

ATRASORB PHARMA FIX

1. Identification of the product and the company

1.1. Product Identifier

Name of the Product: **Atrasorb Pharma FIX with indicator and permanent color change (white to violet) granules approximately 4.5 mm.**

Codes: 9094, 9105, 9106, 9107, 9108, 9109, 9110, 9182, 9254

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

1.2 Other means of identification: data not available

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, with the use of halogenated anaesthetics. Also in cases where the color change after saturation has to be permanent.

As it only contains calcium hydroxide as absorber, in addition to calcium chloride and calcium sulfate, which optimize the hydration of the product, its use in procedures with halogenated anaesthetics, such as Sevoflurane, Desflurane, Halothane, Enflurane and Isoflurane is more recommended, because the absorption reaction is less exothermic, significantly reducing the formation of toxic compounds.

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

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

Company: ATRASORB Indústria de Produtos Hospitalares Ltda.

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CEP 04581-060, São Paulo – SP - Brasil
Fones: + 55 11 5521-2076

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

1.5. Emergency Telephone Number

São Paulo-SP: Phones: + + 55 11 5521-2076

Abiquim 24 hours: +55 11 0800-118270

2. Hazards identification

2.1. Classification GHS

Skin irritation	(Category 2)
Severe eye damage	(Category 1)
Systemic toxicity of specific target organ – single exposure	(Category 3), Respiratory system
Acute Aquatic Toxicity	(Category 3)

2.2 Label elements

Pictograms



Signal word: Danger

Hazard Statements

H315 It can cause skin irritation

H318 It can cause severe eye damage.

H335 It can cause respiratory tract irritation.

H402 It can cause harmful to aquatic life

Precautionary Statement

Prevention

P261

Avoid breathing dust/fume/gas/mist/vapors/spray.

P264

Wash skin thoroughly after handling.

P271

Use only outdoors or in a well-ventilated area.

P273

Avoid release to the environment.

P280

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

P304 + P340 + 312

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.

P305 + P351 + P338 + 310

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.

P332 + P313

If skin irritation occurs: Get medical advice/attention..

Storage

P403 + P233

Store in a well-ventilated place. Keep container tightly closed.

Disposal

P501

Dispose of contents/container to approved waste disposal facility.

2.3. Other hazards

None

3. Composition/Information on ingredients

3.1 Substance: not applicable

3.2 Mixture

Chemical nature:

Mix of organic and inorganic components

Component	Classification	Concentration
Calcium Hydroxide CAS nr 1305-62-0 CE nr 215-173-3	- Severe eye damage, Category 1 - Skin irritation, Category 2 - Systemic toxicity of specific target organ – single exposure, Category 3 - Acute aquatic toxicity, Category 3	≥ 68.0 % - ≤ 75.0 %
Calcium chloride CAS nr 10043-52-4 CE nr 233-140-8	- Eyes irritation, Category 2A	≥ 2.5 % - ≤ 3.0 %

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

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

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

- Avoid mechanical shocks or great shaking.
- Temperature range from -20 ° C to + 50 ° C.
- Relative humidity between 10 and 90% (without condensation).
- The direction of the arrow in the correct positioning.
- Maximum stacking = 05 boxes

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 to slightly purple / bluish
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
Explosion risks
Oxidizing properties

No data available.
Not classified as explosive.
no

9.2. Other information

Bulk density $\geq 800 \text{ kg/m}^3$
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)

Calcium chloride

Acute oral toxicity:

LD50 rabbit: 500-1000 mg / kg

401 test guideline OECD (anhydrous substance)

LD50 Rat: 1000 mg / kg (anhydrous substance) (IUCLID)

Skin irritation

Rabbit

Result: No irritation.

Guideline 404 OECD test (anhydrous substance)

Eye irritation

Rabbit

Result: Irritations in the eye

Guideline 405 OECD test (anhydrous substance)

Causes serious eye irritation

Calcium Sulphate

Acute oral toxicity:

Rat LD50:> 10,000 mg / kg (IUCLID)

Skin irritation

human

Result: No irritation (IUCLID)

Eye irritation

human

Result: no irritation (IUCLID)

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.

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.

Calcium chloride

Toxicity to fish: LC50 *Lepomis macrochirus* (Bluegill sunfish): 10,650 mg / l; 96 h (anhydrous substance) (IUCLID)

Toxicity to daphnia and other aquatic invertebrates.

EC50 *Daphnia magna* (water flea *Daphnia* or): 144 mg / l; 48 h (anhydrous substance) (IUCLID)

IC50 toxicity to algae: 3,130 mg / l; 120 h (anhydrous substance) (IUCLID)

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

Calcium Sulphate

Toxicity to fish: LC50 *Lepomis macrochirus* (Bluegill sunfish): 2,980 mg / l; 96 h (IUCLID)

Not applicable to inorganic substances: The substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No. 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

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 FIX (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 (Absorbent 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

R Sentence(s)	41	Risk of severe eye lesions.
S - Sentence(s)	S 2 S 26	Keep children out of reach. 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.

15.1 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

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.
R36: Causes eye irritation.
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.

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.

