

SAFETY DATA SHEET

1. Identification

Name of the substance or mixture (trade name) Oil-based vaccine from PHARMAQ AS (part of Zoetis)

Synonyms Oil adjuvant vaccine from PHARMAQ

Major recommended uses for the substance or mixture Veterinary vaccine (Fish)

Specific restrictions for use of the substance or mixture Not for human use

Manufacturer/Importer/Distributor information

Company Name: PHARMAQ AS (part of Zoetis)

Office address: Industrivegen 50

Postal address: Skogmo Industriområde
7863

Overhalla, Norge

Phone number: +47 74 28 08 00

Fax number: +47 74 28 08 01

Email: customer.service@pharmaq.no

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

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

United Kingdom: 999 or 112

Italy: 112

Additional emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887

2. Hazards identification

Classification of the substance or mixture

Physical hazards Not classified.

Health hazards Not classified.

Environmental hazards Not classified.

GHS labeling elements, including precautionary statements

Hazard symbol(s) None.

Signal word None.

Hazard statement(s) The mixture does not meet the criteria for classification.

Precautionary statement(s)

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials.

Disposal Dispose of waste and residues in accordance with local authority requirements.

Other hazards which do not result in classification None known.

Supplemental information 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.

Other information The Safety Information Sheet Chemicals of hazardous chemical can be obtained through phone, email or on the company website.

3. Composition/information on ingredients

Mixture

Common chemical name or technical name	CAS number	Concentration or concentration range (%)
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

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.

Personal protection for first-aid responders 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.

Notes to physician 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.

5. Fire-fighting measures

Means of fire extinguishing

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

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 fire fighting procedures Move containers from fire area if you can do so without risk.

Protective measures taken by firefighting crews Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

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. Control measures for spills and leaks

Personal precautions, protective equipment and emergency procedures

To be taken by those who are not involved in rendering emergency services Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.

To be taken by those who are involved in rendering emergency services Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS. In case of spills, beware of slippery floors and surfaces.

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

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.

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

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

Brazil. OELs (Ordinance No. 3214, 6/8/78, NR-15, Annex 11 (amended through ACGIH))

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	2.3 mg/m3
		1.6 ppm

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.

Personal protective measures

Eyes and 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.

Hygiene measures

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 temperature 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.
Solubility(ies)	
Solubility (water)	Soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other physical and chemical parameters	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

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

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	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
Eye contact	Direct contact with eyes may cause temporary irritation.
Formaldehyde	Species: Rabbit Severity: Severe
Ingestion	May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms 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.

Acute toxicity 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.

Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
Acute		
Inhalation		
LC50	Rat	0.48 mg/l, 4 Hours
Oral		
LD50	Rat	800 mg/kg 100 mg/kg
Chronic		
Inhalation		
LOAEL	Mouse	15 ppm, 2 years Tumors
	Rat	15 ppm, 9 days Respiratory system 6 ppm, 2 years Tumors

Skin irritation and corrosion Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye Contact
Formaldehyde

Species: Rabbit
Severity: Severe

Respiratory or skin sensitization

ACGIH sensitization

FORMALDEHYDE (CAS 50-00-0)

Dermal sensitization
Respiratory sensitization

Respiratory sensitization Based on available data, the classification criteria are not met. In the event of accidental injection, an allergic reaction may occur.

Skin sensitization 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.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity
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

Carcinogenicity 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%.

ACGIH Carcinogens

Formaldehyde (CAS 50-00-0) A1 Confirmed human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0) 1 Carcinogenic to humans.

Toxic to reproduction This product is not expected to cause reproductive or developmental effects.

Reproductive toxicity

Developmental effects

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

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

Other information 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)			
Aquatic			
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.		
Bioconcentration factor (BCF)	Not available.		
Mobility in soil	No data available for this product.		
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. Considerations on final disposal

Recommended methods for final destination

Residual waste 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.

Local disposal regulations 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.

14. Transport information

National regulations

ANTT

Not regulated as dangerous goods.

International regulations

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

Federal regulations

This chemical product safety data sheet was prepared in accordance with the Brazilian Standard (ABNT NBR 14725-4: (Safety data sheet for chemicals (SDS))). This product is not classified for Transportation in accordance with Resolution ANTT 5232/2016, amended by Resolutions ANTT No 420 of 2004, No 701 of 2004, No 1.644 of 2006, No 2.657 of 2008, No 2.975 of 2008, No 3.383 of 2010, No 3.632 of 2011, No 3.648 of 2011, No 3.763 of 2012, No 3.887 of 2012 and No 4.081 of 2013.

Brazil. Controlled products that must be reported to the Army (Decree No. 3655, Annex 1, as amended)

Not applicable.

Brazil. Drug precursors (Ordinance No. 1.274)

Not applicable.

Brazil. Ozone depleting substances (Decree No. 99.280, Annexes A, B, C and E, as amended)

Not applicable.

Brazil. Use and physiological effects of chemical products (Decree No. 3665, Annex 3)

Not applicable.

POPs (Decree No. 5.472 promulgates the Stockholm Convention on persistent organic pollutants)

Not listed.

International regulations

Montreal Protocol

Not applicable.

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Basel Convention

Not applicable.

16. Other information

Significant information, yet not specifically related to the previous sections Not available.

Legends and abbreviations Not available.

Disclaimer 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.