



SAFETY DATA SHEET

AMX®

The safety data sheet is in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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

Date issued 15.02.2017

1.1. Product identifier

Product name AMX®

No requirement for SDS There is no requirement according to the REACH Regulation (EC) No. 1907/2006, Article 31.

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

Product group Veterinary medicinal products

Use of the substance/preparation Veterinary medicine for treatment against Salmon louse

1.3. Details of the supplier of the safety data sheet

Distributor

Company name Pharmaq AS

Office address Industrivegen 50

Postal address Skogmo Industriområde

Postcode NO-7863

City Overhalla

Country Norway

Tel +47 74280800

Fax +47 74280801

E-mail customer.service@pharmaq.no

Website <http://www.pharmaq.no>

1.4. Emergency telephone number

Emergency telephone Tel: 999 or 112
Description: Emergency telephone number (UK)

Tel: 112
Description: Emergency telephone number (Italy)

Tel: +47 22 59 13 00
Description: Emergency telephone number Norway (Giftinformasjonen)

SECTION 2: Hazards identification

2.1. Classification of substance or mixture

CLP Classification, comments This is a veterinary medicinal product, and is therefore not a subject to classification and labelling of chemicals.

Substance / mixture hazardous properties
 Irritating to respiratory system and skin.
 Causes serious eye irritation.
 Very toxic to aquatic life with long lasting effects.
 May cause harm to the unborn child.

2.2. Label elements

Precautionary statements
 P273 Avoid release to the environment.
 P280 Wear protective gloves / protective clothing / eye protection / face protection.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P337+P313 If eye irritation persists: Get medical advice / attention.
 P391 Collect spillage.
 P501 Dispose of contents / container to an approved waste disposal plant

Other EU labelling requirements
 This is a veterinary medicinal product, and is thus not a subject to classification and labelling of chemicals.

2.3. Other hazards

PBT / vPvB PBT/vPvB assessment has not been performed.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Substance	Identification	Classification	Contents
N-Methyl-2-pyrrolidone	CAS no.: 872-50-4 EC no.: 212-828-1 Index no.: 606-021-00-7 Synonyms for section 3: N-Methyl-2-pyrrolidone	Repr. 1B;H360D Eye Irrit. 2;H319 STOT SE 3;H335 Skin Irrit. 2;H315 Comments on note: Sk	≥ 25 %
Deltamethrin (ISO)	CAS no.: 52918-63-5 EC no.: 258-256-6 Index no.: 607-319-00-X	Acute Tox. 3;H331 Acute Tox. 3;H301 Aquatic Acute 1;H400 Aquatic Chronic 1;H410 M-factor comments: 1000000	~ 1 %
2-Methylpropan-1-ol	CAS no.: 78-83-1 EC no.: 201-148-0 Index no.: 603-108-00-1 Synonyms for section 3: 2-Methylpropan-1-ol	Flam. Liq. 3;H226 STOT SE 3;H335 Skin Irrit. 2;H315 Eye Dam. 1;H318 STOT SE 3;H336	~ 0,5 – %
Remarks, substance	CAS no 872-50-4 has specific concentration limits: Repr. 1B; H360D: C ≥ 5% STOT SE 3; H335: C ≥ 10%		
Substance comments	See section 16 for explanation of hazard statements (H) listed above.		

SECTION 4: First aid measures

4.1. Description of first aid measures

General	In case of unconsciousness or severe accidents, call 112. Emergency telephone number: see section 1.4.
Inhalation	Fresh air and rest. Get medical attention if any discomfort continues.
Skin contact	Remove contaminated clothing. Wash skin with soap and water. Contact physician if irritation continues.
Eye contact	Promptly rinse eyes with plenty of water (tempered at 20-30°C) for at least 15 minutes. Remove any contact lenses. Hold the eyelids apart. Contact physician if irritation persists.
Ingestion	Drink plenty of water. Do not induce vomiting. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

Acute symptoms and effects	Inhalation: Inhalation of vapour/aerosols may be irritating to the respiratory system. Skin contact: The chemical irritates the skin and can cause itching, burning and redness. Eye contact: Causes serious eye irritation. May cause severe burning and pain.
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4.3. Indication of any immediate medical attention and special treatment needed

Other Information	Treat symptomatically. No specific information from the manufacturer.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	Dry-powder, carbon dioxide (CO ₂), water mist, alcohol resistant foam.
Improper extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

Fire and explosion hazards	The chemical is not classified as flammable.
Hazardous combustion products	May include, but is not limited to: Carbon dioxide (CO ₂). Carbon monoxide (CO). Nitrous gases (NO _x).

5.3. Advice for firefighters

Personal protective equipment	Use compressed air equipment when the chemical is involved in fire. In case of evacuation, an approved protection mask should be used. See also section 8.
Other Information	Containers close to fire should be removed immediately or cooled with water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal protection measures	Provide adequate ventilation. Use protective equipment as referred to in section 8. Avoid inhalation of vapours and contact with skin and eyes.
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6.2. Environmental precautions

Environmental precautionary measures	Prevent spillage of large quantity to sewer, waterway or ground.
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6.3. Methods and material for containment and cleaning up

Cleaning method	Absorb in vermiculite, dry sand or earth and place into containers. Collect in suitable containers and deliver as hazardous waste according to section 13.
Clean up	Wash the contaminated surface with water.

6.4. Reference to other sections

Other instructions	See also sections 8 and 13.
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling	Provide adequate ventilation. Use protective equipment as referred to in section 8. Avoid contact with skin and eyes. Residues must not be poured back into original container. Pregnant women should not work with the product, if there is the least risk of exposure.
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Protective Safety Measures

Advice on general occupational hygiene	Do not eat, drink or smoke during work. Wash hands at the end of each work shift and before eating, smoking and using the toilet. Wash contaminated clothing before reuse.
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7.2. Conditions for safe storage, including any incompatibilities

Storage	Store in tightly closed original container. Store at room temperature. Keep out of reach of children.
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Conditions for safe storage

Advice on storage compatibility	Keep away from: Food and feed.
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7.3. Specific end use(s)

Specific use(s)	See section 1.2.
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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Substance	Identification	Value	TWA Year
N-Methyl-2-pyrrolidone	CAS no.: 872-50-4	TWA (8h): 10 ppm	TWA Year: 2011
	EC no.: 212-828-1	TWA (8h): 40 mg/m ³	
	Index no.: 606-021-00-7	OEL Short Term Value	
	Synonyms for section 3: N-Methyl-2-pyrrolidone	Value: 20 ppm OEL Short Term Value Value: 80 mg/m ³	
2-Methylpropan-1-ol	CAS no.: 78-83-1	TWA (8h): 50 ppm	TWA Year: 2011
	EC no.: 201-148-0	TWA (8h): 154 mg/m ³	
	Index no.: 603-108-00-1	OEL Short Term Value	
	Synonyms for section 3: 2-Methylpropan-1-ol	Value: 75 ppm OEL Short Term Value Value: 231 mg/m ³	
N-Methyl-2-pyrrolidone (Norway)	CAS no.: 872-50-4	TWA (8h): 5 ppm TWA (8h): 20 mg/m ³ HRE OEL Short Term Value Value: 20 ppm	

OEL Short Term Value

Value: 80 mg/m³ S

Other Information about threshold limit values

CAS no.: 872-50-4 (UK) has got note S.
 Explanation of the notations:
 H = Can be absorbed through the skin.
 R = Toxic for Reproduction.
 E = The substance has an EU workplace exposure limit.
 S = allergy-causing agent.
 (UK)
 References (laws/regulations): EH40/2005 Workplace exposure limits, with later amendments. (Norway)
 Norwegian regulation on exposure limits: "FOR-2011-12-06-1358 Forskrift om tiltaksverdier og grenseverdier for fysiske og kjemiske faktorer i arbeidsmiljøet samt smitterisikogrupper for biologiske faktorer (forskrift om tiltaks- og grenseverdier)".
 (Italy)
 Italian regulation on exposure limits Allegato XXXVIII Valori limite di esposizione professionale (Italy) Contains no substances with occupational exposure limit values.

8.2. Exposure controls

Limitation of exposure on workplace

Provide adequate ventilation. The personal protective equipment must be CE-marked and the latest version of the standards shall be used. The protective equipment and the specified standards recommended below are only suggestions, and should be selected on advice from the supplier of such equipment.
 A risk assessment of the work place/work activities (the actual risk) may lead to other control measures. The protection equipments suitability and durability will depend on application.

Respiratory protection

Respiratory protection

Use respiratory equipment with combination filter, type A2/P3.

Reference to relevant standard

EN 14387 (Respiratory protective devices. Gas filter(s) and combined filter(s). Requirements, testing, marking).
 EN 143 (Respiratory protective devices. Particle filters. Requirements, testing, marking).

Hand protection

Hand protection

Use chemical resistant gloves. The gloves abilities may vary among the different glove manufacturers. Glove thickness must be chosen in consultation with the glove supplier, who can inform about the breakthrough time for the glove.

Reference to relevant standard

BS-EN 374 (Protective gloves against chemicals and micro-organisms).
 BS-EN 420 (Protective gloves. General requirements and test methods).

Suitable materials

Nitrile. Neoprene.

Breakthrough time

Value: No specific information from the manufacturer.

Thickness of glove material

Value: No specific information from the manufacturer.

Eye / face protection

Eye protection

Wear tight-fitting goggles or face shield.

Reference to relevant standard

EN 166 (Personal eye-protection. Specifications).

Skin protection

Skin protection (except hands)

Wear appropriate protective clothing to protect against possible skin contact.

Appropriate environmental exposure control

Environmental exposure controls Do not allow to enter into sewer, water system or soil.

Other Information

Other Information Eye wash facilities and emergency shower should be available when handling this chemical.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid.
Colour	Lightly coloured. Yellow.
Odour	Amine. Slight odour.
Odour limit	Comments: Not specified by the manufacturer.
pH	Status: In delivery state Comments: Not specified by the manufacturer.
Melting point / melting range	Comments: Not specified by the manufacturer.
Boiling point / boiling range	Comments: Not specified by the manufacturer.
Flash point	Value: 100 °C
Evaporation rate	Comments: Not specified by the manufacturer.
Flammability (solid, gas)	Not specified by the manufacturer.
Explosion limit	Comments: Not specified by the manufacturer.
Vapour pressure	Comments: Not specified by the manufacturer.
Density	Value: 1,04 g/cm ³ Temperature: 20 °C
Solubility in water	Easily miscible. @ 20°C
Partition coefficient: n-octanol/water	Comments: Not specified by the manufacturer.
Spontaneous combustability	Comments: Not specified by the manufacturer.
Decomposition temperature	Comments: Not specified by the manufacturer.
Viscosity	Comments: Not specified by the manufacturer.
Explosive properties	Not explosive.
Oxidising properties	Not specified by the manufacturer.

9.2. Other information

Other physical and chemical properties

Physical and chemical properties Not specified by the manufacturer.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity Data lacking.

10.2. Chemical stability

Stability The chemical is stable under normal conditions of storage and use.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal conditions.

10.4. Conditions to avoid

Conditions to avoid None known.

10.5. Incompatible materials

Materials to avoid None expected.

10.6. Hazardous decomposition products

Hazardous decomposition products None under normal conditions. See also section 5.2.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Other toxicological data Deltamethrin (ISO):
LD50 oral, rat: 138 mg/kg

Acute toxicity, Mixture estimate

Assessment of acute toxicity classification Based on available data, the classification criteria are not met.

Potential acute effects

Inhalation Vapours may irritate throat and respiratory system and cause coughing.

Skin contact Irritates the skin. May cause redness, stinging and itching.

Eye contact Causes serious eye irritation. May cause severe burning and pain.

Ingestion No specific information from the manufacturer.

Assessment of skin corrosion / irritation, classification Irritating to skin.

Assessment aspiration hazard classification Based on available data, the classification criteria are not met.

Assessment eye damage or irritation, classification Causes serious eye irritation.

Delayed effects / repeated exposure

Assessment respiratory sensitisation, classification Based on available data, the classification criteria are not met.

Assessment skin sensitisation, classification Based on available data, the classification criteria are not met.

STOT-single exposure May cause respiratory irritation.

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

Carcinogenic, Mutagenic or Reprotoxic

Assessment carcinogenicity classification	Based on available data, the classification criteria are not met.
Assessment Germ Cell Mutagenicity, Classification	Based on available data, the classification criteria are not met.
Reproductive toxicity	May cause harm to the unborn child.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	Very toxic to aquatic life with long lasting effects.
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12.2. Persistence and degradability

Persistence and degradability	No specific information from the manufacturer.
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12.3. Bioaccumulative potential

Bioaccumulative potential	No specific information from the manufacturer.
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12.4. Mobility in soil

Mobility	Miscible with water.
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12.5. Results of PBT and vPvB assessment

PBT assessment results	PBT assessment has not been performed.
vPvB evaluation results	vPvB assessment has not been performed.

12.6. Other adverse effects

Other adverse effects / Remarks	Do not allow to enter into sewer, water system or soil. The substance is toxic to crustaceans and should therefore not be used in systems where it is stored crabs and lobsters are in close proximity (<200 m) or when local current conditions makes exposure likely.
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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Specify the appropriate methods of disposal	Disposed of as hazardous waste by approved contractor. The waste code (EWC-Code) is intended as a guide. The code must be chosen by the user, if the use differs from the one mentioned below. Any unused medicine or remaining medicine should be disposed of in accordance with local and national requirements.
Product classified as hazardous waste	Yes
EWC waste code	EWC: 18 02 05 chemicals consisting of or containing dangerous substances
Other Information	Do not empty into drains.

SECTION 14: Transport information

14.1. UN number

ADR / RID / ADN	3082
IMDG	3082
ICAO/IATA	3082

14.2. UN proper shipping name

ADR / RID / ADN	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Deltamethrin)
IMDG	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Deltamethrin)
ICAO/IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Deltamethrin)

14.3. Transport hazard class(es)

ADR / RID / ADN	9
IMDG	9
ICAO/IATA	9

14.4. Packing group

ADR / RID / ADN	III
IMDG	III
ICAO/IATA	III

14.5. Environmental hazards

IMDG Marine pollutant	Yes
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14.6. Special precautions for user

EmS	F-A, S-F
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14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Pollution category	Data lacking.
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ADR / RID - Other information

Hazard no.	90
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SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

References (laws/regulations)	<p>Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP-regulation) with later amendments.</p> <p>Commission Regulation (EU) No 453/2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)</p> <p>The List of Wastes (England) (Amendment) Regulations 2005. (SI 2005 No. 895).</p> <p>The List of Wastes Regulations (Northern Ireland) 2005.</p> <p>Dangerous Goods regulations</p> <p>DIRECTIVE 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products</p> <p>FOR-2012-06-16 nr 622 Norwegian regulation on classification, labeling and packaging of</p>
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substances and mixtures (CLP), with later amendments.
 FOR-2008-05-30 nr 516 Norwegian regulation on the registration, evaluation, authorization and restriction of chemicals (REACH Regulation), with later amendments.
 Norwegian regulations on waste, no. 930/2004, from the Ministry of Environment.
 Dangerous Goods regulations.

Norwegian regulation FOR-2007-01-16 nr 50 on the use of veterinary medicines, as amended.

Comments

CAS-nr.: 872-50-4 is listed in the candidate list of Substances of Very High Concern. (SVHC, REACH).
 CAS No .: 872-50-4 covered by paragraph 30. Restrictions do not apply to the application of this chemical.

15.2. Chemical safety assessment

Chemical safety assessment performed No

SECTION 16: Other information

Supplier's notes

The information contained in this SDS must be made available to all those who handle the product.

List of relevant H-phrases (Section 2 and 3).

H360D May damage the unborn child.
 H318 Causes Serious eye damage.
 H331 Toxic if inhaled.
 H226 Flammable liquid and vapour.
 H336 May cause drowsiness or dizziness.
 H400 Very toxic to aquatic life.
 H315 Causes skin irritation.
 H335 May cause respiratory irritation.
 H301 Toxic if swallowed.
 H410 Very toxic to aquatic life with long lasting effects.
 H319 Causes serious eye irritation.

Key literature references and sources for data

Suppliers Safety data sheet dated: 28.02.2014

Abbreviations and acronyms used

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road
 IATA: The International Air Transport Association
 ICAO-TI: International Civil Aviation Organization - Technical Instructions for the Safe Transport of Dangerous Goods by Air
 IMDG: The International Maritime Dangerous Goods Code
 LD50: Lethal dose, is the amount of a substance given to a group of test animals, which causes the death of 50%.
 PBT: Persistent, Bioaccumulative and Toxic
 RID: The Regulations concerning the International Carriage of Dangerous Goods by Rail
 vPvB: very Persistent and very Bioaccumulative

Checking quality of information

This SDS is quality controlled by Kiwa Teknologisk Institutt in Norway, certified according to the Quality Management System requirements specified in ISO 9001:2008.