# SAFETY DATA SHEET
# Water-based vaccine from PHARMAQ

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 | 15.11.2016 |

### 1.1. Product identifier

| | |
|---|---|
| Product name | Water-based vaccine from PHARMAQ |
| 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 (Italy):112<br>Emergency telephone number (UK):999 or 112<br>Emergency telephone number Norway (Giftinformasjonen):+47 22 59 13 00 |

## 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 Formaldehyd. May produce an allergic reaction. |

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

| Substance | Identification | Classification | Contents |
|---|---|---|---|
| Formaldehyde ...% | CAS no.: 50-00-0<br>EC no.: 200-001-8<br>Index no.: 605-001-00-5<br>Synonyms: Formaldehyde | Acute Tox. 3;H331<br>Acute Tox. 3;H311<br>Acute Tox. 3;H301<br>Skin Corr. 1B;H314<br>Skin Sens. 1;H317<br>Muta. 2; H341<br>Carc. 1B; H350 | < 0,1 % |
| Formaldehyde (engelsk navn, norsk adm norm) | CAS no.: 50-00-0<br>EC no.: 200-001-8<br>Index no.: 605-001-00-5 | | |

| | |
|---|---|
| Remarks, substance | CAS no 50-00-0 has spesific consentration limits: .<br>Skin Irrit. 2; H315: 5% ≤ C < 25%<br>Skin Sens. 1; H317: C ≥ 0,2%<br>Eye Irrit. 2; H319: 5% ≤ C < 25%<br>STOT SE 3; H335: C ≥ 5%<br>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 | If in doubt, seek medical advice. |
| Inhalation | Fresh air and rest. Get medical attention if any discomfort continues. |
| Skin contact | By accidental injection of fish vaccine:<br>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.<br>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 | Prolonged and repeated skin contact will cause defatting and possible irritation. |

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

| | |
|---|---|
| Other Information | No specific treatment required, see section 4.1. |

## 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 non-combustible. |
| 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.<br>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. |
| Clean up | Wash the contaminated surface with water. Beware of slippery floors and surfaces. |

### 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. 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 | Protect from freezing and direct sunlight. Keep out of reach of children. |

### Conditions for safe storage

| | |
|---|---|
| Advice on storage compatability | Keep away from: Food and feed. |
| 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

| Substance | Identification | Value | TWA Year |
|---|---|---|---|
| Formaldehyde ...% | CAS no.: 50-00-0<br>EC no.: 200-001-8<br>Index no.: 605-001-00-5<br>Synonyms: Formaldehyde | 8-hour TWA: 2 ppm<br>8-hour TWA: 2,5 mg/m3<br>15 min.: 2 ppm<br>15 min.: 2,5 mg/m3 | 2011 |
| Formaldehyde (Norway) | CAS no.: 50-00-0<br>EC no.: 200-001-8<br>Index no.: 605-001-00-5 | 8-hour TWA: 0,5 ppm<br>8-hour TWA: 0,6 mg/m³ AK<br>15 min.: 1 ppm<br>15 min.: 1,2 ppm<br>mg/m³ T | |

| | |
|---|---|
| Other Information about threshold limit values | Explanation of the notations:<br>A = Allergenic substances.<br>K = Capable of causing cancer and/or heritable genetic damage.<br>T = ceiling value<br><br>References (laws/regulations):<br>EH40/2005 Workplace exposure limits, with later amendments.<br><br>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)\".<br><br>Italian regulation on exposure limits Allegato XXXVIII Valori limite di esposizione professionale (Italy)<br>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.<br>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.<br>If ventilation is insufficient, use a respirator with AX filter against solvent vapours. |
| Reference to relevant standard | 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. Multi-layer material (e.g. 4H, Saranex). |
| Reference to relevant standard | BS-EN 374 (Protective gloves against chemicals and micro-organisms).<br>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). |

### 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 |
| Colour | Turbid. Light yellow. - Brownish. suspensjon |
| Odour | Characteristic. |
| 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 | Negligible. |
| Comments, Explosion limit | Not specified by the manufacturer. |
| Comments, Vapour pressure | Not specified by the manufacturer. |
| Comments, Vapour density | Not specified by the manufacturer. |
| 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 | Arise in inappropriate conditions (section 10.4). |

### 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. |

### Acute toxicity, Mixture estimate

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

### 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. The chemical contains small amount of allergy-causing material which may give rise to allergy to sensitive persons. |
| 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 harmful to the environment. |

### 12.2. Persistence and degradability

| | |
|---|---|
| Persistence and degradability | Contains substances that are not considered readily biodegradable. (Mineral oil) |

### 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 06 chemicals other than those mentioned in 18 02 05 |
| 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.<br>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)<br>The List of Wastes (England) (Amendment) Regulations 2005. (SI 2005 No. 895).<br>The List of Wastes Regulations (Northern Ireland) 2005.<br>Dangerous Goods regulations<br>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<br><br>FOR-2012-06-16 nr 622 Norwegian regulation on classification, labeling and packaging of substances and mixtures (CLP), with later amendments.<br>FOR-2008-05-30 nr 516 Norwegian regulation on the registration, evaluation, authorization and restriction of chemicals (REACH Regulation), with later amendments.<br>Norwegian regulations on waste, no. 930/2004, from the Ministry of Environment.<br>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.<br>H350 May cause cancer<br>H314 Causes severe skin burns and eye damage.<br>H301 Toxic if swallowed.<br>H317 May cause an allergic skin reaction.<br>H311 Toxic in contact with skin.<br>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)<br>ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road<br>RID: The Regulations concerning the International Carriage of Dangerous Goods by Rail<br>IMDG: The International Maritime Dangerous Goods Code<br>ICAO-TI: International Civil Aviation Organization - Technical Instructions for the Safe Transport of Dangerous Goods by Air<br>PBT: Persistent, Bioaccumulative and Toxic<br>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 |