

SAFETY DATA SHEET

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

Revision date: 12 Jul 2021

Print date: 22 Jul 2021

Version: 2.0

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DIVARIO® Putty

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

1.1 Product identifier

Trade name/designation:

DIVARIO® Putty

Other means of identification:

UFI: not required

Article No.:

14070

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

Use of the substance/mixture:

Silicone modelling material for dental-technical application.

For professional use only.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Mälzer Dental GmbH & Co. KG

Schlesierweg 27

31515 Wunstorf

GERMANY

Telephone: +49 (0) 5033 963099-0

Telefax: +49 (0) 5033 963099-99

E-mail: info@maelzer-dental.de

Website: <https://www.maelzer-dental.de>

E-mail (competent person): info@maelzer-dental.de

1.4 Emergency phone number

+49 (0) 5033 963099-0 (Only available during office hours.)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]:

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2 Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Hazard statements: -

Supplemental hazard information

EUH210 Safety data sheet available on request.

Precautionary statements - General: -

2.3 Other hazards

Adverse human health effects and symptoms:

May cause eye irritation. May cause skin irritation.

Other adverse effects:

Special danger of slipping by leaking/spilling product.

SECTION 3: Composition / information on ingredients

3.2 Mixtures

Description:

Mixture of Polydimethylsiloxane, Filler and additives.

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Additional information:

The following substances are fixed in a Polydimethylsiloxane matrix: Cristobalite, White mineral oil (petroleum).

Ingredients:

Product identifiers	Substance name Classification according to Regulation (EC) No. 1272/2008 [CLP]	Content
CAS No.: 14464-46-1 EC No.: 238-455-4	Cristobalite Substance with a community workplace exposure limit.	30 - < 35 weight-%
CAS No.: 8042-47-5 EC No.: 232-455-8 REACH No.: 01-2119487078-27	White mineral oil (petroleum) Asp. Tox. 1  Danger H304	1 - < 5 weight-%

Full text of H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Take off contaminated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended. Warning First aider: Pay attention to self-protection!

Following inhalation:

Provide fresh air.

In case of skin contact:

Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Following ingestion:

Rinse mouth. Let water be drunken in little sips. Get medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause eye irritation. May cause skin irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Water spray jet, alcohol resistant foam, extinguishing powder, carbon dioxide (CO₂).

5.2 Special hazards arising from the substance or mixture

Not readily flammable. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hazardous combustion products:

In case of fire may be liberated: carbon oxides (CO_x), pyrolysis products, toxic.

5.3 Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

5.4 Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Personal precautions:

Provide adequate ventilation. Avoid contact with skin, eyes and clothes. Special danger of slipping by leaking/spilling product.

Protective equipment:

Wear protective gloves/protective clothing/eye protection/face protection. See section 8.

6.1.2 For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8.

6.2 Environmental precautions

Do not allow to enter into surface water or drains.

Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

For containment:

Wipe up with absorbent material (eg. cloth, fleece). Handling larger quantities: Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

For cleaning up:

Water with tenside additive

6.4 Reference to other sections

Safe handling: see section 7.

Personal protection equipment: see section 8.

Disposal: see section 13.

6.5 Additional information

Use appropriate container to avoid environmental contamination.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures

Advices on safe handling:

Provide adequate ventilation. Avoid contact with skin, eyes and clothes.

Wear personal protection equipment (refer to section 8).

Fire prevent measures:

No special measures are necessary.

Environmental precautions:

Discharge into the environment must be avoided.

Advices on general occupational hygiene

When using do not eat, drink or smoke. Wash hands and face before breaks and after work and take a shower if necessary. Apply skin care products after work.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Keep container tightly closed. Store in a cool dry place. Keep away from heat.

Requirements for storage rooms and vessels:

Ensure adequate ventilation of the storage area. Floors should be impervious, resistant to liquids and easy to clean. Keep/Store only in original container.

Hints on storage assembly:

Keep away from food, drink and animal feedingstuffs.

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7.3 Specific end use(s)

Recommendation:

Silicone modelling material for dental-technical application.
Observe instructions for use.

SECTION 8: Exposure controls / Personal protection

8.1 Control parameters

8.1.1 Occupational exposure limit values

Limit value type (country)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
WEL (GB)	Cristobalite CAS No.: 14464-46-1	① 0.1 mg/m ³ ⑤ (Silica, crystalline; respirable fraction)
BOELV (EU)	Cristobalite CAS No.: 14464-46-1	① 0.1 mg/m ³ ⑤ (Silica, crystalline; respirable fraction)

8.1.2 Biological limit values

No data available.

8.1.3 DNEL-/PNEC-values

No data available.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

See section 7. No additional measures necessary.

8.2.2 Personal protection equipment



Eye/face protection:

Recommendation: Eye glasses with side protection (EN 166).

Skin protection:

Recommendation: Wear suitable gloves (EN ISO 374).

Suitable material: NBR (Nitrile rubber)

Material thickness: 0,11 mm

Breakthrough time: > 480 min

Breakthrough times and swelling properties of the material must be taken into consideration. Check leak tightness/impermeability prior to use. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Respiratory protection:

Usually no personal respiratory protection necessary.

Other protection measures:

Wear suitable protective clothing.

8.2.3 Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: solid, pasty

Colour: orange - red

Odour: characteristic

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Safety relevant basic data

Parameter		at	Method	Remark
pH	not applicable			
Melting point	not determined			
Freezing point	not determined			
Initial boiling point and boiling range	not determined			
Decomposition temperature	> 250 °C			
Flash point	> 100 °C		DIN 51755	
Evaporation rate	not determined			
Auto-ignition temperature	> 200 °C		DIN 51794	
Upper/lower flammability or explosive limits	not determined			
Vapour pressure	< 1 hPa	20 °C		
Vapour density	not determined			
Density	1.67 g/cm ³	20 °C	DIN 51757	
Bulk density	not applicable			
Water solubility	insoluble			
Partition coefficient: n-octanol/water	not determined			
Dynamic viscosity	≈ 25,000,000 mPa*s	23 °C	Brookfield	
Kinematic viscosity	not applicable			

9.2 Other information

No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

Not readily flammable.

10.2 Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not expose to temperatures exceeding 150 °C.

10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

Temperature > 150 °C: Formation of Formaldehyde (possible in traces).

In case of fire may be liberated: silicon dioxide (SiO₂), carbon oxides (CO_x), Formaldehyde.

Further information

No data available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity:

Based on available data, the classification criteria are not met.

Acute dermal toxicity:

Based on available data, the classification criteria are not met.

Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

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Skin corrosion/irritation:

Based on available data, the classification criteria are not met.
May cause skin irritation.

Serious eye damage/irritation:

Based on available data, the classification criteria are not met.
May cause eye irritation.

Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

Carcinogenicity:

Based on available data, the classification criteria are not met.

Reproductive toxicity:

Based on available data, the classification criteria are not met.

STOT-single exposure:

Based on available data, the classification criteria are not met.

STOT-repeated exposure:

Based on available data, the classification criteria are not met.

Aspiration hazard:

Based on available data, the classification criteria are not met.

Additional information:

No data available.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

Based on available data, the classification criteria are not met.

Additional ecotoxicological information:

No data available.

12.2 Persistence and degradability

Biodegradation:

The product is not biodegradable.

12.3 Bioaccumulative potential

Accumulation / Evaluation:

No indication of bioaccumulation potential.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

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

12.6 Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

13.1.1 Product/Packaging disposal

Waste codes/waste designations according to EWC

Waste code product:

07 02 17	waste containing silicones other than those mentioned in 07 02 16
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Waste treatment options

Appropriate disposal / Product:

Dispose of waste according to applicable legislation. Consult the appropriate local waste disposal expert about waste disposal. Do not allow to enter into surface water or drains.

Appropriate disposal / Package:

Completely emptied packages can be recycled.

Other disposal recommendations:

The allocation of waste code numbers / waste names must be carried out in accordance with the European Waste Catalogue (EWC). Collect in closed and suitable containers for disposal.

13.2 Additional information

Waste for disposal is to be classified and labelled.

SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI-/IATA-DGR)
14.1 UN-No.			
-	-	-	-
14.2 UN proper shipping name			
Not restricted	Not restricted	Not restricted	Not restricted
14.3 Transport hazard class(es)			
No data available.			
14.4 Packing group			
No data available.			
14.5 Environmental hazards			
No data available.			
14.6 Special precautions for user			
No data available.			

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

not relevant

Additional information:

No data available.

SECTION 15: Regulatory information

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

15.1.1 EU legislation

Other EU regulations:

Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC).

15.1.2 National regulations

No data available.

15.2 Chemical Safety Assessment

No data available.

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SECTION 16: Other information

16.1 Indication of changes

Changes executed in version 2.0:

General revision of all sections

16.2 Abbreviations and acronyms

ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route

ATE = acute toxicity estimate

AVV = Abfallverzeichnis-Verordnung

AwSV: Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen

BGI = Berufsgenossenschaftliche Informationen

CAS = Chemical Abstracts Service

CLP = Classification, Labelling and Packaging

DMEL = Derived Minimum Effect Level

DNEL = Derived No Effect Level

EC50 = Median effective concentration

ECB = European Chemicals Bureau

EEC = European Economic Community

EINECS = European Inventory of Existing Commercial Chemical Substances

ELINCS = European List of Notified Chemical Substances

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC-Code = International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk

IC50 = Inhibition concentration, 50%

IMDG = International Maritime Code for Dangerous Goods

IUCLID = International Uniform Chemical Information Database

LC50 = Lethal concentration, 50%

LD50 = Median lethal dose

LC0 = lethal concentration, 0%

LOAEL = lowest-observed-adverse-effect level

LGK = Lagerklasse

MARPOL = International Convention for the Prevention of Marine Pollution from Ships

NOAEL = No Observed Adverse Effect Level

NOEC = No Observed Effect Content

PBT = Persistent, Bioaccumulative and Toxic substance

PNEC = Predicted No-Effect Content

RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses

REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals

STP = Sewage Treatment Plant

TLV®/TWA = Threshold limit value - time-weighted average

TLV®STEL = Threshold limit value - short-time exposure limit

TRGS = Technical Rules for Hazardous Substances

VOC = Volatile Organic Compounds

vPvB = very Persistent and very Bioaccumulative

16.3 Key literature references and sources for data

European Chemicals Agency (ECHA): <http://www.echa.europa.eu>

ECHA, C&L Inventory: <http://echa.europa.eu/information-on-chemicals/cl-inventory-database>

ECHA, Registered substances: <http://echa.europa.eu/information-on-chemicals/registered-substances>

GESTIS (Gefahrstoffinformationssystem der DGUV): <http://www.dguv.de/ifa/GESTIS/index.jsp>

Hörath Gefährliche Stoffe und Gemische, 8. Auflage, Dr. Angela Schulz

Safety data sheets of the manufacturers

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16.4 Classification for mixtures and used evaluation method according to regulation (EC) No. 1272/2008 [CLP]

Classification according to Regulation (EC) No. 1272/2008 [CLP]:

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

16.5 Relevant H- and EUH-phrases

Hazard statements	
H304	May be fatal if swallowed and enters airways.

16.6 Training advice

No data available.

16.7 Additional information

The information in this safety data sheet has been established to our best knowledge and was up-to-date at time of revision. The information is intended to give you advice about the safe handling of the product for storage, processing, transport and disposal. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.