

MATERIAL SAFETY DATA SHEET

SECTION 1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Commercial name: REST AUTOMIX PRIMA

Relevant use of product: Modified bi-acrylic resin for temporary bridges and crowns, in dual cartridges of 50 ml or 10 ml

Product references: RAP-A1-50, RAP-A2-50, RAP-A3-50, RAP-A1-20, RAP-A2-20, RAP-A3-20

Information concerning safety data sheet supplier:

G-PHARMA

ZI des Bellevues – 35, avenue du Gros Chêne

BP 50072 HERBLAY

95612 CERGY PONTOISE cedex France

Email : elsodent@elsodent.com

Téléphone : 0033 (0)1 30 37 75 75

Emergency telephone number: N° ORFILA: 0033 (0)1 45 42 59 59

SECTION 2 – HAZARDS IDENTIFICATION

2.1 Classification of the mixture

The mixture meets the criteria for classification of Regulation 1272/2008 / EC amending Directives 67/548 / EEC and 1999/ 45 / EC and regulation 1907/2006 / EC (CLP). The mixture requires security sheet according to the requested requirements.

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. : **R22**

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

Labeling according to Regulation (EC) No 1272/2008 (CLP) and its exemptions from Article 17 (relating to labeling and packaging requirements) provided for products with a capacity of less than 125 ml (Annex I of Regulations section 1.5.2.1)

Pictogram:

SGH07



Signal word:

Warning

H statements:

H317: Can cause a skin allergy

P statements:

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: N/A

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

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Products

EC designation : N/A

EEC classification : Class IIa

3.2 Mixture of substances listed below

CE/CAS index	Chemical name	Mass %	Classification according to directive N° 67/548/CEE (DPD)	Classification according to rules (CE) N° 1272/2008 (CLP)	Generic threshold
Index : N/A CAS : 244448-20-2	BISEMA Bisphenol A Ethoxylat dimethacrylate	10-40	Xi irr. Eyes, skin resp.: R36/37/38 Skin sens. : R43	Skin irrit 2: H315 STOT SE 3 : H335 Eyes irrit. 2: H319 Skin sens. 1 : H317	≥ 1 % ≥ 0,1 %
Index : N/A CAS : 94-36-0	BPO Benzoyl Peroxyde	0,1 – 1	Explosive, E : R2 Combustion, O : R7 Irrit, Xi, eyes : R36 Skin Sens. : R43	Organic peroxide C: H242 Eyes irrit. 2: H319 Skin sens. 1: H317	≥ 1 % ≥ 0,1 %
Index : N/A CAS: 65997-17-3	Boro Aluminosilicate glass	25-40	Irrit. Xi, eyes, skin resp.: R36/37/38 Skin sens.: R43	STOT SE 3: H335; Eyes Irrit. 2 : H319; Skin Irrit. 2: H315; Sens skin. 1: H317	≥ 1 % ≥ 0,1 %

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

SECTION 4 - FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation: N/A under normal condition of use

Swallowing: None toxic under normal condition of use (small quantity). For a larger amount swallowed, induced regurgitation.

Skin contact: Wash skin with soap and water.

Eye contact: Rinse opened eye with precaution for several minutes under running water. If the eyes irritation continues, consult a doctor as soon as possible.

Other measure: Take off contaminated clothes (Large quantity)

4.2 Most important symptoms and effects, both acute and delayed: Can cause skin and eyes irritation. Can cause a sensitization in case of a long exposure or contact with the skin

Inhalation: None toxic under normal condition of use

Swallowing: Potentially irritating in case of a large amount swallowed. Can cause digestive disorders.

Skin contact: Potentially irritating, Can cause a sensitization in case of a long exposure or contact.

Eye contact: Potentially irritating.

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

SECTION 5 - FIREFIGHTING MEASURES

Suitable Extinguishing media: Sprayed water

Inflammation temperature: N/A

Danger of explosion: N/A

Flammability: Yes

Unsuitable extinguishing media: N/A

Flash point: N/A

Melting point: N/A

5.2 Special hazards arising from the substance or mixture: Not available

SECTION 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 in

6.3 Methods and material for containment and cleaning up:

Wear goggles and gloves. Remove the product with absorbent textile. Rinse abundantly the contaminated area with soap and water.

6.4 Reference to other sections

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7 – HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid skin and eyes contact. This product is for dental professional use only. Wash hands with water and soap in case of a contact with the product.

P270 : Do not smoke, drink or eat while manipulating the product

P271: Use only outdoor or in a well ventilated area

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, and well ventilated place. Keep the container closed. Use only the original container.

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

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Respiratory and ventilating protection: Not necessary in normal condition of use.

Personal protective equipment: Goggles, mask, gloves and blouse

Specific hygiene measure: Avoid prolonged contact with skin. In case of eye contact, rinse opened eye for several minutes under running water. Wash hands after use.

P363: Clean contaminated clothes before reuse

SECTION 9 - PHYSICAL & CHEMICAL PROPERTIES

9.1 Information regarding the physicals and chemicals properties

Appearance: off-white liquid paste

Odour: light

Boiling point: > 200°C

Melting point: N/A

Solubility in water: Negligeable

Reactivity in water: N/A

PH: N/A

Explosive properties: N/A

Auto flammability: N/A

Vapour density: N/A

Flash point: > 150°C

Vapour pressure: 30 mm Hg to 20°C

SECTION 10 – STABILITY & REACTIVITY

10.1 Reactivity: N/A.

10.2 Chemical stability: Stable

10.3 Possibility of hazardous reactions: No dangerous reactions known

10.4 Conditions to avoid: Avoid direct light and high temperature

10.5 Incompatible materials: N/A

10.6 Hazardous decomposition products: N/A

10.7 Uncontrolled polymerization: N/A

SECTION 11 – TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity for health: May cause skin sensitization or irritation if the product is not removed rapidly.

Chronical toxicit : May cause skin sensitization in case of a long contact or exposition to the product.

Signs and symptoms of exposure: skin, eyes and respiratory tracts irritation

11.2 Other Information: N/A

SECTION 12 – ECOLOGICAL INFORMATION

12.1 Toxicity

No ecological or environmental impact known, in the quantity of a regular packaging.

12.2 Persistence and degradability: N/A

12.3 Bioaccumulative potential: N/A

12.4 Mobility in soil: N/A

12.5 Results of PBT and vPvB assessment: N/A

12.6 Other adverse effects: N/A

SECTION 13 - DISPOSAL MEASURES

13.1 Waste treatment methods

Large quantity:

Disposal must be made according to local, state and federal regulations. Do not pour into the sink

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Small quantity:

Store in approved container for removal. Remove the containing like the product itself

SECTION 14 - TRANSPORT INFORMATION

No restriction for the road, boat or plane transportation.

SECTION 15 - REGULATORY INFORMATION**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:** N/A**SECTION 16 - OTHER INFORMATION**

N/A : Non applicable

Symbol of potential danger:

Xi : Irritating, Xn: noxious

R phrases

R 22: Harmful if swallowed

R 36: Irritating to eyes.

R 37: Irritating to respiratory system.

R 38: Irritating to skin.

R 43: Can cause skin sensitization

S phrases

S 3: Keep in a cool and well ventilated area

H phrases

Category 2, H315: Causes skin irritation.

H319: Causes serious eye irritation.

STOT, SE, H335: specific target organ toxicity – Single exposure, Category 3: May cause respiratory irritation.

Category 1: Skin sensitization, H317: May cause skin allergy

Category 4: Dermal toxicity, H302: Harmful if swallowed

P phrases:

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

P264: Wash hands meticulously after use

P270: Do not eat, drink or smoke while manipulating the product

P271: Use only outdoor or in a well ventilated area

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

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

P304 + P340: IF INHALATION: Move and keep the victim at rest outside where he can breath

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.

P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.

P363: Wash contaminated clothing before reuse.

P312: Call a POISON CENTER or doctor/physician if you feel unwell.

P330: Rinse mouth

Some of the information presented and conclusions drawn herein are from sources other than direct test data on the product itself. The information in this MSDS was obtained from sources that we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or method of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, G PHARMA 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. If the product is used as a component in another product or used in a way other than recommended by the Company, this MSDS information may not be applicable.