Material Safety Data Sheet

according to Regulation (EU) 2015/830

Revision:03

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

1.1. Product identifier

Product Name: PRESIGUM FAST PUTTY BASE- Fast Setting A Silicone Base

Code: PRD.01.PGUMP01

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

İntendent use : For professional use only. Addition silicone for dental impression.

1.2. Details of the supplier of the safety data sheet

Company Name: President Dental GmbH

Street: Kesselbodenstrasse 5

Zip-Code / Town: 85391, Allershausen

Web: www.presidentdental.com

Contact for technical information: +49 8166 389 9 820

Phone / Fax / E-Mail: +49 8166 389 9 820 / +49 8166 389 9 821 / info@presidentdental.com

1.3. Emergency Telephone Number

+49 8166 389 9 820 (8.00 am – 4.30 pm Mon-Fri)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP) Adverse physicochemical, human health and environmental effects:	The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP). No other hazards

2.2. Label Elements

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the CLP labeling requirements.	
Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.	
Hazard pictograms	None
Hazard statements:	None
Precautionary statements:	None
Special Provisions:	EUH210 Safety data sheet available on request.
Special provisions according to Annex XVII of REACH and subsequent amendments:	None

2.3. Other Hazards

	There is no exposure to breathable free crystalline silica during normal use of this product. For more information see section 11. vPvB Substances: None - PBT Substances: None

SECTION 3: Composition/information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Hazardous components within the meaning of the CLP regulation and related classification:

Chemical Name	Index No.	CAS No.	EC No.	Conc. (%w/w)	Classification
CRISTOBALITE	-	14464-46-1	238-455-4	5 ≤ x < 8	 3.9/1 STOT RE 1 H372

- The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Remove casualty to fresh air and keep warm and at rest.
Eye Contact:	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Skin Contact:	Wash with plenty of water and soap.
Ingestion	Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

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

	None

4.3. Indication of any immediate medical attention and special treatment needed

	None

SECTION 5: Fire Fighting Measures

5.1. Extinguishing media

Suitable extinguishing media:	Water.

Unsuitable extinguishing media:	Carbon dioxide (CO2).. None in particular.

5.2. Special Hazards arising from the substance or mixture

	Do not inhale explosion and combustion gases. Burning produces heavy smoke.

5.3. Advice for firefighters

	Use suitable breathing apparatus . Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measures

6.1. Personal Precautions, protective equipment and emergency procedures.

	For non emergency personnel: Wear personal protection equipment. Remove persons to safety. See protective measures under point 7 and 8. For emergency responders: Wear personal protection equipment.

6.2. Environmental precautions

	Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains. Retain contaminated washing water and dispose it. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities. Suitable material for taking up: absorbing material, organic, sand.

6.3. Methods and material for containment and cleaning up

	Wash with plenty of water.

6.4. Reference to other sections

	See also section 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements:	Avoid contact with skin and eyes, inhalation of vapours and mists. See also section 8 for recommended protective equipment. Advice on general occupational hygiene: Do not eat or drink while working.

7.2. Conditions for safe storage, including any incompabilities.

Storage conditions:	Keep away from food, drink and feed. Incompatible materials: See section 10.5. Instructions as regards storage premises: Adequately ventilated premises.

7.3. Specific end use(s)

	See section 1.2.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

CRISTOBALITE - CAS: 14464-46-1							
OEL Type	**Country**	**TWA/8h**		**STEL/15min**			
		mg/m^3	**ppm**	**mg/mg^3**	**ppm**	**Notes**	
VEL	SWITZERLAND	0.15				Respirable (aerosol)	
AK	HUNGARY	0.15				Respirable (aerosol)	
OELV	IRELAND	0.1				Respirable (aerosol)	
NGV/KGV	SWEDEN	0.05				Respirable (aerosol)	(USA-NIOSH)
VLEP	FRANCE	0.05				Respirable (aerosol)	
VLEP	BELGIUM	0.05					
TLV	DENMARK	0.15		0.3			
VLA	SPAIN	0.05				Respirable	
TLV-ACGIH		0.025					
TLV	NETHERLANDS	0.075				Respirable	
NIOSH	UNITED STATES	0.05					

ACGIH	0.025	(R), A2 – Pulm fibrosis, lung cancer

DNEL Exposure Limit Values
Not available
PNEC Exposure Limit Values
Not available

8.2. Exposure Control

Precautionary measures:	Give adequate ventilation to the premises where the product is stored and/or handled.
Respiratory Protection:	Use respiratory protection where ventilation is insufficient or exposure is prolonged. Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered (e.g. TLV-TWA).
Hand Protection:	Protect hands with work gloves. The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability. The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.
Eye protection:	Wear airtight protective goggles.
Skin protection:	Wear professional overalls and safety footwear.
Enviromental exposure controls :	None
Appropriate engineering controls:	None

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appereance	Putty
Colour	Blue
Odour	odourless
Odour treshold	Not available
pH	Not applicable
Melting point/freezing point	Not available
Initial boiling point	Not available
Boiling range	Not available
Flash point	>135 ° C
Evaporation rate	Not available

Flammability of solids and gases	Not available
Lower inflammability limit	Not available
Upper inflammability limit	Not available
Lower explosive limit	Not available
Upper explosive limit-	Not available
Vapour pressure	Not available
Vapour density	Not available
Relative density	Not available
Solubility	Insoluble in water
Partion coefficient: n- octano/water	Not available
Auto-ignition tempreature	Not available
Decomption tempreature	Not applicable
Viscosity	Not available
Explosive properties	Not available
Oxiding properties	Not availabe

9.2. Other Information

Properties	Value	Method	Notes
Miscibility:	Not available	-	-
Fat Solubility:	Not available	-	-
Conductivity:	Not available	-	-
Substance Groups relevant properties	Not available	-	-

SECTION 10: Stability and reactivity

10.1. Reactivity

	Stable under normal conditions.

10.2. Chemical Stability

	Stable under normal conditions

10.3. Possibility of Hazardous Reactions

	None

10.4. Conditions to avoid

	Stable under normal conditions.

10.5 Incompatibles materials

	None in particular.

10.6. Hazardous decomposition products

	None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

"For the purposes of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified" (annex I, section 1.1.1.5, EC Regulation 1272/2008).
Monitoring activities conducted at the company related to possible inhalation exposure, in accordance with industrial hygiene standards for paste and fluid products, showed levels of exposure to free crystalline silica (breathable part) below the limit of quantification of the method, therefore exposure is not expected during the use indicated in section 1.2 for this specific product.
However, the actual levels of free crystalline silica (breathable part) present in the workplace must be obtained through monitoring as required by regulations for the safety and health of workers.

ACUTE TOXICITY	Not classified
SKIN CORROSION / IRRITATION	Not classified
SERIOUS EYE DAMAGE / IRRITATION	Not classified
RESPIRATORY OR SKIN SENSITISATION	Not classified
GERM CELL MUTAGENICITY	Not classified
CARCINOGENICITY	Not classified
REPRODUCTIVE TOXICITY	Not classified
STOT - SINGLE EXPOSURE	Not classified
STOT - REPEATED EXPOSURE	Not classified
ASPIRATION HAZARD	Not classified

Toxicological information of the main substances found in the product:

CRISTOBALITE		
Acute Toxicity:		-
Irritation/Corrosion		
	Skin irritation:	-
	Eye irritation	-
Sensitization:		-

Mutagenicity:		-
Carcinogenicity:		-
Toxicity		-
	Toxicity to reproduction:	-
	Toxicity for aspiration	-
STOT Repeated Exposure:		Route: Inhalation - Notes: Target organ: lungs - Positive - Source: (MSDS supplier).

SECTION 12: Ecological information

12.1 Toxicity

	Adopt good working practices, so that the product is not released into the environment. PRESIGUM PUTTY FAST - BASE Not classified for environmental hazards Based on available data, the classification criteria are not met

12.2. Persistance and degradability

CRISTOBALITE	CAS: 14464-46-1 Biodegradability: Non-readily biodegradable

12.3. Bioaccumulative potential

CRISTOBALITE	CAS: 14464-46-1 Not bioaccumulative

12.4. Mobility in Soil

	Not available

12.5. Results of PBT and vPvB assessment

	vPvB Substances: None - PBT Substances: None

12.6. Other adverse effects

	None

SECTION 13: Disposal Considerations

13.1. Waste Treatment methods

	Recover if possible. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

14.1 UN number

	Not classified as dangerous in the meaning of transport regulations.

14.2. UN proper shipping name

	Not available

14.3. Transport hazard class(es)

	Not available

14.4. Packing Group

	Not available

14.5. Environmental hazards

	ADR-Enviromental Pollutant:	No
	IMDG-Marine pollutant:	No

14.6. Special precautions for user

	Not available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

	Not Applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific fort he substance or mixture

Dir. 98/24/EC (Risks related to chemical agents at work)
Dir. 2000/39/EC (Occupational exposure limit values)
Regulation (EC) n. 1907/2006 (REACH)
Regulation (EC) n. 1272/2008 (CLP)
Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013
Regulation (EU) 2015/830
Regulation (EU) n. 286/2011 (ATP 2 CLP)
Regulation (EU) n. 618/2012 (ATP 3 CLP)
Regulation (EU) n. 487/2013 (ATP 4 CLP)

Regulation (EU) n. 944/2013 (ATP 5 CLP) Regulation (EU) n. 605/2014 (ATP 6 CLP) Regulation (EU) n. 2015/1221 (ATP 7 CLP) Regulation (EU) n. 2016/918 (ATP 8 CLP) Regulation (EU) n. 2016/1179 (ATP 9 CLP) Regulation (EU) n. 2017/776 (ATP 10 CLP) Regulation (EU) n. 2018/669 (ATP 11 CLP) Regulation (EU) n. 2018/1480 (ATP 13 CLP) Regulation (EU) n. 2019/521 (ATP 12 CLP)	
Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006 (REACH) and subsequent modifications:	
Restrictions related to the product:	No restriction.
Restrictions related to the substances contained:	No restriction.
Provisions related to directive EU 2012/18 (Seveso III):	Seveso III category according to Annex 1, part 1 None
Lagerklasse according to TRGS 510:	LGK 10: Combustible liquids
WGK Classification (Water hazard class - Verwaltungsvorschrift wassergefährdende Stoffe)	WGK1 - Slightly hazardous for water
Lagerklasse according to TRGS 510:	LGK 10: Combustible liquids
Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:	None.
California Proposition 65	Substance(s) listed under California Proposition 65: Cristobalite - Listed as carcinogen.

15.2. Chemical safety assessment

	No Chemical Safety Assessment has been carried out for the mixture. Substances for which a Chemical Safety Assessment has been carried out: None

SECTION 16: Other information

Other Information

Full text of phrases referred to in Section 3:

H372 Causes damage to organs (lungs) through prolonged or repeated exposure if inhaled.

Hazard class and hazard category	Code	Description
STOT RE 1	3.9/1	Specific target organ toxicity - repeated exposure, Category 1

Further Information

	This document was prepared by a competent person who has received appropriate training. Main bibliographic sources:

ECHA – European Chemical Agency
GESTIS - Information system on hazardous substances of the German Social Accident Insurance
IARC – International Agency for Research on Cancer
IPCS INCHEM – International Programme on Chemical Safety
ISS – Istituto Superiore di Sanità
PubChem - open chemistry database at the National Institutes of Health (NIH)

A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC. This safety data sheet has been created on a voluntary basis.

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.
It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.
This MSDS cancels and replaces any preceding release.

LEGEND:
- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit

	- VOC: Volatile organic Compounds - vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation - WGK: Water hazard classes (German).