

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

- **1.1 Product identifier**
- **Trade name: ACRY LUX CREMA**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **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

Eye Dam. 1 H318 Causes serious eye damage.



GHS09 environment

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



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT SE 3 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.

- **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



GHS09

- **Signal word** Danger
- **Hazard-determining components of labelling:**
Silicic acid, sodium salt
Terpineol
Kerosine (petroleum)
2-aminoethanol

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· Hazard statements

- H315 Causes skin irritation.
 H318 Causes serious eye damage.
 H317 May cause an allergic skin reaction.
 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.
 H411 Toxic to aquatic life with long lasting effects.

· Precautionary statements

- P261 Avoid breathing dust.
 P273 Avoid release to the environment.
 P280 Wear protective gloves / eye protection / face protection.
 P302+P352 IF ON SKIN: Wash with plenty of soap and 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.
 P308+P313 IF exposed or concerned: Get medical advice/attention.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Additional information:**· Regulation (EC) No 648/2004 on detergents / Indication of content**

perfumes

· Labelling of packages where the contents do not exceed 125 ml**· Hazard pictograms**

GHS05 GHS07 GHS09

· Signal word Danger**· Hazard-determining components of labelling:**

Silicic acid, sodium salt
 Terpeneol
 Kerosine (petroleum)
 2-aminoethanol

· Hazard statements

- H318 Causes serious eye damage.
 H317 May cause an allergic skin reaction.

· Precautionary statements

- P261 Avoid breathing dust.
 P273 Avoid release to the environment.
 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.
 P308+P313 IF exposed or concerned: Get medical advice/attention.

· 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 the following substances sodium silicate, siliceous earth, aliphatic hydrocarbons and adjuvants

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· Dangerous components:		
CAS: 1344-09-8 EINECS: 215-687-4 Reg.nr.: 01-2119448725-31	Silicic acid, sodium salt ⚠ Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335	25-40%
CAS: 8008-20-6 EINECS: 232-366-4 Index number: 649-404-00-4 Reg.nr.: 01-2119485517-27-xxxx	Kerosine (petroleum) ⚠ Flam. Liq. 3, H226; ⚠ Asp. Tox. 1, H304; ⚠ Aquatic Chronic 2, H411; ⚠ Skin Irrit. 2, H315; STOT SE 3, H336	25-40%
CAS: 8000-41-7 EINECS: 232-268-1 Reg.nr.: 2119553062-49	Terpineol ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	2-5%
CAS: 141-43-5 EINECS: 205-483-3 Index number: 603-030-00-8 Reg.nr.: 01-2119486455-28-xxxx	2-aminoethanol ⚠ Skin Corr. 1B, H314; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332 Specific concentration limit: STOT SE 3; H335: C ≥ 5 %	1-2%

· **Additional information:**

For the wording of the listed hazard phrases refer to section 16.

*The percentage of cryptocrystalline silicic acid in this component is < 0.1%. It can create fine dust, which, if inhaled, can have a fibrogenic effect in the lungs. Prolonged inhalation of high (> 0.15 mg/m³) concentrations of cryptocrystalline silica dust capable of penetrating into the alveoli (dust A) may cause silicosis. Exposure to cryptocrystalline silica A-dust in the workplace must be measured and controlled.

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:** 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. Then consult a doctor.

· **After swallowing:**

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: corrosive, corneal damage, irritation

Skin: irritation

Allergic reactions

· **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 agents:**

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **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.

Nitrogen oxides (NO_x)

Carbon monoxide (CO)

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- **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**
Wear protective clothing.
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:**
Pick up mechanically.
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**
You should follow the usual precautions for handling chemical products
Ensure good ventilation/exhaustion at the workplace.
Avoid contact with eyes and skin.
- **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.
Store in a cool location.
- **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:**

CAS: 141-43-5 2-aminoethanol (1-2%)

OEL	Short-term value: 7.6 mg/m ³ , 3 ppm Long-term value: 2.5 mg/m ³ , 1 ppm Sk, IOELV
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- **DNELs**

CAS: 1344-09-8 Silicic acid, sodium salt

Dermal	Short term, systemic effect	1.59 mg/kg (professional workers)
Inhalative	Long term, systemic effect	1.38 mg/m ³ (general population) 5.61 mg/m ³ (industry workers)

- **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.

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- **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:
FP2

- **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**

PVC gloves

Neoprene 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.

- **Penetration time of glove material**

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

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

- **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**

Solid

- **Colour:**

Beige

- **Odour:**

Petroleum-like

- **Odour threshold:**

Not determined.

- **Melting point/freezing point:**

0 °C

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

>60 °C

- **Lower and upper explosion limit**

- **Lower:**

Not determined.

- **Upper:**

Not determined.

- **Flash point:**

> 66 °C

- **Decomposition temperature:**

>250 °C

- **pH**

Not determined.

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<ul style="list-style-type: none"> · Viscosity: · Kinematic viscosity at 40 °C >20.5 mm²/S · Dynamic: Not determined. · Solubility · water: Slightly soluble. · Partition coefficient n-octanol/water (log value) Kerosene di petrolio > 3.5 log POW · Vapour pressure at 20 °C: <0.133 KPa · Density and/or relative density · Density at 20 °C: 1.1 +/- 0.1 g/cm³ · Relative density Not determined. · Vapour density Not determined. 	
<ul style="list-style-type: none"> · 9.2 Other information · Appearance: · Form: creamy · Important information on protection of health and environment, and on safety. · Auto-ignition temperature: Product is not selfigniting. · Explosive properties: Product does not present an explosion hazard. · Change in condition · Evaporation rate Not determined. 	
<ul style="list-style-type: none"> · 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 · Organic peroxides Void · Corrosive to metals Void · Desensitised explosives 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 variations in temperature, below 0 °C and above 40 °C
- **10.5 Incompatible materials:** Avoid contact with acids and oxidants.
- **10.6 Hazardous decomposition products:**
When heated or in case of fire can release gases and vapors which are dangerous to health.

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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	3,583-5,917 mg/kg (rat)
Inhalative	LC50/4 h	733 mg/l

CAS: 1344-09-8 Silicic acid, sodium salt

Oral	LD50	1,300-2,200 mg/kg (rat)
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CAS: 8008-20-6 Kerosine (petroleum)

Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>5,000 mg/l (rat)

CAS: 141-43-5 2-aminoethanol

Oral	LD50	1,515 mg/kg (rat)
Dermal	LD50	2,504 mg/kg (rabbit)
Inhalative	LC50/4 h	11 mg/l (ATE)

- **Skin corrosion/irritation** Causes skin irritation.
- **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** May cause respiratory irritation. May cause drowsiness or dizziness.
- **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: 8008-20-6 Kerosine (petroleum)

CL50	>100 mg/l (fish)
EC50	>100 mg/l (algae)
	>100 mg/l (daphnia)

CAS: 141-43-5 2-aminoethanol

EC50	65 mg/kg (daphnia)
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- **12.2 Persistence and degradability**

Easily biodegradable

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.

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- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
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"> · 14.1 UN number or ID number · ADR, IMDG, IATA | UN3082 | |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR · IMDG, IATA | 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (KEROSENE)
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (KEROSENE) | |
| <ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR, IATA <div style="display: flex; align-items: center; gap: 10px;">   </div> | <ul style="list-style-type: none"> · Class · Label | <ul style="list-style-type: none"> 9 Miscellaneous dangerous substances and articles. 9 |
| <ul style="list-style-type: none"> · IMDG <div style="display: flex; align-items: center; gap: 10px;">  </div> | <ul style="list-style-type: none"> · Class · Label | <ul style="list-style-type: none"> 9 Miscellaneous dangerous substances and articles. 9 |

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<ul style="list-style-type: none"> · 14.4 Packing group · ADR, IMDG, IATA 	III
<ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: · Special marking (ADR): · Special marking (IATA): 	<p>No</p> <p>Symbol (fish and tree)</p> <p>Symbol (fish and tree)</p>
<ul style="list-style-type: none"> · 14.6 Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category 	<p>Warning: Miscellaneous dangerous substances and articles.</p> <p>90</p> <p>F-A,S-F</p> <p>A</p>
<ul style="list-style-type: none"> · 14.7 Maritime transport in bulk according to IMO instruments 	Not applicable.
<ul style="list-style-type: none"> · Transport/Additional information: 	Not dangerous according to the above specifications.
<ul style="list-style-type: none"> · ADR · Limited quantities (LQ) · Excepted quantities (EQ) 	<p>5L</p> <p>Code: E1</p> <p>Maximum net quantity per inner packaging: 30 ml</p> <p>Maximum net quantity per outer packaging: 1000 ml</p>
<ul style="list-style-type: none"> · Transport category · Tunnel restriction code 	<p>3</p> <p>(-)</p>
<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) 	<p>5L</p> <p>Code: E1</p> <p>Maximum net quantity per inner packaging: 30 ml</p> <p>Maximum net quantity per outer packaging: 1000 ml</p>
<ul style="list-style-type: none"> · UN "Model Regulation": 	<p>UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (KEROSENE), 9, III</p>

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.

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· 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

H226 Flammable liquid and vapour.
 H302 Harmful if swallowed.
 H304 May be fatal if swallowed and enters airways.
 H312 Harmful in contact with skin.
 H314 Causes severe skin burns and eye damage.
 H315 Causes skin irritation.
 H317 May cause an allergic skin reaction.
 H318 Causes serious eye damage.
 H319 Causes serious eye irritation.
 H332 Harmful if inhaled.
 H335 May cause respiratory irritation.
 H336 May cause drowsiness or dizziness.
 H411 Toxic 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 Irrit. 2, H315 - Calculation method
 Skin Sens. 1 / 1A / 1B, H317 - Calculation method
 Eye Dam. 1, H318 - Calculation method
 Aquatic Chronic 2, H411 - Calculation method

· Version number of previous version: 6**· 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)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 Flam. Liq. 3: Flammable liquids – Category 3
 Acute Tox. 4: Acute toxicity – Category 4
 Skin Corr. 1B: Skin corrosion/irritation – Category 1B
 Skin Irrit. 2: Skin corrosion/irritation – Category 2
 Eye Dam. 1: Serious eye damage/eye irritation – Category 1
 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 Skin Sens. 1: Skin sensitisation – Category 1
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
 Asp. Tox. 1: Aspiration hazard – Category 1
 Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2