

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

- **1.1 Product identifier**
- **Trade name: RUTHINIUM FIBRA - RESINA BASE**
- **UFI: A800-F0JA-W00W-N6MF**
- **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**



GHS09 environment

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.  
 Eye Irrit. 2 H319 Causes serious eye irritation.  
 Skin Sens. 1 H317 May cause an allergic skin reaction.

- **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**



GHS07



GHS09

- **Signal word** Warning
- **Hazard-determining components of labelling:**  
 reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight ≤ 700)  
 Reaction products of hexane-1,6-diol with 2-(chloromethyl)oxirane (1:2)
- **Hazard statements**  
 H315 Causes skin irritation.  
 H319 Causes serious eye irritation.  
 H317 May cause an allergic skin reaction.  
 H411 Toxic to aquatic life with long lasting effects.

(Contd. on page 2)

# Safety data sheet

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

Printing date 30.05.2023

Version number 4 (replaces version 3)

Revision: 30.05.2023

**Trade name: RUTHINIUM FIBRA - RESINA BASE**

(Contd. of page 1)

- **Precautionary statements**

P261 Avoid breathing vapours.

P280 Wear protective gloves / 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.

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

- **Additional information:**

EUH205 Contains epoxy constituents. May produce an allergic reaction.

- **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: 25068-38-6 NLP: 500-033-5 Index number: 603-074-00-8 Reg.nr.: 01-2119456619-26-	reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight $\leq$ 700) ⚠ Aquatic Chronic 2, H411; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317, EUH205 Specific concentration limits: Eye Irrit. 2; H319: C $\geq$ 5 % Skin Irrit. 2; H315: C $\geq$ 5 %	60-80%
CAS: 933999-84-9 EC number: 618-939-5 Reg.nr.: 01-2119463471-41	Reaction products of hexane-1,6-diol with 2-(chloromethyl) oxirane (1:2) ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	25-40%

- **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:**

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 wash with water and soap and rinse thoroughly.

- **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- **After swallowing:**

Rinse out mouth and then drink plenty of water.

If ingested do not induce vomiting, seek medical assistance showing the safety data sheet or the hazard label

- **4.2 Most important symptoms and effects, both acute and delayed**

Eyes: irritation

Skin: irritation

- **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

IE

(Contd. on page 3)

# Safety data sheet

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

Printing date 30.05.2023

Version number 4 (replaces version 3)

Revision: 30.05.2023

**Trade name: RUTHINIUM FIBRA - RESINA BASE**

(Contd. of page 2)

### 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**  
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:**  
Wear personal protective clothing.  
See Section 8 for information on personal protection equipment.

### 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.  
Inform respective authorities in case of seepage into water course or sewage system.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb liquid components with liquid-binding material.  
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**  
Avoid contact with eyes and skin.  
Use only in well ventilated areas.
- **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:**  
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.

(Contd. on page 4)

# Safety data sheet

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

Printing date 30.05.2023

Version number 4 (replaces version 3)

Revision: 30.05.2023

**Trade name: RUTHINIUM FIBRA - RESINA BASE**

(Contd. of page 3)

**· DNELs**
**CAS: 25068-38-6 reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight  $\leq 700$ )**

Dermal	Long term, systemic effect	8.3 mg/kg bw/day (fish)
Inhalative	Long term, local effect	12.3 mg/m <sup>3</sup> (professional workers)

**· PNECs**
**CAS: 25068-38-6 reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight  $\leq 700$ )**

PNEC	0.5 mg/kg (fresh water sediments)
	0.5 mg/kg (marine water sediments)

**· 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**

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.

Nitrile rubber, NBR

Neoprene gloves

**· Penetration time of glove material**

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

 Breakthrough time:  $\geq$  480 min - Material thickness:  $\geq$  0.7 mm

 Breakthrough time:  $\geq$  60 min - Material thickness:  $\geq$  0.5 mm

 Breakthrough time:  $\geq$  30 min - Material thickness:  $\geq$  0.2 mm

**· Eye/face protection**


Tightly sealed goggles

(Contd. on page 5)

# Safety data sheet

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

Printing date 30.05.2023

Version number 4 (replaces version 3)

Revision: 30.05.2023

Trade name: RUTHINIUM FIBRA - RESINA BASE

(Contd. of page 4)

### SECTION 9: Physical and chemical properties

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

##### · General Information

· Physical state	Liquid
· Colour:	Colourless
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	180 °C
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	130 °C
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity at 40 °C	20.5 mm <sup>2</sup> /sec
· Dynamic:	Not determined.
· Solubility	
· water:	Partly soluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	1.0 - 1.4 g/cm <sup>3</sup> (Picnometro)
· Relative density	Not determined.
· Vapour density	Not determined.

#### · 9.2 Other information

· Appearance:	
· Form:	Liquid Viscous
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Solids content:	100 %
· Change in condition	
· Evaporation rate	Not determined.

#### · Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void

(Contd. on page 6)

# Safety data sheet

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

Printing date 30.05.2023

Version number 4 (replaces version 3)

Revision: 30.05.2023

Trade name: RUTHINIUM FIBRA - RESINA BASE

(Contd. of page 5)

· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

### 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.
- **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:**

**CAS: 25068-38-6 reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight ≤ 700)**

Oral	LD50	>2,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)

**CAS: 16096-31-4 1,6-bis(2,3-epoxypropoxy)hexane**

Oral	LD50	3,010 mg/kg (rat) (OECD 401)
------	------	------------------------------

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **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: 25068-38-6 reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight ≤ 700)**

EC50	1.8 mg/l (daphnia) (esposizione 48 h)
	2 mg/l (fish) (esposizione 96 h)

**CAS: 16096-31-4 1,6-bis(2,3-epoxypropoxy)hexane**

CL50	30 mg/l (fish) (esposizione 96 h)
EC50	88.3 mg/l (algae) (esposizione 96 h)

(Contd. on page 7)

# Safety data sheet

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

Printing date 30.05.2023

Version number 4 (replaces version 3)

Revision: 30.05.2023

**Trade name: RUTHINIUM FIBRA - RESINA BASE**

(Contd. of page 6)

47 mg/l (daphnia) (esposizione 48 h)

- **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**
- **Remark:** Toxic for fish
- **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.  
Danger to drinking water if even small quantities leak into the ground.  
Also poisonous for fish and plankton in water bodies.  
Toxic for aquatic organisms

### 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

- |   |   |
|---|---|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN number or ID number</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>                                    | UN3082  |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR</b></li> <li>· <b>IMDG</b></li> <li>· <b>IATA</b></li> </ul> | 3082 ENVIRONMENTALLY HAZARDOUS<br>SUBSTANCE, LIQUID, N.O.S. (reaction product:<br>bisphenol-A-(epichlorhydrin) epoxy resin (number<br>average molecular weight ≤ 700))<br>ENVIRONMENTALLY HAZARDOUS<br>SUBSTANCE, LIQUID, N.O.S. (reaction product:<br>bisphenol-A-(epichlorhydrin) epoxy resin (number<br>average molecular weight ≤ 700)), MARINE<br>POLLUTANT<br>ENVIRONMENTALLY HAZARDOUS<br>SUBSTANCE, LIQUID, N.O.S. (reaction product:<br>bisphenol-A-(epichlorhydrin) epoxy resin (number<br>average molecular weight ≤ 700)) |

(Contd. on page 8)

# Safety data sheet

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

Printing date 30.05.2023

Version number 4 (replaces version 3)

Revision: 30.05.2023

Trade name: RUTHINIUM FIBRA - RESINA BASE

(Contd. of page 7)

· **14.3 Transport hazard class(es)**

· ADR, IMDG, IATA



· **Class**

9 Miscellaneous dangerous substances and articles.

· **Label**

9

· **14.4 Packing group**

· ADR, IMDG, IATA

III

· **14.5 Environmental hazards:**

Product contains environmentally hazardous substances: reaction product: bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight  $\leq 700$ )

· **Marine pollutant:**

Symbol (fish and tree)

· **Special marking (ADR):**

Symbol (fish and tree)

· **Special marking (IATA):**

Symbol (fish and tree)

· **14.6 Special precautions for user**

Warning: Miscellaneous dangerous substances and articles.

· **Hazard identification number (Kemler code):** 90

· **EMS Number:**

F-A, S-F

· **Stowage Category**

A

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

Not applicable.

· **Transport/Additional information:**

Not dangerous according to the above specifications.

· **ADR**

· **Limited quantities (LQ)**

5L

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 1000 ml

· **Transport category**

3

· **IMDG**

· **Limited quantities (LQ)**

5L

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 1000 ml

· **UN "Model Regulation":**

UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (REACTION PRODUCT: BISPHENOL-A-(EPICHLORHYDRIN) EPOXY RESIN (NUMBER AVERAGE MOLECULAR WEIGHT  $\leq 700$ )), 9, III

(Contd. on page 9)



# Safety data sheet

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

Printing date 30.05.2023

Version number 4 (replaces version 3)

Revision: 30.05.2023

**Trade name: RUTHINIUM FIBRA - RESINA BASE**

(Contd. of page 8)

### 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.

· **Seveso category E2** Hazardous to the Aquatic Environment

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t

· **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**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H411 Toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

EUH205 Contains epoxy constituents. May produce an allergic reaction.

· **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 Irrit. 2, H315 - Calculation method

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

Eye Irrit. 2, H319 - Calculation method

Aquatic Chronic 2, H411 - 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)

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)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

(Contd. on page 10)

**Safety data sheet**  
**according to 1907/2006/EC, Article 31**

Printing date 30.05.2023

Version number 4 (replaces version 3)

Revision: 30.05.2023

**Trade name: RUTHINIUM FIBRA - RESINA BASE**

(Contd. of page 9)

*PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**Skin Sens. 1: Skin sensitisation – Category 1**Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2**Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3***· \* Data compared to the previous version altered.**

IE