according to Regulation (EC) No. 1907/2006

REPLISIL

Duplicating silicone

SILCONIC GmbH & Co. KG

Erlenweg 3/1 D-89173 Lonsee

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

1.1 Product identifier:

Commercial product name: REPLISIL 25 NF Component A

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

Use of substance/preparation: Silicone for the manufacturing of duplicating models

1.3 <u>Manufacturer/distributer</u>: SILCONIC GmbH & Co. KG

Erlenweg 3/1 D-89173 Lonsee

E-Mail: <u>info@silconic.de</u>
Internet: <u>www.silconic.de</u>

1.4 Emergency telephone number: Department of work safety, Mrs. Fischer

Phone: +49 7336 49697-0 (only to office hours available)

Fax: +49 7336 49697-99

24h emergency: please call your local emergency

department.

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.

2.2 <u>Label elements:</u>

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

No labeling according to GHS required.

2.3 Other hazards:

The product contains substances which are relevant for the assessment in chapter 12.5. Endocrine disrupting properties - human health: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Endocrine disrupting properties - environment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Section 3: Composition/information on ingredients

3.1. Substances: not applicable

3.2. Mixtures:

Chemical characteristics: Polydimethylsiloxane with functional groups and auxiliary.

3.2.2 Hazardous ingredients:

This material does not contain any ingredients above the permitted limit(s).

according to Regulation (EC) No. 1907/2006

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The Product contains the following substances of very high concern (Regulation (EC) NO. 1907/2006 (REACH), Article 57) in amounts ≥ 0,1%:

- <i>,</i> , -			='
CAS-No.	Substance	Content [%]	
540-97-6	Dodecamethylcyclohexasiloxane	>=0,1 - <0,3	Persistent, bioaccumulative and tocix (article 57d) Very persistent and very bioaccumulative (article 57e)
			i (ai ticle 37e) – i

Тур	CAS-No.	EG-No. REACH-No.	Material	Content %	classification*	Remark
INHA	14464-46-1	238-455-4	Cristobalit	10 - <15	Xn; R48/20 STOT RE 1 inhalati	(1) iv:

Type: INHA: ingredient H372

(1) = substance hazardous to health or the environment;

* The information on classification is explained in Chapter 16.

Cristobalite: This ingredient does not lead to classification due to its physical nature

There is no risk of inhalation due to the material.

Section 4: First aid measures

4.1 <u>Description of first aid measures:</u>

General information: In case of accident or if you feel unwell seek medical advice

(show label or SDS where possible).

After contact with the eyes: Rinse immediately with plenty of water.

Seek medical advice in case of continuous irritation.

After contact with the skin: Wipe off excess material with cloth or paper. Wash with

plenty of water or water and soap. In the event of a visible skin change or other complaints, seek medical

advice (show label or SDS where possible).

After inhalation: Material cannot be inhaled under normal conditions.

After swallowing: Give several small portions of water to drink.

Do not induce vomiting.

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

Any relevant information can be found in other parts of this section.

4.3 <u>Indication of any immediate medical attention and special treatment needed:</u>

Further toxicology information in section 11 must be observed.

Section 5: Firefighting measures

5.1 Extinguishing media:

Suitable extinguishing media:

Alcohol-resistant foam, carbon dioxide, water mist, sprinkler system, sand, extinguishing powder.

Extinguishing media which must not be used for safety reasons:

Water jet.

according to Regulation (EC) No. 1907/2006

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5.2 **Special hazards arising from the substance or mixture:**

Risk of hazardous gasses or fumes in the event of fire. Exposure to combustion products may be a health hazard! Hazardous combustion products: carbon oxides, silicon oxides, incompletely burnt hydrocarbons, toxic and very toxic fumes.

5.3 Advice for firefighters:

Special protective equipment for fire fighting:

Use respiratory protection independent of recirculated air. Keep unprotected persons away.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Secure the area. Wear personal protection equipment (see section 8). Keep unprotected persons away. If material is released indicate risk of slipping. Do not walk through spilled material.

6.2 Environmental precautions:

Prevent material from entering surface waters, drains or sewers and soil. Close leak if possible without risk. Contain any fluid that runs out using suitable material (e.g. earth). Retain contaminated water/extinguishing water. Dispose of in prescribed marked containers. Inform authorities if substance leaks into surface waters, sewerage or ground.

6.3 Methods and material for containment and cleaning up:

Take up mechanically and dispose of according to local/state/federal regulations. Do not flush away with water. For small amounts: Absorb with a neutral (non-acidic / non-basic) liquid binding material such as diatomaceous earth and dispose of according to government regulations. For large amounts: Liquids may be recovered using suction devices or pumps. If flammable, only air driven or properly rated electrical equipment should be used. Clean any slippery coating that remains using a detergent / soap solution or another biodegradable cleaner. Silicone fluids are slippery; spills are a safety hazard. Apply sand or other inert granular material to improve traction.

6.4 Reference to other sections:

Relevant information in other sections hast o be considered. This applies in particular for information given on personal protetctive equipment (section 8) and on disposal (section 13).

Section 7: Handling and storage

7.1 Precautions for safe handling:

Precautions for safe handling:

Avoid formation of aerosols. In case of aerosol formation special protective measures are required (exhausting by suction, respiratory protection). Spilled substance increases risk of slipping. Observe information in section 8.

Precautions against fire and explosion:

Observe the general rules for fire prevention.

7.2 Conditions for safe storage, including any incompatibilities:

Conditions for storage rooms and vessels:

according to Regulation (EC) No. 1907/2006

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Observe local/state/federal regulations.

Advice for storage of incompatible materials:

Observe local/state/federal regulations.

Further information for storage:

Store in a dry and cool place.

7.3. Specific end use(s):

No data available.

Section 8: Exposure controls/personal protection

8.1 Control parameters:

Maximum airborne concentrations at the workplace:

exempt

8.2 **Exposure controls:**

Exposure in the work place limited and controlled:

General protection and hygiene measures:

Observe standard industrial hygiene practices for the handling of chemical substances. Do not eat or drink when handling.

Personal protection equipment:

Respiratory protection: No personal respiratory protective equipment normally required.

In case of mist, spray or aerosol exposure wear suitable personal respiratory protection and protective suit. Suitable respiratory equipment: Filtering half-face mask, according to

acknowledged standards such as EN 149.

Recommended Filter type FFP1 or equivalent filter, according to

acknowledged standards such as EN 149.

Observe the equipment manufacturer's information and wear

time limits for respirators.

Eye protection: Recommendation: protective goggles.

Hand protection: Use of protective gloves is recommended when handling the

material, according to recognized standards such as EN374. Recommended glove types: Protective gloves made of nitrile

Rubber thickness of the material: > 0,1 mm

Breakthrough time: > 480 min

Recommended glove types: Protective gloves made of butyl

rubber thickness of the material: > 0,3 mm

Breakthrough time: > 480 min

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the

gloves.

Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. Note that, due to the numerous external

influences (such as temperature), a chemically resistant

protective

glove in daily use may have a service life that is considerably

shorter than the measured break through time.

Exposure to the environment limited and controlled:

according to Regulation (EC) No. 1907/2006

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Prevent material from entering surface waters and soil.

Section 9: Physical and chemical properties

9.1 <u>Information on basic physical and chemical properties:</u>

General information: Form: paste

Colour: transparent/white

Odour: odourless

Important information about the protection of health, safety and the environment:

Property: Value: Method:

Physical state: liquid

Odour Threshold: no data available
Melting point/melting range: not applicable
Boiling point/boiling range: not applicable

Flash point: > 250°C (not specified)
Ignition temperature: > 400°C (not specified)

Lower explosion limit (LEL): exempt
Upper explosion limit (UEL): exempt
Vapour pressure: not applicable

Density: 1,05 – 1,5 g/cm³ bei 20°C (DIN 51757)

Water solubility/miscibility: virtually insoluble

pH-Value: not applicable. Insoluble in water

Viscosity (dynamic): 2000-2240 mPa.s bei 23°C (Brookfield)

Viscositiy (kinematic):

Thermal decomposition:

Partition coefficient: n-ocatnol/water: not applicable
Relative vapour density:

Particle Size Distribution:

no data available
no data available
not applicable

9.2 Other information: Evaporation rate: No data available. No data available.

Molecular weight:

No data available.

Section 10: Stability and reactivity

10.1 - 10.3: Reactivity; Chemical stability; Possibility of hazardous reactions:

If stored and handled in accordance with standard industrial practices no hazardous reactions are known. Relevant information can possibly be found in other parts of this section.

10.4 Conditions to avoid:

none known.

10.5 Incompatible materials:

none known.

10.6 <u>Hazardous decomposition products:</u>

If stored and handled properly: none known . Measurements have shown the formation of small amounts of formaldehyde at temperatures above about 150 °C (302 °F) through oxidation.

according to Regulation (EC) No. 1907/2006

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Section 11: Toxicological information

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

11.1.1 Acute toxicity:

Product details:

Route of exposure Result/Effect Species/Test system Source

oral LD_{50} : > 2000mg/Kg rat Conclusion by analogy dermal LD_{50} : > 2000mg/Kg rat Conclusion by analogy

11.1.2 Skin corrosion/irritation:

Product details:

Result/Effect Species/Test system Source

No Skin irritation rabbit Conclusion by analogy

11.1.3 Serious eye damage/eye irritation:

Product details:

Result/Effect Species/Test system Source

No eye irritation rabbit Conclusion by analogy

11.1.4 Respiratory or skin sensitization:

Product details:

Exposure routes Result/Effect Species/Test system Source

Skin contact not sensitizing guinea-pig; Bühler Test Conclusion by analogy

OECD 406

Inhalation no data available

11.1.5 Germ cell mutagenicity:

Assessment:

For this endpoint no toxicological test data is available for the whole product.

11.1.6 Carcinogenicity:

Assessment:

For this endpoint no toxicological test data is available for the whole product.

11.1.7 Reproductive toxicity:

Assessment:

For this endpoint no toxicological test data is available for the whole product.

11.1.8 Specific target organ toxicity - single exposure:

Assessment:

For this endpoint no toxicological test data is available for the whole product.

11.1.9 Specific target organ toxicity - repeated exposure:

Assessment:

For this endpoint no toxicological test data is available for the whole product.

11.1.10 Aspiration hazard:

according to Regulation (EC) No. 1907/2006

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Assessment:

For this endpoint no toxicological test data is available for the whole product.

11.2 Information on other hazards:

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

11.2.2 Further toxicological information

None known.

Section 12: Ecological information

12.1. **Toxicity:**

Assessment:

Evaluation on basis of physical-chemical properties: No expected damaging effects to aquatic organism.

12.2. Persistence and degradability:

Assessment:

Polymer component: biologically not degradable. Elimination by adsorption to activated sludge.

12.3. Bioaccumulative potential:

Assessment:

Polymer component: No adverse effects expected.

Data on substances

Dodecamethylcyclohexasiloxane (D6):

Under controlled laboratory conditions D6 dissolved in water bioconcentrates in fish. However, available monitoring data indicate that the substance does not biomagnify in aquatic and terrestrial food webs in the environment.

12.4. Mobility in soil:

Assessment:

Polymer component: Insoluble in water.

Data on substances

Dodecamethylcyclohexasiloxane (D6):

Under controlled laboratory conditions D6 dissolved in water bioconcentrates in fish. However, available monitoring data indicate that the substance does not biomagnify in aquatic and terrestrial food webs in the environment.

12.5. Results of PBT and vPvB assessment:

The product contains substances >= 0.1% that have been subjected to the SVHC process according to REACh regulation (EC) No 1907/2006 Art. 57 as fulfilling the PBT and/or vPvB criteria according to REACh regulation (EC) No 1907/2006 Annex XIII.

Data on substances

according to Regulation (EC) No. 1907/2006

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Dodecamethylcyclohexasiloxane (D6):

Under controlled laboratory conditions D6 dissolved in water bioconcentrates in fish. However, available monitoring data indicate that the substance does not biomagnify in aquatic and terrestrial food webs in the environment.

12.6 Endocrine disrupting properties:

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

12.7 Other adverse effects:

None known.

Section 13: Disposal considerations

13.1 Waste treatment methods:

Material:

Recommendation:

Material that cannot be used, reprocessed or recycled should be disposed of in accordance with Federal, State, and local regulations at an approved facility. Depending on the regulations, waste treatment methods may include, e.g., landfill or incineration.

13.1.2 Uncleaned packaging:

Recommendation:

Completely discharge containers (no tear drops, no powder rest, scraped carefully). Containers may be recycled or re-used. Observe local/state/federal regulations. Uncleaned packaging should be treated with the same precautions as the material.

13.1.3 Waste Disposal Legislation Ref. No. (EC):

It is not possible to determine a waste code for this product in accordance with the European Waste Catalogue (EWC) since it is only possible to classify it according to how it is used by the customer. The waste code is to be determined within the EU in liaison with the waste-disposal operator.

Section 14: Transport information

14.1. – 14.4. <u>UN number; UN proper shipping name; Transport hazard class(es); Packing group:</u>

Road ADR:

Valuation: Not regulated for transport

Railway RID:

Valuation: Not regulated for transport **Transport by sea IMDG-Code:**Valuation: Not regulated for transport

Air transport ICAO-TI/IATA-DGR: Valuation: Not regulated for transport

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14.5. Environmental hazards:

Hazardous to the environment: no

14.6. Special precautions for user:

Relevant information in other sections has to be considered.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code:

Bulk transport in tankers is not intended.

Section 15: Regulatory information

15.1. <u>Safety, health and environmental regulations/legislation specific for the substance or mixture:</u>

National and local regulations must be observed.

For information on labelling please refer to section 2 of this document.

Technical instructions on air:

CAS No. Substance Number Category 14808-60-7 quartz 5.2.1

Water contaminating class:

1 - slightly water contaminating (VwVwS, Germany)

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

Not applicable

Other specifications, restrictions and prohibitions:

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

Regulation (EU) 2019/1148 on the marketing and use of explosives precursors - ANNEX I. RESTRICTED EXPLOSIVES

PRECURSORS: Not applicable

Regulation (EU) 2019/1148 on the marketing and use of explosives precursors - ANNEX II.

REPORTABLE EXPLOSIVES

PRECURSORS: Not applicable

Details of international registration status:

Relevant information about individual substance inventories, where available, is given below.

Japan:

ENCS (Handbook of Existing and New Chemical Substances):

This product is listed in, or complies with, the substance inventory.

Australia:

AICS (Australian Inventory of Chemical Substances):

This product is listed in, or complies with, the substance inventory.

People's Republic of China:

IECSC (Inventory of Existing Chemical Substances in China):

This product is listed in, or complies with, the substance inventory.

Canada

DSL (Domestic Substance List):

This product is listed in, or complies with, the substance inventory.

Philippines:

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PICCS (Philippine Inventory of Chemicals and Chemical Substances):

This product is listed in, or complies with, the substance inventory.

United States of America (USA):

TSCA (Toxic Substance Control Act Chemical Substance Inventory):

All components of this product are listed as active or are in compliance with the substance inventory.

Taiwan:

TCSI (Taiwan Chemical Substance Inventory): This product is listed in, or complies with, the substance inventory. General note: The Taiwanese chemicals regulation requires a phase 1 registration for TCSI-listed or TCSI-compliant substances if imports to Taiwan or manufacturing in Taiwan exceed the trigger quantity of 100 kg/a (for mixtures to be calculated per each ingredient). It is the duty of the importing/manufacturing legal entity to take care of this obligation.

European Economic Area (EEA):

REACH (Regulation (EC) No 1907/2006):

General note: The registration obligations for substances imported into the EEA or manufactured within the EEA by the supplier mentioned in section 1 are fulfilled by the said supplier. The registration obligations for substances imported into the EEA by customers or other downstream users must be fulfilled by the latter.

South Korea (Republic of Korea):

AREC (Act on Registration and Evaluation of Chemicals; "K-REACH"): General note: in case of registration obligations for substances or polymers imported into Korea or manufactured within Korea these are fulfilled by the supplier mentioned in section 1. The registration obligations for substances or polymers imported into Korea by customers or other downstream users must be fulfilled by the latter.

15.2 <u>Chemical safety assessment:</u>

Due to the results of the chemical safety assessment, exposure scenarios and identified uses are not of relevance for this safety data sheet.

Section 16: Other information

16.1 <u>Material:</u>

The details in this document are based on the state of our knowledge at the time of revision. They do not constitute an assurance

of the described product properties in terms of statutory warranty requirements.

The providing of this document to a recipient does not relieve the recipient of his or her responsibility toward compliance with all laws and stipulations applicable to the product. This applies in particular to the further sale or distribution of the product or substances or items containing the product, in other jurisdictions and with regard to the protection of third-party intellectual property rights. If the described product is processed or mixed with other substances or materials, the details stated in this document cannot be conferred to the resultant new product unless this has been expressly mentioned. If the product is repackaged, the recipient is obligated to additionally provide the required safety-related information.

SILCONIC restricts the use of its products inside the human body or in contact with bodily fluids and mucosa.

16.2 Further information:

Commas appearing in numerical data denote a decimal point. Vertical lines in the left-hand margin indicate changes compared with the previous version. This version supersedes all previous versions.

Key or legend to abbreviations and acronyms used in the safety data sheet

ABEK - Multi-Range Filter A, B, E, K; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; APF

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- Assigned Protection Factor; CAS No. Chemical Abstracts Service Registry Number; DFG German Research Foundation; DIN
- German institute for standardization; DOC Dissolved Organic Carbon; d/w days per week; EC / CE / EG European Community; EC50 / CE50 Median effective concentration; ECHA European Chemicals Agency; ED endocrine disruptor; EGRL
- test method according to Regulation 440/2008; EN European Standard; ERC -Environmental Release Category; g/cm3 - gram per cubic centimeter; h - hour(s); H-Code hazard statement code(s); hPa - Hectopascal; IATA Regs - International Air Transport Association (IATA) Dangerous Goods Regulations; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 / CI50 half maximal inhibitory concentration; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IMDG Code - International Maritime Dangerous Goods Code; ISO - International Organization for Standardization; LC50 / CL50 - medium lethal concentration; LD50 / DL50 - medium lethal dose; LOAEC -Lowest Observed Adverse Effect Concentration; LOAEL - Lowest Observed Adverse Effect Level; MARPOL - International Convention for the Prevention of Marine Pollution from Ships; mg/g - milligrams per gram; mg/kg - milligrams per kilogram; mg/l - milligrams per liter; mg/m³ - milligrams per cubic meter; min - minutes; mJ - millijoule; mm millimeter; mm²/s - square millimeter per second; mPa.s - Millipascal second(s); MSDS / SDB / SDS - safety data sheet; No Observed Adverse Effect Concentration; NOAEL - No Observed adverse effect level; NOEC - No Observed Effect Concentration; NOEL - No Observed Effect Level: OECD - Organization for Economic Cooperation and Development; PBT - persistent, bioaccumulative, toxic; PC - product category; P-Code precautionary statement code(s); ppm - parts per million; PROC - process category; RCP reciprocal calculation-based procedure; RID - convention concerning international carriage by rail; SU - sector of use; SVHC - substance of very high concern; Vol% - volume percent; UN No. - United Nations Dangerous Goods Number; vPvB - very Persistent, very Bioaccumulative.

Additional information:

Explanation of information on GHS classification:

STOT RE 1; H372: Specific target organ toxicity (repeated exposure) Category 1;

Causes damage to organs through prolonged or repeated exposure.

R-phrase Description

R48/20 Harmful: danger of serious damage to health by prolonged exposure

through inhalation.

General Information:

The details in this document are based on the state of our knowledge at the time of revision. They do not constitute an assurance of the described product properties in terms of statutory warranty requirements. The providing of this document to a recipient does not relieve the recipient of his or her responsibility toward compliance with all laws and stipulations applicable to the product. This applies in particular to the further sale or distribution of the product or substances or items containing the product, in other jurisdictions and with regard to the protection of third-party intellectual property rights. If the described product is processed or mixed with other substances or materials, the details stated in this document cannot be conferred to the resultant new product unless this has been expressly mentioned. If the product is repackaged, the recipient is obligated to additionally, provide the required safety-related information.