

SAFETY DATA SHEET



1. Identification

Product identifier	Water-based vaccine from PHARMAQ (part of Zoetis)	
Other means of identification	None.	
Recommended use	Veterinary vaccine (Fish)	
Recommended restrictions	Not for human use	
Manufacturer/Importer/Supplier/Distributor information		
Company name:	PHARMAQ AS (part of Zoetis)	
Office address:	Industrivegen 50	
Postal address:	Skogmo Industriområde NO-7863 Overhalla, Norway	
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 (Gifftinformasjonen): +47 22 59 13 00 United Kingdom: 999 or 112 Italy: 112 Spain (Servicio De Información Toxicológica): +34 91 562 04 20 International CHEMTREC (24 hours): +1-703-527-3887	
Additional emergency telephone number:		
Supplier	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7 productsupport@zoetis.com Product Support 1-800-461-0917 Emergency telephone no. +1-703-527-3887	

2. Hazard identification

Physical hazards	Not classified.	
Health hazards	Sensitization, skin	Category 1A
	Carcinogenicity	Category 1A
	Reproductive toxicity	Category 1B
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3

Label elements



Signal word	Danger
Hazard statement	May cause an allergic skin reaction. May cause cancer. May damage fertility or the unborn child. Harmful to aquatic life.

Precautionary statement

Prevention

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing mist/vapours. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection.

Response

IF ON SKIN: Wash with plenty of water. IF exposed or concerned: Get medical advice/attention. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

Storage

Store locked up.

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental information

Contains Formaldehyde. May produce an allergic reaction. In the event of accidental injection, an allergic reaction may occur.

Other hazards

None known.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Antigen		Not assigned	*
Formaldehyde		50-00-0	≤ 0.4
Water for Injection		7732-18-5	*

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

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

Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. 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. Rinse with water. Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists.

Ingestion

Rinse mouth. Call a physician or poison control centre 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. May cause an allergic skin reaction. Dermatitis. Rash. 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.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Symptoms may be delayed. Persons developing anaphylactic (allergic) reactions must receive immediate medical assistance.

General information

IF exposed or concerned: Get medical advice/attention. If you feel unwell, seek medical advice (show the label where possible). 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. Wash contaminated clothing before reuse. For personal protection, see section 8 of the SDS.

5. Fire-fighting measures

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 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. Keep people away from and upwind of spill/leak. In case of spills, beware of slippery floors and surfaces. Wear appropriate protective equipment and clothing during clean-up. Avoid breathing mist/vapours. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Avoid release to the environment. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Clean surface thoroughly to remove residual contamination.

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. Put material in suitable, covered, labeled containers. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage**Precautions for safe handling**

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing mist/vapours. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Should be handled in closed systems, if possible. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices. 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.

Conditions for safe storage, including any incompatibilities

Store locked up. Keep away from heat, sparks and open flame. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the SDS). Store in tightly closed original container in a well-ventilated place. @ 2 - 8°C (36 - 46°F). Do not freeze.

8. Exposure controls/personal protection**Occupational exposure limits****US. ACGIH Threshold Limit Values (TLV)**

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

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2), as amended

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	1.3 mg/m ³
		1 ppm
	TWA	0.9 mg/m ³ 0.75 ppm

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

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

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act), as amended

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

Canada. New Brunswick OELs: Threshold Limit Values (TLVs) Based on the 1991 and 1997 ACGIH TLVs and BEIs Publication (New Brunswick Regulation 91-191)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	1.5 ppm
	TWA	0.5 ppm

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents), as amended

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	1.5 ppm
	STEL	1 ppm

Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety), as amended

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	3 mg/m ³
		2 ppm

Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21), as amended

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm

Biological limit values	No biological exposure limits noted for the ingredient(s).
Control banding approach	Not available.
Appropriate engineering controls	Good general ventilation 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.
Other	Wear appropriate chemical resistant clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection	Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.
Thermal hazards	Not applicable.
General hygiene considerations	Observe any medical surveillance requirements. 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. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Physical state	Liquid.
Form	Liquid.
Colour	Light yellow. - Brown.
Odour	Characteristic.
Melting point/freezing point	Not available.

Boiling point or initial boiling point and boiling range	Not available.
Flammability	Not applicable.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Flash point	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
pH	Not available.
Kinematic viscosity	Not available.
Solubility	
Solubility (water)	Soluble
Partition coefficient (n-octanol/water) (log value)	Not available.
Vapour pressure	Not available.
Density and/or relative density	Not available.
Vapour density	Not available.
Particle characteristics	Not available.
Other information	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

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 oxidising agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

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

Symptoms related to the physical, chemical and toxicological characteristics	<p>Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause an allergic skin reaction. Dermatitis. Rash. 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.</p>
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Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel. In the event of accidental injection, an allergic reaction may occur.

Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
Acute		
Oral		
LD50	Rat	800 mg/kg
Chronic		
Inhalation		
LOAEL	Mouse	15 ppm, 2 years Tumours
	Rat	15 ppm, 9 days Respiratory system 6 ppm, 2 years Tumours
Skin corrosion/irritation	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 sensitisation		
ACGIH sensitisation		
Formaldehyde (CAS 50-00-0)		Dermal sensitisation Respiratory sensitisation
Canada - Manitoba OELs Hazard: Dermal sensitization		
Formaldehyde (CAS 50-00-0)		Dermal sensitisation
Canada - Manitoba OELs Hazard: Respiratory sensitization		
Formaldehyde (CAS 50-00-0)		Respiratory sensitisation
Canada - Saskatchewan OELs Hazard Data: Sensitiser		
Formaldehyde (CAS 50-00-0)		Sensitiser.
Respiratory sensitisation	Based on available data, the classification criteria are not met. In the event of accidental injection, an allergic reaction may occur.	
Skin sensitisation	May cause an allergic skin reaction. 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	May cause cancer. Contains a substance which may cause cancer by inhalation.	
ACGIH Carcinogens		
Formaldehyde (CAS 50-00-0)		A1 Confirmed human carcinogen.
Canada - Alberta OELs: Carcinogen category		
Formaldehyde (CAS 50-00-0)		Suspected human carcinogen.

Canada - Manitoba OELs: carcinogenicity

Formaldehyde (CAS 50-00-0)	Confirmed human carcinogen.
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Canada - Quebec OELs: Carcinogen category

Formaldehyde (CAS 50-00-0)	Suspected carcinogenic effect in humans.
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IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0)	1 Carcinogenic to humans.
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US. National Toxicology Program (NTP) Report on Carcinogens

Formaldehyde (CAS 50-00-0)	Known To Be Human Carcinogen.
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Reproductive toxicity May damage fertility or the unborn child.

Developmental effects

Formaldehyde	185 mg/kg/day Embryo / Fetal Development, Not teratogenic Maternal toxicity Species: Mouse Organ: Oral
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	40 ppm Embryo / Fetal Development, Not Teratogenic Maternal Toxicity Species: Rat Organ: Inhalation
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Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.

Further information The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms.

12. Ecological information

Ecotoxicity Avoid release to the environment. 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.

Components	Species		Test Results
Formaldehyde (CAS 50-00-0)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (<i>Daphnia pulex</i>)	4.3 - 7.8 mg/l, 48 hours
Fish	LC50	Bluegill (<i>Lepomis macrochirus</i>)	8.7 mg/l, 96 hours

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

Bioaccumulative potential No data available for this product.

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. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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.

Contaminated packaging

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

14. Transport information**TDG**

Not regulated as dangerous goods.

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**Canadian regulations**

This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

Not regulated.

International regulations**Stockholm Convention**

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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**Issue date**

05-February-2024

Version No.

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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.

Revision information

Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
GHS: Classification