

Safety data sheet

according to 1907/2006/EC, Article 31

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

1.1 PRODUCT IDENTIFIER:

- **Trade name:** Ambroxol powered by Lipodisq™ Sterile Solution.
- **Article number:** IAX-700-108.
- **Substances:** Ambroxol nanoformulation in water.

Substance name	CAS #	EC #	REACH #
Water (sterile)	7732-18-5	231-791-2	Not subject to REACH
Poly(styrene maleic acid)	26762-29-8	607-996-1	Not available*
Lecithin	92128-87-5	295-786-7	Not subject to REACH
Ambroxol hydrochloride	23828-92-4	245-899-2	Not available*

*A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST:

- **Relevant identified uses:** Laboratory chemical. For research use only.
- **Uses advised against:** Not for drug, household or other uses.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET:

- **Company:** Innaxon
 Basepoint Business Centre
 Oakfield Close
 Tewkesbury, GL20 8SD
 United Kingdom.
Phone: +44 (0)1684 851 274.
Email: info@innaxon.com.
- **Emergency telephone number:** During normal opening times (GMT): +44 (0)1684 851 274.

2 Hazards identifications

2.1 CLASSIFICATION OF THE MIXTURE (COMPONENTS):

Substance name	CAS #	EC #	REACH #	Conc.	Classification according Regulation (EC) No. 1272 [CLP]
Water (sterile)	7732-18-5	231-791-2	Not subject to REACH	96.5%	None. This substance is not classified as dangerous according to Regulation (EC) 1272/2008.
Poly(styrene maleic acid)	26762-29-8	607-996-1	Not available	2.5%	None. This substance is not classified as dangerous according to Regulation (EC) 1272/2008.
Lecithin	92128-87-5	295-786-7	Not subject to REACH	0.9%	None. This substance is not classified as dangerous according to Regulation (EC) 1272/2008.
Ambroxol hydrochloride	23828-92-4	245-899-2	Not available	0.1%	None. This substance is not classified as dangerous according to Regulation (EC) 1272/2008.

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2 Hazards identifications

2.2 LABEL ELEMENTS:

Labelling according to Regulation (EC) No 1272/2008 [CLP/GHS].

- **Hazard pictograms:** *Warning!* According to the classification provided by companies to ECHA in CLP notifications this substance causes serious eye irritation.



- **Signal word:** Danger.
- **Hazard statements all components:**
 - **H315 Skin Irrit. 2:** Causes skin irritation.
 - **H319:** Causes serious eye irritation.
 - **STOT SE 3 H335:** May cause respiratory irritation.
- **Precautionary statements:**

Prevention:

 - **P261:** Avoid breathing dust/fume/gas/mist/vapours/spray.
 - **P280:** Wear protective gloves/eye protection/face protection.

2.3 OTHER HAZARDS: None.

3 Composition / information on ingredients

3.1 MIXTURES:

- **Description of the mixture:** Aqueous solution of Ambroxol and polymer stabilised phospholipid complex. Nanoformulation.

Substance name	Synonym	Formula	MW	Purity
Water (sterile)	N/A	H ₂ O	18.015	95-100%
Poly(styrene maleic acid)	Styrene Maleic Acid, Sodium Salt	C ₂₈ H ₂₆ O ₄ Na ₂	MW 9,500 (MN 3,050)	95-100%
Lecithin	Phospholipids derived from Soy	Mixture	Mixture	95-100%
Ambroxol hydrochloride	Ambroxol	C ₁₃ H ₁₈ Br ₂ N ₂ O · HCl	414.61	95-100%



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4 First aid measures

4.1 DESCRIPTION OF FIRST AID MEASURES:

- **General information:** Take off all contaminated clothing immediately.
- **After inhalation:** If symptoms persist, call a doctor.
- **After skin contact:** Wash off immediately with plenty of water.
- **After eye contact:** Rinse immediately with plenty of water and seek medical advice.
- **After ingestion:** Obtain medical attention.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED:

- **Symptoms:** No information available.
- **Effects:** No information available.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED:

- **Notes for the doctor:** No information available.
- **Special treatment:** No information available.

5 Fire fighting measures

5.1 EXTINGUISHING MEDIA:

- **Suitable extinguishing media:** Water, dry powder, foam, carbon dioxide (CO₂).
- **Unsuitable extinguishing media:** No information available.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE:

- **Hazardous combustion products:** No information available.

5.3 ADVICE FOR FIRE-FIGHTERS:

Standard procedure for chemical fires.

- **Additional information:** No further information available.

6 Accidental release measures

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:

- **Personal precautions, protective equipment and emergency procedures:** Wear protective clothing.
Safely dispose broken/damaged glass container using wear cut-resistant gloves and safety glasses with side shields.

6.2 ENVIRONMENTAL PRECAUTIONS:

Do not flush into surface water or sanitary sewer system. Avoid subsoil penetration.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP:

- **Methods for cleaning up:** Wipe up with an absorbent material (e.g. cloth, fleece). Soak up with an inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).

6.4 REFERENCE TO OTHER SECTIONS: See sections 8 and 13.



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7 Handling and storage

7.1 PRECAUTIONS FOR SAFE HANDLING:

- **Advice on safe handling:** Handle and open container with care. Access to this material must be restricted to personnel, who is appropriately experienced, qualified, competent and properly trained to use it. Check the glass container to ensure it is free of cracks, flaws or scratches. Wear slip-resistant and/or cut-resistant gloves, safety glasses with side shields, and lab coat.
- **Advice on protection against fire and explosion:** No special protective measures against fire required.
- **Hygiene measures:** Take off all contaminated clothing immediately.
- **Advice on general occupational hygiene:** Smoking, eating and drinking should be prohibited in the application area.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES:

- **Requirements for storage areas and containers:** Store in original container.
- **Further information on storage conditions:** Keep away from direct sunlight. Limited stability. Keep container tightly closed.
- **Advice on common storage:** Keep away from food and drink.
- **Storage Temperature:** 2-8°C.

7.3 SPECIFIC END USES: None.

8 Exposure controls / personal protection

8.1 CONTROL PARAMETERS:

- **Occupational exposure limits:** Contains no substances with occupational exposure limit values.

8.2 EXPOSURE CONTROLS:

- **Eye Protection:** Tightly fitting safety goggles / Safety glasses with side-shields, tested and approved under appropriate government standards, such as NIOSH (US) or EN 166 (EU).
- **Hand Protection:** Impervious gloves Splash protection. Glove material: for example nitrile rubber. The selected protective gloves should satisfy the specific Regulation (EU) 2016/425 and the standard EN 374 derived from it.
- **Respiratory protection:** For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
- **Protective measure:** Avoid contact with skin and eyes.
- **Hygiene measures:** When using, do not eat or drink. Avoid contact with skin, eyes and clothing.

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9 Physical and chemical properties

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

- **Appearance:** Liquid.
- **Colour:** Colourless clear aqueous solution.
- **Odour:** Characteristic.
- **Odour threshold:** No data available.
- **pH value:** 7.00-7.50.
- **Boiling point/range:** No data available.
- **Flash point:** No data available.
- **Evaporation rate:** No data available.
- **Flammability:** Not flammable.
- **Upper explosion limit:** No data available.
- **Lower explosion limit:** No data available.
- **Vapour pressure:** No data available.
- **Relative vapour pressure:** No data available.
- **Density:** No data available.
- **Water solubility:** Soluble.
- **Dissolution rate in water:** No data available.
- **Partition co-efficient: (n-octanol/water):** No data available.
- **Auto-ignition temperature:** No data available.
- **Viscosity:** No data available.
- **Flow time:** No data available.
- **Explosive properties:** No data available.
- **Oxidizing properties:** No data available.

9.2 OTHER INFORMATION:

No data available.

10 Stability and reactivity

10.1 REACTIVITY:

Stable under recommended storage conditions.

10.4 CONDITIONS TO AVOID:

Protect from heat and sunlight.

10.2 CHEMICAL STABILITY:

Stable under recommended storage conditions.

10.5 INCOMPATIBLE MATERIALS:

Strong oxidising agents.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS:

None reasonably foreseeable.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS:

None reasonably foreseeable.

11 Toxicological information

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS (MIXTURE):

• Acute toxicity

- **Poly(styrene-maleic acid):** No data available.
- **Lecithin:** The product can be considered as non-toxic for human beings and animals.
- **Ambroxol hydrochloride:** LD50 Oral – Rat 4,203 mg/kg.

Remarks: Behavioural: Ataxia, Somnolence (general depressed activity). Lungs, Thorax or Respiration: Dyspnea.

- **Primary irritant effect:** - **On the skin:** Causes skin irritation. - **On the eye:** Causes serious eye irritation.
- **Sensitisation:** No sensitisation known. • **Germ cell mutagenicity:** No data available.
- **Information on other hazards:** This product does not contain any known or suspected endocrine disruptors.
- **Carcinogenicity:** - **IARC:** No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. - **NTP:** No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP. - **OSHA:** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens. - **RTECS:** Not available.



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11 Toxicological information

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS (MIXTURE):

- **Additional toxicological information:** The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

TOXICITY: • **Aquatic toxicity:** No data available. • **Persistence and degradability:** No data available.

BEHAVIOUR IN ENVIRONMENTAL SYSTEMS:

- **Bioaccumulative potential:** No data available. • **Mobility in soil:** No data available.
- **Endocrine disrupting properties:** This product does not contain any known or suspected endocrine disruptors.

ADDITIONAL ECOLOGICAL INFORMATION: • **General notes:** Generally not hazardous for water.

RESULTS OF PBT AND vPvB ASSESSMENT: • **PBT:** Not applicable. • **vPvB:** Not applicable.

OTHER ADVERSE EFFECTS: No data available.

13 Disposal considerations

WASTE TREATMENT METHODS:

- **Recommendation:** All waste must be handled in accordance with local, state and federal regulations. This material and its container must be disposed of in a safe way.

14 Transport information

- 14.1 **UN NUMBER:** Not regulated as a dangerous good.
- 14.2 **UN PROPER SHIPPING NAME:** Not regulated as a dangerous good.
- 14.3 **TRANSPORT HAZARD CLASS(ES):** Not regulated as a dangerous good.
- 14.4 **PACKING GROUP:** Not regulated as a dangerous good.
- 14.5 **ENVIRONMENTAL HAZARDS:** Not regulated as a dangerous good.
- 14.6 **SPECIAL PRECAUTIONS FOR USER:** For personal protection see section 8.
- 14.7 **TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE:** Not applicable.

15 Regulatory information

- 15.1 **SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE:** COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
- 15.2 **CHEMICAL SAFETY ASSESSMENT:** For this substance a chemical safety assessment is not required.



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16 Other information

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out. This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. - For research use only. Not for drug, household or other uses.
- **Department issuing MSDS:** Customer service. - **Contact phone number:** +44 (0)1684 851 274.
- **Abbreviations and acronyms:** RID: Regulations Concerning the International Transport of Dangerous Goods by Rail. ICAO: International Civil Aviation Organization 35.0.2. ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road. IMDG: International Maritime Code for Dangerous Goods. IATA: International Air Transport Association. GHS: Globally Harmonized System of Classification and Labelling of Chemicals.
- The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Innaxon shall not be held liable for any damage resulting from handling or from contact with the above product.