according to Regulation (EC) No. 1907/2006 (REACH)

Silicone oil TT 5, dried, low viscosity, 5 cSt

article number: 1971 date of compilation: 07.04.2021 Version: 3.0 en Revision: 03.03.2024

Replaces version of: 24.10.2022

Version: (2)

SECTION 1: Identification of the substance/mixture and of the company/ undertaking

Product identifier 1.1

Identification of the substance Silicone oil TT 5, dried, low viscosity, 5 cSt

Article number 1971

Registration number (REACH) The substance does not require registration ac-

cording to Regulation (EC) No 1907/2006 [REACH].

EC number 613-156-5 CAS number 63148-62-9

Alternative name(s) Polydimethylsiloxane

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: Laboratory chemical

Laboratory and analytical use

Uses advised against: Do not use for private purposes (household).

Food, drink and animal feedingstuffs.

1.3 Details of the supplier of the safety data sheet

> Carl Roth GmbH + Co. KG Schoemperlenstr. 3-5 D-76185 Karlsruhe Germany

Telephone:+49 (0) 721 - 56 06 0 Telefax: +49 (0) 721 - 56 06 149 e-mail: sicherheit@carlroth.de Website: www.carlroth.de

Competent person responsible for the safety data
Department Health, Safety and Environment

sheet:

sicherheit@carlroth.de e-mail (competent person):

Emergency telephone number 1.4

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

This substance does not meet the criteria for classification in accordance with Regulation No 1272/ 2008/EC.

2.2 **Label elements**

Labelling according to Regulation (EC) No 1272/2008 (CLP)

not required

2.3 Other hazards

Special danger of slipping by leaking/spilling product.

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Results of PBT and vPvB assessment

The substance was identified as a PBT (persistent, bioaccumulative and toxic). The substance was identified as a vPvB (very persistent and very bioaccumulative). Non-classified PBT substance. Non-classified vPvB substance.

Endocrine disrupting properties

The substance has an endocrine disrupting potential.

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance Silicone oil Molecular formula $(C_2H_6OSi)n$ CAS No 63148-62-9 EC No 613-156-5

Impurities/additives/constituents:

Name of substance	Identifier	Wt%
Dodecamethylcyclohexasiloxane	CAS No 540-97-6	0,1 - 3
	EC No 208-762-8	
Decamethylcyclopentasiloxane	CAS No 541-02-6	0,1 - 3
	EC No 208-764-9	
Octamethylcyclotetrasiloxane	CAS No 556-67-2	0,1 – 1
	EC No 209-136-7	
	Index No 014-018-00-1	

Remarks

For full text of abbreviations: see SECTION 16

SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

No special measures are necessary.

Following inhalation

Provide fresh air.

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Following skin contact

Wash with plenty of soap and water.

Following eye contact

Rinse cautiously with water for several minutes.

Following ingestion

Rinse mouth. Call a doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures

5.1 Extinguishing media



Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings! water spray, dry extinguishing powder, BC-powder, carbon dioxide (CO₂)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Combustible.

Hazardous combustion products

In case of fire may be liberated: Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

Special danger of slipping by leaking/spilling product.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

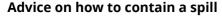
6.3 Methods and material for containment and cleaning up

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Covering of drains.

Other information relating to spills and releases

Place in appropriate containers for disposal.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Provision of sufficient ventilation.

Advice on general occupational hygiene

Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed.

Incompatible substances or mixtures

Observe hints for combined storage.

Consideration of other advice:

Specific designs for storage rooms or vessels

Recommended storage temperature: 15 - 25 °C

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

This information is not available.

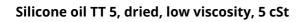
Relevant DNELs of components

Name of sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time
Dodecamethylcyclo- hexasiloxane	540-97-6	DNEL	11 mg/m³	human, inhalat- ory	worker (industry)	chronic - systemic effects
Dodecamethylcyclo- hexasiloxane	540-97-6	DNEL	1,22 mg/ m³	human, inhalat- ory	worker (industry)	chronic - local ef- fects
Dodecamethylcyclo- hexasiloxane	540-97-6	DNEL	6,1 mg/m ³	human, inhalat- ory	worker (industry)	acute - local ef- fects
Decamethylcyclo- pentasiloxane	541-02-6	DNEL	97,3 mg/ m³	human, inhalat- ory	worker (industry)	chronic - systemic effects
Decamethylcyclo- pentasiloxane	541-02-6	DNEL	97,3 mg/ m³	human, inhalat- ory	worker (industry)	acute - systemic effects

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Relevant DNELs of components

Name of sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time
Decamethylcyclo- pentasiloxane	541-02-6	DNEL	24,2 mg/ m³	human, inhalat- ory	worker (industry)	chronic - local ef- fects
Decamethylcyclo- pentasiloxane	541-02-6	DNEL	24,2 mg/ m³	human, inhalat- ory	worker (industry)	acute - local ef- fects
Octamethylcyclotet- rasiloxane	556-67-2	DNEL	73 mg/m³	human, inhalat- ory	worker (industry)	chronic - systemic effects
Octamethylcyclotet- rasiloxane	556-67-2	DNEL	73 mg/m³	human, inhalat- ory	worker (industry)	acute - systemic effects
Octamethylcyclotet- rasiloxane	556-67-2	DNEL	73 mg/m³	human, inhalat- ory	worker (industry)	chronic - local ef- fects
Octamethylcyclotet- rasiloxane	556-67-2	DNEL	73 mg/m³	human, inhalat- ory	worker (industry)	acute - local ef- fects

Relevant PNECs of components

Name of sub-	CAS No	End-	Threshol	Organism	Environmental	Exposure time
stance		point	d level		compartment	
Dodecamethylcyclo- hexasiloxane	540-97-6	PNEC	1 ^{mg} / _l	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Dodecamethylcyclo- hexasiloxane	540-97-6	PNEC	13 ^{mg} / _{kg}	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
Dodecamethylcyclo- hexasiloxane	540-97-6	PNEC	1,3 ^{mg} / _{kg}	aquatic organ- isms	marine sediment	short-term (single instance)
Dodecamethylcyclo- hexasiloxane	540-97-6	PNEC	3,77 ^{mg} / _{kg}	terrestrial organ- isms	soil	short-term (single instance)
Decamethylcyclo- pentasiloxane	541-02-6	PNEC	1,2 ^{µg} / _l	aquatic organ- isms	freshwater	short-term (single instance)
Decamethylcyclo- pentasiloxane	541-02-6	PNEC	0,12 ^{µg} / _l	aquatic organ- isms	marine water	short-term (single instance)
Decamethylcyclo- pentasiloxane	541-02-6	PNEC	10 ^{mg} / _l	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Decamethylcyclo- pentasiloxane	541-02-6	PNEC	11 ^{mg} / _{kg}	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
Decamethylcyclo- pentasiloxane	541-02-6	PNEC	1,1 ^{mg} / _{kg}	aquatic organ- isms	marine sediment	short-term (single instance)
Decamethylcyclo- pentasiloxane	541-02-6	PNEC	1,27 ^{mg} / _{kg}	terrestrial organ- isms	soil	short-term (single instance)
Octamethylcyclotet- rasiloxane	556-67-2	PNEC	1,5 ^{µg} / _l	aquatic organ- isms	freshwater	short-term (single instance)
Octamethylcyclotet- rasiloxane	556-67-2	PNEC	0,15 ^{µg} / _I	aquatic organ- isms	marine water	short-term (single instance)
Octamethylcyclotet- rasiloxane	556-67-2	PNEC	10 ^{mg} / _l	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Octamethylcyclotet- rasiloxane	556-67-2	PNEC	3 ^{mg} / _{kg}	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)

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Relevant PNECs of components

Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Octamethylcyclotet- rasiloxane	556-67-2	PNEC	0,3 ^{mg} / _{kg}	aquatic organ- isms	marine sediment	short-term (single instance)
Octamethylcyclotet- rasiloxane	556-67-2	PNEC	0,54 ^{mg} / _{kg}	terrestrial organ- isms	soil	short-term (single instance)

8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection





Use safety goggle with side protection.

Skin protection





hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374.

type of material

NBR (Nitrile rubber)

material thickness

>0,11 mm

breakthrough times of the glove material

>480 minutes (permeation: level 6)

other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

Respiratory protection





Respiratory protection necessary at: Aerosol or mist formation. Type: A (against organic gases and vapours with a boiling point of > 65 $^{\circ}$ C , colour code: Brown). Usually no personal respirative protection necessary.

Environmental exposure controls

Keep away from drains, surface and ground water.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state liquid
Form viscous
Colour colourless
Odour odourless

Melting point/freezing point not determined

Boiling point or initial boiling point and boiling not determined

range

Flammability this material is combustible, but will not ignite

readily

Lower and upper explosion limit not determined

Flash point 120 °C

Auto-ignition temperature not determined

Decomposition temperature >150 °C

pH (value) not determined

Kinematic viscosity 4,5-5,5 mm²/_s at 25 °C

Solubility(ies)

Water solubility (The study does not need to be conducted be-

cause the substance is known to be insoluble in

water)

Solubility in hydrocarbons, aliphatic soluble
Solubility in hydrocarbons, aromatic soluble

Solubility in ethylene glycol practically insoluble

Solubility in ethyl acetate soluble
Solubility in n-butyl acetate soluble
Solubility in toluene soluble
Solubility in trichloroethylene soluble

Solubility in methanol practically insoluble

Solubility in trichloromethane (chloroform) soluble

Partition coefficient

Partition coefficient n-octanol/water (log value): this information is not available

Vapour pressure not determined

Density and/or relative density

Density 0,92 – 0,93 ^g/_{cm³} at 25 °C

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Relative vapour density Information on this property is not available.

Particle characteristics not relevant (liquid)

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard

classes:

hazard classes acc. to GHS (physical hazards): not relevant

Other safety characteristics:

Temperature class (EU, acc. to ATEX)

Maximum permissible surface temperature on

the equipment: 300°C

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions.

If heated

Vapours may form explosive mixtures with air.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

Violent reaction with: strong oxidiser

10.4 Conditions to avoid

Keep away from heat. Decompostion takes place from temperatures above: >150 °C.

10.5 Incompatible materials

There is no additional information.

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

Classification according to GHS (1272/2008/EC, CLP)

This substance does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

Acute toxicity

Shall not be classified as acutely toxic.

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Acute toxicity										
Exposure route	Endpoint	Value	Species	Method	Source					
oral	LD50	>5.000 ^{mg} / _{kg}	rat		TOXNET					
dermal	LD50	>2.000 ^{mg} / _{kg}	rabbit		TOXNET					

Acute toxicity of components

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Dodecamethylcyclohexasiloxane	540-97-6	oral	LD50	>2.000 ^{mg} / _{kg}	rat
Dodecamethylcyclohexasiloxane	540-97-6	dermal	LD50	>2.000 ^{mg} / _{kg}	rat
Decamethylcyclopentasiloxane	541-02-6	oral	LD50	>5.000 ^{mg} / _{kg}	rat
Decamethylcyclopentasiloxane	541-02-6	inhalation: dust/mist	LC50	8,67 ^{mg} / _l /4h	rat
Decamethylcyclopentasiloxane	541-02-6	dermal	LD50	>2.000 ^{mg} / _{kg}	rabbit
Octamethylcyclotetrasiloxane	556-67-2	oral	LD50	>4.800 ^{mg} / _{kg}	rat
Octamethylcyclotetrasiloxane	556-67-2	inhalation: dust/mist	LC50	36 ^{mg} / _l /4h	rat

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

If swallowed

Data are not available.

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• If in eyes

Data are not available.

If inhaled

Data are not available.

• If on skin

Data are not available.

Other information

Health effects are not known. This information is based upon the present state of our knowledge.

11.2 Endocrine disrupting properties

Endocrine disrupting chemicals (EDC)

Name of substance	CAS No	Combined cat- egory	Human health category	Wildlife cat- egory
Octamethylcyclotetrasiloxane	556-67-2	CAT1	CAT1	CAT3b

Legend

CAT1 Category 1 - evidence of endocrine disruption in at least one species using intact animals CAT3b Category 3b - no evidence of endocrine disruption or no data available

11.3 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute) of components

_					
Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time
Dodecamethylcyclo- hexasiloxane	540-97-6	ErC50	>2 ^{µg} / _l	algae	72 h
Decamethylcyclo- pentasiloxane	541-02-6	LC50	>16 ^{µg} / _l	fish	96 h
Decamethylcyclo- pentasiloxane	541-02-6	EC50	>2,9 ^{µg} / _l	aquatic invertebrates	48 h
Octamethylcyclotet- rasiloxane	556-67-2	LC50	>22 ^{µg} / _I	fish	96 h
Octamethylcyclotet- rasiloxane	556-67-2	EC50	>15 ^{µg} / _I	aquatic invertebrates	48 h
Octamethylcyclotet- rasiloxane	556-67-2	ErC50	>22 ^{µg} / _I	algae	96 h

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Aquatic toxicity (chronic) of components

Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time
Dodecamethylcyclo- hexasiloxane	540-97-6	EC50	>100 ^{mg} / _l	microorganisms	3 h
Decamethylcyclo- pentasiloxane	541-02-6	EC50	>15 ^{µg} / _I	aquatic invertebrates	21 d
Octamethylcyclotet- rasiloxane	556-67-2	EC50	>15 ^{µg} / _I	aquatic invertebrates	21 d

12.2 Persistence and degradability

Biodegradation

Not readily biodegradable.

Degradability of components

Name of substance	CAS No	Process	Degrada- tion rate	Time	Method	Source
Dodecamethyl- cyclohexasilox- ane	540-97-6	carbon dioxide generation	4,47 %	28 d		ECHA
Decamethyl- cyclopentas- iloxane	541-02-6	carbon dioxide generation	0,14 %	28 d		ECHA
Octamethylcyc- lotetrasiloxane	556-67-2	carbon dioxide generation	3,7 %	29 d		ECHA

12.3 Bioaccumulative potential

Data are not available.

Bioaccumulative potential of components

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Dodecamethylcyclohexasiloxane	540-97-6	1.160	8,87 (23,6 °C)	
Decamethylcyclopentasiloxane	541-02-6	7.060	8,023 (25,3 °C)	
Octamethylcyclotetrasiloxane	556-67-2	12.400	6,488 (25,1 °C)	

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

The substance was identified as a PBT (persistent, bioaccumulative and toxic). The substance was identified as a vPvB (very persistent and very bioaccumulative).

12.6 Endocrine disrupting properties

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Endocrine disrupting chemicals (EDC)

Name of substance	CAS No	Combined cat- egory	Human health category	Wildlife cat- egory
Octamethylcyclotetrasiloxane	556-67-2	CAT1	CAT1	CAT3b

Legend

CAT1 Category 1 - evidence of endocrine disruption in at least one species using intact animals CAT3b Category 3b - no evidence of endocrine disruption or no data available

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods



Consult the appropriate local waste disposal expert about waste disposal.

Sewage disposal-relevant information

Do not empty into drains.

Waste treatment of containers/packagings

Handle contaminated packages in the same way as the substance itself. Completely emptied packages can be recycled.

13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

Properties of waste which render it hazardous

HP 10 toxic for reproduction

HP 14 ecotoxic

13.3 Remarks

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Please consider the relevant national or regional provisions. Non-contaminated packages may be recycled.

SECTION 14: Transport information

14.1 UN number or ID number not subject to transport regulations

14.2 UN proper shipping name not assigned

14.3 Transport hazard class(es) none

14.4 Packing group not assigned

14.5 Environmental hazards non-environmentally hazardous acc. to the dan-

gerous goods regulations

14.6 Special precautions for user

There is no additional information.

14.7 Maritime transport in bulk according to IMO instruments

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The cargo is not intended to be carried in bulk.

14.8 Information for each of the UN Model Regulations

International Maritime Dangerous Goods Code (IMDG) - Additional information Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information Not subject to ICAO-IATA.

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)

Name of substance	Name acc. to inventory	CAS No	Restriction	No
Dodecamethylcyclohexasiloxane	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3
Decamethylcyclopentasiloxane	decamethylcyclopentasiloxane	541-02-6	R70	70
Decamethylcyclopentasiloxane	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3
Octamethylcyclotetrasiloxane	octamethylcyclotetrasiloxane	556-67-2	R70	70
Octamethylcyclotetrasiloxane	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3
Octamethylcyclotetrasiloxane	flammable / pyrophoric		R40	40
Octamethylcyclotetrasiloxane	substances in tattoo inks and permanent make-up		R75	75

Legend

1. Shall not be used in:

- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,

tricks and jokes,

- games for one or more participants, or any article intended to be used as such, even with ornamental aspects,
2. Articles not complying with paragraph 1 shall not be placed on the market.
3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume,

can be used as fuel in decorative oil lamps for supply to the general public, and

- present an aspiration hazard and are labelled with H304.

 4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation
- (CEN).
 5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following require-
- (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil or even sucking the wick of lamps may lead to life-threatening lung damage"; (b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage'; (c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black

opaque containers not exceeding 1 litre by 1 December 2010.';

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Legend

1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:

- metallic glitter intended mainly for decoration, R40

- artificial snow and frost,
- 'whoopee' cushions,
- silly string aerosols,

- imitation excrement, horns for parties, decorative flakes and foams,
- artificial cobwebs,
- stink bombs.
- 2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with:

 "For professional users only."
- 3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC (2).
- 4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to
- the requirements indicated.

 1. Shall not be placed on the market in wash-off cosmetic products in a concentration equal to or greater than 0,1 % by weight of either substance, after 31 January 2020.

 2. For the purposes of this entry, "wash-off cosmetic products" means cosmetic products as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009 that, under normal conditions of use, are washed off with water after application. R70

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Legend

R75

1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:

(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category

1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight; (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by

(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:

(i) 0,1 % by weight, if the substance is used solely as a pH regulator

(ií) 0,01 % by weight, in all other cases;

(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*1), the substance is present in the

mixture in a concentration equal to or greater than 0,00005 % by weight;

(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:

(i) "Rinse-off products";
(ii) "Not to be used in products applied on mucous membranes";
(iii) "Not to be used in eye products";

(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concen-

(n) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.

2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

as also falls within one of more of points (a) to (g) of paragraph 1, the concentration limit faid down in point (ii) of paragraph 1 shall apply to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that now or revised classification in fifty the date referred to in paragraph 1 or as the case may be paragraph. plication of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the

amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

(a) the statement "Mixture for use in tattoos or permanent make-up";

(a) the statement "Mixture for use in tattoos or permanent make-up";
(b) a reference number to uniquely identify the batch;
(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

tion limit specified in Appendix 13

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below

the concentration limit specified in Appendix 13; (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this para-

graph. 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.

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Legend

9. This entry does not apply to substances that are gases at temperature of 20 $^{\circ}$ C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 $^{\circ}$ C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

Substance of Very Hig	h Conce	rn (SVHC)				
Name acc. to invent- ory	CAS No	Listed in	Remarks	Latest application date	Sunset date	Date of in- clusion
dodecamethylcyclo- hexasiloxane	540-97- 6	Candidate list	PBT A57d vPvB A57e			27.06.2018
decamethylcyclopentasilox- ane	541-02- 6	Candidate list	PBT A57d vPvB A57e			27.06.2018
octamethylcyclotetrasilox- ane	556-67- 2	Candidate list	PBT A57d vPvB A57e			27.06.2018

Legend

Candidate list PBT A57d vPvB A57e Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV Persistent, Bioaccumulative and Toxic (article 57d) Very Persistent and very Bioaccumulative (article 57e)

Seveso Directive

2012/	2012/18/EU (Seveso III)				
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements	Notes		
	not assigned				

Deco-Paint Directive

VOC content	0 %
VOC content	0 ^g / _l

Industrial Emissions Directive (IED)

VOC content	0 %
VOC content	0 ^g / _l

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

not listed

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

not listed

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Water Framework Directive (WFD)

List of pollutants (WFD)

Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Octamethylcyclotetrasiloxane	Substances and preparations, or the breakdown products of such, which have been proved to pos- sess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine- related functions in or via the aquatic environment		a)	

Legend

a) Indicative list of the main pollutants

Regulation on the marketing and use of explosives precursors

not listed

Regulation on drug precursors

not listed

Regulation on substances that deplete the ozone layer (ODS)

not listed

Regulation concerning the export and import of hazardous chemicals (PIC)

not listed

Regulation on persistent organic pollutants (POP)

not listed

Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

National inventories

Country	Inventory	Status
AU	AIIC	all ingredients are listed
CA	DSL	all ingredients are listed
CN	IECSC	all ingredients are listed
EU	ECSI	all ingredients are listed
EU	REACH Reg.	all ingredients are listed
JP	CSCL-ENCS	all ingredients are listed
KR	KECI	all ingredients are listed
MX	INSQ	not all ingredients are listed
NZ	NZIoC	all ingredients are listed
PH	PICCS	all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	all ingredients are listed

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Country	Inventory	Status
US	TSCA	all ingredients are listed (ACTIVE)
VN	NCI	all ingredients are listed

Legend

Australian Inventory of Industrial Chemicals CICR CSCL-ENCS DSL ECSI

Chemical Inventory of Industrial Chemicals
Chemical Inventory and Control Regulation
List of Existing and New Chemical Substances (CSCL-ENCS)
Domestic Substances List (DSL)
EC Substance Inventory (EINECS, ELINCS, NLP)
Inventory of Existing Chemical Substances Produced or Imported in China
National Inventory of Chemical Substances IECSC INSQ

Korea Existing Chemicals Inventory NCI National Chemical Inventory
NZIOC New Zealand Inventory of Chemicals
PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg. REACH registered substances

Taiwan Chemical Substance Inventory

TSCA Toxic Substance Control Act

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance. According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.3	Results of PBT and vPvB assessment: Containing a PBT-/vPvB-substance in a concen- tration of ≥ 0,1%.	Results of PBT and vPvB assessment: The substance was identified as a PBT (persistent, bioaccumulative and toxic). The substance was identified as a vPvB (very persistent and very bioaccumulative). Non-classified PBT substance. Non-classified vPvB substance.	yes
14.8	Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information: Not subject to ADR, RID and ADN.		yes
15.1		Substance of Very High Concern (SVHC): change in the listing (table)	yes
15.1	VOC content: 7 % , 63,7 ^g / _l	VOC content: 0 %	yes
15.1		VOC content: 0 ^g / _l	yes
15.1	VOC content: 7 %	VOC content: 0 %	yes
15.1	VOC content: 63,7 ^g / _l	VOC content: 0 ^g / _l	yes
15.1		National inventories: change in the listing (table)	yes

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Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
15.2	Chemical Safety Assessment: No Chemical Safety Assessment has been car- ried out for this substance.	Chemical safety assessment: No Chemical Safety Assessment has been carried out for this substance. According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.	yes

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations	
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)	
BCF	Bioconcentration factor	
BOD	Biochemical Oxygen Demand	
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)	
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures	
COD	Chemical oxygen demand	
DGR	Dangerous Goods Regulations (see IATA/DGR)	
DNEL	Derived No-Effect Level	
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval	
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)	
EINECS	European Inventory of Existing Commercial Chemical Substances	
ELINCS	European List of Notified Chemical Substances	
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control	
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations	
IATA	International Air Transport Association	
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)	
ICAO	International Civil Aviation Organization	
IMDG	International Maritime Dangerous Goods Code	
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008	
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 (lethality during a specified time interval	
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval	
log KOW	n-Octanol/water	
NLP	No-Longer Polymer	
PBT	Persistent, Bioaccumulative and Toxic	

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Abbr.	Descriptions of used abbreviations
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SVHC	Substance of Very High Concern
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

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