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ATRASORB PHARMA FREE

1. Product and company identification

1.1. Product identifier

Product name: **ATRASORB PHARMA FREE with indicator (white to violet change).**

Codes: 9007, 9008, 9009, 9010, 9011, 9023, 9038, 9174, 9178, 9219, 9290, 9291, 9292, 9293, 9294, 9295, 9296, 9297, 9345, 9350, 9393, 9398, 9400, 9420, 9421, 9422, 9423, 9424.

REACH registration number: This product is a preparation. For REACH registration number see chapter 3.

1.2 Other means of identification: UFI Atrasorb Pharma Free - A800-U0RP-S00P-16AK

1.3. Identified uses of the substance or mixture and uses not recommended

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.

As it contains only calcium hydroxide as an absorbent, its use in procedures involving 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.

For additional information on uses, please see "Instructions for Use"

1.4. Identification of the supplier of the Chemical Product Safety Information Sheet - MSDS

Enterprise: ATRASORB Hospital Products Industry Ltd.
email: atrasorb@atrasorb.com.br

BRANCH: 351, Piracicaba Avenue - Vila Nova Sao Roque
ZIP Code 18131-230, Sao Roque/SP - Brazil
Phone: + 55 11 5521-2076

1.5. Emergency telephone number

São Paulo/SP: Phones: + 55 11 5521-2076 (Opening hours from Monday to Friday from 8:00 to 18:00)

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

2. Hazard identification

2.1. GHS Classification

Skin irritation (Category 2)
Serious eye injuries (Category 1)

2.2 Label elements

Pictogram



GHS05 GHS07

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 Get medical advice/attention if you feel unwell.

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	Classification	Concentration
Calcium hydroxide CAS No. 1305-62-0 EC No. 215-137-3	Skin irritation (Category 2) - Causes skin irritation – H315 Serious eye injuries (Category 1) - Causes serious eye damage. Specific target organ toxicity - single exposure (Category 3), Respiratory system - May cause respiratory irritation. – H335	≥ 68.0 % - ≤ 75.0 %
Sodium silicate CAS No. 6834-92-0 EC No. 229-912-9	Skin corrosion (Category 1B) - Causes severe skin burns and eye damage – H314, Specific target organ toxicity - single exposure (Category 3), Respiratory system - May cause respiratory irritation. – H335	≥ 1.5% - ≤ 2.5%

4. First aid measures

4.1 Description of first aid measures

General recommendation

Individuals contaminated by chemical exposure should be taken to a medical facility if any adverse effects occur. The injured person should seek medical care if necessary. Take a copy of the product label and the MSDS to the healthcare professional who is with the contaminated person.

After inhalation: Move the person to an outdoor area and keep them in a position that is comfortable for breathing. Seek medical attention if necessary.
 After skin contact: Rinse thoroughly 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 eye doctor immediately.
 After ingestion: Do not induce vomiting. Have the victim drink water immediately (two glasses maximum) and rinse the mouth thoroughly with water. Seek medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Acute: Exposure to product may be irritating to 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.
 Chronicle: none known.

4.3 Target organs

Acute: Eyes, respiratory system, skin.

Chronic: None known.

4.4 Indication of immediate medical attention and special treatment needed

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

4.5 Indication of immediate medical attention and special treatment required

Treat the symptoms.

5. Fire-fighting 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 explosive.

5.1. Extinguishing media

Suitable extinguishing media: Adapt fire-fighting measures to local conditions and the surrounding environment.

Inadequate extinguishing agents

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

5.2. Special hazards arising from the substance or mixture

Non-combustible.

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

5.3. Precautions for firefighters

Special equipment to protect people involved in fighting fires.

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 suitable protective clothing.

6. Control measures for spillage or leakage

6.1 Personal precautions, protective equipment and emergency procedures

If the product is spilled or leaked, collect mechanically in a tightly closed container. Respecting individual protection measures. Wash any residue with plenty of water.

6.2 Spill Response PPE

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

6.3 Consultation of other sections

For information on waste treatment, see section 13

7. Handling and storage


7.1 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 putting this product on your skin or ingesting it.

7.2 Storage practices

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

- Avoid mechanical shocks or large vibrations.
- Temperature range between -20°C to +50°C.
- Relative humidity between 10 and 90% (without condensation).

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- d) The direction of the arrow in terms of correct positioning.
e) Maximum stacking as indicated on the packaging.

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

Follow instructions in item 8.

After opening, it is recommended that it be used within a maximum of 30 days and that the container remains 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/m ³	5 mg/m ³

8.2 Ventilation and engineering controls

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 eyewash stations are available near areas where this product is used.

8.3 Personal protective measures

The characteristics of body protection equipment must be selected according to the concentration and quantity of toxic substances in accordance with the specific conditions of the workplace. The resistance of protective equipment to chemical agents must be clarified with the 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

Respiratory protection

Necessary in case of post-graduation.

Recommended Filter Type: PFF2 Filter

The entrepreneur must ensure that maintenance, cleaning and testing of respiratory protective devices are carried out 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

Solid physical state

White

to slightly yellowish or grayish color

Characteristic odor

Odor Threshold	not applicable
pH at 50 g/l (20 °C):	alkaline, (filtered)
Melting point	No information available.
Boiling point	No information available.
Evaporation rate	No information available.
Vapor pressure	No information available.
Relative vapor density	No information available.
Relative density	≥ 800 kg/m ³
Particle size	2.36 – 4.75 mm
Solubility in water (20 °C)	Slightly soluble
Partition coefficient (n- octanol/water)	No information available.
Viscosity, dynamics	No information available.
Oxidizing properties	No

10. Stability and reactivity

10.1 Stability

Sensitive to humidity. Stable under normal handling conditions.

10.2 Hazardous decomposition products

There are no indications

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 produce hydrogen.

Contact with aluminum at high temperature

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 Reactivity

Heat generated if exposed to acid.

11. Toxicological information

11.1 Toxicity

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

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

11.2 Carcinogenicity

There is no information on the effects of this product and its components.

11.3 Irritability

Contact with this product may be irritating to exposed skin, eyes and respiratory system.

11.4 Awareness

This product is not considered a sensitizer.

11.5 Reproductive toxicity

There is no information on the effects of this product and its components on the human reproductive system.

11.6 Exposure risks or health risks

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

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

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Eye: May cause irritation.
Skin: may cause irritation.
Ingestion: May cause irritation of the gastrointestinal tract.
Chronicle: none known.

11.7 Target organs

Acute: eye, respiratory system, skin.
Chronicle: none known.

12. Ecological information

Mixture

12.1 Toxicity

No information available.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

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

12.6 Other adverse effects

Additional ecological information

Biological effects: harmful effect due to pH change. Despite dilution, it still forms caustic mixtures with water.

Additional information on ecology

Discharge into the environment must be avoided.

Components

Calcium hydroxide

Toxicity to fish: LC50 *Gambusia affinis* (mosquitofish): 160 mg/l; 96 h (IUCLID)

Biodegradability: The methods for determining biological degradability are not applicable to inorganic substances.

Not applicable for inorganic substances: The substance does not meet the criteria for PBT or vPvB in accordance with Regulation (EC) No. 1907/2006, Annex XIII.

Sodium silicate


Toxicity to fish: LC50 *Brachydanio rerio* (Zebra fish): 3.185 mg/l; 96 h (IUCLID)

Toxicity to daphnia and other aquatic invertebrates.

EC50 *Daphnia magna*: 494 mg/l; 48 h (ECOTOX Database) (anhydrous substance)

Biodegradability: The methods for determining biological degradability are not applicable to inorganic substances.

Not applicable for inorganic substances: The substance does not meet the criteria for PBT or vPvB in accordance with Regulation (EC) No. 1907/2006, Annex XIII.

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13. Treatment and disposal considerations

Waste Treatment Methods: Waste must be disposed of as solid waste in accordance with local, state and federal waste disposal regulations.

Waste Category: EWL (European Waste List) 16 03 3* / 18 01 06*

Legislation relevant to disposal:

- Law 12,305/2010 National Solid Waste Policy;
- RDC ANVISA No. 222/018 Regulates Good Practices for the Management of Health Service Waste;
- CONAMA Resolution No. 358/2005 Treatment and final disposal of health service waste;
- The Hazardous Waste (England & Wales) Regulations 2005;
- Waste code number, applicable for Europe - Waste code number, applicable for Europe

14. Transport information

14.1 UN Number

ADR/RID, DOT (US), IMDG, IATA, ANTT: By special provision 62 in the transport regulations (code IMDG/RID/ADR/ADN) it is specified that welded lime is not considered dangerous goods for transport with sodium hydroxide concentrations below 4%, as well as special provision A16 for the IATA regulation.

14.2 UN proper shipping name

ADR/RID: ATRASORB PHARMA FREE (CO₂ absorbing lime)
DOT (US): ATRASORB PHARMA FREE Absorbent lime (Carbon dioxide absorber)
IMDG: ATRASORB PHARMA FREE Absorbent lime (Carbon dioxide absorber)
IATA: ATRASORB PHARMA FREE Absorbent lime (Carbon dioxide absorber)
co₂ absorbing lime)

14.3 Hazard classes for transport purposes

ADR/RID, DOT (US), IMDG, IATA, ANTT: exempted by special provisions 62 and A16

14.4 Packing group

ADR/RID, DOT (US), IMDG, IATA, ANTT: exempted by special provisions 62 and A16

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

15.1 Regulation/legislation specific to the substance or mixture in question health, safety and environment

This Chemical Product Information Sheet was prepared in accordance with NBR 14725-4/2014 of ABNT (Brazilian Association of Technical Standards)

Other state regulations may apply. Check individual state requirements.

16. Other information

This information is based on our current knowledge. However, it does not constitute a guarantee for any specific product characteristics and shall not establish a legally valid contractual relationship.

16.1 Relevant phrases

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

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H314: Causes severe skin burns and eye damage.

H315: Causes skin irritation.

H318: Causes serious eye damage.

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 in a position that does not hinder breathing. If you feel unwell, call a POISON CENTER or doctor.
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	Get medical advice/attention if you feel unwell.
P332 + P313	If skin irritation occurs: 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 in the state in which it is delivered. It is intended to describe our products from the point of view of safety requirements 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 knowledge available at the time and current legislation. It provides guidance on the health, safety and environmental aspects of the product and should not be construed as any guarantee of technical performance or suitability for a specific application. Since the specific conditions of use are beyond the control of the supplier, the user is responsible for ensuring that the product is used safely and in accordance with the relevant requirements of the legislation.