

# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Oil-based vaccine from PHARMAQ AS (part of Zoetis)</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	Oil adjuvant vaccine from PHARMAQ
<b>Recommended use</b>	Veterinary vaccine ( Fish )
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name:</b>	PHARMAQ AS (part of Zoetis)
<b>Office address:</b>	Industrivegen 50
<b>Postal address:</b>	Skogmo Industriområde 7863 Overhalla, Norge
<b>Phone number:</b>	+47 74 28 08 00
<b>Fax number:</b>	+47 74 28 08 01
<b>Email:</b>	customer.service@pharmaq.no
<b>Website:</b>	http://www.pharmaq.no
<b>Emergency telephone number:</b>	Norway (Giftinformasjonen):+47 22 59 13 00  United Kingdom: 999 or 112 Italy: 112
<b>Additional emergency telephone number:</b>	International CHEMTREC (24 hours): +1-703-527-3887

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>Environmental hazards</b>	Not classified.
<b>Label elements</b>	
<b>Hazard symbol</b>	None.
<b>Signal word</b>	None.
<b>Hazard statement</b>	The mixture does not meet the criteria for classification.
<b>Precautionary statement</b>	
<b>Prevention</b>	Observe good industrial hygiene practices.
<b>Response</b>	Wash hands after handling.
<b>Storage</b>	Store away from incompatible materials.
<b>Disposal</b>	Dispose of waste and residues in accordance with local authority requirements.
<b>Other hazards which do not result in classification</b>	None known.
<b>Supplemental information</b>	Contains Formaldehyde. May produce an allergic reaction. In the event of accidental injection, an allergic reaction may occur. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

## 3. Composition/information on ingredients

### Mixtures

<b>Non-hazardous components</b>			
<b>Chemical name</b>	<b>Common name and synonyms</b>	<b>CAS number</b>	<b>%</b>
Antigen		Not assigned	*
Formaldehyde		50-00-0	≤ 0.04
Mineral oil and emulsifier		Mixture	*
Water for Injection		7732-18-5	*

**Composition comments** \*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

#### 4. First-aid measures

**Inhalation** Move to fresh air. Call a physician if symptoms develop or persist.

**Skin contact** In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.

**Eye contact** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.

**Ingestion** Rinse mouth. Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

**Most important symptoms/effects, acute and delayed** Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

**Indication of immediate medical attention and special treatment needed** Treat symptomatically. Where parenteral oil-adjuvanted vaccine exposure has occurred, the patient should be promptly evaluated for the development of vasospasm and/or compartment syndrome. Persons developing anaphylactic (allergic) reactions must receive immediate medical assistance.

**General information** IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

#### 5. Fire-fighting measures

**Suitable extinguishing media** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**Unsuitable extinguishing media** Do not use water jet as an extinguisher, as this will spread the fire.

**Specific hazards arising from the chemical** During fire, gases hazardous to health may be formed.

**Special protective equipment and precautions for firefighters** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Fire fighting equipment/instructions** Move containers from fire area if you can do so without risk.

**Specific methods** Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards** No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures** Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS. In case of spills, beware of slippery floors and surfaces.

**Methods and materials for containment and cleaning up** Avoid release to the environment.

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

#### 7. Handling and storage

**Precautions for safe handling** Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapor. Avoid accidental injection. Special care should be taken to avoid accidental self injection and needle stick injury when administering the product. Fish can be slippery. Use non-slip gloves. Wash thoroughly after handling. When using, do not eat, drink or smoke. Wear personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

**Conditions for safe storage, including any incompatibilities** Store in tightly closed original container in a well-ventilated place. Store in a cool, dry place out of direct sunlight. @ 2 - 8°C (36 - 46°F). Do not freeze. Keep away from heat, sparks and open flame. Use care in handling/storage. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### Vietnam. OELs

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	1 mg/m <sup>3</sup>
	TWA	0.5 mg/m <sup>3</sup>

#### US. ACGIH Threshold Limit Values

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	0.3 ppm
	TWA	0.1 ppm

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Control banding approach

Not available.

### Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

#### Skin protection

##### Hand protection

Wear appropriate chemical resistant gloves. Neoprene, butyl rubber, nitrile or Viton gloves are recommended. Non-slip gloves.

##### Other

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

#### Respiratory protection

No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment.

#### Thermal hazards

Not applicable.

### General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

### Appearance

Emulsion.

#### Physical state

Liquid.

#### Form

Liquid.

#### Color

White - Cream.

### Odor

Odorless.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

Not available.

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

### Evaporation rate

Not available.

### Flammability (solid, gas)

Not applicable.

### Upper/lower flammability or explosive limits

#### Flammability limit - lower (%)

Not available.

#### Flammability limit - upper (%)

Not available.

#### Explosive limit - lower (%)

Not available.

#### Explosive limit - upper (%)

Not available.

### Vapor pressure

Not available.

### Vapor density

Not available.

### Relative density

Not available.

<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Soluble
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials. Sunlight. Do not allow material to freeze.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Prolonged skin contact may cause temporary irritation. Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis. In the event of accidental injection, an allergic reaction may occur. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.
Formaldehyde	Species: Rabbit Severity: Moderate Severe
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
Formaldehyde	Species: Rabbit Severity: Severe
<b>Ingestion</b>	May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.
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### Information on toxicological effects

<b>Acute toxicity</b>	In the event of accidental injection, an allergic reaction may occur. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.
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Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
<b>Acute</b>		
<b>Inhalation</b>		
LC50	Rat	0.48 mg/l, 4 Hours
<b>Oral</b>		
LD50	Rat	800 mg/kg 100 mg/kg
<b>Chronic</b>		
<b>Inhalation</b>		
LOAEL	Mouse	15 ppm, 2 years Tumors
	Rat	15 ppm, 9 days Respiratory system

Components	Species	Test Results
		6 ppm, 2 years Tumors
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.	
<b>Serious eye damage/eye irritation</b>	Direct contact with eyes may cause temporary irritation.	
<b>Eye Contact</b> Formaldehyde		Species: Rabbit Severity: Severe
<b>Respiratory or skin sensitization</b>		
<b>ACGIH sensitization</b> FORMALDEHYDE (CAS 50-00-0)		Dermal sensitization Respiratory sensitization
<b>Respiratory sensitization</b>	Based on available data, the classification criteria are not met. In the event of accidental injection, an allergic reaction may occur.	
<b>Skin sensitization</b>	Based on available data, the classification criteria are not met. In the event of accidental injection, an allergic reaction may occur. This product contains formaldehyde which is considered to be a skin sensitizer.	
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Mutagenicity</b> Formaldehyde		In Vitro Bacterial Mutagenicity (Ames) Result: Positive Species: Bacteria
		In Vitro Chromosome Aberration Result: Positive Species: Rodent
		In Vitro Sister Chromatid Exchange Result: Positive Species: Rodent
		In Vivo Chromosome Aberration Result: Positive Species: Not specified
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met. Contains a substance which may cause cancer by inhalation. No known carcinogens are present at greater than 0.1%.	
<b>ACGIH Carcinogens</b> Formaldehyde (CAS 50-00-0)		A1 Confirmed human carcinogen.
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b> Formaldehyde (CAS 50-00-0)		1 Carcinogenic to humans.
<b>US NTP Report on Carcinogens: Known carcinogen</b> Formaldehyde (CAS 50-00-0)		Known To Be Human Carcinogen.
<b>Reproductive toxicity</b>	This product is not expected to cause reproductive or developmental effects.	
<b>Developmental effects</b> Formaldehyde		185 mg/kg/day Embryo / Fetal Development, Not teratogenic Maternal toxicity Species: Mouse Organ: Oral
		40 ppm Embryo / Fetal Development, Not Teratogenic Maternal Toxicity Species: Rat Organ: Inhalation
<b>Specific target organ toxicity - single exposure</b>	Not classified.	
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.	
<b>Aspiration hazard</b>	Not an aspiration hazard.	
<b>Further information</b>	Allergic reactions are possible. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms.	

## 12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components		Species	Test Results
Formaldehyde (CAS 50-00-0)			
<b>Aquatic</b>			
Crustacea	EC50	Water flea ( <i>Daphnia pulex</i> )	4.3 - 7.8 mg/l, 48 hours
Fish	LC50	Striped bass ( <i>Morone saxatilis</i> )	10.302 - 16.743 mg/l, 96 hours

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

**Disposal instructions** Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging** Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not established.

## 15. Regulatory information

### National regulations

#### Ozone Depleting Substances (ODS) Joint circular No. 14/2005/TTLT-BTM-BTNMT

Not regulated.

#### Vietnam. Chemicals that must be declared (Decree No. 108/2008/ND-CP, App. 5, Oct. 7, 2008, as amended through Decree No. 26/2011/ND-CP, April 8, 2011)

Not regulated.

#### Vietnam. Toxic Chemicals Requiring Sale & Purchase Control Slips (Decree No. 26/2011/ND-CP, App. 6, April 8, 2011)

Formaldehyde (CAS 50-00-0)

#### Vietnam. CWC (Decree No. 100/2005/ND-CP, Implementation of Chemical Weapons Convention, Appendix 1, Schedules 1-3, August 3, 2005)

Not regulated.

#### Vietnam. Drug Precursor & Essential Substances (Decree No. 67/2001/ND-CP, List IV, as amended through Decree No. 17/2011/ND-CP, Feb. 22, 2011)

Not regulated.

### International regulations

#### Stockholm Convention

Not applicable.

#### Rotterdam Convention

Not applicable.

#### Montreal Protocol

Not applicable.

**Kyoto protocol**

Not applicable.

**Basel Convention**

Not applicable.

**International Inventories**

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

<b>Issue date</b>	08-22-2018
<b>Version #</b>	01
<b>Disclaimer</b>	Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.