

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Alpha Ject Vaccine</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	Oil-based vaccine
<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 (USA)</b>	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
<b>Rocky Mountain Poison &amp; Drug Safety</b>	1-866-531-8896
<b>Product Support/Technical Services</b>	1-888-963-8471
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300  International CHEMTREC (24 hours): +1-703-527-3887
<b>Company Name (CA)</b>	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
<b>Emergency telephone number</b>	CHEMTREC (24 hours): 1-800-424-9300
<b>Contact E-Mail</b>	productsupport@zoetis.com
<b>Product Support</b>	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

**Supplier** Not available.

## 2. Hazard identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>Environmental hazards</b>	Not classified.

### Label elements

<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.

**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 hazards** None known.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Antigen		Not assigned	*
Formaldehyde		50-00-0	≤ 0.04
Mineral oil and emulsifier		Mixture	*
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** \* Non-hazardous Ingredients

#### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	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.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.
<b>Ingestion</b>	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.
<b>Most important symptoms/effects, acute and delayed</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.
<b>Indication of immediate medical attention and special treatment needed</b>	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.
<b>General information</b>	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. For personal protection, see section 8 of the SDS.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Avoid release to the environment. Ensure adequate ventilation.  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. 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. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

### Precautions for safe handling

Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. When using, do not eat, drink or smoke. Wear 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 at 2-8°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze. Store away from incompatible materials (see Section 10 of the SDS). Store out of direct sunlight in dark, dry conditions. Keep away from heat, sparks and open flame. Keep out of the reach of children.

## 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 <sup>3</sup>
		1 ppm
	TWA	0.9 mg/m <sup>3</sup> 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. 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.

<b>Appropriate engineering controls</b>	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.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear appropriate chemical resistant gloves. Neoprene, butyl rubber, nitrile or Viton gloves are recommended. Non-slip gloves.
<b>Other</b>	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection</b>	In case of insufficient ventilation, wear suitable respiratory equipment.
<b>Thermal hazards</b>	Not applicable.
<b>General hygiene considerations</b>	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

<b>Appearance</b>	Emulsion.
<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Colour</b>	White - Cream.
<b>Odour</b>	Odourless.
<b>Melting point/freezing point</b>	Not available.
<b>Boiling point or initial boiling point and boiling range</b>	Not available.
<b>Flammability</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit – upper (%)</b>	Not available.
<b>Flash point</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>pH</b>	Not available.
<b>Kinematic viscosity</b>	Not available.
<b>Solubility</b>	
<b>Solubility (water)</b>	Soluble
<b>Partition coefficient (n-octanol/water) (log value)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Density and/or relative density</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Particle characteristics</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidising properties</b>	Not oxidising.

## 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. Store at 2-8°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.

**Incompatible materials** As a precautionary measure, keep away from strong oxidizers. This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.

**Hazardous decomposition products** No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

**Inhalation** No adverse effects due to inhalation are expected.

**Skin contact** Prolonged skin contact may cause temporary irritation. Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.

Formaldehyde Species: Rabbit  
Severity: Moderate Severe

**Eye contact** Direct contact with eyes may cause temporary irritation.

Formaldehyde Species: Rabbit  
Severity: Severe

**Ingestion** May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

**Symptoms related to the physical, chemical and toxicological characteristics** 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.

### Information on toxicological effects

**Acute toxicity** In the event of accidental injection, an allergic reaction may occur.

Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	800 mg/kg
<b>Chronic</b>		
<b>Inhalation</b>		
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.

<b>Skin sensitisation</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	<p>In Vitro Bacterial Mutagenicity (Ames) Result: positive Species: Bacteria</p> <p>In Vitro Chromosome Aberration Result: positive Species: Rodent</p> <p>In Vitro Sister Chromatid Exchange Result: positive Species: Rodent</p> <p>In Vivo Chromosome Aberration Result: positive Species: Not specified</p>
<b>Carcinogenicity</b>	Contains a substance which may cause cancer by inhalation. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. No known carcinogens are present at greater than 0.1%.
<b>ACGIH Carcinogens</b> Formaldehyde (CAS 50-00-0)	A1 Confirmed human carcinogen.
<b>Canada - Alberta OELs: Carcinogen category</b> Formaldehyde (CAS 50-00-0)	Suspected human carcinogen.
<b>Canada - Manitoba OELs: carcinogenicity</b> Formaldehyde (CAS 50-00-0)	Confirmed human carcinogen.
<b>Canada - Quebec OELs: Carcinogen category</b> Formaldehyde (CAS 50-00-0)	Suspected carcinogenic effect in humans.
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b> Formaldehyde (CAS 50-00-0)	1 Carcinogenic to humans.
<b>US. National Toxicology Program (NTP) Report on Carcinogens</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	<p>185 mg/kg/day Embryo / Fetal Development, Not teratogenic Maternal toxicity Species: Mouse Organ: Oral</p> <p>40 ppm Embryo / Fetal Development, Not Teratogenic Maternal Toxicity Species: Rat Organ: Inhalation</p>
<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

<b>Ecotoxicity</b>	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.
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Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50	Water flea ( <i>Daphnia pulex</i> )
Fish	LC50	Bluegill ( <i>Lepomis macrochirus</i> )
<b>Persistence and degradability</b>	No data is available on the degradability of this product.	
<b>Bioaccumulative potential</b>		
<b>Mobility in soil</b>	No data available.	
<b>Other adverse effects</b>	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

<b>Disposal instructions</b>	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Dispose of contents/container in accordance with local/regional/national/international regulations. 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.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company. None known.
<b>Waste from residues / unused products</b>	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.
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

<b>TDG</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not established.

### 15. Regulatory information

<b>Canadian regulations</b>	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.
<b>Controlled Drugs and Substances Act</b>	
	Not regulated.
<b>Export Control List (CEPA 1999, Schedule 3)</b>	
	Not listed.
<b>Greenhouse Gases</b>	
	Not listed.
<b>Precursor Control Regulations</b>	
	Not regulated.
<b>International regulations</b>	
<b>Stockholm Convention</b>	
	Not applicable.
<b>Rotterdam Convention</b>	
	Not applicable.
<b>Kyoto Protocol</b>	
	Not applicable.
<b>Montreal Protocol</b>	
	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**

<b>Issue date</b>	19-June-2017
<b>Revision date</b>	01-July-2024
<b>Version No.</b>	02
<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.
<b>Revision information</b>	This document has undergone significant changes and should be reviewed in its entirety.