

SAFETY DATA SHEET (GHS)

Issue Date: 24.07.2016
Version: 1.0.3
Revision Date: 12.07.2017
Print Date: 21.12.2016

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE/PRODUCT AND MANUFACTURER/IMPORTER**1.1 Product identifier:-**

Product name: IvoBase Hybrid Polymer / IvoBase High Impact Polymer
Product number: Void

1.2 Other means of identification:-

Not applicable.

1.3 Recommended use of the chemical and restrictions on use:-

Not applicable.

Identified uses: Denture base material

1.4 Details of the manufacturer and importer:-

Manufacturer: Ivoclar Vivadent AG
 Bendererstrasse 2
 FL-9494 Schaan
 PRINCIPALITY OF LIECHTENSTEIN

Importer: Ivoclar Vivadent Pty Ltd
 1- 5 Overseas Drive Noble Park North VIC 3174
 Tel: + 61 3 9795 9599 Fax: + 61 3 9795 9645
 Email: info@ivoclarvivadent.com
 13 11 26
 Poisons Hotline (24 hours / 7 days)

1.5 Emergency phone number:**2. HAZARD(S) IDENTIFICATION****2.1 GHS Classification:-**

Skin Sens. 1 H317 May cause an allergic skin reaction.

2.2 GHS Label elements, including precautionary statements:-**Hazard Pictogram:**

GHS07
 Warning
 dibenzoyl peroxide

Signal word:**Hazard-determining components of labelling:****Hazard statements:****Precautionary statements:**

H317 May cause an allergic skin reaction
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P262 Do not get in eyes, on skin, or on clothing.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Additional information: Void**Other hazards:-**

Dust generation
 Particular danger of slipping on leaked/spilled product.

Results of PBT and vPvB assessment;

PBT: Not applicable.
vPvB: Not applicable.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture of substances listed below with nonhazardous additions.

Description: Dental alloy

Ingredient name	CAS No.	Classification	Concentration
dibenzoyl peroxide	94-36-0	Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317	0.3-<1%

4. FIRST AID MEASURES

4.1 Description of necessary first aid measures:-

If inhaled:

In case of skin contact:

In case of eye contact:

If swallowed:

Supply fresh air; consult doctor in case of complaints

Rinse with water.

Generally the product does not irritate the skin.

Rinse opened eye for several minutes under running water.

Then consult a doctor

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor

4.2 Symptoms caused by exposure:-

No further relevant information available

4.3 Medical attention and special treatment:-

No further relevant information available.

5. FIRE FIGHTING MEASURES

5.1 Suitable extinguishing equipment:-

Suitable extinguishing media:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Unsuitable extinguishing media:

No further relevant information available.

5.2 Specific hazards arising from the substance/mixture/product:-

No further relevant information available.

5.3 Special protective equipment and precautions for fire fighters:-

Special personal protective equipment:

Do not inhale explosion gases or combustion gases

Precautions:

No further relevant information available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:-

Not required

6.2 Environmental precautions:-

Do not allow to enter sewers/ surface or ground water.

6.3 Methods and materials for containment and cleaning up:-

Pick up mechanically

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling:-

Only adequately trained personnel should handle this product.

For use in dentistry only

7.2 Conditions for safe storage, including any incompatibilities:-

Store only in the original receptacle

Protect from heat and direct sunlight

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure control measures:-

Occupational exposure limits:

Component	CAS No.	Value	Parameters	Basis
dibenzoyl peroxide	94-36-0	Long-term value: 5 mg/m ³		

Ingredients with biological limit values:

8.2 Biological monitoring:-

The lists valid during the making were used as basis.

Exposure controls / Personal protective equipment / General protective and hygienic measures:

Usual hygienic measures for dental practice and dental laboratories.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Avoid contact with the skin

8.3 Control banding:-

Use good industrial hygiene practice and general ventilation.

8.4 Engineering controls:-

Void

8.5 Individual protection measures include PPE:-

Eye/face protection:



Safety glasses

Required Use tightly fitting safety glasses as per Australian Standard AS 1336 and AS/NZS 1337.

Skin protection:



After use of gloves apply skin-cleaning agents and skin cosmetics.

• Material of gloves

Butyl rubber, BR

Chloroprene rubber, CR

Natural rubber, NR

Nitrile rubber, NBR

Fluorocarbon rubber (Viton)

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.

• 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.

Use respiratory protective device against the effects of dust

Respiratory protection:



9. PHYSICAL/CHEMICAL PROPERTIES

9.1 Information on physical/chemical properties:-

a)	Appearance/Form:	Powder
b)	Colour:	According to product specification
c)	Odour:	Characteristic
d)	Odour threshold:	Not determined.
e)	pH-value (10 g/l) at 20 °C:	Not determined.
f)	Melting point/melting range:	150 °C
g)	Boiling point/boiling range:	Not determined.
h)	Flash point:	Not determined
i)	Ignition temperature:	Not determined
j)	Self-igniting:	Product is not self-igniting.
k)	Danger of explosion:	Not determined.
l)	Upper/lower flammability or explosive limits:	Lower Not determined Upper Not determined.
m)	Vapour pressure 20°C:	Not determined.
n)	Density at 20°C:	1.2 g/cm ³
o)	Relative density:	Not determined.
p)	Vapour density:	Not applicable.
q)	Evaporation rate:	Not applicable.
r)	Solubility in/miscibility with water:	Nearly insoluble
s)	Partition coefficient: n- octanol/water:	Not determined.
t)	Viscosity:	Dynamic Not applicable. Kinematic Not applicable.
u)	Solids content:	Not determined.

10. STABILITY AND REACTIVITY

10.1 Reactivity:-

No further relevant information available.

10.2 Chemical stability:-

Stable under normal handling and storage conditions.

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions:-

No dangerous reactions known.

10.4 Conditions to avoid:-

Keep away from heat and direct sunlight.

10.5 Incompatible materials:-

No further relevant information available.

10.6 Hazardous decomposition products:-

None under normal conditions of storage and use.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:-

Acute toxicity / Values relevant for classification:

Skin corrosion/irritation:

No further relevant information available.

Serious eye damage/eye irritation:

No further relevant information available.

Respiratory or skin sensitization:

No further relevant information available.

Germ cell mutagenicity:

No further relevant information available.

Carcinogenicity:

No further relevant information available.

Reproductive toxicity:

No further relevant information available.

Specific target organ toxicity - single exposure:

No further relevant information available.

Specific target organ toxicity - repeated exposure:

No further relevant information available.

Aspiration hazard:

No further relevant information available.

Additional information: | No further relevant information available.

11.2 Information on possible routes of exposure:-

Short Term (Acute) Exposure:

Swallowed:

Eyes:

Skin:

Inhaled:

Long Term (Chronic) Exposure:

Swallowed:

Eyes:

Skin:

Inhaled:

11.3 Early onset symptoms related to exposure:-

11.4 Delayed health effects from exposure:-

11.5 Exposure levels and health effects:-

11.6 Interactive effects:-

11.7 Other:-

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity:-

No further relevant information available.

12.2 Persistence/degradability:-

No further relevant information available.

12.3 Bioaccumulative potential:-

No further relevant information available.

12.4 Mobility in soil:-

No further relevant information available.

12.5 Other adverse effects:-

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.

12.6 Other adverse effects:-

No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1 Disposal methods:-

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

Uncleaned packaging:

· **Recommendation:** Disposal must be made according to official regulations.

14. TRANSPORT INFORMATION

UN number ADR / IMDG / IATA:-

| Void.

UN proper shipping name or technical name:-

ADR:

| Void.

IMDG, IATA:

| Void.

Transport hazard class(es):

| Void.

Label:

| Void.

Packaging group:

| Void.

Environmental hazards:

| Not applicable.

Special precautions for user:

| Not applicable.

Danger code:

| Void.

EMS Number:	Void.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:	Not applicable.
Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

15. REGULATORY INFORMATION**15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture/product:-**

The product is a medical device according to the Directive 93/42/EEC.

15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16. OTHER INFORMATION**Key to abbreviations/acronyms used in SDS:-**

H241 Heating may cause a fire or explosion.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

Key literature references/data sources used to compile SDS:-

Void

Copyright statement:-

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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 Harmonised 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).

LC50: Lethal concentration, 50 percent.

LD50: Lethal dose, 50 percent.

Flam. Liq. 2: Flammable liquids, Hazard Category 2.

Flam. Liq. 3: Flammable liquids, Hazard Category 3.

Acute Tox. 4: Acute toxicity, Hazard Category 4.

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2.

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2.

Repr. 2: Reproductive toxicity, Hazard Category 2.

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3.

STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2.

Asp. Tox. 1: Aspiration hazard, Hazard Category 1.

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

Disclaimer:-

Ivoclar Vivadent Pty Ltd believes the information in this document to be accurate as at the date of preparation, but, to the maximum extent permitted by law, Ivoclar Vivadent Pty Ltd accepts no responsibility for any loss or damage caused by any person acting or refraining from action because of this information.

The provision of this information should not be construed by anyone as a recommendation to use this product. In particular, no one should use any product in violation of any patent or other intellectual proprietary rights or in breach of any statute or regulation.

Users should rely on their own knowledge and inquiries and make their own determination as to the applicability of this information in relation to their particular purposes and specific circumstances. Each user should read this SDS and consider the information in the context of how the product will be handled and used in the workplace and in conjunction with other substances or products.

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.