



1. Identification of the preparation

1.1 Identification of the preparation

Insulator for resin.

1.2 Use of the preparation

Applied on plaster model to prevent the adhesion of resin to the model.

1.3 Company identification

Leone s.p.a.

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Tel. ++39 (0)55.30.44.1 – Fax ++39 (0)55 374808.

1.4 Emergency telephone

++39 (0)55.30.44.1. An answering machine is on during closing time.

2. Hazards identification

Routes of entry: the preservative is absorbed into the body by swallowing.

Carcinogenic aspects: none of components of this product are listed by IARC¹, NTP², OSHA³, ACGIH⁴ as carcinogens.

Maximum concentration on workplace (MAC⁵): the preservative has a MAC value of 0.1ppm = 0.3 mg/m³.

Short-term effects: the preservative can irritate eyes, respiratory system and mucous membrane.

Long-term effects, repeated exposures: the preservative acts on the vascular system.

3. Composition/information on ingredients

Information on hazardous ingredients and composition %

Chemical Name	EC ⁶ Number	%	CAS ⁷ Number	Hazard symbols ⁸	R ⁸ Phrases
Demineralized water	-	> 95	-	-	-
Sodium alginate	-	< 5	9005-38-3	-	-
Preservative	247-852-1	<<0.001	26628-22-8	T	R28-32
Pigment	-	<<0.01	-	-	-

4. First aid measures

- Inhalation: remove to fresh air, rest, sit half way up. Get medical help if discomfort persists.
- Ingestion: wash out mouth with water and transport immediately to the hospital.
- Skin contact: remove contaminated clothing. Wash with plenty of water and soap.
- Eye contact: rinse with plenty of water for 15 minutes and seek medical advice.
- Protection of first-aiders: avoid exposure. Use appropriate protection (see section 8).

5. Fire-fighting measures

- Suitable fire extinguishing methods: dry chemical, AFFF (aqueous film forming foam), foam, carbon dioxide.
- Hazardous decomposition products: only a small amount of nitric acid.
- Hazardous reactions: reacts slowly with acids.

6. Accidental release measures

- Leakage/spillage: absorb spilled liquid with a towel. See section 13 for disposal of the liquid.
- Personal precautions: see section 8.
- Environmental precautions: see section 12.

7. Handling and storage

7.1. Handling

A clean brush should always be used to avoid contamination of the separating solution. Therefore, don't leave the brush standing in the bottle after application and, to avoid infection, never work directly from main supply.

¹ IARC: International Agency for Research on Cancer, France. IARC is part of the World Health Organization (WHO), Switzerland.

² NTP: National Toxicology Program, USA.

³ OSHA: Occupational Safety and Health Administration, USA.

⁴ ACGIH: American Conference of Governmental Industrial Hygienists, USA.

⁵ MAC: maximum permitted concentration value on workplace.

⁶ Number of European Catalogue. The EC number is made of a sequence of 7 figures, whose first group of 3 figures begins with 2 or 4 depending on which substance is included in the EINECS (European Inventory of Existing Commercial Chemical Substances) or in the ELINCS (European List of Notified Chemical Substances), or it begins with 5 if the substance is included in the list of "ex-polymers."

⁷ CAS Number (Chemical abstract service).

⁸ Hazards related to the ingredients of the product are indicated in section 2, information to be shown on the label are indicated in section 15.

15.Explanation of hazardous symbols and Risk phrases is indicated in section 15 and 16.



7.2 Storage

Store in a cool, dry place.

8. Exposure controls/personal protection

Respiratory protection: no special precautions.

Hand protection: latex gloves.

Eye protection: protecting glasses.

Other protection: none.

Unusual work/hygienic practices: keep working clothes separately. Take off contaminated clothing immediately. Keep away from food, drinks and animal feed.

9. Physical and chemical properties

9.1. General information

Appearance: liquid, blue

Odour: inodorous.

9.2. Health, safety and environmental information

Boiling point: 100°C

Freezing point: <0°C

Vapour pressure: very low

Relative density (H₂O=1): 1.014

Water solubility: soluble

pH: not applicable

Viscosity: high

Oxidising properties: not applicable

Flash point: not applicable

Auto ignition temperature: not applicable

Explosive properties: not applicable

Lower limit of explosion: not applicable

Upper limit of explosion: not applicable.

10. Stability and reactivity

- Stability: the liquid is stabilised with a preservative.

- Conditions to avoid: none, by use according to the instructions.

- Hazardous decomposition products: none, by use according to the instructions.

11. Toxicological information

According to literature

Chemical name: sodium alginate

Acute toxicity - oral: LD₅₀⁹ (rat) => 5000 mg/kg

Skin irritation rabbit: not irritating

Eye irritation rabbit: not irritating

Chemical name: preservative

Acute toxicity - oral: LD₅₀ (rat) = 27 mg/kg

Skin irritation: LD₅₀ (rabbit) = 20 mg/kg.

12. Ecological information

The product is allowed to drain into sewers.

13. Disposal considerations

Dispose of in accordance with local and national regulations. In Italy dispose of according to Legislative Decree of April 3 2006 no. 152 "Regulations on environmental subject", application of European Directives on environmental protection, and subsequent modifications and integrations.

14. Transport information

The product is not hazardous within the meaning of transport regulations.

Further information: solution based on water and alginate. The product contains more than 90% demineralised water.

⁹ LD₅₀ Lethal Dose, dose of substance which results to be lethal for 50% of organisms used in a toxicity test.



15. Regulatory information

- Health, safety and environmental information shown on the label according to European Directives on hazardous materials and substances

None.

- Information related to further dispositions

Preservative is a substance classified under Annex I of Directive 67/548/EEC with the number 011-004-00-7.

16. Other information

The safety data sheet has been written according to relevant European provisions, on the basis of information received by the supplier of preparation.

Hazard symbols or risk phrases shown on section 3:

T	Toxic
R28	Very toxic in contact with skin and if swallowed
R32	Contact with acids liberates very toxic gas

are specific for some ingredients and not shown on the product label.

The product is intended for orthodontic and odontological use only. The use of the product has to be restricted to skilled and licensed professionals.

The information drawn herein is based on our knowledge at the date of the issue.

The information is exclusively provided related to the product herewith specified and is not intended as a warranty of quality.

Leone disclaims any responsibility arising out of the use of the information here furnished, or of the handling, the application or the manufacture of the product here described. The final user is called to verify the application and completeness of the information herein in relationship to the specific use and reliability of the rules and local applicable dispositions.

The present information doesn't imply any liberty to break patent rights.

Previous safety data sheet n. R11/3E dated 17/05/2001 is to be considered cancelled. In comparison to the preceding revision, meaningful changes have not been effected but only adjustments to the European provisions which regulate the compilation of safety data sheet.

This safety data sheet is subject to revision.

Visit our web site www.leone.it for an updated version of the present sheet.