



## Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 31.08.2020

Version number 1

Revision: 31.08.2020

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### · 1.1 Product identifier

· **Product name:** Ambroxol hydrochloride 100 µg/mL in Acetonitrile

· **Part number:** DRE-A10148800AL-100

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.

· **Application of the substance / the mixture** Reference material for laboratory use only

#### · 1.3 Details of the supplier of the safety data sheet

##### · **Manufacturer/Supplier:**

LGC Limited  
Queens Road  
Teddington  
Middlesex TW11 0LY  
UNITED KINGDOM

Tel : +44 (0) 20 8943 7000  
Fax : +44 (0) 20 8943 2767  
eMail : gb@lgcstandards.com  
Web : www.lgcstandards.com

##### · **Further information obtainable from:**

Product safety department  
eMail : sds-request@lgcgroup.com

##### · **1.4 Emergency telephone number:**

For Hazardous Materials or Dangerous Goods Incident  
Spill, Leak, Fire Exposure, or Accident  
Call CHEMTREC:  
USA & Canada 1-800-424-9300  
Rest of the world +1 703-741-5970

### SECTION 2: Hazards identification

#### · 2.1 Classification of the substance or mixture

· **Classification according to Regulation (EC) No 1272/2008**



GHS02 flame

Flam. Liq. 2 H225 Highly flammable liquid and vapour.



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

Acute Tox. 4 H312 Harmful in contact with skin.

Acute Tox. 4 H332 Harmful if inhaled.

Eye Irrit. 2 H319 Causes serious eye irritation.

#### · 2.2 Label elements

· **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

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· **Hazard pictograms**



GHS02 GHS07

· **Signal word** *Danger*

· **Hazard-determining components of labelling:**

Acetonitrile

· **Hazard statements**

- H225 *Highly flammable liquid and vapour.*  
 H302+H312+H332 *Harmful if swallowed, in contact with skin or if inhaled.*  
 H319 *Causes serious eye irritation.*

· **Precautionary statements**

- P210 *Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.*  
 P241 *Use explosion-proof [electrical/ventilating/lighting] equipment.*  
 P280 *Wear protective gloves/protective clothing/eye protection/face protection.*  
 P303+P361+P353 *IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].*  
 P305+P351+P338 *IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*  
 P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.  
 · **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** Mixture: consisting of the following components.

· **Dangerous components:**

CAS: 75-05-8 EINECS: 200-835-2 RTECS: AL 7700000	Acetonitrile ⚠ Flam. Liq. 2, H225; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2, H319	>95%
CAS: 23828-92-4 EINECS: 245-899-2 RTECS: GV8425000	Ambroxol hydrochloride ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	<0.1%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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### SECTION 4: First aid measures

#### · 4.1 Description of first aid measures

##### · General information:

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.

##### · After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

In case of unconsciousness place patient in recovery position for transport.

Seek medical treatment.

##### · After skin contact:

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

##### · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

##### · After swallowing:

Rinse mouth. Do not induce vomiting.

Seek medical treatment.

#### · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

#### · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

### SECTION 5: Firefighting measures

#### · 5.1 Extinguishing media

##### · Suitable extinguishing agents:

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

##### · For safety reasons unsuitable extinguishing agents: Water with full jet

#### · 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

#### · 5.3 Advice for firefighters

##### · Protective equipment:

Mouth respiratory protective device.

Wear self-contained respiratory protective device.

### SECTION 6: Accidental release measures

#### · 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

#### · 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

#### · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose of contaminated material as waste according to item 13.

Ensure adequate ventilation.

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**· 6.4 Reference to other sections***See Section 7 for information on safe handling.**See Section 8 for information on personal protection equipment.**See Section 13 for disposal information.***SECTION 7: Handling and storage****· 7.1 Precautions for safe handling***Ensure good ventilation/extraction at the workplace.**Store in cool, dry place in tightly closed receptacles.**Prevent formation of aerosols.***· Information about fire - and explosion protection:***Keep ignition sources away - Do not smoke.**Protect against electrostatic charges.***· 7.2 Conditions for safe storage, including any incompatibilities****· Storage:****· Requirements to be met by storerooms and receptacles:***Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.**Store only in the original receptacle unless other advice is given on the CoA.**Keep container in a well-ventilated place. Keep away from sources of ignition and heat.***· Information about storage in one common storage facility: Store away from foodstuffs.****· Further information about storage conditions:***Keep container tightly sealed.**Store in cool, dry conditions in well sealed receptacles.***· 7.3 Specific end use(s) No further relevant information available.****SECTION 8: Exposure controls/personal protection****· Additional information about design of technical facilities: No further data; see item 7.****· 8.1 Control parameters****· Ingredients with limit values that require monitoring at the workplace:****CAS: 75-05-8 Acetonitrile**WEL Short-term value: 102 mg/m<sup>3</sup>, 60 ppmLong-term value: 68 mg/m<sup>3</sup>, 40 ppm**· Additional information: Lists used were valid at the time of SDS preparation.****· 8.2 Exposure controls****· Personal protective equipment:****· General protective and hygienic measures:***Keep away from foodstuffs, beverages and feed.**Immediately remove all soiled and contaminated clothing**Wash hands before breaks and at the end of work.**Avoid contact with the eyes.**Avoid contact with the eyes and skin.*

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- **Respiratory protection:**  
*In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.*
- **Protection of hands:**  
*The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation*  
*The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374*



Protective gloves

- **Material of gloves** *Butyl rubber, BR*
- **Penetration time of glove material**  
*The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.*
- **Eye protection:**



Tightly sealed goggles

**SECTION 9: Physical and chemical properties**

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· <b>Form:</b>	<i>Liquid</i>
· <b>Colour:</b>	<i>Colourless</i>
· <b>Odour:</b>	<i>Aromatic</i>
· <b>Odour threshold:</b>	<i>Not determined.</i>

· **pH-value:** *Not determined.*

· **Change in condition**

· <b>Melting point/freezing point:</b>	<i>-46 °C</i>
· <b>Initial boiling point and boiling range:</b>	<i>81 °C</i>

· **Flash point:** *2 °C*

· **Flammability (solid, gas):** *Not determined.*

· **Ignition temperature:** *525 °C*

· **Decomposition temperature:** *Not determined.*

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· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
· <b>Explosion limits:</b>	
<b>Lower:</b>	3 Vol %
<b>Upper:</b>	17 Vol %
· <b>Vapour pressure at 20 °C:</b>	97 hPa
· <b>Density at 20 °C:</b>	0.7822 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water at 25 °C:</b>	74 g/l
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic at 20 °C:</b>	0.39 mPas
<b>Kinematic:</b>	Not determined.
· <b>9.2 Other information</b>	No further relevant information available.

### SECTION 10: Stability and reactivity

- **10.1 Reactivity**  
Stable under normal conditions.  
No further relevant information available.
- **10.2 Chemical stability** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:**  
Formation of toxic gases is possible during heating or in case of fire.
- **10.3 Possibility of hazardous reactions** May form flammable/explosive vapour-air mixture.
- **10.4 Conditions to avoid**  
Sources of ignition  
Heat.
- **10.5 Incompatible materials:**  
Strong oxidizing agents.  
Strong acids.
- **10.6 Hazardous decomposition products:**  
Formation of toxic gases is possible during heating or in case of fire.

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### SECTION 11: Toxicological information

#### · 11.1 Information on toxicological effects

##### · Acute toxicity

Harmful if swallowed, in contact with skin or if inhaled.

##### · LD/LC50 values relevant for classification:

CAS: 75-05-8 Acetonitrile

Oral	(LD50)	2,460 mg/kg (rat)
Dermal	(LD50)	>2,000 mg/kg (rabbit)

##### · Primary irritant effect:

· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.

##### · Serious eye damage/irritation

Causes serious eye irritation.

· **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.

##### · CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

· **Carcinogenicity** Based on available data, the classification criteria are not met.

· **Reproductive toxicity** Based on available data, the classification criteria are not met.

· **STOT-single exposure** Based on available data, the classification criteria are not met.

· **STOT-repeated exposure** Based on available data, the classification criteria are not met.

· **Aspiration hazard** Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

#### · 12.1 Toxicity

##### · Aquatic toxicity:

CAS: 75-05-8 Acetonitrile

EC50/48 h	3,600 mg/l (daphnia)
LC50/96 h	1,640 mg/l (fish)

· **12.2 Persistence and degradability** No further relevant information available.

· **12.3 Bioaccumulative potential** No further relevant information available.

· **12.4 Mobility in soil** No further relevant information available.

##### · Additional ecological information:

###### · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

##### · 12.5 Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Other adverse effects** No further relevant information available.

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**SECTION 13: Disposal considerations**

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **European waste catalogue**  
Waste disposal key numbers from EWC have to be assigned depending on origin and processing.
- **Uncleaned packaging:**
- **Recommendation:** Dispose of in accordance with national regulations.

**SECTION 14: Transport information**

- **14.1 UN-Number**
- **ADR, IMDG, IATA** UN1648
- **ADR** 1648 ACETONITRILE mixture
- **IMDG, IATA** ACETONITRILE mixture

- **14.3 Transport hazard class(es)**
- **ADR, IMDG, IATA**



- **Class** 3 Flammable liquids.
- **Label** 3

- **14.4 Packing group**
- **ADR, IMDG, IATA** II

- **14.5 Environmental hazards:** Not applicable.

- **14.6 Special precautions for user** Warning: Flammable liquids.
- **Danger code (Kemler):** 33
- **EMS Number:** F-E,S-D
- **Stowage Category** B
- **Stowage Code** SW2 Clear of living quarters.

- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

· **Transport/Additional information:**

- **ADR**
- **Limited quantities (LQ)** 1L
- **Excepted quantities (EQ)** Code: E2  
Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 500 ml
- **Transport category** 2

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· <b>Tunnel restriction code</b>	D/E
· <b>UN "Model Regulation":</b>	UN 1648 ACETONITRILE MIXTURE, 3, II

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category P5c** FLAMMABLE LIQUIDS
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. LGC makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

#### · **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (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 Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

#### · **Sources**

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.

- **Data compared to the previous version altered.** All sections have been updated.