



SECTION 1: Identification of the substance or mixture and of the company

1.1. Product identifier

Product description: Insulator for resin.

1.2. Relevant identified uses of the substance or mixture and uses advised against

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

1.3. Details of the supplier of the safety data sheet

Leone s.p.a.

I – 50019 Sesto Fiorentino – Firenze - Via P. a Quaracchi, 50

e-mail: research@leone.it – <http://www.leone.it>

Tel. +39 055.30.44.1 – Fax +39 055 374808.

1.4. Emergency telephone number

+39 055.30.44.1. An answering machine is on during closing time.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

According to Regulation (EC) no. 1272/2008 [CLP].

This product does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) no. 1272/2008 on classification, labelling and packaging of substances and mixtures.

2.2. Label elements

Not applicable.

2.3. Other hazards

Not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1. Substances

This product is a mixture.

3.2. Mixtures

According to Regulation (EC) no. 1272/2008 [CLP], this product does not meet the criteria for classification as hazardous in accordance with Titles I and II. Substances in the product which may present a health or environmental hazard, or which have been assigned occupational exposure limits, are detailed below. Note that the concentration of hazardous goods in the mixture are too low to give the mixture some of their specific hazards.

According to Regulation (EC) no. 1272/2008 [CLP]

Hazardous ingredient(s)	%W/W	EC no.	CAS no.	Hazard Class and Category Code(s)	Hazard statement Code (s)
Disodium Dihydrogen Diphosphate	< 0.75	231-835-0	7758-16-9	Eye Irrit. 2	H319

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation IF INHALED: Remove person to fresh air and keep comfortable for breathing. Obtain medical attention in case of complaints.

Skin contact IF ON SKIN (or hair): Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Take off contaminated clothing immediately.

Eye contact IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation effect occur.

Ingestion Do not induce vomiting. Rinse mouth. If person in conscious and alert, give 2 glasses of water. Get medical attention if symptoms occur.

4.2. Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3. Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media In case of fire, use water spray, foam, dry powder or CO₂.

Unsuitable extinguishing Media -.

5.2. Special hazards arising from the substance or mixture

Not applicable.

5.3. Advice for firefighters

No special measure required.



SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Caution – spillages may be slippery. Wear protective gloves and eye protection. See Section 8.

6.2. Environmental precautions

The product is allowed to drain into sewers.

6.3. Methods and material for containment and cleaning up

Collect spillage. The product can be disposed as house waste and be incinerated in accordance with the local regulations.

6.4. Reference to other sections

See Sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Do not eat, drink or smoke at the work place. Wash thoroughly after handling. Use always a clean brush to avoid contamination of the product. To avoid infection: never work directly from the main supply.

7.2. Conditions for safe storage, including any incompatibilities

Store in a cool, dry place.

7.3 Specific end use(s)

Only intended for separating plaster from denture base material and separating plaster from plaster.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Substance: Disodium Dihydrogen Diphosphate, EC No. 231-835-0 (CAS No.7758-16-9).

DNEL (100% component)	Inhalation
Worker - Long Term – Systemic effects	2.79 mg/m ³ .
Consumer - Long Term – Systemic effects	0.68 mg/m ³ .

PNEC (100% component)	W
Aquatic Compartment	0.05 mg/l (Fresh water). 0.005 mg/l (Sea water).

8.2. Exposure controls

Appropriate engineering controls

Do not eat, drink or smoke at the work place. Keep working clothes separately. Take off contaminated clothing immediately.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection	Wear eye/face protection.
Skin protection	Wear suitable gloves (Latex).
Respiratory protection	No special precautions.

Environmental exposure controls

Not applicable.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid.
Colour	Blue, Clear, red or orange.
Odour	Odorless.
pH	Not applicable.
Melting point	< 0°C.
Boiling point	>100°C.
Flash point	Not applicable.
Vapour pressure	2.3 kPa at 20°C.
Solubility (Water)	Soluble, not difficult to mix.
Auto ignition temperature	Not selfigniting.
Explosive properties	No explosion hazard.
Oxidizing properties	Not applicable.
Relative density	1.01 (water = 1) at 15.5°C.

9.2. Other information

None.



SECTION 10: Stability and reactivity

10.1. Reactivity

None.

10.2. Chemical stability

Stable.

10.3. Possibility of hazardous reactions

None.

10.4. Conditions to avoid

Use always a clean brush to avoid contamination of the material.

10.5. Incompatible materials

By use according the instructions: none.

10.6. Hazardous decomposition product(s)

By use according the instructions: none.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

The product does not meet the criteria for classification in any hazard class according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

(Based on 100% Disodium Dihydrogen Diphosphate)

Acute toxicity

Ingestion	Ingestion may cause irritation.
Ingestion toxicity data	LD50 (oral)(rat) > 2400 mg/kg.
Ingestion STOT-single exposure	Not applicable.
Inhalation	May cause respiratory irritation.
Inhalation toxicity data	LC50 (vapour)(rat)(4 hr) >0.58 mg/l.
Inhalation STOT-single exposure	Exposure to high concentrations may produce adverse effects on the nasal epithelium.
Skin contact	May cause an allergic skin reaction.
Skin contact toxicity data	LD50 (dermal)(rat) > 2000 mg/kg.
Skin contact STOT-single exposure	Not applicable.
Eye contact	Will cause irritation.
Eye contact STOT-single exposure	Not applicable.
Aspiration hazard data	Not an aspiration hazard.

Sensitization

Skin sensitization data	Primary Skin irritation Index (rabbit)(24 hr) 2.58.
Respiratory sensitization data	Not a respiratory sensitizer.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity data	No evidence of carcinogenicity. (OECD 451).
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SECTION 12: Ecological information

This product is allowed to drain into sewers.

12.1. Toxicity

Disodium Dihydrogen Diphosphate (100%).

Toxicity to fish LC50 (96 h) (Oncorhynchus mykiss) 840 mg/l.

Toxicity to aquatic invertebrates (mg/l) EC50 (48 h) (Daphnia magna) >100 mg/l.

Toxicity to algae EC50 (72 h) (Selenastrum capricornutum) >100 mg/l.

12.2. Persistence and degradability

Disodium Dihydrogen Diphosphate (100%): Not applicable.

12.3. Bioaccumulative potential

Disodium Dihydrogen Diphosphate (100%): Not applicable.

12.4. Mobility in soil

The products is predicted to have high mobility in soil.

12.5. Results of PBT and vPvB assessment



Not classified as PBT or vPvB.

12.6. Other adverse effects

Not subject to international restrictions.

SECTION 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.

13.1. Waste treatment methods

The product can be disposed as house waste and be incinerated in accordance with the local regulations.

SECTION 14: Transport information

Not dangerous according to current transportation regulations.

14.1. UN-number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Not applicable.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: Regulatory information

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

Regulation (EC) no. 1272/2008 (Classification, labeling and packaging of substances and mixtures) and subsequent amendments, amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) no. 1907/2006.

Directive 2009/161/EU (third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC).

15.2. Chemical safety assessment

Not applicable.

SECTION 16: Other information

This Safety data sheet was prepared in accordance with the Commission Regulation (EU) no. 453/2010 and Commission Regulation (EU) no. 2015/830.

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

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 relates only to specific product designated 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 does not imply any liberty to break patent rights.

Previous safety data sheet no. R11/5E dated 16/01/2017 is to be considered obsolete. 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 sheets.

This safety data sheet is subject to revision. Visit our web site www.leone.it for an updated version of the present sheet.

Frasi H

H319: Causes serious eye irritation.

Legend

CAS No.: Chemical Abstract Service Registry number.

DNEL: Derived No-Effect Levels.



EC50: Half maximal Effective Concentration: Refers to the concentration of toxicant which induces a response halfway between the baseline and maximum after a specified exposure time.

EC No.: European Inventory of Existing Commercial Chemical Substances.

IBC Code: International Bulk Chemicals Code.

LC50: Lethal Concentration 50: lethal concentration of substance for 50% of organisms of a certain population during a certain exposure period.

LD50 Lethal Dose 50: the dose required to kill half the members of a tested population after a specified test duration.

OECD 451: Organization for Economic Co-operation and Development, Carcinogenicity Studies.

PBT: Persistent, Bioaccumulative And Toxic Substances.

PNEC: Predicted No Effect Concentration.

STOT RE: Specific Target Organ Toxicity.

TWA: Time Weighted Average.

vPvB: Very Persistent And Very Bioaccumulative Substances.

WEL: Work Place Exposure Limits.