

ALBUMINA

1110XXX

FDS0222ENG-REV01 Data de revisão: 04/2024

1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade Name: Albumina Article N°: 1110XXX MS: 80115310072

1.2 Relevant identified uses of the substance or mixture and uses advised against

Reagent for in-vitro diagnostics in human samples

For professional use only.

1.3 Manufacturer

Kovalent do Brasil Ltda.

Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro – São Gonçalo – RJ – Brasil.

Tel: +(55 21) 2623-1367

e-mail: kovalent@kovalent.com.br

1.4 Emergency telephone number

Tel: +(55 21) 2623-1367 - Costumer Service from 8am to 5pm

0800 015 1414

Information in case of emergency - 24 hours service

0800-722-6001 - RENACIAT (Rede Nacional de Centros de Informação e Assistência Toxicológica)

2 Hazards Identification

2.1 Classification of the substance or mixture

This mixture is classified as not hazardous according to ABNT NBR 14725.

2.2 Label elements

Labelling (GHS)

Hazard statements: Not applicable

Precautionary statements: Not applicable

2.3 Other hazards

No risks worthy of mention.

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical characterization: Aqueous solution with organic materials

Additional information: The product does not contain dangerous substances above limits that need to be mentioned

in this section according to applicable legislation.

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4 First aid measures

4.1 Description of first aid measures

In case of inhalation: Provide fresh air. If the casualty has difficulty breathing, call a doctor immediately.

Following skin contact: Change contaminated clothing. Remove residues with water. In case of skin irritation,

consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids

apart. Remove contact lenses, if present and easy to do. Continue rinsing. In case of

troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Rinse mouth immediately and drink plenty of water. Do not induce vomiting without

medical advice. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

After eye contact. May cause irritations.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to the doctor: Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

5.2 Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours.

In case of fire may be liberated: Nitrogen oxides (NOx), sulphur oxides, carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighter: Wear self-contained breathing apparatus.

Do not allow fire water to penetrate surface or ground water.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes. Do not breathe vapours. Provide fresh air. Wear appropriate protective equipment.

6.2 Environmental precautions

Do not allow to penetrate soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of water.

7 Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes.

Keep all containers, equipment and working place clean.

Provide adequate ventilation, and local exhaust as needed. Do not breathe vapours. Wear appropriate protective equipment. Wash hands before breaks and after work. Do not eat, drink, or smoke when using this product.

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7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers: Keep containers tightly closed and at a temperature between 2 °C and

8 °C. Do not freeze. Protect from light. Keep sterile.

Hints on joint storage: Do not store together with: strong acids, alkalis.

Storage class: 12 = Non-combustible liquids.

8 Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Engineering control measures

Provide adequate ventilation, and local exhaust as needed.

8.3 Personal protection equipment

Respiratory protection Provide adequate ventilation. If vapours form, use respiratory protection. Us

filter type A (against vapours of organic substances) according to EN 14387.

Hand protection Protective gloves according to EN 374.

Glove material Nitrile rubber breakthrough time > 480 min. Observe glove manufacturer

instructions concerning penetrability and breakthrough time.

Eye protection Tightly sealed googles according to EN 166.

Body protection Wear suitable protective clothing.

General protection and hygiene

measures

Avoid contact with skin, eyes, and clothing. Change contaminated clothing. E

not breathe vapours.

Wash hands before breaks and after work. Do not eat, drink, or smoke whe

using this product.

Environmental exposure controls

Refer to "6.2 Environmental precautions".

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9 Physical and chemical properties

Physical state at 20 °C and 101.3 kPa: Liquid

Colour: Greenish, clear

Odour: Odourless

Odour threshold: No data available

pH: at 25°C: 4,2

Melting point/freezing point:

No data available

Initial boiling point and boiling range:

No data available

Flash point/flash point range: Not combustible

Evaporation rate: No data available

Flammability solid/gas: No data available

Inferior/superior limits of flammability or Explosion limits: No data available

Vapour pressure: No data available

Vapour density: No data available

Density: at 20°C: 1,000 g/mL

Water solubility: Completely miscible

Partition coefficient: n-octanol/water: No data available

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Viscosity: No data available

Explosive properties: No data available

Oxidizing characteristics: No data available

10 Stability and reactivity

10.1 Reactivity

Refer to item 10.3.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known when handled and stored according to dispositions.

10.4 Conditions to avoid

Protect against heat / sun rays.

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10.5 Incompatible materials

Strong acids and alkalis.

10.6 Hazardous decomposition products

No hazardous decomposition products when regulations for storage and handling are observed.

Thermal decomposition: No data available.

11 Toxical information

Lack of data Acute toxicity (oral): Acute toxicity (dermal): Lack of data Lack of data Serious eye damage/irritation: Sensitization to the respiratory tract or skin: Lack of data Germ cell mutagenicity: Lack of data Carcinogenicity: Lack of data Reproductive toxicity: Lack of data Specific target organ toxicity (single exposure): Lack of data Specific target organ toxicity (repeated exposure): Lack of data Aspiration hazard: Lack of data Endocrine disrupting properties: No data available

Symptoms: The product can cause irritation to the eyes after exposure.

12 Ecological information

12.1 Toxicity

Water Hazard Class: 1 = slightly hazardous to water

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential:

Partition coefficient: n-octanol/water: No data available

12.4 Mobility in soil

No data available

12.5 Other adverse effects

General information: Do not allow to enter groundwater, surface water, or drains.

13 Disposal considerations

13.1 Waste treatment methods

Product: Dispose of waste according to applicable legislation.

Contaminated packages: Dispose of waste according to applicable legislation.

Non-contaminated packages may be recycled.

Additional information: Do not reuse empty containers.

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14 Transport information

14.1 UN number

ADR/RID, IMDG, IATA, ANTT Not applicable.

14.2 UN proper shipping name

ADR/RID, IMDG, IATA, ANTT Not restricted.

14.3 Transport hazard class(es)

ADR / RID

IMDG

IATA

ANTT

Not applicable.

Not applicable.

Not applicable.

Not applicable.

14.4 Risk Number

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14.5 Packing group

ADR / RID, IMDG, IATA, ANTT: Not applicable.

14.6 Environmental hazards

Marine pollutant: No

14.7 Special precautions for user

No dangerous good in sense of these transport regulations.

15 Regulatory information

- Product produced in accordance with the requirements established by RDC 665 of 30/03/2022 and with labeling information in accordance with RDC 206 of 17/11/2006.
- For more details on product disposal refer to RDC 222 of 28/03/2018 and NBR 10004.
- This safety data sheet was prepared in accordance with ABNT/NBR 14725:23.

16 Other information

The above information is considered correct but is not intended to be complete and should be used only as a guide. Kovalent is not responsible for any damage resulting from handling or use.

In article XXX: The tree X are for the volume.

Abbreviations and acronyms:

ABNT: Associação Brasileira de Normas Técnicas / National Standards Forum

ADR: Accord européen relatif au transport international des marchandises Dangereuses par Route ANTT: Agência Nacional de Transporte Terrestre / National Agency of Transportation by Road

CAS: Chemical Abstracts Service
CE: Conformite Europeenne

GHS: Globally Harmonized System IATA: International Air Transport Association

IATA-DGR: IATA - Dangerous Goods Regulations IMDG: International Maritime Dangerous Goods

MS: Anvisa's Registry Code

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NBR: Brazilian technical ordinance

pH: Potential of Hydrogen

PPE: Personal protective equipment RDC: Resolution from the Directory Board

RENACIAT: Rede Nacional de Centros de Informação e Assistência Toxicológica

UN: United Nations

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1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade Name: Albumin Standard

Article N°: 1110XXX MS: 80115310072

1.2 Relevant identified uses of the substance or mixture and uses advised against

Reagent for in vitro diagnostics in human samples

For professional use only.

1.3 Manufacturer

Kovalent do Brasil Ltda.

Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro – São Gonçalo – RJ – Brasil.

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1.4 Emergency telephone number

Tel: +(55 21) 2623-1367 – Costumer Service from 8am to 5pm 0800 015 1414

Information in case of emergency – 24 hours service

0800-722-6001 - RENACIAT (Rede Nacional de Centros de Informação e Assistência Toxicológica

2 Hazards Identification

2.1 Classification of the substance or mixture

This mixture is classified as not hazardous according to ABNT NBR 14725.

2.2 Label elements

Labelling (GHS)

Hazard statements: Not applicable

Precautionary statements: Not applicable

2.3 Other hazards

No risks worthy of mention.

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical characterization: Aqueous solution of inorganic salts and organic compounds.

Additional information: The product does not contain dangerous substances above limits that need to be mentioned

in this section according to applicable legislation. Contains sodium azide (0.95 g/L) as preservative.

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4 First aid measures

4.1 Description of first aid measures

In case of inhalation: Provide fresh air. If the casualty has difficulty breathing, call a doctor immediately.

Following skin contact: Change contaminated clothing. Remove residues with water. In case of skin irritation,

consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids

apart. In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Rinse mouth thoroughly with water. Induce vomiting.

Have victim drink large quantities of water, with active charcoal if possible. Seek

medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

5.2 Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours.

In case of fire may be liberated: Nitrogen oxides (NOx), sulphur oxides, phosphorus oxides, carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters: Wear self-contained breathing apparatus. Wear suitable protective clothing. Do not allow fire water to penetrate into surface or ground water.

6 Accidental release measures vazamento

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes. Wear appropriate protective equipment. In enclosed areas: Provide fresh air.

6.2 Environmental precautions

Do not allow to penetrate soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of water.

7 Handling and storage

7.1 Precautions for safe handling

Provide adequate ventilation, and local exhaust as needed.

Avoid contact with skin and eyes. Wear appropriate protective equipment.

Keep all containers, equipment and working place clean.

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7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers: Keep containers tightly closed and at a temperature between 2 °C and

8 °C. Protect from light. Keep sterile.

Storage Class: 12 = Non-combustible liquids.

8 Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Engineering control measures

Provide adequate ventilation, and local exhaust as needed.

8.3 Personal protection equipment

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Hand protection Protective gloves according to EN 374.

Glove material Nitrile rubber breakthrough time > 480 min. Observe glove manufacti

instructions concerning penetrability and breakthrough time.

Eye protection Tightly sealed googles according to EN 166.

Body protection Lab coat.

General protection and hygiene measures Change contaminated clothing.

Wash hands before breaks and after work.

Environmental exposure controls

Refer to "6.2 Environmental precautions".

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9 Physical and chemical properties

Physical state at 20 °C and 101.3 kPa: liquid

Colour: weak yellowish, clear

Odour: no characteristic odour

Odour threshold:

No data available

pH: at 25°C: 7.5

Melting point/freezing point: Approximately 0°C

Initial boiling point and boiling range: Approximately 100°C

Flash point/flash point range: Not combustible

Evaporation rate: No data available

Flammability solid/gas: No data available

Inferior/superior limits of flammability or Explosion limits: No data available

Vapour pressure: No data available

Vapour density: No data available

Density: at 20°C: 1.024 g/mL

Water solubility: Completely miscible

Partition coefficient: n-octanol/water: No data available

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Viscosity: No data available

Explosive properties: No data available

Oxidizing characteristics: No data available

10 Stability and reactivity

10.1 Reactivity

Refer to item 10.3.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Protect against heat / sun rays.

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10.5 Incompatible materials

Strong acids and alkalis

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10.6 Hazardous decomposition products

Nitrogen oxides (NOx), sulphur oxides, phosphorus oxides, carbon monoxide and carbon dioxide.

Thermal decomposition: No data available.

11 Toxical information

Acute toxicity (oral): Lack of data Acute toxicity (dermal): Lack of data Serious eye damage/irritation: Lack of data Sensitization to the respiratory tract or skin: Lack of data Lack of data Germ cell mutagenicity: Lack of data Carcinogenicity: Reproductive toxicity: Lack of data Specific target organ toxicity (single exposure): Lack of data Specific target organ toxicity (repeated exposure): Lack of data Aspiration hazard: Lack of data

Endocrine disrupting properties No data available

Other information: Contains Sodium azide (0.95 g/L):

After resorption of toxic quantities: Headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure,

unconsciousness, collapse.

12 Ecological information

12.1 Toxicity

Slightly hazardous to water.

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential:

Partition coefficient: n-octanol/water: No data available

12.4 Mobility in soil

No data available

12.5 Other adverse effects

General information: Contains in traces phosphates: May contribute to the eutrophication of water supplies. Do not allow to enter into groundwater, surface water or drains.

13 Disposal considerations

13.1 Waste treatment methods

Product: Dispose of waste according to applicable legislation.

Packages: Dispose of waste according to applicable legislation.

Non-contaminated packages may be recycled.

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Additional information: Do not reuse empty containers.

14 Transport information

14.1 UN number

ADR/RID, IMDG, IATA, ANTT Not applicable.

14.2 UN proper shipping name

ADR/RID, IMDG, IATA, ANTT Not restricted.

14.3 Transport hazard class(es)

ADR / RID

IMDG

IATA

ANTT

Not applicable.

Not applicable.

Not applicable.

Not applicable.

14.4 Risk Number

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14.5 Packing group

ADR / RID, IMDG, IATA, ANTT: Not applicable.

14.6 Environmental hazards

Marine pollutant: No

14.7 Special precautions for user

No dangerous good in sense of these transport regulations.

15 Regulatory information

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16 Other information

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GHS: Globally Harmonized System

IATA: International Air Transport Association IATA-DGR: IATA - Dangerous Goods Regulations

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IMDG: International Maritime Dangerous Goods

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