

Material Safety Data Sheet

(CLP Regulation N°1272/2008)

1. Identification of mixture and the company

1.1 Commercial name

Name **Duroc**
Type of product Resin based bite registration materials
Reference DU-50

1.2 Relevant use of product: Resin based bite registration material, implant transfer caps splinting

1.3 Information concerning safety data sheet manufacturer:

Name : G-PHARMA
Localisation : 35, avenue du Gros Chêne - ZI des Bellevues
BP 10279 Herblay
95617 Cergy-Pontoise Cedex France
Email: elsodent@elsodent.com
Phone: + 33 (0)1 30 37 75 75

1.4 Emergency telephone number

Number ORFILA: + 33 (0)1 45 42 59 59

2. Hazards Identification

The mixture meets the classification criteria of CLP Regulation 1272/2008 amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation 1907/2006/EC. Mixing requires a safety card in accordance with the requirements.

2.1 Classification of the mixture:

2.1.1 Classification according to regulation (EC) N° 1272/2008 (CLP):

Eyes irrit. 2 : H319, STOT SE 3 : H335; Skin irrit. 2: H315; Skin sens. 1: H317

2.1.2 Classification according to the directive N° 67/548/CEE:

Xi : R36, R37, R38; Skin sens. : R43

2.1.3 Additional Information

The full text of the classes and categories of danger: hazards H and R phrases are mentioned in Section 16.

2.2 Label elements

Labelling in accordance with Regulation (EC) No 1272/2008 (CLP) and its derogations from Article 17 (concerning labelling and packaging requirements) for products with a capacity of less than 125 ml (Annex I of the Regulation 1.5.2.1).

Pictogram

SGH07



Warning

Signal word

Hazard statements

Precautionary statement(s)

H317 May cause an allergic skin reaction.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves/protective clothing/eye protection/face protection

Additional hazards information:

None

2.3 Other hazards: The mixtures do not contain PBT or vPvP.

3. Composition / Information on ingredients

3.1 Product

EC designation: Not Applicable
Classification according to the directive 93/42/EEC: Class IIa

3.2 Mixture

Index CE CAS	Chemical name	% Mass	Classification according to (CLP) N° 1272/2008 (CE)	Generic threshold
Index : N/A CAS : -	Methacrylate	70 - 90	STOT SE 3: H335; Irrit oc. 2 : H319; Irrit. Cut. 2: H315; Sens cut. 1: H317	≥ 1 % ≥ 1 % ≥ 1 % ≥ 0,1 %
Index : N/A CAS : 94-36-0	Benzoyl peroxyde	0,1 - 1	Peroxyde organique C : H242 Irrit. oc 2 : H319 Sens. Cut. 1: H317	≥ 1 % ≥ 0,1 %

Note: The full text of hazard H and R-phrases is specified in section 16.

4. First aid measures

4.1 Description of first aid measures

Skin contact: Wash skin with water and soap.
 Inhalation: Not applicable in normal
 Eye contact: Wash abundantly with water. Seek medical advice if the irritation persists.
 Swallowing: None toxic in normal condition of use (small quantity), for a large quantity swallowed, induce regurgitation.
 Other measures: Remove contaminated clothes

4.2 Most important symptoms and effects, both acute and delayed Not available

4.3 Indication of any immediate medical attention and special treatment needed: Not available

5. Firefighting measures

5.1 Extinguishing media:

Suitable Extinguishing media:	Water spray	Non-suitable Extinguishing media:	Not applicable
Self-ignition temperature:	Not applicable	Flash Point:	Not applicable
Explosion limits in air:	Not applicable	Melting point:	Not applicable
Inflammability:	Yes	Specific protection gear:	No

5.2 Special hazards arising from the substance or mixture:

High heat can cause a polymerization with a sudden release of energy

5.3 Tips for firefighters

Not applicable

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Avoid contact with eyes and skin. Wash with water and soap.

6.2 Environmental precautions:

Large amount: Remove the product following national, federal, regional or local current laws (by incineration).
Remove the content the same way.
 Small quantity: Polymerized the product before a conventional removal.

6.3 Methods and material for containment and cleaning up:

Wear gloves and goggles. Absorb with liquid binding material. Clean up affected area with water and soap

6.4 References to other sections

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

Avoid eyes and skin contact. For use in dentistry only. Wash hands with water and soap in case of a contact with the product.

7.2 Conditions for safe storage, including any incompatibilities

Avoid exposure to temperature above 25 ° C. Store in a dry, cool place, away from light and moisture. Do not store near a source of heat or flame. Keep containers tightly closed.

7.3 Specific end use(s): Dental professional use only.

8. Exposure controls / personal protection

8.1 Control parameters

Respiratory and ventilating protection:	Not necessary in normal condition of use.
Personal protective equipment:	Gloves, goggles and blouse
Specific hygiene measure:	Avoid prolonged contact with skin. In case of an eye contact, rinse opened eye for several minutes under running water. Wash hands after use.

8.2 Explosion parameters Not applicable

9. Physical & Chemical properties

9.1 Information regarding the physicals and chemicals properties

Colour:	Blue gel	Density of vapour:	Not applicable
Odour:	Light smell	Solubility in water:	Almost insoluble
Boiling point:	Not applicable	Flash point:	Not established
Specific gravity:	~1,2	Reactivity in water:	Not applicable
Melting point:	Not applicable	Explosion level in air:	Not applicable
Auto flammability:	Not applicable	PH:	Neutral
Vapour pressure:	Negligible at room temperature	Oxidizing properties:	No

9.2 Other information None

10. Stability & reactivity

10.1 Reactivity:	Not applicable
10.2 Chemical stability:	Generally stable
10.3 Possibility of hazardous reactions:	No dangerous reactions known
10.4 Conditions to avoid:	High temperature
10.5 Incompatible materials:	Amines
10.6 Hazardous decomposition products:	Unknown
10.7 uncontrolled polymerization:	Can appear if a large amount of this product is exposed

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity for health:	May cause irritation or a skin sensitization if the product is not wash rapidly.
Chronical toxicity :	May be cause a sensitization after a long-term or repeated exposure with skin.
Signs and symptoms of exposure:	Irritation of skin or eyes and respiratory tract

11.2 Other information: None

12. Ecological information

12.1 Toxicity

No ecological toxicity or impacts on the environment have been identified for this product in the quantities present in the normal packaging. It is inert once polymerized.

12.2 Persistence and degradability:	Not applicable
12.3 Bioaccumulative potential:	Not applicable
12.4 Mobility in soil:	Not applicable
12.5 Results of PBT and vPvB assessment:	Not applicable
12.6 Other adverse effects:	Not applicable

13. Disposal measures

13.1 Waste treatment methods

Large quantity:	Disposal must be made according to local, state and federal regulations. Do not pour down the drain.
Small quantity:	Polymerize and dispose of normally

13.2 Uncleaned packaging: Disposal must be in accordance to all federal, national and local

14. Transport information

This information regarding the transportation follows the international transportation requirements. No restriction for the road, boat or plane transportation. Avoid high temperatures during transportation.

15. Regulation

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

Class IIa medical device according to the Directive 93/42 / EEC

15.2 Chemical safety assessment: Not applicable

16. Other information

Symbol of potential danger

STOT SE 3: Specific target organ toxicity - single exposure hazard category 3

Xi: irritating

E: Explosive

O: Comburant

R phrases

R 2: Risk of explosion because of chock, friction, fire or other sources of ignitions

R 7: May cause a fire

R 36: Irritating to eyes.

R 37: Irritating to respiratory system.

R 38: Irritating to skin.

R 43: May cause a sensitization of the skin

S phrases

S3: Maintain in a well ventilated and fresh area

S9, S14: Avoid extremely high temperature, direct sunlight, flammable and humidity sources

H phrases

H315: Causes skin irritation.

H319: Causes serious eye irritation.

H335: May cause respiratory irritation

H317: May cause skin allergy

P phrases:

P261: Avoid breathing dust/fume/gas/mist/vapours/spray

P272: Contaminated work clothing should not be allowed out of the workplace

P280 : Wear protective gloves/protective clothing/eye protection/face protection.

P305 + P351 + P338 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P302 + P352 : IF ON SKIN: Wash with plenty of soap and water.

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