

ATRASORB PHARMA

1. Identification of the product and the company

1.1. Product Identifier

Name of the Product: **Atrasorb PHARMA with indicator (color change: white to violet)**

Codes: 9001, 9002, 9003, 9004, 9005, 9006, 9022, 9139, 9173, 9176, 9177, 9218, 9258, 9259, 9260, 9261, 9262, 9263, 9264, 9265, 9338, 9339, 9341, 9344, 9346, 9347, 9374, 9377, 9392, 9395.

Number of register REACH: this product is a preparation. Number of register REACH see chapter 3.

1.2 Other means of identification: UFI Atrasorb Pharma - Q200-U0CW-500P-QEX3

1.3. Identified uses of the substance/mixture and non-recommended uses

Identified uses: CO₂ (carbon dioxide) absorbent in pellets for medical use, in closed or semi-closed anaesthetic inhalation circuits.

Produced with low concentration of sodium hydroxide and without potassium hydroxide, which significantly reduces interaction with halogenated anaesthetics, such as sevoflurane, desflurane, halothane, enflurane and isoflurane. It can be used with these agents, always keeping the ideal humidity for the product, avoiding, for example, unnecessary gas flows and keeping the closed system (valves, fans, etc.) out of the procedures.

For additional information about its uses, please go to "Instructions for use"

1.4. Details of the supplier of the Material Safety Data Sheet - MSDS

Company: ATRASORB Indústria de Produtos Hospitalares Ltda.

Av. Piracicaba, 351, Vila Nova São Roque,
ZIP CODE 18131-230, São Roque - SP – Brasil

1.5. Emergency Telephone Number

São Paulo/SP: Phones: + 55 11 5521-2076 (Service from Monday to Friday from 8:00 am to 6:00 pm)
Pro-Chemistry: + 55 0800 110 8270 (24 hours)

2. Hazards identification

2.1. Classification GHS

Skin irritation (Category 2)
Eye damage (Category 1)

2.2 Label elements

Pictograms



GHS05 GHS07

Signal Word: Danger / Warning
Hazard Statement (s)
H315 Causes skin irritation.
H318 Causes serious eye damage.

Precautionary Statement (s)

Prevention

P280 Wear protective gloves/protective clothing/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/Information on ingredients

3.1 Substance: not applicable

3.2 Mixture

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

Component	Classification	Concentration
Calcium hydroxide CAS # 1305-62-0 EC No 215-137-3	Skin irritation (Category 2) - Causes skin irritation - H315 Eye damage (Category 1) - Causes serious eye damage - H318 Specific target organ toxicity (STOT) Single Exp. 3 - May cause respiratory irritation - H335	$\geq 68.0\% - \leq 75.0\%$
Sodium hydroxide CAS # 1310-73-2 EC No 215-185-5	Skin corrosion (Category 1B) - Causes severe skin burns and eye damage - H314	$\geq 2.5\% - \leq 3.0\%$

4. First aid measures

4.1. Description of first-aid measures

General recommendation: Contaminated individuals of chemical exposure must be taken for medical attention if any adverse effect occurs. Rescuers should be taken for medical attention, if necessary. Take copy of label and MSDS to health professional with individual contaminated.

After inhalation: Take the person to an outdoor area and keep him/her in a position that does not make breathing difficult. Seek medical attention if necessary.
 After skin contact: Rinse thoroughly with water. Take off contaminated clothes. Seek medical advice 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. Make the victim immediately drink water (two glasses maximum) and rinse the mouth thoroughly with water. Seek medical attention immediately.

4.2. Most important, acute and delayed symptoms and effects

Acute: exposure to the product can 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.
 Chronic: none known.

4.3 Target organs

Acute: eyes, respiratory system, skin.
 Chronic: none known.

4.4 Medical conditions aggravated by exposure

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

4.5 Indication of immediate medical attention and special treatment required

Treat symptoms.

5. Fire-fighting measures

Combustion point	No information is available
Auto-ignition temperature	No information is available.
Flammability (solid, gas)	No information is available.
Lower explosiveness limit	No information is available.
Upper limit of explosiveness	No information is available
Explosion hazards	Not classified as explosive.

5.1. Means of extinction

Suitable means of extinction: Adapt fire fighting measures to local conditions and the environment around you.

Inadequate extinguishing agents

No limitation of extinguishing agents is given for this substance/mixture.

5.2. Special hazards arising from the substance or mixture

Not fuel.

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

5.3. Precautions for firefighters

Special equipment for the protection of people involved in fire fighting.

Do not stay in the danger zone without autonomous breathing apparatus suitable for breathing regardless of the environment. In order to avoid contact with the skin, keep a safe distance and wear suitable protective clothing.

6. Accidental release measures

6.1 Response to spillage or leakage

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

6.2 Spill response PPE

Adequate eye and skin protection should be used, as well as a protective mask.

6.3 Consultation with other sections

Indications for waste treatment, see section 13

7. Handling and storage

7.1 Handling, work and hygiene practices

Wash your hands well after handling the product. Do not eat, drink, smoke or apply cosmetics when handling this product. Avoid breathing the dust generated by this product as well as avoid getting this product on your skin or in you.

7.2 Storage practices

Storage in the packaging itself, in a covered environment without exposing the packaging to the weather.

- Avoid mechanical shocks or major trepidations.
- Temperature range between -20°C to +50°C.
- Relative humidity between 10 and 90 % (without condensation).
- The direction of the arrow as to the correct positioning.
- maximum stacking as indicated on the packaging.

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

Follow instructions for item 8.

After opening, it is recommended that it be used no later than 30 days and that the container remains protected from heat and light (preferably stored in the box itself). After this period, it should be discarded according to item 13.

8. Exposure control and personal protection

8.1 Exposure limits/Guidelines

Component	ACGIH TWA	OSHA TWA
Calcium hydroxide CAS # 1305-62-0	5 mg/m ³	5 mg/m ³
Sodium hydroxide CAS # 1310-73-2	2 mg/m ³	2 mg/m ³

8.2 Ventilation and engineering controls

An environment with adequate ventilation to keep exposure levels below the limits described above. Use exhaust fans to control the dust generated by the product. Make sure that eyewash/safety shower stations are available near the areas where this product is used.

8.3 Personal protective measures

Personal protective equipment for the body should be selected based on the concentration and the amount of toxic substances according to the specific conditions at the workplace. Resistance of protective equipment to chemical agents should be cleared up with suppliers.

Skin/eye protection
Fitted safety glasses

Hand protection
Immersion protection:
Glove material: Nitrile rubber
Glove thickness: 0.11 mm
Break through time: > 480 min

Splash protection:
Glove material: Nitrile rubber
Glove thickness: 0.11 mm
Break through time: > 480 min

Other protection equipment
Protection suit

Respiratory protection
Necessary in case of dust formation.
Type of Filter recommended: Filter P2
The entrepreneur must make sure that the maintenance, cleaning and test of respiratory protection equipment be executed according to the producer's instructions. These measures should be properly documented.

9. Physical and chemical properties

9.1. Information on basic physical-chemical properties

Physical state	solid
Color	white to slightly yellowish or greyish
Odor	characteristic
Odor Limit	not applicable
pH at 50 g/l (20 °C):	alkaline, (filtered).
Melting point	Not determined.
Boiling point	Not determined.
Evaporation rate	Not applicable.
Steam pressure	Not applicable.
Relative steam density	Not applicable.
Apparent density	≥ 850 kg/m ³
Particle size	2.36 - 4.75 mm

Solubility in water (20 °C)

Sligth soluble

VOC

Not applicable.

10. Stability and Reactivity**10.1 Stability**

Sensitive to moisture action. Stable under normal handling conditions.

10.2 Hazardous decomposition products

There are no indications

10.3 Possibility of dangerous reactions

Dangerous polymerizations will not occur.

10.4 Conditions to be avoided

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

Contact with strong acids: strong exothermic reaction.

Contact low density metal, basic metal, aqueous metal solutions produce hydrogen.

Contact with aluminum at high temperature

10.5. Materials with which substance is incompatible

Chloroform, trichloroethylene, low density metals or basic 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

CAS # 1310-73-2 LD (lo)

500 mg/kg Rabbit - Oral

11.2 Carcinogenicity

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

11.3 Irritability

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

11.4 Sensitization

This product is not considered 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 Risks to exposure or risk to health

Acute: exposure to the product can be irritating to the eyes, respiratory system and skin.

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

Eye: may cause irritation.

Skin: may cause irritation.

Ingestion: may cause irritation to gastrointestinal tract.

Chronic: none known.

11.7 Target organs

Acute: eye, respiratory system, skin.

Chronic: none known.

12. Ecological information

Mixture

12.1. Toxicity

No data available.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

PBT/vPvB* assessment not performed because chemical safety assessment is not required/was not performed.

*PBT – Persistent – Bioaccumulative – Toxic

vPvB – Very persistent and very bioaccumulative

12.6. Other adverse effects

Additional ecological data

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

Additional data about ecology

Disposal in the environment must be avoided.

Components

Calcium hydroxide

Toxicity to fish: CL50 *Gambusia affinis* (mosquitofish): 160 mg/l; 96 h (IUCRID)

Biodegradability: Methods to determine biological degradability are not applicable to inorganic substances.

Not applicable to inorganic substances: The substance does not meet the criteria to PBT or vPvB according to regulation (CE) Number 1907/2006, Annex XIII.

Sodium hydroxide

Toxicity to fish: CL50 *Gambusia affinis* (mosquitofish): 125 mg/l; 96 h

Toxicity in daphnias and other aquatic invertebrates: CE50 *Daphnia magna*: 76 mg/l; 24 h

Toxicity to bacteria: CE50 *Photobacterium phosphoreum*: 22 mg/l; 15 min

Biodegradability: Methods to determine biological degradability are not applicable to inorganic substances.

13. Treatment and disposal considerations

Waste treatment methods: Waste must be disposed in solid form in accordance with federal, state and local disposal regulations.

Residue category: EWL (European list of residues) 16 03 3* / 18 01 06*

Disposal legislation:

- Law 12.305 / 2010 Solid Residues National Politic;
- RDC ANVISA Number 306 / 2004 Technical Regulation to health service residues management;
- Resolution CONAMA Number 358/2005 Treatment and final destination of health service residues;
- The Hazardous Waste (England & Wales) Regulations 2005;
- Residue code number, applicable to Europe – residue code number, applicable to Europe

14. Transport information**14.1 UN Number**

ADR / RID, DOT (US), IMDG, IATA, ANTT: Special Provision 62 in Transport Regulations (IMDG / RID / ADR / ADN code) specifies that soda lime is not considered to be a dangerous goods for transport with sodium hydroxide concentrations less than 4% as well as special provision A16 to the IATA Regulation.

14.2 UN proper shipping name

ADR / RID: ATRASORB PHARMA (Soda lime)
DOT (US): ATRASORB PHARMA Soda lime (Carbon dioxide absorber)
IMDG: ATRASORB PHARMA Soda lime (Carbon dioxide absorber)
IATA: ATRASORB PHARMA Soda lime (Carbon dioxide absorber)
ANTT: ATRASORB PHARMA (Soda lime)

14.3 Transport hazard class (es)

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

14.4 Packing Group

ADR / RID, DOT (US), IMDG, IATA, ANTT: exempt by the 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. Regulatory information

15.1 Regulations

Additional classification according to GefStoffV Annex II No (only if different of EC classification):

Occupation restriction: n/a
State Law about hazardous incidents: n/a
Water pollution class: 1 (autoclassification)

Information according to 1999/13/EC about volatile limitations of organic compound emissions (guideline VOC):

Other regulations, restrictions and prohibitions:
(like industrial medicine principles and health and safety regulations).
Instruction sheet BG-Chemie (Chemical Professional Association):
Other state regulations may be applicable. See state individual requirements.

16. Other information

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

16.1 Relevant phrases

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

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 statements P 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

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P304 + P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
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 or doctor/physician.
P314	Get medical advice/attention if you feel unwell.
P332 + P313	If skin irritation occurs: Get medical advice/attention.

16.2 Training recommendation

Provide appropriate information, instructions, and training for 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 security requirements and is not intended to guarantee any particular properties.

16.3 Disclaimer

The information in this safety data sheet is based on the best knowledge available at the time and current legislation. It provides guidance on health, safety and environmental aspects of the product and should not be construed as any guarantee of technical performance or suitability for particular application. As the specific conditions of use are outside the control of the supplier, the user is responsible for ensuring that the product is used in a safe way and in compliance with the relevant requirements of legislation.