SAFETY DATA SHEET
Oil-based vaccine from PHARMAQ AS


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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Identification</th>
<th>Classification</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>CAS no.: 50-00-0</td>
<td>Acute Tox. 3; H331</td>
<td>≤ 0,04%</td>
</tr>
<tr>
<td></td>
<td>EC no.: 200-001-8</td>
<td>Acute Tox. 3; H311</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Index no.: 605-001-00-5</td>
<td>Acute Tox. 3; H301</td>
<td></td>
</tr>
<tr>
<td>Synonyms: Formaldehyde</td>
<td>Skin Corr. 1B; H314</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Skin Sens. 1; H317</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mut. 2; H341</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Carc. 1B; H350</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 lukewarm 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.

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.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Dry-powder, carbon dioxide (CO2), 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 (CO2).
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.

6.2. Environmental precautions

Environmental precautionary measures
Avoid discharge into drains, water courses or onto the ground.

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.

6.4. Reference to other sections

Other instructions
See also sections 8 and 13.

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).

Protective Safety Measures
Advice on general occupational hygiene
Do not eat, drink or smoke during work. Wash contaminated clothing before reuse.

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.

Conditions for safe storage
Storage Temperature
Value: 2-8 °C

7.3. Specific end use(s)

Specific use(s)
See section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational Exposure limit values

<table>
<thead>
<tr>
<th>Substance</th>
<th>Identification</th>
<th>Value</th>
<th>TWA Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde ...%</td>
<td>CAS no.: 50-00-0</td>
<td>8-hour TWA: 2 ppm</td>
<td>2011</td>
</tr>
<tr>
<td></td>
<td>EC no.: 200-001-8</td>
<td>8-hour TWA: 2,5 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Index no.: 605-001-00-5</td>
<td>15 min.: 2 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Synonyms: Formaldehyde</td>
<td>15 min.: 2,5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Formaldehyde (Norway)</td>
<td>CAS no.: 50-00-0</td>
<td>8-hour TWA: 0,5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC no.: 200-001-8</td>
<td>8-hour TWA: 0,6 mg/m³ AK</td>
<td></td>
</tr>
</tbody>
</table>
Index no.: 605-001-00-5

<table>
<thead>
<tr>
<th>Other Information about threshold limit values</th>
<th>Explanation of the notations:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A = Allergic substances.</td>
</tr>
<tr>
<td></td>
<td>K = Capable of causing cancer and/or heritable genetic damage.</td>
</tr>
<tr>
<td></td>
<td>T = ceiling value</td>
</tr>
</tbody>
</table>

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**
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**
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
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**
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**
Ordinary workwear.

Oil-based vaccine from PHARMAQ AS
**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

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

### 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
**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.

**12.2. Persistence and degradability**

Persistence and degradability

Mineral oil. - Not readily biodegradable.

**12.3. Bioaccumulative potential**

Bioaccumulative potential

No specific information from the manufacturer.

**12.4. Mobility in soil**

Mobility

No specific information from the manufacturer.

**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

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
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.
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.
### 15.2. Chemical safety assessment

Chemical safety assessment performed

### SECTION 16: Other information

<table>
<thead>
<tr>
<th>Supplier's notes</th>
<th>The information contained in this SDS must be made available to all those who handle the product.</th>
</tr>
</thead>
</table>
| 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 |