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ATRASORB PHARMA FIX

1. Identification

1.1 Product identification

Product name: ATRASORB PHARMA FIX, with permanent turning indicator (white to violet).

Codes: 9094, 9105, 9106, 9107, 9109, 9254, 9280, 9282, 9283, 9284, 9285, 9286, 9287, 9288, 9289, 9348, 9349, 9369, 9394, 9435, 9436, 9437, 9438 and 9439.

REACH registration number: This product is a preparation. For the REACH registration number, see Chapter 3.

1.2 Other means of identification: UFI Atrasorb Pharma Fix - S500-C029-G005-DURA

1.3 Recommended uses and restrictions on use

Identified uses: CO2 (carbon dioxide) absorbent in pills for medical use, in closed or semi-closed inhalation anesthetic circuits, with the use of halogenated anesthetics. Also in cases where a permanent color change is desired during use after saturation.

As it contains only calcium hydroxide as an absorbent, in addition to the presence of calcium chloride and calcium sulfate, which optimize the hydration of the product, its use in procedures using halogenated anesthetics, such as sevoflurane, desflurane, halothane, enflurane and isoflurane is more recommended, as the absorption reaction is less exothermic, greatly reducing the formation of toxic compounds.

Usage restrictions: Do not use in procedures involving trichloroethylene and chloroform, as the reaction may lead to the formation of toxic products.

For additional information on applications, see "Instructions for Use".

1.4 Identification of the supplier of the Safety Data Sheet - SDS

Enterprise: ATRASORB Hospital Products Industry Ltd.

email: atrasorb@atrasorb.com.br

BRANCH: Avenue Piracicaba, 351 - Vila Nova São Roque

Zip Code 18131-230, São Roque/SP - Brazil

Phone: + 55 11 5521-2076

1.5 Emergency telephone number

Brazil: Phones: + 55 11 5521-2076 (Opening hours: Monday to Friday, 8:00 am to 5:48 pm);

Pro-Chemistry 24 hours: + 55 0800 110 8270 (24 hours).

Germany: 0800 180 3968. Argentina: 0800-345-1321. Australia: 1800 865 237. Chile: +56 2 3210 0961. China: 400 120 1768.

Colombia: +57 601 9172546 and/or 01 800 519 0040.

Dominican Republic: 1 (849) 936-1303.

Greece: 800 848 1066. India: 000 800 919 1522. Indonesia: 0800 1503250. Mexico: 800 681 9387. Paraguay: +595 21 728 8643.

Peru: +51 1 7089763.

Philippines: 1800 1 322 0441. Puerto Rico: 1 (787) 919-0858. South Africa: 080 099 8390. Taiwan: +886 2 7737 4438. Thailand: 1800 014 752.

United States: + 1 385-264-7545 and/or +1 800 219 839.

Global Contact: +1 800 219 839.



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2. Hazard identification

2.1 GHS classification of the substance/mixture

Causes skin irritation – H315 (Category 2); Causes serious eye damage – H318 (Category 1).

2.2 Labeling elements

Pictogram



Signal word Danger / Warning

Danger Phrases

H315 Causes skin irritation.
H318 Causes serious eye damage.

Precautionary Phrases

Prevention

P280 Wear protective gloves/ eye protection/ face protection.

Response

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.

P332 + P313 If skin irritation occurs: Get medical advice/attention.

P314 If you feel unwell, seek medical advice.

2.3 Other hazards not resulting in classification

Not applicable.

3. Composition and information on ingredients

3.1 Substance: not applicable.

3.2 Mixing

Chemical nature: Mixture of inorganic and organic components (solid compound)

Component	Synonymous	CAS No. and CE No.	Classification	Concentration
Calcium hydroxide	Hydrated lime	CAS No. 1305-62-0 CE No. 215-137-3	Skin irritation (Category 2) - Causes skin irritation – H315 Serious eye injuries (Category 1) - Causes serious eye damage - H318 Specific target organ toxicity - single exposure (Category 3) - Respiratory system - May cause respiratory irritation. – H335	≥ 68.0% - ≤ 75.0%
Calcium chloride	Calcium dichloride	CAS No. 10043-52-4 CE No. 233-140-8	Skin irritation (Category 2) - Causes skin irritation – H315 Eye irritation (Category 2) - Causes serious eye irritation – H319 Specific target organ toxicity - single exposure (Category 3), Respiratory system	≥ 3.0% - ≤ 4.5%



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			- May cause respiratory irritation. – H335	
Sodium silicate	Liquid glass	CAS No. 1344-09-8 CE No. 215-687-4	Skin corrosion (Category 1B) - Causes severe skin burns and eye damage – H314, Serious eye injuries (Category 1) - Causes serious eye damage - H318	≥ 1.5% - ≤ 2.5%

4. First aid measures

4.1 General recommendation

Individuals contaminated by chemical exposure should seek medical attention if any adverse effects occur. The injured person should receive medical attention if necessary. Bring a copy of the product label and SDS to the healthcare professional accompanying the infected person.

After inhalation: Move the person outdoors and keep them in a position comfortable for breathing.

Seek medical attention if necessary.

After skin contact: Rinse well with water. Remove contaminated clothing. Seek medical attention if

irritation develops or persists.

After eye contact: Rinse thoroughly with water for at least 15 minutes. Consult an ophthalmologist

immediately.

After ingestion: Do not induce vomiting. Have the victim drink water immediately (two glasses

maximum) and rinse their mouth thoroughly with water. Seek medical attention

immediately.

4.2 Most important symptoms and effects, acute and delayed

Acute: Exposure to the product may be irritating to the eyes, respiratory system and skin.

Inhalation: Inhalation of dust from the product may cause irritation to the nose, respiratory tract and throat.

Eye: May cause irritation. Skin: may cause irritation.

Ingestion: May cause irritation of the gastrointestinal tract.

Late: none known.

4.3 Indication of immediate medical measures and specific treatments required

Skin, respiratory system, or eye problems may be aggravated by prolonged contact. Treat the symptoms.

4.4 Target organs

Acute: Eyes, respiratory system, skin.

Late: None known.

5. Firefighting measures

Flash point No information available.
Autoignition temperature No information available.
Flammability (solid, gas) No information available.

Lower explosive limit No information available. Upper explosive limit No information available.

Explosion hazards Not classified as explosives.

5.1 Extinguishing media

Suitable extinguishing media: Adapt firefighting measures to local conditions and the surrounding environment.

Unsuitable extinguishing media: No limitations on extinguishing agents are given for this substance/mixture.



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5.2 Specific hazards arising from the substance or mixture

Non-combustible.

Possibility of formation of dangerous fumes in case of fire in nearby areas.

5.3 Special protective measures for firefighting personnel

Special equipment to protect people involved in firefighting.

Do not remain in the danger zone without self-contained breathing apparatus suitable for breathing independently of the environment. To avoid skin contact, maintain a safe distance and wear appropriate protective clothing.

6. Control measures for spills or leaks

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non - emergency personnel

Avoid staying in dusty areas.

Do not touch the pills.

Do not try to sweep or collect.

Move away and notify trained staff.

6.1.2 For emergency service personnel

Use personal protective measures as per section 8.

If the product is spilled or leaked, collect mechanically with a shovel or industrial vacuum cleaner with a Hepa filter and store in a tightly closed container.

Wash off any residue with plenty of water.

6.2 Environmental precautions

Ensure waste is collected and contained.

Do not allow the product to come into contact with surface water or sewage.

6.3 Methods and materials for containment and cleaning

Collect in closed and suitable containers for disposal.

Carefully clean contaminated objects and areas, observing environmental regulations.

Ventilate the affected area.

6.4 Spill Response PPE

Appropriate eye and skin protective equipment, as well as a protective mask, must be worn.

6.5 Consult other sections

For information on waste treatment, see section 13.

7. Handling and storage

7.1 Safe handling, work and hygiene practices

Wash your hands thoroughly after handling the product.

Do not eat, drink, smoke or apply cosmetics while handling this product.

Avoid breathing dust generated by this product, as well as avoiding getting this product on your skin or ingesting it.

7.2 Conditions for safe storage, including any incompatibilities

In the packaging itself, in a covered environment without exposing the packaging to the elements.

- a) Avoid mechanical shocks or large vibrations.
- b) Temperature range between -20°C and +50°C.
- c) Relative humidity between 10 and 90% (without condensation).
- d) The direction of the arrow regarding correct positioning.
- e) Maximum stacking as indicated on the packaging.



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Storage class: LGK 10-13 (VCI – concept)

Follow instructions in item 8.

After opening, it is recommended that it be used within 30 days and that the container remain protected from heat and light (preferably stored in its own box). After this period, it should be discarded as per item 13.

8. Exposure control and personal protection

8.1 Control parameters

Component	ACGIH TWA	OSHA TWA
Calcium hydroxide		
CAS # 1305-62-0	5 mg/m3	5 mg/m3
CE No. 215-137-3		
Calcium chloride		
CAS # 10043-52-4	There is no established limit.	There is no established limit.
CE No. 233-140-8		
Sodium silicate		
CAS # 1344-09-8	There is no established limit.	There is no established limit.
CE No. 215-687-4		

8.2 Engineering control measures

An environment with adequate ventilation to keep exposure levels below the limits described above. Use an exhaust fan to control dust generated by the product.

Ensure that safety eye wash stations are available near areas where this product is used.

8.3 Personal protective measures

The characteristics of body protection equipment should be selected based on the concentration and quantity of toxic substances and the specific workplace conditions. The resistance of protective equipment to chemical agents should be clarified with suppliers.

Skin/eye protection

Well-fitting safety glasses

Hand protection

Full contact:

Glove material: Nitrile rubber Glove thickness: 0.11 mm

Break: > 480 min

Splash contact:

Glove material: Nitrile rubber Glove thickness: 0.11 mm

Break: > 480 min

Other protective equipment

Protective clothing to avoid skin contact.

Respiratory protection

Necessary in case of post-graduation.

Recommended Filter Type: PFF2 Filter.

The employer must ensure that the maintenance, cleaning, and testing of respiratory protective devices are performed in accordance with the manufacturer's instructions. These measures must be adequately documented.

9. Physical and chemical properties

9.1 Information on basic physicochemical properties



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Property	Description
Physical state	Solid
Color	White to slightly yellowish or grayish
Odor	Characteristic
Odor Threshold	Not applicable
Melting point/freezing point	No information available
Boiling point or initial boiling point and boiling range	No information available
Flammability (solid, gas)	No information available
Lower/upper flammability or explosive limits	No information available
Flash point	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
pH at 50 g/l (20 °C)	Alkaline, (filtered)
Kinematic viscosity	No information available
Solubility in water (20 °C)	Slightly soluble
n-octanol/water partition coefficient (log Kow value)	No information available
Vapor pressure	No information available
Density	≥ 640 kg/m³;
Relative vapor density	No information available
Particle characteristics	2.36 – 4.75 mm
Evaporation rate	No information available
Oxidizing properties	No

9.2 Relevant data regarding physical hazard classes

- Reactivity with water: Reacts exothermically, releasing heat.
- Corrosivity to metals: May be corrosive to metals.
- Flammability: Non-flammable.
- Explosivity: Not applicable the mixture does not contain functional groups explosives.
- Oxidability: Not applicable the mixture does not have oxidizing properties .

9.3 Other security features

- Hygroscopic product: Absorbs moisture and carbon dioxide from the air.
- Reacts with water: Releasing heat (exothermic reaction).

10. Stability and reactivity

10.1 Reactivity

Heat generated if exposed to acid.

Reacts with water releasing heat (exothermic reaction).

10.2 Chemical stability

Sensitive to the action of humidity.

Stable under normal handling conditions.

10.3 Possibility of hazardous reactions

Hazardous polymerizations will not occur.

10.4 Conditions to avoid

Contact with air, formation of calcium carbonate and sodium carbonate.

Contact with strong acids: strong exothermic reaction.

Contact with low density metals, base metal, aqueous metal solutions produces hydrogen.

Contact with aluminum at high temperatures.



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10.5 Materials with which the substance is incompatible

Chloroform, trichloroethylene, low density metals or base metals, aqueous solutions of metals and acids.

10.6 Hazardous decomposition products

There are no indications

11. Toxicological information

11.1 Acute Toxicity

There is no information available for the product, only for the components.

CAS # 1305-62-0 LD (50) > 7000 mg/kg Rat - Oral

CAS # 10043-52-4 - Concentration in the mixture insufficient to classify the mixture as acutely toxic.

CAS # 1344-09-8 - Concentration in the mixture insufficient to classify the mixture as acutely toxic.

11.2 Skin corrosion/irritation

GHS Classification: Category 2 – Skin Irritation and Category 1B – Skin Corrosion;

The mixture is corrosive to the skin. Contact can cause intense redness, pain, blistering, tissue destruction, and deep lesions. Exposure may not cause immediate pain, making it difficult to assess its severity. The risk is increased in the presence of moisture or sweat;

Responsible components: Sodium silicate (CAS 1344-09-8), Calcium hydroxide (CAS 1305-62-0).

11.3 Serious eye damage/eye irritation

GHS classification: Serious eye damage – Category 1;

The product can cause serious and irreversible damage to the eyes, including corneal opacity, permanent damage and loss of vision;

Responsible components: Sodium silicate (CAS 1344-09-8), Calcium hydroxide (CAS 1305-62-0).

11.4 Respiratory or skin sensitization

Not classified as a sensitizer. There is insufficient evidence to classify it as a skin or respiratory tract sensitizer.

11.5 Germ cell mutagenicity

Not classified as mutagenic. There is no conclusive mutagenicity data for the mixture or its components at the concentrations present.

11.6 Carcinogenicity

Not classified as a carcinogen. None of the components are listed as carcinogens by IARC, NTP, or OSHA at the concentrations in the mixture.

11.7 Reproductive toxicity

Not classified as toxic to reproduction. No reproductive effects have been identified for the components of the mixture.

11.8 Specific target organ toxicity - single exposure

It affects the skin, eyes and respiratory system due to its irritating effect.

11.9 Specific target organ toxicity – repeated exposure

Not classified. There is insufficient evidence of toxic effects from repeated exposure.



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11 .10 Aspiration hazard

Not classified as an aspiration hazard. The product is in solid form (pills), which minimizes the risk of liquid aspiration. Chronic: none known.

12. Ecological information

Mixture

12.1 Ecotoxicity

No data are available for the mixture as a whole.

Component information:

Calcium hydroxide

o CL ₅₀ (Gambusia affinis): 160 mg/L (96 h) – IUCLID.

• Calcium chloride

- o LC 50 (Lepomis macrochirus): 10.650 mg/L (96 h) anhydrous substance (IUCLID)
- o EC 50 (Daphnia magna): 144 mg/L (48 h) anhydrous substance (IUCLID)
- o IC 50 (Algae)3.130 mg/L (120 h) anhydrous substance (IUCLID)

Sodium silicate

- LC 50 Brachydanio rerio (Zebra fish): 3.185 mg/L (96 h) (IUCLID)
- Toxicity to daphnia and other aquatic invertebrates.
- o EC 50 Daphnia magna: 494 mg/L (48 h) (ECOTOX Database) anhydrous substance

12.2 Persistence and degradability

The methods for determining biodegradability for inorganic substances do not apply.

12.3 Bioaccumulative potential

Not available for mixing.

For the components, the bioaccumulation potential is considered low, given the high water solubility and the inorganic nature of the substances.

12.4 Mobility in soil

Not available for mixing.

12.5 Other adverse effects

The product may cause adverse ecological effects due to changes in the pH of the aquatic environment.

Even diluted, it can form caustic solutions with water.

Release into the environment should be avoided.

12.5. Results of PBT and vPvB assessment

PBT/vPvB* assessment not performed as chemical safety assessment is not required/has not been performed.

*PBT - Persistent - Biocumulative - Toxic.

*vPvB – Very persistent and very biocumulative.

The components do not meet the criteria for classification as PBT or vPvB according to Regulation (EC) No. 1907/2006. Annex XIII.

13. Considerations on final destination

13.1 Treatment and disposal of the product

Residue and waste from this product must be disposed of as solid waste in accordance with applicable local, state and federal regulations.

Waste Category:

EWL (European Waste List);

16 03 03 – Inorganic waste containing hazardous substances;



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18 01 06 - Chemicals consisting of or containing hazardous substances.

13.2 Waste and contaminated packaging

Packaging containing product residue must be treated as hazardous waste when contaminated and disposed of in accordance with applicable local, state and federal regulations.

13.3 Additional precautions

Avoid direct contact of waste with skin and eyes during handling and disposal. Use appropriate personal protective equipment (PPE).

13.4 Legislation relevant to disposal

Law 12,305/2010 National Solid Waste Policy;

RDC ANVISA Nº 222/2018 Management of health waste;

CONAMA Resolution No. 358/2005 Treatment and final disposal of health service waste;

Waste Code Number (EWL) - waste code number, applicable for Europe;

And other federal, state and municipal environmental legislation.

14. Transportation information

14.1 UN Number

Not applicable. According to Special Provision 62 of the ADR, RID, IMDG, and ADN regulations, and IATA Special Provision A16, soda lime is not classified as a dangerous substance for transport.

14.2 UN proper shipping name

ADR/RID: ATRASORB PHARMA FIX (CO 2 absorbent lime)

DOT (US): ATRASORB PHARMA FIX Absorbent lime (Carbon dioxide absorber) IMDG: ATRASORB PHARMA FIX Absorbent lime (Carbon dioxide absorber) IATA: ATRASORB PHARMA FIX Absorbent lime (Carbon dioxide absorber)

ANTT: ATRASORB PHARMA FIX (CO 2 absorbing lime)

14.3 Risk classes for transportation

Not applicable. Exempt product according to special provisions 62 (ADR, RID, IMDG, ADN) and A16 (IATA).

14.4 Packing group

Not applicable. Exempt product according to special provisions 62 (ADR, RID, IMDG, ADN) and A16 (IATA).

14.5 Environmental hazards

ADR/RID: no DOT (US): no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

Data not available.

15. Regulations

This Safety Data Sheet (SDS) was prepared in accordance with NBR 14725/2023 of ABNT (Brazilian Association of Technical Standards)

Other state regulations may apply. Check individual state requirements.

16. Other information

This Safety Data Sheet (SDS) was prepared in accordance with NBR 14725/2023 — Chemical products - Information on safety, health and environment - General aspects of the Globally Harmonized System (GHS), classification, SDS and product labeling.

Other state regulations may apply. Check individual state requirements.

16.1 Relevant phrases



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Full text of the H-statements mentioned in sections 2 and 3.

H314: Causes severe skin burns and eye damage

H315: Causes skin irritation.

H318: Causes serious eye damage. H319: Causes serious eye irritation.

H335: May cause respiratory irritation.

Full text of the P statements mentioned in sections 2 and 3.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P264 Wash skin thoroughly after handling.

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

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

P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin

with water/shower.

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep away from

in a position that does not hinder breathing. If you feel unwell, call a POISON CENTER or

doctor/physician.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor. P314 If you feel unwell, seek medical advice.

P332 + P313 If skin irritation occurs: Get medical advice/attention.
P337 + P313 If eye irritation persists: Get medical advice/attention.

16.2 Training recommendation

Provide adequate information, instructions and training to operators.

This information is based on our current level of knowledge and refers to the product as delivered. It is intended to describe our products from a safety perspective and is not intended to guarantee any specific properties.

16.3 Legal Notice

The information in this safety data sheet is based on the best available knowledge and current legislation. It provides guidance on the health, safety, and environmental aspects of the product and should not be construed as a guarantee of technical performance or suitability for a specific application. Since specific conditions of use are beyond the supplier's control, the user is responsible for ensuring that the product is used safely and in compliance with applicable legal requirements.