

ATRASORB PHARMA FREE

1. Identification of the product and the company

1.1. Product Identifier

Name of the Product: **Atrasorb Pharma Free with indicator (color change: white to violet), granules approximately 4.5 mm**

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

1.2. 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, with the use of halogenated anaesthetics.

As it only contains calcium hydroxide as absorbent, its use in procedures with use of halogenated anaesthetics, such as Sevoflurane, Desflurane, Halothane, Enflurane and Isoflurane is more recommended, because the absorption reaction is less exothermic, reducing the formation of toxic compounds significantly.

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

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

Company: ATRASORB Indústria de Produtos Hospitalares Ltda.

Head Office: Rua Pascoal Pais, 288 – Vila Cordeiro
ZIP CODE: 04581-060 – São Paulo-SP
Phone: + 55 11 5521-2076

Branch: Av. Piracicaba, 351, Vila Nova São Roque,
ZIP CODE 18131-230, São Roque - SP – Brasil
Fones: + 55 11 4719-6688 / 4784-1086 / 5521-2076

1.4. Emergency Telephone Number

São Paulo-SP: Phones: + + 55 11 5521-2076
Abiquim 24 hours: +55 11 0800-118270

2. Hazards identification

2.1. Classification of the substance or mixture

Classification (According to Regulation (EC) N° 1272/2008)

Severe eye damage, Category 1, H318

Systemic toxicity of specific target organ – single exposure, Category 3, Respiratory system, H335

For the full text of the hazard statements mentioned in this section, go to section 16.

Classification (67/548/CEE or 1999/45/CE)

Xi Irritating R41 – Risk of severe eye damage

Xi Irritating R37 – Irritating for the respiratory tracts

For the full text about the R-statements mentioned in this section, see section 16.

2.2 Label elements

Labeling (According to regulation (EC) N° 1272/2008)

Pictograms



Signal word: Danger

Hazard Statements

H318 It can cause severe eye damage.

H335 It can cause respiratory tract irritation.

Precautionary Statement

Prevention

P280 Wear eye protection.

First aid measures

P305 + P351 + P338 IN CASE OF EYE CONTACT: Rinse eyes thoroughly with water for several minutes. Remove contact lenses and keep and keep rinsing eyes with water.

Labeling (67/548/CEE ou 1999/45/CE)

Hazard symbol(s):



Xi

Irritating

R - phrase(s)

37-41

Respiratory tract irritating. Risk of severe eye damage.

S - phrases(s)

26-39

In case of eye contact, rinse immediately with plenty of water and seek medical advice

2.3. Other hazards

None

3. Composition/Information on ingredients

Chemical nature: Mix of organic and inorganic components

3.1 Substance: not applicable**3.2 Mixture**

Hazardous components (According to regulation (EC) N° 1272/2008)

Chemical name (Concentration)

CAS-No.

EC-No.

Classification

Calcium hydroxide (≥ 68.0 % - ≤ 75.0 %)

Non applicable to inorganic substances

1305-62-0

(*)

Severe eye damage, Category 1, H318

Skin irritation, Category 2, H315

Systemic toxicity of specific target organ – single exposure, Category 3, H335

(*) There is no available registration number for this substance because this substance or its use is exempt from registration according to Article 2 of REACH regulation (CE) No. 1907/2006.

For the full text about the hazard sentences mentioned in this section, see section 16.

Hazardous components (1999/45/CE)

Chemical name (Concentration)

CAS – No.

Classification

Calcium hydroxide (≥ 68.0 % - ≤ 75.0 %)

1305-62-0

Xi, Irritating; R37/38-41- Irritating for respiratory tracts and skin. Risk of severe eye damage.

4. First aid measures**4.1. Description of first aid measures**

If inhaled: Move exposed person to fresh air. If the exposed person is indisposed, get medical attention.

In case of skin contact: Wash off with plenty of water. Take off contaminated clothing.
In case of eye contact: Rinse with plenty of water. Get medical attention immediately.
If ingested: Make the exposed person drink water (two glasses maximum). Get medical attention.

4.2. Most important, acute and retarded symptoms and effects

Irritation and corrosion, Cough, Artificial respiration.
Risk of opacification of the cornea.

4.3. Indication of immediately medical attention and necessary special treatment

There is no available information.

5. Fire-fighting measures**5.1. Extinguishing media**

Suitable extinguishing media: Use an extinguishing agent suitable to the local conditions and to the surroundings.

Not suitable extinguishing media:

No limitation of extinguishing media is given to this substance/mixture.

5.2. Special exposure hazards

Non-combustible.

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

5.3. Precautions for fire-fighters

Special equipment to protect any involved people in the fire fighting.

Do not stay in the danger zone without self contained breathing apparatus. To avoid skin contact, keep a safe distance and wear protective gear.

Additional information

Avoid surface and ground water contamination with the water used in the fire fighting.

6. Accidental release measures**6.1. Personal precautions, protection equipment and emergency procedures**

Recommendation to personnel not involved with emergencies: Avoid contact with the substance. Avoid dust inhalation. Provide adequate ventilation. Evacuate the area, observe the emergency procedures, consult a specialist.

Recommendations to emergency personnel: Protective equipment, see section 8

6.2 Environmental precautions

Do not disperse residues in the sewer.

6.3 Methods and materials for containing and cleaning up

Cover drains. Collect, patch and pump spills.

Observe the possible material restrictions (see sections 7 and 10).

Absorb the product in its dry state. Dispose the residues. Clean afterwards. Avoid dust formation.

6.4 Reference to other sections

For treatment of waste, see section 13.

7. Handling and storage

- Avoid mechanical shocks or big vibrations;
- Range of temperature between -20°C to +50°C;
- Relative humidity between 10 and 90% (no condensation);

Use the original package to load and unload containers. Follow instructions on item 8.

Store in the original package, in a covered place without weather exposure.

After opening, it is recommended to be used within a maximum of 30 days and that the recipient remains protected from heat and light (preferably in its own box). After this period, the product must be discarded as in item 13.

8. Exposure control and personal protection

8.1. Control parameters

Does not contain substances with occupational exposure limits.

8.2. Exposure limits

Planning measures

Technical measures and proper work operations must have priority over the use of personal protection equipment. See section 7.

Personal protection 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.

Environmental risk control
Do not dispose residues in the sewer.

9. Physical and chemical properties

9.1. Information on basic physical-chemical properties

Physical state	solid
Color	white
Odor	odorless
Odor threshold	non applicable
PH in 50 g/l (20 °C):	alkaline, (filtered)
Melting point	No data available.
Boiling point	No data available.
Flash point	No data available.
Evaporation rate	No data available.
Flammability (solid, gas)	No data available.
Lower explosive limit	No data available.
Upper explosive limit	No data available.
Vapor pressure	No data available.
Vapor relative density	No data available.
Relative density	No data available.
Water solubility (20 °C)	insoluble

Partition coefficient (n- octanol/water)	No data available.
Auto ignition temperature	No data available.
Decomposition temperature	No data available.
Viscosity, dynamic	No data available.
Explosion risks	Not classified as explosive.
Oxidizing properties	no

9.2. Other information

Bulk density	≥ 800 kg/m ³
Particle size	2.00 – 4.75 mm

10. Stability and Reactivity

10.1. Reactivity

See section 10.3.

10.2. Chemical Stability

Humidity sensitive

10.3. Possibility of hazardous reactions

Possible violent reactions with acids, hydrogen sulfide, light metals, phosphorus, organic nitro-compounds
Risk of explosion in the presence of anhydrides

10.4. Conditions to be avoided

Humidity

10.5. Incompatible materials

Light metals

10.6. Hazardous decomposition products

There are no indications

11. Toxicological information

11.1. Information on toxicological effects

Mixture

Acute oral toxicity

Symptoms:

Irritation of: Gastrointestinal tract

Acute respiratory toxicity

Symptoms:

- mucous irritation, cough, superficial breathing, possible consequences: lesion in the respiratory tracts

Acute skin toxicity

No data available.

Skin irritation

Rabbit

Result: No skin irritation

Guidelines for test 404 of OECD
(test in mixture)

Eye Irritation

Rabbit

Result: Causes severe eye lesions.

Guidelines for test 405 of OECD.
(test in mixture)

Can cause opacification of the cornea.

The mixture causes severe eye damage.

Sensitivity

No data available.

Germ cell mutagenicity

No data available.

Carcinogenicity

No data available.

Reproductive and lactation toxicity

No data available.

Teratogenicity

No data available.

Specific target organ toxicity – single exposure

Can cause irritation in the respiratory tracts.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration risk

No data available.

11.2. Additional information

Other hazardous properties cannot be excluded.

Handle according to good hygiene and safety industrial practices.

Components

Calcium hydroxide

Acute oral toxicity: DL50 rat: 7340 mg/kg (IUCLID)

Skin irritation

Rabbit

Result: No irritation.

Guidelines for test 404 of OECD in case of sweat/corrosive humidity.

Eye irritation

Rabbit

Result: Severe irritation (RTECS)

Sodium silicate

Acute oral toxicity: DL50 rat: 2000 mg/kg (IUCLID)

Skin irritation

Rabbit

Result: No irritation

Eye irritation

Rabbit

Result: Slight irritation (RTECS)

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 (IUCLID)

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

Sodium silicate

Toxicity to fish: CL50 *Brachydanio rerio* (Zebra fish): 3,185 mg/l; 96 h (IUCLID)

Toxicity in daphnias and other aquatic invertebrates

CE50 *Daphnia magna*: 494 mg/l; 48 h (ECOTOX Database) (anidrous substance)

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.

13. Treatment and disposal considerations

Waste treatment methods: Waste must be disposed in solid form in accordance with federal, state and local disposal regulations. Keep chemical substances in its original recipients. Handling of recipients must be done the same way as the product.

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

Storage:

-Avoid mechanical shocks or big vibrations;
-Range of temperature between -20°C to +50°C;
-Relative humidity between 10 and 90% (no condensation);

Storage class:

LGK 10-13 (VCI – concept)

14. Transport information

Ground transportation (ADR/RID)

14.1 - 14.6 Not hazardous product according to transport regulations.

Inland waterway transportation (ADN)

Not relevant

Air transportation (IATA)

14.1 - 14.6 Not hazardous product according to transport regulations.
Sea transportation (IMDG)

14.1 - 14.6 Not hazardous product according to transport regulations.

14.7. Mass transportation according to Annex II de MARPOL 73/78 and Code IBC

Not relevant

15. Regulatory information

15.1. Labeling according to Norm EC and ANVISA records

Symbols and indicators to hazardous substances and preparations:  Xi Irritating

R Sentence(s) 41 Risk of severe eye lesions.

S - Sentence(s) S 2 Keep children out of reach.
S 26 In case of contact with eyes, rinse immediately and with plenty of water and see a specialist.
S 37/39 Wear gloves and eye/face protective equipment.

15.2 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

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

H290: May be metal corrosive.

H314: Cause severe skin burn and eye damage.

H315: Cause skin irritation.

H318: Cause severe eye lesions.

H335: May cause irritation of respiratory tracts.

Text of R-sentences mentioned in titles 2 and 3

R35: Cause severe burns.


R37: Irritating to respiratory tracts.

R37/38: Irritating to skin and respiratory tracts.

R41: Risk of severe eye lesions.

Training recommendations

Provide information, instructions and proper training to operators.

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Caption of abbreviations and acronyms

Abbreviations and acronyms used may be consulted in <http://www.wikipedia.org>.

The indications are based in the present date of our knowledge and are applicable to the characterization of the product with regard to appropriate safety measures. They do not represent any guarantee of the properties of the described product.

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