

Safety Data Sheet

According to 1907/2006/EC, Article 3131 – Regulation 2020/878

IMPORTANT

Read this MSDS before handling and disposing of this product and pass this information on to employees, customers and users of this product.

1. IDENTIFICATION

1.1 Product Identifier

Product Name	ImpressPLUS Bite Reg
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1.2 Relevant identified uses of the substance of mixture and uses advised against

Product Use	Addition curing vinyl polysiloxane dental impression materials (consisting of base and catalyst)
Restricted Use	
Description	Dental Product.

1.3 Supplier of the Safety Data Sheet

Company Name	Perfection Plus Ltd
Company Address	6 Westwood Court, Brunel Road, Totton, Hants. SO40 3WX. UK
Company Phone No.	+44 (0) 2380 866 677
Website	www.perfectionplus.com
Telephone	0044 (0) 2380 866677
Email	Regulatory@perfectionplus.com
Email address of Competent Person	Regulatory@perfectionplus.com

1.4 Emergency telephone number

Emergency telephone number	0044 (0) 230 866 677 (8am – 5pm Monday to Friday)
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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.2. Classification – EC 1272/2008	
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2.2 Label Elements

Hazard Pictograms	
Signal Word	
Hazard Statement	

2.3 Other hazards

Other hazards	PBT. vPvB. Not applicable.
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Further information

Medical devices as defined Medical Device Regulation (MDR) 2017/745 are exempted from the provisions of regulation (EC) No 1272/2008 (CLP; Article 1, paragraph 5). The product is not classified according to the CLP Regulation.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed.

4. FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Supply fresh air; consult doctor in case of complaints. In case of unconsciousness place patient stably in side-position for transportation.
Eye Contact	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

Skin contact	Instantly wash with water and soap and rinse thoroughly.
Ingestion	Rinse mouth. If you feel unwell get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation	No further relevant information available.
Eye Contact	No further relevant information available.
Skin contact	No further relevant information available.
Ingestion	No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

Inhalation	No further relevant information available.
Eye Contact	No further relevant information available.
Skin contact	No further relevant information available.
Ingestion	No further relevant information available.

General information

	If you feel unwell, seek medical advice (show the label where possible).
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5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

	CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire extinguishing methods suitable to surrounding conditions.
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5.2 Special hazards arising from the substance or mixture

	Formation of toxic gases is possible during heating or in case of fire.
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5.3 Advice for firefighters

	Wear self-contained respiratory system.
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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

	For non-emergency personnel: Use personal protective equipment, see section 8. For emergency responders: Remove persons to safety. Isolate hazard area and deny entry. Ventilate closed spaces before entering. Use personal protective equipment, see section 8.
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6.2 Environmental precautions

	Avoid release to the environment. Do not allow product to enter sewers/surface or ground water.
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6.3 Methods and material for containment and cleaning up

	Collect mechanically. The product may be absorbed by liquid-binding material (sand, diatomite, acid binders). Wash spill area with alcohol or water and soap.
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6.4 Reference to other sections

	See section 7 for information on safe handling. See section 8 for exposure controls/personal protection. See section 13 for disposal information.
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7. HANDLING AND STORAGE

7.1 Precautions for safe handling

	No special precautions are necessary if used correctly. Information about fire – and explosion protection: No special measures required.
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7.2 Conditions for safe storage, including any incompatibilities

	Storage: 10-25°C (50-77°F) Requirements to be met by storerooms and receptacles: Store only in original receptacles. Information about storage in one common storage facility: Not required Further information about storage conditions: Protect from heat and direct sunlight. Keep container tightly sealed.
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7.3 Specific end use(S)

	No further relevant information available.
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

8.1 Control parameters

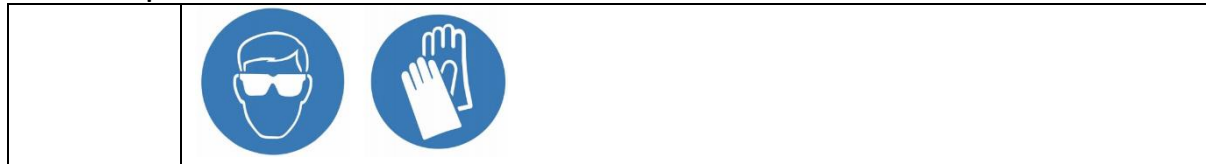
Ingredients with limit values that require monitoring at the workplace:

	This product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
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Additional information:

	The lists that were valid during the making were used as a basis.
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8.2 Exposure controls



8.2.1 General protective and hygiene measures

	The usual precautionary measures are to be adhered to when handling chemicals. Avoid contact with eyes and skin. Wash hands before breaks and at the end of work. Immediately remove all soiled and contaminated clothing. Keep away from foodstuffs, beverages and feed.
Eye/face protection	Approved safety goggles.
Skin protection – Hand protection	Protective gloves are recommended to avoid possible sensitization. The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. 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 cannot be calculated in advance and has therefore to be checked prior to the application. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed
Respiratory protection	Not required.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Paste	Relative Vapour density	Not applicable.
Colour	According to specification	Evaporation rate	Not determined.
Odour	Odourless	Solubility/ Miscibility with water	Insoluble.
Odour threshold	Not applicable.	Partition coefficient (n-octanol/water)	Not determined.
pH	Not applicable.	Decomposition temperature	Not determined.
Melting point	Undetermined	Explosive properties	No explosion hazard
Boiling point	Undetermined	Lower explosion limits	Not determined.
Flash point	Not applicable.	Upper explosion limits	Not determined.
Auto ignition temperature	Not determined	Viscosity Dynamic	Not determined.
Flammability (solid, gas)	Not determined.	Viscosity Kinematic	Not determined.
Self-igniting	Not self-igniting	Nanoform particle characteristics:	Not determined.
Vapour pressure	Not applicable.	Nanoform solubility:	Not determined.
Density	Not determined.	Partition coefficient n-octanol/water (log value)	Not determined.
Relative density	Not determined.		

9.2. Other information
9.2.1 Information with regard to physical hazard classes

	No further relevant information available.
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9.2.2 Other safety characteristics

	No further relevant information available.
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10. STABILITY AND REACTIVITY
10.1 Reactivity

	No further relevant information available.
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10.2 Chemical stability

	Thermal decomposition/conditions to be avoided: No decomposition if used according to specifications.
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10.3 Possibility of hazardous reactions

	No dangerous reactions known.
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10.4 Conditions to avoid

	No further relevant information available.
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10.5 Incompatible materials

	No further relevant information available.
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10.6 Hazardous decomposition products

	Not known.
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11. TOXICOLOGICAL INFORMATION
11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity	LD/LC50 values relevant for classification: No further relevant information available.
Primary irritant effect:	
On the skin	No irritant effect.
On the eye	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness.
Sensitization	No sensitizing effects known.
Additional toxicological information	No further relevant information available.

11.2 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Endocrine disrupting properties	No further relevant information available.
Other information	No further relevant information available.

12. ECOLOGICAL INFORMATION
12.1 Toxicity

	No further relevant information available.
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12.2 Persistence and degradability

	No further relevant information available.
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12.3 Bio accumulative potential

	No further relevant information available.
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12.4 Mobility in soil

	Do not allow product to reach ground water, water bodies or sewage system. Danger to drinking water, even if small quantities leak into the soil.
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12.5 Results of PBT and vPvB assessment

	No data is available on this product.
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12.6 Endocrine disrupting properties

	No further relevant information available.
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12.7 Other adverse effects

	No further relevant information available.
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13. DISPOSAL CONSIDERATIONS
13.1 Waste treatment methods

	Must not be disposed together with household garbage. Do not allow to reach sewage system.
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Disposal of uncleaned packaging

	Disposal must be carried out in accordance with the local and national regulations currently in force.
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14. TRANSPORT INFORMATION
14.1 UN number

ADR, ADN, IMDG, IATA	-
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14.2 UN proper shipping name

ADR, ADN, IMDG, IATA	-
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14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA	-
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14.4 Packing group

ADR, IMDG, IATA	-
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14.5 Environmental hazards

Marine pollutant	No
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14.6 Special precautions for user

	Not applicable
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14.7 Special precautions for user

Transport in bulk according to Annex II of MARPOL 73/78 and IBC Code	Not applicable
Transport/Additional information	
UN 'Model Regulation'	

15. REGULATORY INFORMATION
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

	No further relevant information available.
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15.2 Chemical Safety Assessment

	A Chemical Safety Assessment has not been carried out.
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16. OTHER INFORMATION
Other information

The information used in this SDS is believed to be correct however, the information is provided without any warranty, neither expressed nor implied, regarding its correctness.

This SDS is relevant for large quantities of product, the instructions for safe use of quantities typically used during a normal procedure is as referenced in the Instructions for Use.

The conditions or methods for handling, storage, lone use and/or in combination with other products and disposal are beyond our control.

For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

This SDS was prepared and is to be used only for this product. If the product is used as a component in or in combination with another product, this SDS information may not be applicable.

Abbreviations and acronyms:

ADR Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association+

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

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)