

SAFETY DATA SHEET

Oil-based vaccine from PHARMAQ AS

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 15.09.2016

1.1. Product identifier

Product name Oil-based vaccine from PHARMAQ AS

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 Fish vaccine (for veterinary use only)

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 7863

City Overhalla

Country Norge

Tel 74280800

Fax 74280801

E-mail customer.service@pharmaq.no

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

1.4. Emergency telephone number

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

Emergency telephone number (UK):999 or 112

Emergency telephone number (Italy):112

SECTION 2: Hazards identification

2.1. Classification of substance or mixture

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

2.2. Label elements

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.

Health effect Contains Formaldehyde. May produce an allergic reaction.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Substance	Identification	Classification	Contents
Formaldehyde ...%	CAS no.: 50-00-0 EC no.: 200-001-8 Index no.: 605-001-00-5 Synonyms: Formaldehyde	Acute Tox. 3;H331 Acute Tox. 3;H311 Acute Tox. 3;H301 Skin Corr. 1B;H314 Skin Sens. 1;H317 Muta. 2; H341 Carc. 1B; H350	≤ 0,04 %
Description of the mixture	This product contains Formaldehyde inactivated bacterial and/or viral antigens, mineral oil, emulsifier and water.		
Remarks, substance	CAS no 50-00-0 has specific concentration limits: . Skin Irrit. 2; H315: 5% ≤ C < 25% Skin Sens. 1; H317: C ≥ 0,2% Eye Irrit. 2; H319: 5% ≤ C < 25% STOT SE 3; H335: C ≥ 5% Skin Corr. 1B; H314: C ≥ 25%		
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. Promptly seek medical advice even if only a small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.
Inhalation	Fresh air and rest. Get medical attention if any discomfort continues.
Skin contact	By accidental injection of fish vaccine: Seek prompt medical advice even if only a small amount is injected. Take leaflet to the physician. If pain persists for more than 12 hours after medical examination, seek medical advice again. If spilled on the skin: Remove contaminated clothing. Wash with soap and water. Get medical attention if any discomfort continues.
Eye contact	Immediately rinse with water. Remove contact lenses and open eyes wide apart. Continue rinsing for 10 minutes. By prolonged rinsing, use luke warm water to avoid damage to the eye. Get medical attention if any discomfort continues.
Ingestion	Rinse the mouth. Drink 1-3 glasses of water. Consult a physician.

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

Delayed symptoms and effects	The chemical contains small amount of allergy-causing material which may give rise to allergy to sensitive persons.
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4.3. Indication of any immediate medical attention and special treatment needed

Specific details on antidotes	Epinephrine is administered only in consultation with medical professionals.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	Dry-powder, carbon dioxide (CO ₂), water mist, foam.
Improper extinguishing media	Do not use water jet.

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 monoxide (CO). Carbon dioxide (CO ₂).

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	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	Avoid discharge into drains, water courses or onto the 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 waste according to section 13. Flush with plenty of water and detergent to clean spillage area. Risk for slippery surfaces if spilled out.
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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. Avoid inhalation of vapours and contact with skin and eyes. Use protective equipment as referred to in section 8. Pregnant women and people with immunosuppression should not perform vaccination. Anesthetized fish is wet and slippery, and vaccinators should use wet cotton gloves to better manage fish (minimizes the risk of self-injection).
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Protective Safety Measures

Advice on general occupational hygiene	Do not eat, drink or smoke during work. 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 in a well-ventilated place. Protect against direct sunlight. Do not freeze. Keep out of reach of children.
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Conditions for safe storage

Storage Temperature	Value: 2-8 °C
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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

Occupational Exposure limit values

Substance	Identification	Value	TWA Year
Formaldehyde ...%	CAS no.: 50-00-0	8-hour TWA: 2 ppm	2011
	EC no.: 200-001-8	8-hour TWA: 2,5 mg/m ³	
	Index no.: 605-001-00-5	15 min.: 2 ppm	
	Synonyms: Formaldehyde	15 min.: 2,5 mg/m ³	
Formaldehyde (Norway)	CAS no.: 50-00-0	8-hour TWA: 0,5 ppm	
	EC no.: 200-001-8	8-hour TWA: 0,6 mg/m ³ AK	

	Index no.: 605-001-00-5	15 min.: 1 ppm 15 min.: 1,2 ppm mg/m ³ T	
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Other Information about threshold limit values

Explanation of the notations:

A = Allergenic substances.

K = Capable of causing cancer and/or heritable genetic damage.

T = ceiling value

References (laws/regulations):

EH40/2005 Workplace exposure limits, with later amendments.

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)".

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

Normally not required.

If there is insufficient ventilation, use a respirator with type A-filter. Use combination filter A/P2 by aerosol formation.

Reference to relevant standard

EN 143 (Respiratory protective devices. Particle filters. Requirements, testing, marking).

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

Hand protection

Hand protection

Use chemical resistant gloves. The recommended material of gloves is recommended after a study of the single components in the chemical. Glove thickness must be chosen in consultation with the glove supplier. The gloves abilities may vary among the different glove manufacturers.

Suitable gloves type

Butyl rubber. Viton rubber (fluor rubber). Nitrile. Neoprene.

Reference to relevant standard

BS-EN 374 (Protective gloves against chemicals and micro-organisms).

BS-EN 420 (Protective gloves. General requirements and test methods).

Breakthrough time

No specific information from the manufacturer.

Thickness of glove material

No specific information from the manufacturer.

Eye / face protection

Eye protection

If risk of splashing, wear safety goggles or face shield.

Reference to relevant standard

EN 166 (Personal eye-protection. Specifications).

Additional eye protection measures

Eye wash facilities should be at the work place. Either a fixed eye wash facility connected to the drinking water (preferably warm water) or a portable disposable unit.

Skin protection

Skin protection (except hands)

Ordinary workwear.

Appropriate environmental exposure control

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

Other Information

Other Information Emergency shower and eye wash facilities should be available at the workplace.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	Fluid
State under standard conditions	No continuous water phase visible at the bottom of the container when observed at rest.
Colour	White to cream colored homogeneous emulsion when shaken.
Odour	No characteristic odour.
Comments, Odour limit	Not specified by the manufacturer.
Comments, pH (as supplied)	Not specified by the manufacturer.
Comments, Melting point / melting range	Not specified by the manufacturer.
Comments, Boiling point / boiling range	Not specified by the manufacturer.
Comments, Flash point	Not specified by the manufacturer.
Comments, Evaporation rate	Not specified by the manufacturer.
Comments, Explosion limit	Not specified by the manufacturer.
Comments, Vapour pressure	Not specified by the manufacturer.
Comments, Vapour density	Not known.
Comments, Specific gravity	Not specified by the manufacturer.
Solubility in water	Soluble.
Comments, Partition coefficient: n-octanol / water	Not specified by the manufacturer.
Comments, Spontaneous combustability	Not specified by the manufacturer.
Comments, Decomposition temperature	Not specified by the manufacturer.
Comments, Viscosity	Not specified by the manufacturer.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

9.2. Other information**Other physical and chemical properties**

Comments Not specified by the manufacturer.

SECTION 10: Stability and reactivity**10.1. Reactivity**

Reactivity There are no known reactivity hazards associated with this product.

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 No hazardous reactions known.

10.4. Conditions to avoid

Conditions to avoid Protect from direct sunlight. Avoid freezing.

10.5. Incompatible materials

Materials to avoid None under normal conditions.

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 information regarding health hazards

General The greatest risk occurs after repeated self-injections. This can cause allergies to the vaccine. If an allergic person is exposed to self-injection, he/she may risk anaphylactic shock. Without prompt and proper medical treatment it can be fatal.

Potential acute effects

Inhalation	No irritation expected.
Skin contact	After an accidental self-injection with the vaccine, it is usually observed an inflammatory reaction with severe pain and swelling in the sting area, particularly if injected into a joint or finger (in rare cases, the loss of the affected finger is possible if treatment is not initiated promptly). More rarely seen are flu-like symptoms with fever, muscle aches and general malaise.
Eye contact	No irritation expected.
Ingestion	May cause discomfort if swallowed.
Assessment corrosion / irritation classification	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.
Assessment eye damage or irritation, classification	Based on available data, the classification criteria are not met.

Delayed effects / repeated exposure

Sensitisation	Based on available data, the classification criteria are not met. Repeated self-injections can cause allergy to fish vaccine. Contains formaldehyde. May produce an allergic reaction.
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.

Carcinogenic, Mutagenic or Reprotoxic

Carcinogenicity	Based on available data, the classification criteria are not met. Contains a substance/a group of substances which may cause cancer by inhalation.
Mutagenicity	Based on available data, the classification criteria are not met.
Teratogenic properties	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met. Contains a substance/a group of substances with possible risk of impaired fertility.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	The chemical is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills may be potentially hazardous. The product is not expected to be hazardous to waste water treatment processes.
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12.2. Persistence and degradability

Persistence and degradability	Mineral oil. - Not readily biodegradable.
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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	No specific information from the manufacturer.
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12.5. Results of PBT and vPvB assessment

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

12.6. Other adverse effects

Other adverse effects / Remarks Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Specify the appropriate methods of disposal The waste code (EWC-Code) is intended as a guide. The user must select a code 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 No

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

Comments Not considered as dangerous goods under UN, IMO, ADR/RID or IATA/ICAO regulations.

14.2. UN proper shipping name

Comments Not relevant.

14.3. Transport hazard class(es)

Comments Not relevant.

14.4. Packing group

Comments Not relevant.

14.5. Environmental hazards

Comments Not relevant.

14.6. Special precautions for user

Special safety precautions for user Not relevant.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Additional information.

Additional information. Not relevant.

SECTION 15: Regulatory information

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

References (laws/regulations)

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP-regulation) with later amendments.

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)

The List of Wastes (England) (Amendment) Regulations 2005. (SI 2005 No. 895).

The List of Wastes Regulations (Northern Ireland) 2005.

Dangerous Goods regulations

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

FOR-2012-06-16 nr 622 Norwegian regulation on classification, labeling and packaging of 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.

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).	H331 Toxic if inhaled. H350 May cause cancer H314 Causes severe skin burns and eye damage. H301 Toxic if swallowed. H317 May cause an allergic skin reaction. H311 Toxic in contact with skin. H341 Suspected of causing genetic defects
Abbreviations and acronyms used	EWC: European Waste Code (a code from the EU's common classification system for waste) ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road RID: The Regulations concerning the International Carriage of Dangerous Goods by Rail IMDG: The International Maritime Dangerous Goods Code ICAO-TI: International Civil Aviation Organization - Technical Instructions for the Safe Transport of Dangerous Goods by Air LC50: Median concentration lethal to 50% of a test population. 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 vPvB: very Persistent and very Bioaccumulative
Important data sources used to construct the safety data sheet	Suppliers Safety data sheet dated: 06.12.2013
Information which has been added, deleted or revised	New Safety Data Sheet.
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.
Version	1
Responsible for safety data sheet	Pharmaq AS
Prepared by	Teknologisk Institutt as, Norway v/ Maria Andersen