ATRASORB PHARMA FIX

1. Product and company identification

1.1. Product identifier

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

Codes: 9094, 9105, 9106, 9107, 9108, 9109, 9110, 9182, 9254, 9280, 9283, 9284, 9285, 9286, 9287, 9288, 9289, 9348, 9349, 9394.

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

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

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

Identified uses: Absorber of CO_2 (carbon dioxide) in pills for medical use, in closed or semi-closed anesthetic circuits using inhalation methods , 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 absorber, 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 .

For additional information on applications, see “Instructions for Use”.

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

Company: ATRASORB Industria de Produtos Hospitalares Ltda
email: atrasorb@atrasorb.com.br

BRANCH: Av. Piracicaba, 351 - Vila Nova São Roque
CEP 18131-230, São 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)
Pró-Química 24 hours: + 55 0800 110 8270 (24 hours)

2. Hazard identification

2.1. GHS Rating

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

2.2 Label elements

Pictogram

GHS05 GHS07

Signal word Danger /Warning

Hazard 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. If you wear contact lenses, remove them if possible. Continue rinsing.

P332 + P313 If skin irritation occurs: seek medical advice.

P314 If you feel unwell, seek medical advice.

3. Composition and information about 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 CE 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 irritation of the respiratory tract. – H335	≥ 68.0% - ≤ 75.0%
Calcium chloride CAS No. 10043-52-4 CE nº 233-140-8	Eye irritation (Category 2) - Causes serious eye irritation – H319	≥ 3.0% - ≤ 4.5%
Sodium silicate CAS No. 1344-09-8 CE nº 229-912-9	Skin corrosion (Category 1B) - Causes skin burns and serious eye damage – H314, Specific target organ toxicity - single exposure (Category 3), Respiratory system - May cause irritation of the respiratory tract. – 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 medical care if any adverse effects occur. The injured person must receive medical care, if necessary. Take a copy of the product label and MSDS to the healthcare professional with the infected person.

After inhalation: Take the person to an outside area and keep them in a position that does not make breathing difficult. 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 well with water for at least 15 minutes. Consult an ophthalmologist immediately.

After ingestion: Do not induce vomiting. Have the victim immediately drink water (two glasses maximum) and rinse their mouth well with water. Seek medical attention immediately.

4.2 Most important symptoms and effects, acute and delayed
Acute: exposure to the product can be irritating to the eyes, respiratory system and skin.
Inhalation: Inhalation of product dust 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 necessary special treatment
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

Burning point	No information available.
Auto-ignition 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 fire-fighting measures to local conditions and the surrounding environment.

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

5.2. Special hazards arising from the substance or mixture
Not 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 firefighting.
Do not stay in the danger zone without self-contained breathing apparatus suitable for breathing independent of the environment. To avoid contact with the skin, 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 product is spilled or leaked, collect mechanically in a tightly closed container. Respecting individual protection measures. Wash off any residue with plenty of water.

6.2 Spill Response PPE
Appropriate protective equipment for eyes and skin, as well as a protective mask, must be used.

6.3 Consult other sections
Indication on 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 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.
a) Avoid mechanical shocks or strong vibrations.
b) Temperature range between -20ºC to +50ºC.
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.

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 must be discarded according to 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

8.2 Ventilation and engineering controls

An environment with adequate ventilation to maintain exposure levels below the limits described above. Use an exhaust fan to control the dust generated by the product. Ensure that safe eye wash facilities are available near areas where this product is used.

8.3 Personal protection measures

The characteristics of body protection means must be selected depending on 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 suppliers.

Skin/eye protection
Well-fitting safety glasses

Hand protection
Full contact:
Glove substance: Nitrile rubber
Glove thickness: 0.11mm
Pause: > 480 min
Contact with splashes:
Glove substance: Nitrile rubber
Glove thickness: 0.11mm
Pause: > 480 min

Other protective equipment

Protective clothing

Breath protection
Necessary in case of powder formation.
Recommended Filter Type: Filter P FF2

The entrepreneur must ensure that maintenance, cleaning and testing of respiratory protective devices are carried out in accordance with the producer'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 purplish/bluish color
Characteristic odor	
Odor Limit	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	≥ 8 00 kg/m³
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 the action of humidity. 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 avoid
Contact with air, formation of calcium carbonate and sodium carbonate.
Contact with strong acids: strong exthermic reaction.
Contact 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 about 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 the product can be irritating to the eyes, respiratory system and skin.

Inhalation: Inhaling product dust can cause irritation to the nose, respiratory tract and throat.
Eye: may cause irritation.
Skin: may cause irritation.
Ingestion: may cause irritation to 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
There is no information available.

12.2. Persistence and degradability
There is no information available.

12.3. Bioaccumulative potential
There is no information available.

12.4. Soil mobility
There is no information available.

12.5. PBT and vPvB assessment results
vPvB * assessment not carried out as chemical safety assessment is not required/has not been carried out.

*PBT – Persistent – Bioaccumulative – Toxic
vPvB – Very persistent and very bioaccumulative

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 about ecology
Discharge into the environment must be avoided.

Components

Calcium hydroxide
Fish toxicity: 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 v PvB According to regulation (EC) No. 1907/2006, Annex XIII.

Calcium chloride

Fish toxicity: LC50 Lepomis macrochirus (sunfish): 10,650 mg/l; 96 h (anhydrous substance) (IUCLID)
Toxicity to daphnia and other aquatic invertebrates.
EC50 Daphnia magna (water flea or daphnia): 144 mg/l; 48h h (anhydrous substance) (IUCLID)
Toxicity to algae IC50 algae: 3,130 mg/l; 120 h (anhydrous substance) (IUCLID)
Biodegradability: The methods for determining biological degradability are not applicable to inorganic substances.

Sodium silicate

Fish toxicity: 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 v PvB in accordance with regulation (EC) No. 1907/2006, Annex XIII.

calcium sulfate

Fish toxicity: LC50 Lepomis macrochirus (sunfish): 2,980 mg/l; 96 h (IUCLID)

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

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 Health Service Waste Management Practices;
-CONAMA Resolution No. 358/2005 Treatment and final disposal of waste from health services;
-The Hazardous Waste (England & Wales) Regulations 2005;
- Waste code number, applicable for Europe - waste code number, applicable for Europe

14. Transportation 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 soda lime is not considered dangerous goods for transport with hydroxide concentrations sodium content of less than 4%, as well as special provision A16 for the IATA regulations.

14.2 UN proper shipping name

ADR/RID: ATRASORB PHARMA FIX (CO_{2} absorbing 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 Hazard classes for transport purposes
ADR/RID, DOT (US), IMDG, IATA, ANTT: exempt by special provisions 62 and A16

14.4 Packing group
ADR/RID, DOT (US), IMDG, IATA, ANTT: exempt 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 the 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, this does not constitute a guarantee for any specific characteristics of the product and shall not establish a legally valid contractual relationship.

16.1 Relevant phrases

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

H314: Causes serious 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 P statements mentioned in sections 2 and 3.

P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash skin carefully 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	ON SKIN (or hair): immediately take off/remove all contaminated clothing. Rinse skin with water/take a shower.
P304 + P340 + P312	IF INHALED: Remove person to fresh air and keep in a position that does not make breathing difficult. If you feel unwell, contact a POISON CENTER or doctor.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. If you wear contact lenses, remove them if possible. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P314	If you feel unwell, seek medical advice.
P332 + P313	If skin irritation occurs: seek medical advice.
P337 + P313	If eye irritation persists: Consult a doctor.

16.2 Training recommendation
Provide adequate information, instructions and training for operators.