

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name: RUTHINIUM FIBRA - CATALIZZATORE**
- **UFI: JE00-FOX4-H00V-YVSK**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Life cycle stages PW** Widespread use by professional workers
- **Application of the substance / the mixture** Material for dental use
- **Uses advised against** Any use other than those identified is not recommended.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Dental Manufacturing S.p.a.  
Via Cà Mignola Nuova, 1699  
45021 - Badia Polesine (RO) - Italy  
Tel. +39 0425 51628 - Fax +39 0425 590156
- **Further information obtainable from:** info@ruthinium.it
- **1.4 Emergency telephone number:**  
Dental Manufacturing S.p.a. - Tel. +39 0425 51628 (Office Hours)

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS05 corrosion

Skin Corr. 1B      H314 Causes severe skin burns and eye damage.  
Eye Dam. 1      H318 Causes serious eye damage.



GHS07

Skin Sens. 1      H317 May cause an allergic skin reaction.  
Aquatic Chronic 3      H412 Harmful to aquatic life with long lasting effects.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS05    GHS07

- **Signal word** Danger
- **Hazard-determining components of labelling:**  
4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with 3-aminomethyl-3,5,5-trimethylcyclohexylamine  
3-aminomethyl-3,5,5-trimethylcyclohexylamine
- **Hazard statements**  
H314 Causes severe skin burns and eye damage.  
H317 May cause an allergic skin reaction.  
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**  
P261      Avoid breathing vapours.

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 30.05.2023

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- P264 Wash hands thoroughly after handling.  
 P280 Wear protective gloves / eye protection / face protection.  
 P302+P352 IF ON SKIN: Wash with plenty of water.  
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P312 Call a POISON CENTER/doctor if you feel unwell.

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 38294-64-3 NLP: 500-101-4 Reg.nr.: 01-2119965165-33	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with 3-aminomethyl-3,5,5-trimethylcyclohexylamine ⚠ Skin Corr. 1B, H314; Eye Dam. 1, H318; ⚠ Skin Sens. 1, H317; Aquatic Chronic 3, H412	60-80%
CAS: 2855-13-2 EINECS: 220-666-8 Index number: 612-067-00-9 Reg.nr.: 01-2119514687-32-0000	3-aminomethyl-3,5,5-trimethylcyclohexylamine ⚠ Skin Corr. 1B, H314; Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Skin Sens. 1A, H317 ATE: LD50 oral: 1,030 mg/kg Specific concentration limit: Skin Sens. 1A; H317: C ≥ 0.001 %	15-25%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:**  
 Immediately remove any clothing soiled by the product.  
 Rescue workers must wear the protective equipment described in section 8.2 of this safety data sheet.
- **IF INHALATED:**  
 Supply fresh air and to be sure call for a doctor.  
 In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
 Immediately remove contaminated clothes  
 Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:**  
 Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Drink plenty of water and provide fresh air. Call for a doctor immediately.
- **4.2 Most important symptoms and effects, both acute and delayed**  
 Skin: corrosive, burning, irritation  
 Eyes: corrosive, corneal damage, irritation
- **4.3 Indication of any immediate medical attention and special treatment needed**  
 No further relevant information available.

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### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray.  
Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents:** None in particular
- **5.2 Special hazards arising from the substance or mixture**  
Under certain fire conditions, traces of other toxic gases cannot be excluded.
- **5.3 Advice for firefighters**
- **Protective equipment:**  
Wear personal protective clothing.  
See Section 8 for information on personal protection equipment.
- **Additional information** Cool endangered receptacles with water spray.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
See Section 8 for information on personal protection equipment.  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb liquid components with liquid-binding material.  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
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** Store in cool, dry place in tightly closed receptacles.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Store only in the original receptacle.  
To guarantee the quality and characteristics of the product, stuttgart between 15 ° C and 35 ° C and protected from the sun's rays
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- **PNECs**

**CAS: 2855-13-2 3-aminomethyl-3,5,5-trimethylcyclohexylamine**

PNEC	5,784 mg/kg (fresh water sediments)
	578 mg/kg (marine water sediments)

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PNEC	0.06 mg/l (freshwater)
	0.006 mg/l (marine water)

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**

· **Appropriate engineering controls** No further data; see item 7.

· **Individual protection measures, such as personal protective equipment**

· **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· **Respiratory protection:**

Use suitable respiratory protective device in case of insufficient ventilation.

Short term filter device:

Filter A

· **Hand protection**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

Neoprene gloves

Nitrile rubber, NBR

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 can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

Breakthrough time: > = 480 min - Material thickness: > = 0.7 mm

Breakthrough time: > = 60 min - Material thickness: > = 0.5 mm

Breakthrough time: > = 30 min - Material thickness: > = 0.2 mm

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye/face protection**



Tightly sealed goggles

## SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Physical state**

Liquid

· **Colour:**

Colorless - pale

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

-32 °C

· **Boiling point or initial boiling point and boiling range**

180 °C

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<ul style="list-style-type: none"> <li>· <b>Lower and upper explosion limit</b></li> <li>· <b>Lower:</b> Not determined.</li> <li>· <b>Upper:</b> Not determined.</li> <li>· <b>Flash point:</b> 130 °C</li> <li>· <b>pH</b> Not determined.</li> <li>· <b>Viscosity:</b></li> <li>· <b>Kinematic viscosity at 25 °C</b> 1700 cPs</li> <li>· <b>Dynamic:</b> Not determined.</li> <li>· <b>Solubility</b></li> <li>· <b>water:</b> Partly miscible.</li> <li>· <b>Partition coefficient n-octanol/water (log value)</b> Not determined.</li> <li>· <b>Vapour pressure at 20 °C:</b> 2.58 Pa</li> <li>· <b>Density and/or relative density</b></li> <li>· <b>Density at 20 °C:</b> 1.025 g/cm<sup>3</sup></li> <li>· <b>Relative density</b> Not determined.</li> <li>· <b>Vapour density</b> Not determined.</li> </ul>	
<ul style="list-style-type: none"> <li>· <b>9.2 Other information</b></li> <li>· <b>Appearance:</b></li> <li>· <b>Form:</b> Liquid</li> <li>· <b>Important information on protection of health and environment, and on safety.</b></li> <li>· <b>Ignition temperature:</b> Product is not selfigniting.</li> <li>· <b>Explosive properties:</b> Product does not present an explosion hazard.</li> <li>· <b>Solvent content:</b></li> <li>· <b>Solids content:</b> 100 %</li> <li>· <b>Change in condition</b></li> <li>· <b>Evaporation rate</b> Not determined.</li> </ul>	
<ul style="list-style-type: none"> <li>· <b>Information with regard to physical hazard classes</b></li> <li>· <b>Explosives</b> Void</li> <li>· <b>Flammable gases</b> Void</li> <li>· <b>Aerosols</b> Void</li> <li>· <b>Oxidising gases</b> Void</li> <li>· <b>Gases under pressure</b> Void</li> <li>· <b>Flammable liquids</b> Void</li> <li>· <b>Flammable solids</b> Void</li> <li>· <b>Self-reactive substances and mixtures</b> Void</li> <li>· <b>Pyrophoric liquids</b> Void</li> <li>· <b>Pyrophoric solids</b> Void</li> <li>· <b>Self-heating substances and mixtures</b> Void</li> <li>· <b>Substances and mixtures, which emit flammable gases in contact with water</b> Void</li> <li>· <b>Oxidising liquids</b> Void</li> <li>· <b>Oxidising solids</b> Void</li> <li>· <b>Organic peroxides</b> Void</li> <li>· <b>Corrosive to metals</b> Void</li> <li>· <b>Desensitised explosives</b> Void</li> </ul>	

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No hazardous reactions when stored and handled according to instructions
- **10.2 Chemical stability** The product is stable under normal conditions of use and storage
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.

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- **10.4 Conditions to avoid** Excessive temperature variations, below 15 ° C and above 35 ° C
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

**ATE (Acute Toxicity Estimates)**

Oral	LD50	5,150 mg/kg (rat)
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**CAS: 2855-13-2 3-aminomethyl-3,5,5-trimethylcyclohexylamine**

Oral	LD50	1,030 mg/kg (rat)
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Dermal	LD50	>2,000 mg/kg (rat)
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- **Skin corrosion/irritation** Causes severe skin burns and eye damage.
- **Serious eye damage/irritation** Causes serious eye damage.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

### SECTION 12: Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:**

**CAS: 2855-13-2 3-aminomethyl-3,5,5-trimethylcyclohexylamine**

CL50	110 mg/l (fish) (Esposizione 96 h)
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EC50	37 mg/l (algae) (Esposizione 72h)
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	23 mg/l (daphnia) (Esposizione 48h)
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- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** Non significant accumulation in organisms
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **12.6 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

- **12.7 Other adverse effects**

- **Additional ecological information:**

- **General notes:**

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Danger to drinking water if even small quantities leak into the ground.

Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-

values. A high pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is

considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is

only low water-dangerous.

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### SECTION 13: Disposal considerations

**13.1 Waste treatment methods**
**Recommendation**

Do not discard the product or its packaging. Do not empty into drains. Recycle the product. When recycling is not possible, dispose through an authorized company in compliance with the local or national regulations. The assignment of the waste code is the user's responsibility, after determining the properties of the waste and the process generating it and after discussing it with the authorities responsible for disposal.

**Uncleaned packaging:**
**Recommendation:**

Empty the containers before disposal. Do not reuse the emptied containers. Send the empty containers to recycling or to an authorized company in compliance with local and national regulations.

**Recommended cleansing agents:** Water.

### SECTION 14: Transport information

**14.1 UN number or ID number**
**ADR, IMDG, IATA** UN2735

**14.2 UN proper shipping name**
**ADR** 2735 AMINES, LIQUID, CORROSIVE, N.O.S.  
(ISOPHORONEDIAMINE)  
**IMDG, IATA** AMINES, LIQUID, CORROSIVE, N.O.S.  
(ISOPHORONEDIAMINE)

**14.3 Transport hazard class(es)**
**ADR, IMDG, IATA**

**Class** 8 Corrosive substances.

**Label** 8

**14.4 Packing group**
**ADR, IMDG, IATA** II

**14.5 Environmental hazards:**

Not applicable.

**14.6 Special precautions for user**

Warning: Corrosive substances.

**Hazard identification number (Kemler code):** 80

**EMS Number:** F-A,S-B

**Segregation groups** Alkalis

**Stowage Category** A

**Segregation Code** SG35 Stow "separated from" SGG1-acids

**14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

**Transport/Additional information:**
**ADR**
**Limited quantities (LQ)** 1L

**Excepted quantities (EQ)** Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

**Transport category** 2

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· <b>Tunnel restriction code</b>	E
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	UN 2735 AMINES, LIQUID, CORROSIVE, N.O.S. (ISOPHORONEDIAMINE), 8, II

### SECTION 15: Regulatory information

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

Safety data sheet prepared in accordance with Regulation 1907/2006/EC Article 31, Regulation (EU) No 878/2020 as subsequent amendments.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

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.

· **Relevant phrases**

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H412 Harmful to aquatic life with long lasting effects.

· **Classification according to Regulation (EC) No 1272/2008**

As required by Regulation 1272/2008/CE art. 9, the classification of this compound is based on the calculation method taken from the data of the single substances therein and from the experimental data of this compound where available (viewable in sections 9, 11 and 12 in this document).

Procedure used for the classification of the mixture

Skin Corr. 1B H314 - method of calculation

Skin Sens 1 / 1A / 1B, H317 -Calculation method

Eye Dam. 1, H318 - Calculation method

Aquatic Chronic 3, H412 - Calculation method

· **Date of previous version:** 20.01.2022

· **Version number of previous version:** 3

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

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*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)**PNEC: Predicted No-Effect Concentration (REACH)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Acute Tox. 4: Acute toxicity – Category 4**Skin Corr. 1B: Skin corrosion/irritation – Category 1B**Eye Dam. 1: Serious eye damage/eye irritation – Category 1**Skin Sens. 1: Skin sensitisation – Category 1**Skin Sens. 1A: Skin sensitisation – Category 1A**Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3***\* Data compared to the previous version altered.**

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