

**1 – IDENTIFICATION**

Product Name	Single-dose
Internal product identification code	38632
Principal recommended uses for substance or mixture	For dental use only
Company Name	Angelus Indústria de Produtos Odontológicos S/A
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2 - HAZARD IDENTIFICATION

Classification system used:	Norma ABNT-NBR 14725:2023 GHS Classification and WHMIS 2015
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Appropriate labeling elements

Hazard Class	Category	Signal word	Hazard Statement	Pictogram
Skin irritation	2	Warning	H315 Causes skin irritation	
Specific target organ toxicity - single exposure	3	Warning	H335 May cause respiratory irritation	
Eye irritation	1	Perigo Danger	H318 Causes serious eye damage	

P264 - Wash thoroughly after handling

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P261 - Avoid inhaling dust / fumes / gases / mists / vapors / aerosols

P271 - Use outdoors or in well-ventilated areas

P302 + P352 - IF ON SKIN: wash with plenty of soap and water.

P321 - Specific treatment

P332 + P313 - In case of skin irritation: Get medical advice.

P362 + P364 - Take off all contaminated clothing and wash before wearing again.

P305 + P351 + P338 - IF IN EYES: Rinse thoroughly with water for several minutes. If wearing contact lenses, remove them if easy. Continue rinsing.

Frases de precaução
Precautionary statements:

P310 - Immediately contact a TOXIC INFORMATION CENTER or doctor.

P304 + P340 - IF INHALED: Remove person to fresh air and keep at rest in a position that does not hinder breathing.

P312 If you feel unwell, contact a TOXICOLOGICAL INFORMATION CENTER.

INFORMATION CENTER/doctor.

P403 + P233 - Store in a well-ventilated area. Keep container tightly closed.

P501 - Dispose of contents/container in chemical waste garbage can

Other hazards that do not result in a classification:

This product reacts with water to produce a strongly alkaline material.

3 – COMPOSITION AND INFORMATIONS ON INGREDIENTS

Chemical name	CAS number	REACH registration number	Concentration range	Classification according to Regulation (EC) N° 1278/2008 (CLP)
Tricalcium silicate	12168-85-3	235-336-9	20 - 25 %	A classification provided by companies to ECHA in CLP notifications this substance causes serious eye damage and causes skin irritation.
Tricalcium aluminate	12042-78-3	234-932-6	1 – 4 %	
Dicalcium silicate	10034-77-2	233-107-8	5 – 15 %	The notifications provided by companies to ECHA in REACH registrations no hazards have been classified.
Calcium Oxide	1305-78-8	215-138-9	2 – 4 %	The classification provided by companies to ECHA in REACH registrations this substance causes serious eye damage, causes skin irritation and may cause respiratory irritation.
Zirconium Oxide	1314-23-4	215-227-2	25 – 40 %	The notifications provided by companies to ECHA in REACH registrations no hazards have been classified.

Other additives:

- None of them are classified as hazardous to health or the environment and do not contribute to the classification of the product.
- The specific chemical identity and exact concentration of the additive and vehicle in the product have been withheld in accordance with Confidential Business Information (CBI).

4 - FIRST-AID MEASURES

Routes of exposure	Symptoms and most important effects, acute or delayed:	First Aid Treatment / Medical notes:
Inhalation	Irritation to the moist mucus membranes of the nose, throat and upper respiratory system	Remove person to fresh air and keep comfortable for breathing. Inhalation of large amounts of the product requires immediate medical attention.

4 - FIRST-AID MEASURES

<i>Skin contact</i>	<i>Skin irritation</i>	<i>Wash with plenty of cool water and pH-neutral soap. Seek medical treatment in all cases of prolonged exposure to material, freshly cured product, or prolonged wet skin exposure to the paste.</i>
<i>Eye contact</i>	<i>Eye irritation</i>	<i>Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. If eye irritation occurs: Get medical advice /attention.</i>
<i>Ingestion</i>	<i>Irritation to the digestive tract</i>	<i>Do not induce vomiting. If person is conscious, use water to rinse out the mouth and have the person drink plenty of water.</i>

5 - FIRE-FIGHTING MEASURES

<i>Conditions of Flammability</i>	<i>Not flammable or combustible.</i>
<i>Suitable Extinguishing Media</i>	<i>There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.</i>
<i>Specific Hazards Arising from the Product</i>	<i>None</i>
<i>Special protective actions for fire-fighters</i>	<i>Firefighters should always wear full protective gear to fight any fire. Prevent spillage from entering drains or water courses.</i>

6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

<i>For non-emergency personnel</i>	<i>Wear appropriate personal protective equipment to prevent contamination of skin, eyes and personal clothing as described in Section 8. Collect the material using a scoop.</i>
<i>For emergency responders</i>	<i>None</i>
<i>Environmental precautions</i>	<i>Prevent spillage from entering drains or water courses.</i>
<i>Methods and materials for containment and cleaning up</i>	<i>Collect the material using a ladle. Dispose of waste material in accordance with local, state and federal regulations. Clean residue with plenty of water followed by 70° alcohol, leaving no residue that could interact with the humidity of these components.</i>

7 – HANDLING AND STORAGE

<i>Precautions for safe handling</i>	<i>Handle with care and using the appropriate personal protective equipment.</i> <i>Avoid direct contact with skin and eyes.</i> <i>Avoid contact with ammonia, ammonium nitrate, chlorine or items containing chlorine. Wash hands after using the product.</i>
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Conditions for safe storage, including any incompatibilities

Avoid contact with ambient humidity.

The syringe presentation should be stored after use inside the laminated envelope (secondary packaging) with blue silica sachet and in the absence of contact with ambient humidity so that early hardening does not occur. The single-dose presentation should be discarded after use.

8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational exposure limits:

Indicadores biológicos:

Biological indicators:

Other limits and values:

The product does not contain any relevant quantities of materials with critical values that should be monitored in the workplace.

Appropriate engineering controls

The product should be handled in a well-ventilated area.

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

Eye/face protection:



Safety glasses

Activities, in which the paste may come into contact with eyes, use safety glasses. Be careful when using contact lenses when working with EdgeUtopia RRM Monodose.

Skin and body protection:



Protective work clothing

In the event of prolonged exposure to the paste, wear a lab coat and disposable gloves to avoid skin contact. When necessary, wear closed shoes to eliminate exposure of the toes and heels.

Respiratory protection:



Disposable mask

Wear a disposable mask when handling the paste.

Thermal hazards:

None

9 – PHYSICAL AND CHEMICAL PROPERTIES

Properties	
Aspect (physical state, form, color)	Semi-solid in paste form
Colour	Slightly yellow
Odour	No distinct smell
pH	10,0 – 12,5
Melting point/freezing point	Not available
Boiling point or initial boiling point and boiling range	Not available

<i>Boiling point or initial boiling point and boiling range</i>	<i>Not available</i>
<i>Flash point</i>	<i>Not applicable</i>
<i>Evaporation rate</i>	<i>Not applicable</i>
<i>Flammability</i>	<i>Not applicable</i>
<i>Lower and upper limit of flammability or explosiveness</i>	<i>Not applicable</i>
<i>Vapor pressure</i>	<i>Not applicable</i>
<i>Relative density</i>	2,40 g/cm ³
<i>Solubility (According ISO 6876:2012)</i>	≤ 3,0 %
<i>Partition coefficient – n-octanol/water</i>	<i>Not applicable</i>
<i>Autoignition temperature</i>	<i>Not available</i>
<i>Decomposition temperature</i>	<i>Not available</i>
<i>Viscosity</i>	<i>Not available</i>
<i>Setting time (According ISO 6876:2012)</i>	30 – 120 minutes
<i>Radiopacity (According ISO 6876:2012)</i>	4,0 – 9,0 mm Al

10 – STABILITY AND REACTIVITY

Reactivity *The product is reactive in the presence of moisture where the calcium oxide present in the active component reacts and forms calcium hydroxide.*

Chemical Stability *In the presence of moisture, the product's chemical stability is affected, causing it to harden and make it impossible to use. Therefore, after use, the syringe should be closed properly and stored in the laminated sachet (low water vapor permeability) together with the blue silica sachet. The zipper on the sachet should be closed properly to prevent moisture from entering and stored in a place with low contact with moisture.*

Possibility of hazardous reactions: *There are no possible dangerous reactions that could lead to excess pressure or heat.*

Conditions to avoid: *Avoid contact with water to prevent premature setting.*

Incompatible materials: *Acids, ammonia, nitrate, ammonium salts, aluminum metal and chlorine.*

Hazardous decomposition product: *Decomposition will not occur spontaneously, only when it comes into contact with moisture will calcium hydroxide be released.*

11 – TOXICOLOGICAL INFORMATION

Acute toxicity: *Product is not considered harmful if swallowed.
Maximum dose tested was 2,000 mg/kg of the product in mice via oral exposure and there was no death (according to ISO 10993-11:2017 tests).*

Skin corrosion/irritation: *Causes mild irritation and dryness of the skin.
Classification was carried out considering unavailable data. Therefore, it was made considering the composition of the product.*

Serious eye damage/irritation: *May cause serious eye damage.
Classification was carry out considering unavailable data. It was therefore made considering the composition of the product.*

Respiratory or skin sensitization:	<p>Product has no respiratory or skin sensitization.</p> <p>Topical application in 15 mice of 0.2 g of the product in 1 mL of vehicle and followed for 10 to 12 weeks. From the results obtained, no erythema of any kind was observed (according to ISO 10993-11:2017 tests).</p>
Germ cell mutagenicity:	<p>The product does not have a germ cell mutagenicity classification.</p> <p>Classification based on ingredients, germ cell mutagenicity data not available. None of the ingredients in the mixture are classified as mutagenic.</p>
Carcinogenicity:	<p>The product does not have a carcinogenic classification.</p> <p>Classification based on ingredients, carcinogenicity data not available. None of the ingredients in the mixture are classified as carcinogenic.</p>
Reproductive toxicity:	<p>The product has no reproductive toxicity classification. Classification based on ingredients; reproductive toxicity data not available. None of the ingredients in the mixture are classified as toxic for reproduction.</p>
STOT-single exposure:	<p>Classification based on ingredients; data not available.</p> <p>One of the ingredients (calcium oxide) has been classified as category 3 for this health hazard. However, according to the regulations, the effects are transient where the effect alters a human function for a short period of exposure, in this case, according to REACH it is irritation of the respiratory tract.</p>
STOT-repeated exposure:	<p>The product has no Specific Target Organ Toxicity - Repeated Exposure classification.</p> <p>Classification based on ingredients, Specific Target Organ Toxicity - Repeated Exposure data not available. None of the ingredients in the mixture are classified as specific target organ toxicity - repeated exposure.</p>
Aspiration Hazard:	<p>The product does not have an aspiration hazard classification. Classification based on ingredients, aspiration hazard data not available. None of the ingredients in the mixture are classified as toxic for reproduction.</p>

12 – ECOLOGICAL INFORMATION

Ecotoxicity:	<p>Product not harmful to aquatic organisms</p> <p>Classification based on ingredients, ecotoxicity data not available for the mixture. None of the ingredients in the mixture are classified as ecotoxic.</p>
Persistence and degradability:	<p>Product shows persistence and is not considered rapidly degradable</p> <p>Classification based on ingredients, ecotoxicity data not available for mixture. None of the ingredients in the mixture are classified as persistent and not rapidly degradable.</p>
Bioaccumulative potential:	<p>Product has no bioaccumulative potential</p> <p>Classification based on ingredients, bioaccumulative potential data not available for mixture. None of the ingredients in the mixture are classified as having bioaccumulative potential.</p>

Mobility in soil:	No soil mobility Classification based on ingredients; soil mobility data not available for mixture. None of the ingredients in the mixture are classified as soil mobile.
Other adverse effects:	When it comes into contact with water, calcium hydroxide is released, raising the pH of the medium and causing the particle to harden.

13 – DISPOSAL CONSIDERATIONS

Recommended methods for treatment and disposal applied to:

Product:	Dispose of waste material in accordance with local, state and federal regulations.
Product residue:	Dispose of waste material in accordance with local, state and federal regulations.
Used package:	Dispose of the contents/container in a chemical waste container.

15 – TRANSPORT INFORMATION

Air transportation:	Associação Internacional de Transportes Aéreos (IATA)
UN Number:	Not applicable
Appropriate name for shipment:	Not applicable
Main and subsidiary risk class/subclass, if any:	Not applicable
Package group:	Not applicable
Danger to the environment:	No danger to the environment

15 – REGULATORY INFORMATION

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing.

UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE (UNECE). Globally Harmonized System of Classification and Labelling of Chemicals (GHS Rev. 9, 2021).

EdgeUtopia RRM Monodose is classified as a mixture and the provisions of the REACH regulation (Y106, Article 67(1) and (2), Y110) do not apply. Annex XVII specifies substances and the closest to our product are cements, but the restrictions indicated relate to:

- Chromium VI content, which is not currently present in our synthesis process and is therefore not applicable
- Identification on labeling, packaging and storage instructions if reducing agents are used to keep the soluble chromium VI content below the limit specified in item 1 of the restriction - not applicable for EdgeUtopia RRM Monodose as these products do not have the presence of chromium VI or other reducing agents in the cement synthesis.

The third restriction assesses that if the process is controlled and automated, in which only machines are handled (without the possibility of skin contact), the items of regulation Y106; Article 67(1) and (2); Y110 do not apply. In the case of EdgeUtopia RRM Monodose, the product is not used in automated and controlled processes and may have skin contact.

Therefore, "The provisions of the REACH Regulation do not apply to this substance/mixture (Annex XVII; Y113)". The use of the product may have skin contact and we have classified the hazards according to the GHS, described in the product safety data sheet.

16 – OTHER INFORMATION

The information contained in this safety data sheet is based on standardized tests and scientific literature. This information refers only to the product indicated. The user is fully responsible for taking appropriate precautions to protect property and persons against any damage that may result from such handling and use. We recommend that the user carefully observes the destination and manner of use of the product, using it in accordance with the instructions.

