %, testing period: 28 days;

Readily biodegradable.

Propan-2-ol

The product is biodegradable, biodegradability>53% (10 days).

2-aminoethanol

OECD 301 A: biodegradation > 90 % (21 days), activated sludge, aerobic.

Didecyldimethyl-amonium chloride

Method: OECD 301 D (closed-bottle test, activated sludge), biological degradability > 70%, readily biodegradable.

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Decan-1-ol, ethoxylated

The product is biodegradable, biodegradability > 60% (28 days), OECD301B.

2-Phenoxyethanol

biodegradation > 70 % DOC (15 d) (OECD 301 A (new)) (aerobic, activated sludge, household sludge)

12.3 Bioaccumulative potential

No bioaccumulative potential.

12.4 Mobility in soil

Components are soluble in water.

12.5 Results of PBT and vPvB assessment

The mixture does not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6 Endocrine disrupting properties

The product does not contain the substances included in the list endocrine disruptors accordance to with Article 59(1) REACH.

12.7 Other adverse effects

Toxicity for other environment was not determined.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

a) Recommended Methods of Substance and Contaminated Packaging Disposal

According to Waste Catalogue, it is dangerous waste. Personal protective equipment should be used and provisions to be applied when handling and collecting wastes regarding protection of waste spill into environment. Waste hand over to specialized competent company, if need be hand over within the framework of dangerous waste collection in your community. Use absorbents dispose of as dangerous waste. Contaminated packaging should be disposed of as hazardous waste.

b) Physical/chemical properties that may affect waste treatment options

Avoid contact with acids, alkalis, strong oxidizing and reducing agents.

c) Sewage disposal shall be discouraged

Waste should not be disposed of by release to sewers.

d) Special precautions for any recommended waste treatment

Suggestion of waste classification:

Subgroup	16 03	off-specification batches and unused products
	16 03 05*	organic wastes containing dangerous substances
Event.	20 01	separately collected fractions
	20 01 29*	detergents containing dangerous substances

Suggestion of waste container classification

Containers with residues of the mixture:

15 01 10*	packaging containing residues of or contaminated by dangerous substances.
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Waste Legal Regulations

Directive 2008/98/EC on waste and repealing certain Directives. If this mixture and its packaging become waste, the last user has to assign relevant waste code – European Waste Code (EWC code) according to Commission Decision (2000/532/EC).

SECTION 14: TRANSPORT INFORMATION

14.1 UN number or ID number	1760
14.2 UN proper shipping name:	CORROSIVE LIQUID, N.O.S. (quaternary ammonium compounds)
14.3 Transport hazard class(es):	8
14.4 Packing group:	II
14.5 Environmental hazards:	YES
14.6 Special precautions for user:	--
14.7 Maritime transport in bulk according to IMO instrument:	CORROSIVE LIQUID, N.O.S. (quaternary ammonium compounds)
Danger code (Kemler):	80
Limited quantities (LQ):	1 L

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Legislation regulating individual issues of the environmental protection and occupational hygiene conditions.

Regulation No. 1907/2006 (REACH).

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Regulation No. 1272/2008/EC (CLP).

Regulation No. 648/2004/EC on detergents.

Regulation No. 745/2017/EU on medical devices.

Directive 93/42/EEC concerning medical devices.

15.2 Chemical safety assessment

A Chemical Safety Assessment was not carried out for the mixture.

SECTION 16: OTHER INFORMATION

a) Changes during Revision of the MSDS

Version 4.0 – update of classification based on raw materials, a new information about product, see section 8, 11, 12 and other, a new format of MSDS.

The updating sections are indicated with bold line:

b) A key or legend to abbreviations and acronyms used

Flam. Liq.	Flammable liquid
Acute Tox.	Acute toxicity
Skin Corr.	Skin corrosion
Eye Dam.	Serious eye damage
Eye Irrit.	Eye irritation
STOT SE	Specific target organ toxicity – single exposure
STOT RE	Specific target organ toxicity – repeated exposure
Aquatic Acute	Hazardous to the aquatic environment – acute
Aquatic Chronic	Hazardous to the aquatic environment – chronic
LD50	Lethal Dose, 50% death
LC50	Lethal concentration, 50 percent death
EC50	Effective Concentration, 50 percent death
IC50	Inhibition concentration
PBT	Persistent, Bioaccumulative and Toxic
vPvB	Very Persistent and Very Bioaccumulative
NOEC	No Observed Effect Concentration
DNEL	Derived no-effect level
PNEC	Predicted no-effect concentration

c) Key literature references and sources for data

Information contained herein is based on our best knowledge and current legislation, according to regulation 1272/2008/EC. The Material Safety Data Sheet was elaborated on grounds of information provided by suppliers of particular components of the mixture. The MSDS contains information needed for security of safety and occupational health protection and the environmental protection. The mentioned information refers to present state of knowledge and experience and is in accordance with legislation in force. It cannot be considered warrantee of suitability or usability of the product for particular application.

d) The methods of evaluating information

The mixture was classified according to method described in Regulation 1272/2008/EC.

e) List of relevant hazard statements

H 225	Highly flammable liquid and vapour.
H 301	Toxic if swallowed.
H 302	Harmful if swallowed.
H 312	Harmful in contact with skin.
H 314	Causes severe skin burns and eye damage.
H 318	Causes serious eye damage.
H 319	Causes serious eye irritation.
H 332	Harmful if inhaled
H 336	May cause drowsiness or dizziness.
H 373	May cause damage to organs through prolonged or repeated exposure.
H 400	Very toxic to aquatic life.
H 410	Very toxic to aquatic life with long lasting effects.
H 411	Toxic to aquatic life with long-lasting effects

f) Instructions for Training

MATERIAL SAFETY DATA SHEET

Acc. to Regulation (EC) No 1907/2006 of the European Parliament as amended by Regulation (EU) 2020/878

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Product name:

desam effekt +

Personnel handling the preparation must be instructed about manipulation risks and on requirements for health and environmental protection (relevant provisions of the Labor Code as amended) and further, they must be demonstrably familiarized with dangerous properties, occupational health and environmental protection principles and first aid measures (Act No. 258/2000 Coll. on public health protection as amended).

g) Recommended Use Limitations

The substance should not be used for any other purpose than determined (see section 1.2). As specific conditions of use of the substance are beyond control of the supplier, the user is the only responsible to adapt the information and warnings contained herein to local legislation and regulations. The safety information describes the product from perspective of its safety and it cannot be deemed technical specifications of the product.