Safety data sheet

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

Silicone oil M 5, low viscosity, stabilized

article number: **A413**
Version: **5.0 en**
Replaces version of: 2022-10-24
Version: (4)

date of compilation: 2016-03-17
Revision: 2024-03-03

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

1.1 Product identifier

Identification of the substance	**Silicone oil** M 5, low viscosity, stabilized
Article number	A413
Registration number (REACH)	The substance does not require registration according 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 sheet:	Department Health, Safety and Environment
e-mail (competent person):	**sicherheit@carlroth.de**

1.4 Emergency telephone number

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Centre Beaumont Hospital	Beaumont Road	Dublin 9	+353 1 809 2166	https://www.poisons.ie/

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.

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 EC No 208-762-8	0,1 – 3
2-Ethylhexanoic acid, iron salt	CAS No 19583-54-1 EC No 243-169-8	< 0,25

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.

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 (CO_2)

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 (CO_2)

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

Advice on how to contain a spill

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 substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Dodecamethylcyclohexasiloxane	540-97-6	DNEL	11 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects
Dodecamethylcyclohexasiloxane	540-97-6	DNEL	1,22 mg/m³	human, inhalatory	worker (industry)	chronic - local effects
Dodecamethylcyclohexasiloxane	540-97-6	DNEL	6,1 mg/m³	human, inhalatory	worker (industry)	acute - local effects
2-Ethylhexanoic acid, iron salt	19583-54-1	DNEL	0,64 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects
2-Ethylhexanoic acid, iron salt	19583-54-1	DNEL	0,36 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

Relevant PNECs of components						
Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Dodecamethylcyclohexasiloxane	540-97-6	PNEC	1 $^{mg}/_{l}$	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Dodecamethylcyclohexasiloxane	540-97-6	PNEC	13 $^{mg}/_{kg}$	aquatic organisms	freshwater sediment	short-term (single instance)
Dodecamethylcyclohexasiloxane	540-97-6	PNEC	1,3 $^{mg}/_{kg}$	aquatic organisms	marine sediment	short-term (single instance)
Dodecamethylcyclohexasiloxane	540-97-6	PNEC	3,77 $^{mg}/_{kg}$	terrestrial organisms	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

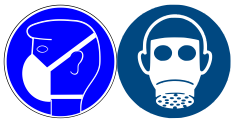
• breakthrough times of the glove material

>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 °C , colour code: Brown). Usually no personal respirative protection necessary.

Environmental exposure controls

Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid
Form	viscous
Colour	yellowish brown
Odour	odourless
Melting point/freezing point	-100 °C
Boiling point or initial boiling point and boiling range	not determined
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 $^{mm^2}/_{s}$ at 25 °C
Solubility(ies)	
Water solubility	(The study does not need to be conducted because 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 $^{g}/_{cm^3}$ at 25 °C
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)	T2 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.

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 estimate (ATE) of components			
Name of substance	**CAS No**	**Exposure route**	**ATE**
2-Ethylhexanoic acid, iron salt	19583-54-1	oral	1.300 $^{mg}/_{kg}$

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
2-Ethylhexanoic acid, iron salt	19583-54-1	oral	LD50	1.300 $^{mg}/_{kg}$	mouse
2-Ethylhexanoic acid, iron salt	19583-54-1	dermal	LD50	>2.000 $^{mg}/_{kg}$	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.

• 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

Not listed.

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 substance	CAS No	Endpoint	Value	Species	Exposure time
Dodecamethylcyclohexasiloxane	540-97-6	ErC50	>2 $^{\mu g}/_{l}$	algae	72 h
2-Ethylhexanoic acid, iron salt	19583-54-1	LC50	>100 $^{mg}/_{l}$	fish	96 h
2-Ethylhexanoic acid, iron salt	19583-54-1	ErC50	49,3 $^{mg}/_{l}$	algae	72 h

Aquatic toxicity (chronic) of components

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Dodecamethylcyclohexasiloxane	540-97-6	EC50	>100 $^{mg}/_{l}$	microorganisms	3 h
2-Ethylhexanoic acid, iron salt	19583-54-1	EC50	75 $^{mg}/_{l}$	aquatic invertebrates	21 d

12.2 Persistence and degradability

Biodegradation

Not readily biodegradable.

Degradability of components						
Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
Dodecamethylcyclohexasiloxane	540-97-6	carbon dioxide generation	4,47 %	28 d		ECHA
2-Ethylhexanoic acid, iron salt	19583-54-1	DOC removal	99 %	28 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)	

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

Not listed.

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 dangerous goods regulations

14.6 Special precautions for user

There is no additional information.

14.7 Maritime transport in bulk according to IMO instruments

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

15.1 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 Regulation No 1272/2008/EC		R3	3
2-Ethylhexanoic acid, iron salt	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		R3	3
2-Ethylhexanoic acid, iron salt	substances in tattoo inks and permanent make-up		R75	75

Legend

R3 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, or both, if they:
— 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.

Legend

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 requirements are met:
(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.’;

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 weight;
(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;
(ii) 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 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.
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 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”;
(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;
(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 paragraph.
8. Mixtures that do not contain the statement “Mixture for use in tattoos or permanent make-up” shall not be used for tattooing purposes.

Legend

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °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 High Concern (SVHC)

Name acc. to inventory	CAS No	Listed in	Remarks	Latest application date	Sunset date	Date of inclusion
dodecamethylcyclohexasiloxane	540-97-6	Candidate list	PBT A57d vPvB A57e			2018-06-27

Legend

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

Seveso Directive

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

Water Framework Directive (WFD)

List of pollutants (WFD)

Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
2-Ethylhexanoic acid, iron salt	Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment		a)	
2-Ethylhexanoic acid, iron salt	Metals and their compounds		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

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

Legend

AIIC	Australian Inventory of Industrial Chemicals
CICR	Chemical Inventory and Control Regulation
CSCL-ENCS	List of Existing and New Chemical Substances (CSCL-ENCS)
DSL	Domestic Substances List (DSL)
ECSI	EC Substance Inventory (EINECS, ELINCS, NLP)
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
INSQ	National Inventory of Chemical Substances
KECI	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
TCSI	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-relevant
2.3	Results of PBT and vPvB assessment: Containing a PBT-/vPvB-substance in a concentration 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		Dangerous substances with restrictions (REACH, Annex XVII): change in the listing (table)	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

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
15.1		List of pollutants (WFD): change in the listing (table)	yes
15.1		National inventories: change in the listing (table)	yes
15.2	Chemical Safety Assessment: No Chemical Safety Assessment has been carried 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)
ATE	Acute Toxicity Estimate
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

Abbr.	Descriptions of used abbreviations
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
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
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). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). 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.