SILICONE UNIVERSALE GRIGIO

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Revision Date: 05.11.2020

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: SILICONE UNIVERSALE GRIGIO cod. 85144001

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

Identified uses: Acetoxy silicone sealant

Uses advised against: This product is not recommended for all those uses not specifically identified on the label.

1.3 Details of the supplier of the safety data sheet COMPANY IDENTIFICATION

Saratoga Int. Sforza Spa Via Edison 76 20090 Trezzano s/Naviglio (MI) ITALY Tel. +39 02.445731 Fax +39 02.4452742 Customer Information e-mail: trading@saratogasforza.com

1.4 EMERGENCY TELEPHONE NUMBER

SARATOGA INT. SFORZA SPA +39 02 445731 from Monday to Friday (h. 09:00-13:00 / 14:00-17:30)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

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

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

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

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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Precautionary statements

P102	Keep out of reach of children.
P262	Do not get in eyes or on skin.
P271	Use only outdoors or in a well-ventilated area.
P501	Dispose of the contents and container to
	authorized collection centers.

Supplemental information

EUH208 Contains: Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane. May produce an

allergic reaction.

2.3 Other hazards

This product contains octamethylcyclotetrasiloxane (D4) that has been identified by the Member State Committee of ECHA as fulfilling the PBT and vPvB criteria laid down in Annex XIII to Regulation (EC) No 1907/2006. See Section 12 for additional information.

This product contains dodecamethylcyclohexasiloxane (D6) that has been identified by the Member State Committee of ECHA as fulfilling the vPvB criteria laid down in Annex XIII to Regulation (EC) No 1907/2006. See Section 12 for additional information.

This product contains decamethylcyclopentasiloxane (D5) that has been identified by the Member State Committee of ECHA as fulfilling the vPvB criteria laid down in Annex XIII to Regulation (EC) No 1907/2006. See Section 12 for additional information.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical nature: Silicone elastomer

3.2 Mixtures

This product is a mixture.

CASRN / EC-No. / Index-No.	REACH Registration Number	Concentration	Component	Classification: REGULATION (EC) No 1272/2008
CASRN 556-67-2 EC-No. 209-136-7 Index-No. 014-018-00-1	_	>= 0,2 - <= 0,29 %	octamethylcyclotetr asiloxane	Flam. Liq. 3; H226 Repr. 2; H361f Aquatic Chronic 1; H410 Fattore-M (Tossicità cronica per l'ambiente acquatico): 10 Stima della tossicità acuta Tossicità acuta per via orale: > 4 800 mg/kg Tossicità acuta per inalazione: 36 mg/l, 4 h, polvere/nebbia Tossicità acuta per via cutanea: > 2 400 mg/kg

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CASRN 68928-76-7 EC-No. 273-028-6 Index-No.	01-2120770324-57	>= 0,01 - <= 0,02 %	Bis[(2-ethyl-2,5- dimethylhexanoyl)o xy](dimethyl)stanna ne	Acute Tox. 4; H302 Skin Irrit. 2; H315 Skin Sens. 1A; H317 Aquatic Chronic 3; H412 Stima della tossicità acuta Tossicità acuta per via orale: 892 mg/kg Tossicità acuta per via cutanea: > 2 000 mg/kg
PBT and vPvB s CASRN 540-97-6 EC-No. 208-762-8 Index-No.	substance –	>= 0,36 - <= 0,43 %	Dodecamethyl cyclohexasiloxane	Non classificato Stima della tossicità acuta Tossicità acuta per via orale: > 2 000 mg/kg Tossicità acuta per via cutanea: > 2 000 mg/kg

CASRN 541-02-6 EC-No. 208-764-9	-	>= 0,2 - <= 0,31 %	Decamethylcyclope ntasiloxane	Not classified Stima della tossicità acuta Tossicità acuta per via orale:
Index-No.				> 24 134 mg/kg Tossicità acuta per inalazione: 8,67 mg/l, 4 h, polvere/nebbia Tossicità acuta per via cutanea: > 2 000 mg/kg

For the full text of the H-Statements mentioned in this Section, see Section 16.

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SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures General advice:

First Aid responders should pay attention to self-protection and use the recommended protective clothing (chemical resistant gloves, splash protection). If potential for exposure exists refer to Section 8 for specific personal protective equipment.

Inhalation: Move person to fresh air and keep comfortable for breathing. If not breathing, give artificial respiration; if by mouth to mouth use rescuer protection (pocket mask, etc). If breathing is difficult, oxygen should be administered by qualified personnel. Call a physician or transport to a medical facility.

Skin contact: Wash off with plenty of water.

Eye contact: Flush eyes thoroughly with water for several minutes. Remove contact lenses after the initial 1-2 minutes and continue flushing for several additional minutes. If effects occur, consult a physician, preferably an ophthalmologist.

Ingestion: No emergency medical treatment necessary.

4.2 Most important symptoms and effects, both acute and delayed:

Aside from the information found under Description of first aid measures (above) and Indication of immediate medical attention and special treatment needed (below), any additional important symptoms and effects are described in Section 11: Toxicology Information.

4.3 Indication of any immediate medical attention and special treatment needed Notes to physician: Maintain adequate ventilation and oxygenation of the patient. No specific antidote. Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray. Alcohol-resistant foam. Carbon dioxide (CO2). Dry chemical.

Unsuitable extinguishing media: None known...

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Carbon oxides. Silicon oxides. Metal oxides. Cobalt compounds. Nitrogen oxides (NOx). Chlorine compounds.

Unusual Fire and Explosion Hazards: Exposure to combustion products may be a hazard to health..

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5.3 Advice for firefighters

Fire Fighting Procedures: Use water spray to cool unopened containers. Evacuate area. Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Remove undamaged containers from fire area if it is safe to do so.

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.. Use personal protective equipment..

SECTION 6: ACCIDENTAL RELEASE MEASURES

- **6.1 Personal precautions, protective equipment and emergency procedures:** Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
- **6.2 Environmental precautions:** Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
- **6.3 Methods and materials for containment and cleaning up:** Wipe up or scrape up and contain for salvage or disposal. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.

6.4 Reference to other sections:

See sections: 7, 8, 11, 12 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling: Avoid contact with eyes. Do not swallow. Avoid prolonged or repeated contact with skin. Take care to prevent spills, waste and minimize release to the environment. Handle in accordance with good industrial hygiene and safety practice. CONTAINERS MAY BE HAZARDOUS WHEN EMPTY. Since emptied containers retain product residue follow all (M)SDS and label warnings even after container is emptied.

Use only with adequate ventilation. See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

7.2 Conditions for safe storage, including any incompatibilities: Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.

Do not store with the following product types: Strong oxidizing agents. Unsuitable materials for containers: None known.

7.3 Specific end use(s): See the technical data sheet on this product for further information.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

If exposure limits exist, they are listed below. If no exposure limits are displayed, then no values are applicable.

Component	Regulation	Type of listing	Value				
octamethylcyclotetrasiloxane	US WEEL	TWA	10 ppm				
Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimet	ACGIH	TWA	0,1 mg/m3 , Tin				
hyl)stannane							
	Further information: A4: Not classifiable as a human carcinogen; Skin: Danger of cutaneous absorption						
	ACGIH	STEL	0,2 mg/m3 , Tin				
	Further information: A4: No cutaneous absorption	t classifiable as a human car	cinogen; Skin: Danger of				
Decamethylcyclopentasiloxa	US WEEL	TWA	10 ppm				
ne							

Although some of the components of this product may have exposure guidelines, no exposure would be expected under normal handling conditions due to the physical state of the material.

Recommended monitoring procedures

Monitoring of the concentration of substances in the breathing zone of workers or in the general workplace may be required to confirm compliance with the Occupational Exposure Limits and the adequacy of exposure controls. For some substances biological monitoring may also be appropriate. Validated exposure measurement methods should be applied by a competent person and samples should be analysed by an accredited laboratory.

Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy); European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents); European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents). Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

Examples of sources of recommended exposure measurement methods are given below or contact the supplier. Further national methods may be available.

National Institute of Occupational Safety and Health (NIOSH), USA: Manual of Analytical Methods. Occupational Safety and Health Administration (OSHA), USA: Sampling and Analytical Methods. Health and Safety Executive (HSE), United Kingdom: Methods for the Determination of Hazardous Substances.

Institut für Arbeitsschutz Deutschen Gesetzlichen Unfallversicherung (IFA), Germany. L'Institut National de Recherche et de Securité, (INRS), France.

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Derived No Effect Level

octamethylcyclotetrasiloxane

Workers

Acute syst	emic effects	Acute local effects			n systemic ects	Long-term local effects			
Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation		
n.a.	73 mg/m3	n.a.	73 mg/m3	n.a.	73 mg/m3	n.a.	73 mg/m3		

Consumers

Acute	systemic e	effects	Acute local effects		Long-term systemic effects			Long-term local effects	
Dermal	Inhalation	Oral	Dermal	Inhalation	Dermal	Inhalation	Oral	Dermal	Inhalation
n.a.	13	3,7	n.a.	13	n.a.	13	3,7	n.a.	13
	mg/m3	mg/kg bw/day		mg/m3		mg/m3	mg/kg bw/day		mg/m3

Dodecamethyl cyclohexasiloxane

Workers

Acute syste	emic effects	Acute local effects			n systemic ects	Long-term local effects		
Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation	
n.a.	n.a.	n.a.	6,1 mg/m3	n.a.	11 mg/m3	n.a.	1,22 mg/m3	

Consumers

Acute	systemic e	effects	Acute local effects		Long-term systemic effects			Long-term local effects		
Dermal	Inhalation	Oral	Dermal	Inhalation	Dermal	Inhalation	Oral	Dermal	Inhalation	
n.a.	n.a.	1,7	n.a.	1,5	n.a.	2,7	1,7	n.a.	0,3	
		mg/kg bw/day		mg/m3		mg/m3	mg/kg bw/day		mg/m3	

Decamethylcyclopentasiloxane

Workers

Acute syste	emic effects	Acute local effects		•	n systemic ects	Long-term local effects		
Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation	
n.a.	97,3	n.a.	24,2	n.a.	97,3	n.a.	24,2 mg/m3	
	mg/m3		mg/m3		mg/m3			

Consumers

Acute	systemic e	effects	Acute local effects		Long-term systemic effects			Long-term local effects	
Dermal	Inhalation	Oral	Dermal	Inhalation	Dermal	Inhalation	Oral	Dermal	Inhalation
n.a.	17,3 mg/m3	5 mg/kg bw/day	n.a.	4,3 mg/m3	n.a.	17,3 mg/m3	5 mg/kg bw/day	n.a.	4,3 mg/m3

Predicted No Effect Concentration

octamethylcyclotetrasiloxane

Compartment	PNEC
Fresh water	0,0015 mg/l
Marine water	0,00015 mg/l

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Fresh water sediment	3 mg/kg	
Marine sediment	0,3 mg/kg	
Soil	0,54 mg/kg	
Sewage treatment plant	10 mg/l	
Orale	41 mg/kg cibo	

Dodecamethyl cyclohexasiloxane

Compartment	PNEC
Fresh water sediment	2,826 mg/kg
Marine sediment	0,282 mg/kg
Soil	3,336 mg/kg
Sewage treatment plant	> 1,0 mg/l

Decamethylcyclopentasiloxane

Compartment	PNEC	
Fresh water	> 0,0012 mg/l	
Marine water	> 0,00012 mg/l	
Fresh water sediment	2,4 mg/kg	
Marine sediment	0,24 mg/kg	
Soil	1,1 mg/kg	
Sewage treatment plant	> 10 mg/l	

8.2 Exposure controls

Engineering controls: Use local exhaust ventilation, or other engineering controls to maintain airborne levels below exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, general ventilation should be sufficient for most operations. Local exhaust ventilation may be necessary for some operations.

Hygiene measures: Ensure that eye flushing systems and safety showers are located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

Individual protection measures

Eye/face protection: Use safety glasses (with side shields). Safety glasses (with side shields) should be consistent with EN 166 or equivalent.

Skin protection

Hand protection: Use gloves chemically resistant to this material when prolonged or frequently repeated contact could occur. Use chemical resistant gloves classified under Standard EN374: Protective gloves against chemicals and micro-organisms. Examples of preferred glove barrier materials include: Butyl rubber. Neoprene. Nitrile/butadiene rubber ("nitrile" or "NBR"). Ethyl vinyl alcohol laminate ("EVAL"). Polyvinyl alcohol ("PVA"). Polyvinyl chloride ("PVC" or "vinyl"). Viton. Examples of acceptable glove barrier materials include: Natural rubber ("latex"). When prolonged or frequently repeated contact may occur, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended. Glove thickness alone is not a good indicator of the level of protection a glove provides against a chemical substance as this level of protection is also highly dependent on the specific composition of the material that the glove is fabricated from. The thickness of the glove must, depending on model and type of material, generally be more than 0.35 mm to offer sufficient protection for prolonged and frequent contact with the substance. As an exception to this general rule it is known that multilayer laminate gloves may offer prolonged protection at thicknesses less than 0.35 mm.

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> Other glove materials with a thickness of less than 0.35 mm may offer sufficient protection when only brief contact is expected. NOTICE: The selection of a specific glove for a particular application and duration of use in a workplace should also take into account all relevant workplace factors such as, but not limited to: Other chemicals which may be handled, physical requirements (cut/puncture protection, dexterity, thermal protection), potential body reactions to glove materials, as well as the instructions/specifications provided by the glove supplier.

Other protection: When prolonged or frequently repeated contact could occur, use protective clothing chemically resistant to this material. Selection of specific items such as faceshield, boots, apron, or full-body suit will depend on the task.

Respiratory protection: Respiratory protection should be worn when there is a potential to exceed the exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, wear respiratory protection when adverse effects, such as respiratory irritation or discomfort have been experienced, or where indicated by your risk assessment process. For most conditions, no respiratory protection should be needed: however, if handling at elevated temperatures without sufficient ventilation, use an approved air-purifying respirator.

Use the following CE approved air-purifying respirator: Organic vapor cartridge, type A (boiling point >65 °C, meeting standard EN 14387).

Environmental exposure controls

See SECTION 7: Handling and storage and SECTION 13: Disposal considerations for measures to prevent excessive environmental exposure during use and waste disposal.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Physical state Thixotropic paste

Color Gray Odor acetic acid

Odor Threshold No data available pН Not applicable Melting point/range No data available Freezing point No data available Boiling point (760 mmHg) Not applicable

Flash point closed cup >100 °C

Evaporation Rate (Butyl Acetate

= 1)

Not applicable

Flammability (solid, gas) Not classified as a flammability hazard

Lower explosion limit No data available **Upper explosion limit** No data available Vapor Pressure Not applicable Relative Vapor Density (air = 1) No data available

Relative Density (water = 1) 1.02

Water solubility No data available

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Partition coefficient: n-

No data available

octanol/water

No data available **Auto-ignition temperature Decomposition temperature** No data available **Dynamic Viscosity** Not applicable **Kinematic Viscosity** No data available **Explosive properties** Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

9.2 Other information

Molecular weight No data available

NOTE: The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity: Not classified as a reactivity hazard.

10.2 Chemical stability: Stable under normal conditions.

10.3 Possibility of hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid: None known.

10.5 Incompatible materials: Avoid contact with oxidizing materials.

10.6 Hazardous decomposition products:

Decomposition products can include and are not limited to: Formaldehyde.

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicological information appears in this section when such data is available.

11.1 Information on toxicological effects

Information on likely routes of exposure

Eye contact, Skin contact, Ingestion.

Acute toxicity (represents short term exposures with immediate effects - no chronic/delayed effects known unless otherwise noted)

Acute oral toxicity

Very low toxicity if swallowed. Harmful effects not anticipated from swallowing small amounts.

As product: Single dose oral LD50 has not been determined.

Based on information for component(s):

LD50, Rat, > 5 000 mg/kg Estimated.

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Information for components:

octamethylcyclotetrasiloxane

LD50, Rat, male, > 4 800 mg/kg No deaths occurred at this concentration.

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

LD50, Rat, male and female, 892 mg/kg OECD 401 or equivalent

Dodecamethyl cyclohexasiloxane

LD50, Rat, male and female, > 2 000 mg/kg No deaths occurred at this concentration.

Decamethylcyclopentasiloxane

LD50, Rat, male and female, > 24 134 mg/kg

Acute dermal toxicity

Prolonged skin contact is unlikely to result in absorption of harmful amounts.

As product: The dermal LD50 has not been determined.

Based on information for component(s):

LD50, Rabbit, > 2 000 mg/kg Estimated.

Information for components:

octamethylcyclotetrasiloxane

LD50, Rat, male and female, > 2 400 mg/kg No deaths occurred at this concentration.

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

LD50, Rat, > 2 000 mg/kg

Dodecamethyl cyclohexasiloxane

LD50, Rabbit, male and female, > 2 000 mg/kg

<u>Decamethylcyclopentasiloxane</u>

LD50, Rabbit, male and female, > 2 000 mg/kg No deaths occurred at this concentration.

Acute inhalation toxicity

Brief exposure (minutes) is not likely to cause adverse effects. Vapor from heated material may cause respiratory irritation.

As product: The LC50 has not been determined.

Information for components:

octamethylcyclotetrasiloxane

LC50, Rat, male and female, 4 Hour, dust/mist, 36 mg/l OECD Test Guideline 403

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

As product: The LC50 has not been determined.

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Dodecamethyl cyclohexasiloxane

The LC50 has not been determined.

Decamethylcyclopentasiloxane

LC50, Rat, male and female, 4 Hour, dust/mist, 8,67 mg/l

Skin corrosion/irritation

Based on information for component(s):

Prolonged exposure not likely to cause significant skin irritation.

Information for components:

octamethylcyclotetrasiloxane

Brief contact is essentially nonirritating to skin.

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

Brief contact may cause skin irritation with local redness.

Dodecamethyl cyclohexasiloxane

Essentially nonirritating to skin.

Decamethylcyclopentasiloxane

Prolonged contact is essentially nonirritating to skin.

Serious eye damage/eye irritation

Based on information for component(s):

May cause slight temporary eye irritation.

May cause mild eye discomfort.

Information for components:

octamethylcyclotetrasiloxane

Essentially nonirritating to eyes.

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

May cause slight eye irritation.

May cause slight temporary corneal injury.

Dodecamethyl cyclohexasiloxane

May cause slight temporary eye irritation.

Corneal injury is unlikely.

<u>Decamethylcyclopentasiloxane</u>

Essentially nonirritating to eyes.

Sensitization

For skin sensitization:

Contains component(s) which did not cause allergic skin sensitization in guinea pigs.

For respiratory sensitization:

No relevant information found.

Information for components:

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octamethylcyclotetrasiloxane

Did not cause allergic skin reactions when tested in guinea pigs.

For respiratory sensitization:

No relevant data found.

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

Has caused allergic skin reactions when tested in guinea pigs.

For respiratory sensitization:

No relevant data found.

Dodecamethyl cyclohexasiloxane

Did not cause allergic skin reactions when tested in guinea pigs.

For respiratory sensitization:

No relevant data found.

Decamethylcyclopentasiloxane

Did not demonstrate the potential for contact allergy in mice.

For respiratory sensitization:

No relevant data found.

Specific Target Organ Systemic Toxicity (Single Exposure)

Evaluation of available data suggests that this material is not an STOT-SE toxicant.

Information for components:

octamethylcyclotetrasiloxane

Evaluation of available data suggests that this material is not an STOT-SE toxicant.

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

Available data are inadequate to determine single exposure specific target organ toxicity.

<u>Dodecamethyl cyclohexasiloxane</u>

Evaluation of available data suggests that this material is not an STOT-SE toxicant.

Decamethylcyclopentasiloxane

Evaluation of available data suggests that this material is not an STOT-SE toxicant.

Aspiration Hazard

Based on physical properties, not likely to be an aspiration hazard.

Information for components:

octamethylcyclotetrasiloxane

May be harmful if swallowed and enters airways.

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

Based on physical properties, not likely to be an aspiration hazard.

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Dodecamethyl cyclohexasiloxane

Based on physical properties, not likely to be an aspiration hazard.

Decamethylcyclopentasiloxane

Based on physical properties, not likely to be an aspiration hazard.

Chronic toxicity (represents longer term exposures with repeated dose resulting in chronic/delayed effects - no immediate effects known unless otherwise noted)

Specific Target Organ Systemic Toxicity (Repeated Exposure)

For similar material(s):

Based on available data, repeated exposures are not anticipated to cause significant adverse effects.

Contains an additional component(s) that is not expected to be bioavailable due to the physical state of the material under normal handling and processing conditions.

Information for components:

octamethylcyclotetrasiloxane

In animals, effects have been reported on the following organs:

Kidney.

Liver.

Respiratory tract.

Female reproductive organs.

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

In animals, effects have been reported on the following organs:

Blood

Kidney

Liver

Immune system.

Dodecamethyl cyclohexasiloxane

Based on available data, repeated exposures are not anticipated to cause significant adverse effects.

Decamethylcyclopentasiloxane

Based on available data, repeated exposures are not anticipated to cause significant adverse effects.

Carcinogenicity

For this family of materials: Did not cause cancer in long-term animal studies which used routes of exposure considered relevant to industrial handling. Positive results have been reported in other studies using routes of exposure not relevant to industrial handling.

Contains an additional component(s) that is not expected to be bioavailable due to the physical state of the material under normal handling and processing conditions.

Information for components:

octamethylcyclotetrasiloxane

Results from a 2 year repeated vapour inhalation exposure study to rats of octamethylcvclotetrasiloxane (D4) indicate effects (benian uterine adenomas) in the uterus of

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female animals. This finding occurred at the highest exposure dose (700 ppm) only. Studies to date have not demonstrated if these effects occur through pathways that are relevant to humans. Repeated exposure in rats to D4 resulted in protoporphyrin accumulation in the liver. Without knowledge of the specific mechanism leading to the protoporphyrin accumulation the relevance of this finding to humans is unknown.

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Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

No relevant data found.

Dodecamethyl cyclohexasiloxane

No relevant data found.

Decamethylcyclopentasiloxane

Results from a 2 year repeated vapour inhalation exposure study to rats of decamethylcyclopentasiloxane (D5) indicate effects (uterine endometrial tumors) in female animals. This finding occurred at the highest exposure dose (160 ppm) only. Studies to date have not demonstrated if this effect occurs through a pathway that is relevant to humans.

Teratogenicity

For similar material(s): Did not cause birth defects or any other fetal effects in laboratory animals.

Information for components:

<u>octamethylcyclotetrasiloxane</u>

Did not cause birth defects or any other fetal effects in laboratory animals.

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

No relevant data found.

Dodecamethyl cyclohexasiloxane

No relevant data found.

Decamethylcyclopentasiloxane

Did not cause birth defects or any other fetal effects in laboratory animals.

Reproductive toxicity

Contains component(s) which have been shown to interfere with reproduction in animal studies. Contains component(s) which have interfered with fertility in animal studies.

Information for components:

octamethylcyclotetrasiloxane

In laboratory animal studies, effects on reproduction have been seen only at doses that produced significant toxicity to the parent animals. In animal studies, has been shown to interfere with fertility.

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

No relevant data found.

<u>Dodecamethyl cyclohexasiloxane</u>

No relevant data found.

Decamethylcyclopentasiloxane

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In animal studies, did not interfere with reproduction.

Mutagenicity

Contains component(s) which were negative in some in vitro genetic toxicity studies and positive in others.

Information for components:

octamethylcyclotetrasiloxane

In vitro genetic toxicity studies were negative. Animal genetic toxicity studies were negative.

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

In vitro genetic toxicity studies were negative in some cases and positive in other cases. Animal genetic toxicity studies were negative.

Dodecamethyl cyclohexasiloxane

In vitro genetic toxicity studies were negative. Animal genetic toxicity studies were negative.

Decamethylcyclopentasiloxane

In vitro genetic toxicity studies were negative. Animal genetic toxicity studies were negative.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicological information appears in this section when such data is available.

12.1 Toxicity

<u>octamethylcyclotetrasiloxane</u>

Acute toxicity to fish

Not expected to be acutely toxic to aquatic organisms.

No toxicity at the limit of solubility

LC50, Oncorhynchus mykiss (rainbow trout), flow-through, 96 Hour, > 0,022 mg/l

No toxicity at the limit of solubility

LC50, Cyprinodon variegatus (sheepshead minnow), flow-through, 14 d, > 0,0063 mg/l

Acute toxicity to aquatic invertebrates

No toxicity at the limit of solubility

EC50, Mysidopsis bahia (opossum shrimp), flow-through test, 96 Hour, > 0,0091 mg/l

No toxicity at the limit of solubility

EC50, Daphnia magna (Water flea), flow-through test, 48 Hour, > 0,015 mg/l

Acute toxicity to algae/aquatic plants

No toxicity at the limit of solubility

ErC50, Pseudokirchneriella subcapitata (green algae), 72 Hour, Growth rate, > 0,022 mg/l

Chronic toxicity to fish

No toxicity at the limit of solubility

NOEC, Oncorhynchus mykiss (rainbow trout), 93 d, >= 0,0044 mg/l

Chronic toxicity to aquatic invertebrates

No toxicity at the limit of solubility

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NOEC, Daphnia magna (Water flea), 21 d, >= 0,0079 mg/l

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

Acute toxicity to fish

Material is harmful to aquatic organisms (LC50/EC50/IC50 between 10 and 100 mg/L in the most sensitive species).

For similar material(s):

LC50, Zebra fish (Danio/Brachydanio rerio), semi-static test, 96 Hour, > 100 mg/l, OECD Test Guideline 203 or Equivalent

Acute toxicity to aquatic invertebrates

EC50, Daphnia magna, static test, 48 Hour, 39 mg/l, OECD Test Guideline 202 or Equivalent

Acute toxicity to algae/aquatic plants

ErC50, Algae (Scenedesmus subspicatus), Growth rate, 72 Hour, Growth rate, 7,6 mg/l, OECD Test Guideline 201 or Equivalent

For similar material(s):

NOEC, Algae (Scenedesmus subspicatus), Growth rate, 72 Hour, Growth rate, 1,1 mg/l, OECD Test Guideline 201 or Equivalent

Toxicity to bacteria

For similar material(s):

EC50, Bacteria, 3 Hour, Respiration rates., 14 mg/l

Dodecamethyl cyclohexasiloxane

Acute toxicity to algae/aquatic plants

Not expected to be acutely toxic to aquatic organisms.

No toxicity at the limit of solubility

ErC50, Pseudokirchneriella subcapitata (green algae), 72 Hour, > 0,002 mg/l

Decamethylcyclopentasiloxane

Acute toxicity to fish

Not expected to be acutely toxic to aquatic organisms.

No toxicity at the limit of solubility

LC50, Oncorhynchus mykiss (rainbow trout), 96 Hour, > 16 μ g/l, OECD Test Guideline 204 or Equivalent

Acute toxicity to aquatic invertebrates

No toxicity at the limit of solubility

EC50, Daphnia magna, 48 Hour, > 2,9 mg/l, OECD Test Guideline 202 or Equivalent

Acute toxicity to algae/aquatic plants

No toxicity at the limit of solubility

ErC50, Pseudokirchneriella subcapitata (green algae), 96 Hour, Growth rate, > 0,012 mg/l No toxicity at the limit of solubility

NOEC, Pseudokirchneriella subcapitata (green algae), 96 Hour, Growth rate, 0,012 mg/l

Chronic toxicity to fish

No toxicity at the limit of solubility

LC50, Oncorhynchus mykiss (rainbow trout), 14 d, > 16 mg/l

No toxicity at the limit of solubility

NOEC, Oncorhynchus mykiss (rainbow trout), 45 d, >= 0,017 mg/l

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No toxicity at the limit of solubility

NOEC, Oncorhynchus mykiss (rainbow trout), 90 d, >= 0,014 mg/l

Chronic toxicity to aquatic invertebrates

NOEC, Daphnia magna, 21 d, 0,015 mg/l

Toxicity to soil-dwelling organisms

This product does not have any known adverse effect on the soil organisms tested.

NOEC, Eisenia fetida (earthworms), >= 76 mg/kg

12.2 Persistence and degradability

<u>octamethylcyclotetrasiloxane</u>

Biodegradability: Material is expected to biodegrade very slowly (in the environment). Fails

to pass OECD/EEC tests for ready biodegradability.

10-day Window: Not applicable **Biodegradation:** 3.7 % Exposure time: 28 d

Method: OECD Test Guideline 310

Stability in Water (1/2-life)

Hydrolysis, DT50, 69,3 - 144 Hour, pH 7, Half-life Temperature 24,6 °C, OECD Test Guideline

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

Biodegradability: For similar material(s): Material is expected to biodegrade very slowly (in

the environment). Fails to pass OECD/EEC tests for ready biodegradability.

For similar material(s): 10-day Window: Fail

Biodegradation: 3 % Exposure time: 28 d

Method: OECD Test Guideline 301F or Equivalent

Dodecamethyl cyclohexasiloxane

Biodegradability: Based on stringent OECD test guidelines, this material cannot be considered as readily biodegradable; however, these results do not necessarily mean that the material is not biodegradable under environmental conditions.

10-day Window: Fail **Biodegradation:** 4.5 %

Exposure time: 28 d

Method: OECD Test Guideline 301B

Decamethylcyclopentasiloxane

Biodegradability: Material is expected to biodegrade very slowly (in the environment). Fails

to pass OECD/EEC tests for ready biodegradability.

10-day Window: Not applicable **Biodegradation:** 0,14 % Exposure time: 28 d

Method: OECD Test Guideline 310

12.3 Bioaccumulative potential

<u>octamethylcyclotetrasiloxane</u>

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Bioaccumulation: Bioconcentration potential is high (BCF > 3000 or Log Pow between 5 and

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7).

Partition coefficient: n-octanol/water(log Pow): 6.49 Measured

Bioconcentration factor (BCF): 12 400 Pimephales promelas (fathead minnow) Measured

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

Bioaccumulation: No relevant data found.

Dodecamethyl cyclohexasiloxane

Bioaccumulation: Bioconcentration potential is low (BCF less than 100 or log Pow greater

than 7).

Partition coefficient: n-octanol/water(log Pow): 8,87

Decamethylcyclopentasiloxane

Bioaccumulation: Bioconcentration potential is moderate (BCF between 100 and 3000 or

Log Pow between 3 and 5).

Partition coefficient: n-octanol/water(log Pow): 5,2 Measured

Bioconcentration factor (BCF): 2 010 Fish Estimated.

12.4 Mobility in soil

octamethylcyclotetrasiloxane

Expected to be relatively immobile in soil (Koc > 5000).

Partition coefficient (Koc): 16596 OECD Test Guideline 106

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

No relevant data found.

Dodecamethyl cyclohexasiloxane

Potential for mobility in soil is very high (Koc between 0 and 50).

Decamethylcyclopentasiloxane

Expected to be relatively immobile in soil (Koc > 5000).

Partition coefficient (Koc): > 5000 Estimated.

12.5 Results of PBT and vPvB assessment

<u>octamethylcyclotetrasiloxane</u>

Octamethylcyclotetrasiloxane (D4) meets the current REACh Annex XIII criteria for PBT and vPvB. In Canada, D4 has been assessed and deemed to meet the PiT criteria. However, D4 does not behave similarly to known PBT/vPvB substances. The weight of scientific evidence from field studies shows that D4 is not biomagnifying in aquatic and terrestrial food webs. D4 in air will degrade by reaction with naturally occurring hydroxyl radicals in the atmosphere. Any D4 in air that does not degrade by reaction with hydroxyl radicals is not expected to deposit from the air to water, to land, or to living organisms.

Bis[(2-ethyl-2,5-dimethylhexanoyl)oxy](dimethyl)stannane

This substance has not been assessed for persistence, bioaccumulation and toxicity (PBT).

<u>Dodecamethyl cyclohexasiloxane</u>

Dodecamethyl cyclohexasiloxane (D6) meets the current REACh Annex XIII criteria for vPvB. However, D6 does not behave similarly to known PBT/vPvB substances. The weight of scientific evidence from field studies shows that D6 is not biomagnifying in aquatic and

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SECTION 13: DISPOSAL CONSIDERATIONS

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SECTION 14: TRANSPORT INFORMATION

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SECTION 15: REGULATORY INFORMATION

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1907/2006 (REACH)., The aforementioned indications of the REACH registration status are provided in good faith and believed to be accurate as of the effective date shown above. However, no warranty, express or implied, is given. It is the buyer's/user's responsibility to ensure that his/her understanding of the regulatory status of this product is correct.

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) Conditions of restriction for the following entries should be considered:

octamethylcyclotetrasiloxane (Number on list

Bis[(2-ethyl-2,5-

dimethylhexanoyl)oxy](dimethyl)stannane

(Number on list 20)

Decamethylcyclopentasiloxane (Number on

list 70)

Authorisation status under REACH:

The following substance/s contained in this product might be or is/are subject to authorization in accordance with REACH:

CAS-No.: 556-67-2 Name: octamethylcyclotetrasiloxane

Authorisation status: listed in the Candidate List of Substances of Very High Concern for Authorisation

Authorisation number: Not available

Sunset date: Not available

Exempted (Categories of) Uses: Not available

CAS-No.: 540-97-6 Name: Dodecamethyl cyclohexasiloxane

Authorisation status: listed in the Candidate List of Substances of Very High Concern for Authorisation

Authorisation number: Not available

Sunset date: Not available

Exempted (Categories of) Uses: Not available

CAS-No.: 541-02-6 Name: Decamethylcyclopentasiloxane

Authorisation status: listed in the Candidate List of Substances of Very High Concern for Authorisation

Authorisation number: Not available

Sunset date: Not available

Exempted (Categories of) Uses: Not available

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Listed in Regulation: Not applicable

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture.

SECTION 16: OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H351	Suspected of causing cancer if inhaled

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H410 Very toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) No 1272/2008

This product is not classified as dangerous according to EC criteria.

Revision

Sections from 1 to 16.

hana I

Legena	
ACGIH	USA. ACGIH Threshold Limit Values (TLV)
STEL	Short-term exposure limit
TWA	8-hour, time-weighted average
US WEEL	USA. Workplace Environmental Exposure Levels (WEEL)
Acute Tox.	Acute toxicity
Aquatic Chronic	Long-term (chronic) aquatic hazard
Flam. Liq.	Flammable liquids
Repr.	Reproductive toxicity
Skin Irrit.	Skin irritation
Skin Sens.	Skin sensitisation

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx -Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS -Emergency Schedule: ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG -International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No

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Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Information Source and References

This SDS is prepared by Product Regulatory Services and Hazard Communications Groups from information supplied by internal references within our company.

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