Safety Data Sheet
acc. to OSHA HCS

Printing date 11/22/2021 Reviewed on 11/22/2021

1 Identification

· **Product identifier**

· **Trade name:** **Provil Novo Dynamix Putty Cat**

· **-**

· **Application of the substance / the mixture** Dental impression material

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**
Kulzer GmbH
Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522

· **Information department:**
Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545
e-mail: customer.servicehkna@kulzer-dental.com

· **Emergency telephone number:**
Emergency CONTACT (24-Hour-Number)
ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

· **Classification of the substance or mixture**

Carc. 1A H350 May cause cancer.

STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS08

· **Signal word** Danger

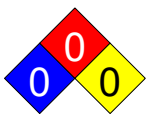
· **Hazard-determining components of labeling:**
cristobalite

· **Hazard statements**
May cause cancer.
Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· **Precautionary statements**
Do not handle until all safety precautions have been read and understood.
Do not breathe dust/fume/gas/mist/vapors/spray.
Wear protective gloves/protective clothing/eye protection/face protection.
Get medical advice/attention if you feel unwell.

· **Classification system**

· **NFPA ratings for USA (scale 0-4)**



Health = 0
Fire = 0
Reactivity = 0

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· **HMIS-Ratings (Scale 0-4)**

HEALTH	*0
FIRE	0
REACTIVITY	0

Health = *0
Fire = 0
Reactivity = 0

· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** -

· **Dangerous components:**

14464-46-1	cristobalite	Carc. 1A, H350; STOT RE 1, H372	50-75%

· **Additional information** For the wording of the listed hazard phrases refer to section 16.

4 First-aid measures

· **Description of first aid measures**
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
· **After eye contact**
Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
· **Information for doctor**
· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents**
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.
· **Additional information** -

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation

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Avoid contact with eyes and skin.
· **Environmental precautions:** Prevent seepage into sewage system, workpits and cellars.
· **Methods and material for containment and cleaning up:**
Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
· **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
-
· **Protective Action Criteria for Chemicals**

· **PAC-1:**		
14464-46-1	cristobalite	0.075 mg/m³
68083-19-2	Polydimethylsiloxan	48 mg/m³
7631-86-9	silicon dioxide, chemically prepared	18 mg/m³
540-97-6	Dodecamethylcyclohexasiloxane	150 mg/m³
556-67-2	octamethylcyclotetrasiloxane	30 ppm
67-63-0	propan-2-ol	400 ppm

· **PAC-2:**		
14464-46-1	cristobalite	33 mg/m³
68083-19-2	Polydimethylsiloxan	530 mg/m³
7631-86-9	silicon dioxide, chemically prepared	740 mg/m³
540-97-6	Dodecamethylcyclohexasiloxane	1,700 mg/m³
556-67-2	octamethylcyclotetrasiloxane	68 ppm
67-63-0	propan-2-ol	2000* ppm

· **PAC-3:**		
14464-46-1	cristobalite	200 mg/m³
68083-19-2	Polydimethylsiloxan	3,200 mg/m³
7631-86-9	silicon dioxide, chemically prepared	4,500 mg/m³
540-97-6	Dodecamethylcyclohexasiloxane	9,900 mg/m³
556-67-2	octamethylcyclotetrasiloxane	130 ppm
67-63-0	propan-2-ol	12000** ppm

7 Handling and storage

· **Handling**
· **Precautions for safe handling**
Store in cool, dry place in tightly closed receptacles.
No special precautions are necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.

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· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the remaining constituent has no known exposure limits.

14464-46-1 cristobalite	
PEL	Long-term value: 0.05* mg/m³ *resp. dust;½ value from resp.dust formulae Quartz
REL	Long-term value: 0.05* mg/m³ *respirable dust; See Pocket Guide App. A
TLV	Long-term value: 0.025* mg/m³ *as respirable fraction

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**
Wash hands before breaks and at the end of work.

· **Breathing equipment:** Not necessary if room is well-ventilated.

· **Protection of hands:**
Check protective gloves prior to each use for their proper condition.
recommended

· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**
Butyl rubber, BR
Nitrile rubber, NBR

· **Eye protection:** Safety glasses

· **Body protection:** Light weight protective clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:**	Pasty
· **Color:**	Light grey
· **Odor:**	Characteristic
· **Odor threshold:**	Not determined.

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· **pH-value:**	Not determined.
· **Change in condition**	
· **Melting point/Melting range:**	undetermined
· **Boiling point/Boiling range:**	undetermined
· **Flash point:**	Not applicable
· **Flammability (solid, gaseous)**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard. Not determined.
· **Explosion limits:**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Vapor pressure:**	Not determined.
· **Density at 20 °C (68 °F):**	1.53 g/cm³ (12.76785 lbs/gal)
· **Relative density**	Not determined.
· **Vapor density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **Water:**	Not miscible or difficult to mix
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
· **dynamic:**	Not determined.
· **kinematic:**	Not determined.
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** none
· **Additional information:** -

*

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**		
68083-19-2 Polydimethylsiloxan		
Oral	LD50	>5000 mg/kg (rat)
8042-47-5 White mineral oil, petroleum		
Oral	LD50	>5000 mg/kg (rat) (OECD 401)

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Dermal	LD50	>2000 mg/kg (rabbit) (OECD 402)
Inhalative	LC0/4h	≥5 mg/L (rat) (OECD 403)

· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**

· **Carcinogenic categories**
· **IARC (International Agency for Research on Cancer)**
Silicosis: Excessive inhalation of respirable crystalline silica dust may cause a progressive, disabling and sometimes fatal lung disease called silicosis. Symptoms include cough, shortness of breath, wheezing, non-specific chest illness and reduced pulmonary function. This disease is exacerbated by smoking. Individuals with silicosis are predisposed to develop mycobacterial infections (tuberculous and non-tuberculous) and fungal infections. Inhalation of air with a very high concentration of respirable silica dust can cause the most serious forms of silicosis in a matter of months or a few years. Some epidemiologic studies have concluded that there is significant risk of developing silicosis even at airborne exposure levels that are equal to the recommended NIOSH REL, the ACGIH TLV.

Cancer Status: The International Agency for Research on Cancer has determined that crystalline silica inhaled in the form of quartz or cristobalite from occupational sources is carcinogenic to humans (Group 1 - carcinogenic to humans). Refer to IARC Monograph 100C, A Review of Human Carcinogens: Arsenic, Fibres and Dusts (published in 2011) in conjunction with the use of these materials. The National Toxicology Program (NTP) classifies respirable crystalline silica as "known to be a human carcinogen". Refer to the Twelfth Report on Carcinogens (2011). The American Conference of Governmental Industrial Hygienists (ACGIH) classifies crystalline silica, quartz, as a suspected human carcinogen (A2).

14464-46-1	cristobalite	1
7631-86-9	silicon dioxide, chemically prepared	3

· **NTP (National Toxicology Program)**		
14464-46-1	cristobalite	K

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Reproductive toxicity** Based on available data, the classification criteria are not met.

*
12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**	
8042-47-5 White mineral oil, petroleum	
LL50/96h	>100 mg/L (fish) (OECD 203)

· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

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· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Disposal must be made according to official regulations.

· **Uncleaned packagings:**
· **Recommendation:**
Disposal must be made according to official regulations.
Non contaminated packagings can be used for recycling.

14 Transport information

· **UN-Number** · **DOT, ADR, IMDG, IATA**	Void
· **UN proper shipping name** · **DOT, ADR, IMDG, IATA**	Void
· **Transport hazard class(es)** · **DOT, ADR, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:** · **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	-
· **UN "Model Regulation":**	Void

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **Sara**

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **SARA Section 313 (specific toxic chemical listings)**

67-63-0	propan-2-ol

· **Hazardous Air Pollutants**

None of the ingredients is listed.

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· **Proposition 65**
· **Prop 65 - Chemicals known to cause cancer**
The listing is for silica, crystalline as "airborne particles of respirable size". Silica, crystalline of this product is within a product matrix.

14464-46-1	cristobalite

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**
None of the ingredients is listed.

· **Cancerogenity categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

14464-46-1	cristobalite	A2

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

14464-46-1	cristobalite

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**
H350 May cause cancer.
H372 Causes damage to organs through prolonged or repeated exposure.

· **Date of preparation / last revision** 11/22/2021 / 1

· **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Carc. 1A: Carcinogenicity – Category 1A
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

· ***** Data compared to the previous version altered.**