

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>POULVAC® MATERNAVAC 4®</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	Poulvac Maternavac 4 * Bursal Disease – Newcastle Disease – Bronchitis – Reovirus Vaccine, Standard & Variant, Massachusetts Type, Killed Virus * Poulvac Maternavac ND LASOTA+IB+IBD+Reo
<b>Recommended use</b>	Veterinary vaccine
<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 <a href="https://www.zoetis.ca/sds/sds.aspx">https://www.zoetis.ca/sds/sds.aspx</a>
<b>Supplier</b>	Not available.
<b>2. Hazard identification</b>	
<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>Supplemental information</b>	Direct contact with eyes may cause temporary irritation. 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.
<b>Other hazards</b>	None known.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Bursal Disease Virus		Not assigned	*
Newcastle disease virus, Kimber strain		Not assigned	*
Infectious bronchitis virus		Not available	*
Reovirus		Not assigned	*
Gentamicin		1403-66-3	##
Amphotericin B		1397-89-3	##
Formaldehyde		50-00-0	##
Adjuvant		Mixture	

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

**Composition comments** % = v/v  
## Trace  
\* Non-hazardous Ingredients  
The exact percentage composition of this mixture has been withheld as a trade secret.

### 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>	Remove contact lenses, if present and easy to do. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	Rinse mouth. If swallowed, do NOT induce vomiting. 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. Exposed individuals may experience eye tearing, redness, and 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>	Provide general supportive measures and 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.
<b>General information</b>	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

<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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid contact with eyes, skin, and clothing. For personal protection, see section 8 of the SDS.
--	---

**Methods and materials for containment and cleaning up**

Remove sources of ignition. Ensure adequate ventilation. Wear personal protective equipment  
Avoid release to the environment.

Large Spills: Stop the flow of material, if this is without risk. 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.

**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. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices. Avoid accidental injection.

**Conditions for safe storage, including any incompatibilities**

Store as directed by product packaging. Storage Temperature: 4 - 7C / 39.2 - 44.6F. Store away from incompatible materials (see Section 10 of the SDS).

**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/m3
	TWA	1 ppm
		0.9 mg/m3
		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
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).	
<b>Control banding approach</b>	Gentamicin: Zoetis OEB 2 (control exposure to the range of 100ug/m3 to < 1000ug/m3)	
<b>Appropriate engineering controls</b>	General ventilation normally adequate.	
<b>Individual protection measures, such as personal protective equipment</b>		
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.	
<b>Skin protection</b>		
<b>Hand protection</b>	Not available.	
<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. 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.	
<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>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Colour</b>	Milky. White.
<b>Odour</b>	Not available.
<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>	Not available.
<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. Excessive heat. Keep away from heat, sparks and open flame. Protect from freezing.
<b>Incompatible materials</b>	Strong oxidising agents. This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## 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.  
Formaldehyde Species: Rabbit  
Severity: Moderate to Severe

**Eye contact**  
Direct contact with eyes may cause temporary irritation.  
Gentamicin Species: Rabbit  
Severity: Non-irritating

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 related to the physical, chemical and toxicological characteristics** Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and 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** Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
Amphotericin B (CAS 1397-89-3)		
<b>Acute</b>		
<b>Intraperitoneal</b>		
LD50	Mouse	27.7 mg/kg
	Rat	> 5000 mg/kg
<b>Intravenous</b>		
LD50	Mouse	1.2 mg/kg
<b>Oral</b>		
LD50	Rat	> 5000 mg/kg
<b>Subacute</b>		
<b>Intravenous</b>		
LOAEL	Dog	37 mg/kg/day, 30 days (Kidney) 16.5 mg/kg/day, 2 months (Kidney)
<b>Subchronic</b>		
<b>Oral</b>		
NOAEL	Dog	1.6 mg/kg/day, 13 weeks (Male reproductive system, Female reproductive system)
	Rat	2 mg/kg/day, 13 weeks (Male reproductive system, Female reproductive system)

Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rabbit	270 mg/kg
<b>Inhalation</b>		
LC50	Mouse	0.414 mg/l, 4 hours
	Rat	0.48 mg/l, 4 hours
<b>Oral</b>		
LD50	Rat	100 mg/kg
<b>Chronic</b>		
<b>Inhalation</b>		
LOAEL	Mouse	15 ppm, 2 years Tumours
	Rat	15 ppm, 90 days Respiratory system
		6 ppm, 2 years Tumours
Gentamicin (CAS 1403-66-3)		
<b>Acute</b>		
<b>Intramuscular</b>		
LD50	Mouse	167 mg/kg
	Rat	463 mg/kg
<b>Oral</b>		
LD50	Rat	6600 mg/kg
<b>Subcutaneous</b>		
LD50	Rat	710 mg/kg
<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>		
Gentamicin	Species: Rabbit Severity: Non-irritating	
Formaldehyde	Species: Rabbit Severity: Severe	
<b>Respiratory or skin sensitisation</b>		
<b>ACGIH sensitisation</b>		
Formaldehyde (CAS 50-00-0)	Dermal sensitisation Respiratory sensitisation	
<b>Canada - Manitoba OELs Hazard: Dermal sensitization</b>		
Formaldehyde (CAS 50-00-0)	Dermal sensitisation	
<b>Canada - Manitoba OELs Hazard: Respiratory sensitization</b>		
Formaldehyde (CAS 50-00-0)	Respiratory sensitisation	
<b>Canada - Saskatchewan OELs Hazard Data: Sensitiser</b>		
Formaldehyde (CAS 50-00-0)	Sensitiser.	
<b>Respiratory sensitisation</b>	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.	
<b>Skin Sensitisation</b>		
Formaldehyde	Species: Guinea Pig Severity: positive	
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	

**Mutagenicity**  
Amphotericin B

Bacterial Mutagenicity (Ames)  
Result: Negative  
Species: Salmonella , E. coli

Formaldehyde

In Vitro Bacterial Mutagenicity (Ames)  
Result: positive  
Species: Bacteria

Amphotericin B

In Vitro Chromosome Aberration  
Result: Negative  
Species: Chinese Hamster Ovary (CHO) cells

Formaldehyde

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

Amphotericin B

In Vivo Micronucleus  
Result: Negative  
Species: Mouse

**Carcinogenicity**

No data available to indicate product or any components present at greater than 0.1% are carcinogenic. Based on available data, the classification criteria are not met.

**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.

**Canada - Quebec OELs: Carcinogen category**

Formaldehyde (CAS 50-00-0)

Suspected carcinogenic effect in humans.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Formaldehyde (CAS 50-00-0)

1 Carcinogenic to humans.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Formaldehyde (CAS 50-00-0)

Known To Be Human Carcinogen.

**Reproductive toxicity**

Based on available data, the classification criteria are not met.

**Developmental effects**

Amphotericin B

10 mg/kg/day Embryo / Fetal Development, Not Teratogenic  
Fetotoxicity  
Result: NOAEL  
Species: Rabbit  
Organ: Oral

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

**Developmental effects**

Amphotericin B

7.5 mg/kg/day Embryo / Fetal Development, Not teratogenic  
 Fetotoxicity  
 Result: NOAEL  
 Species: Rat  
 Organ: Oral

Gentamicin

75 mg/kg/day Embryo / Fetal Development, Developmental  
 toxicity  
 Result: LOAEL  
 Species: Rat  
 Organ: Intramuscular

**Specific target organ toxicity - single exposure** Based on available data, the classification criteria are not met.

**Specific target organ toxicity - repeated exposure** Based on available data, the classification criteria are not met.

**Aspiration hazard** Based on available data, the classification criteria are not met.

**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. Based on available data, the classification criteria are not met for hazardous to the aquatic 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)		
<b>Aquatic</b>		
Crustacea	EC50	Daphnia magna (Water Flea) 42 mg/l, 24 Hours
Fish	LC50	Oncorhynchus mykiss (rainbow trout) 118 ppm, 96 Hours
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia pulex) 4.3 - 7.8 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus) 8.7 mg/l, 96 hours

**Persistence and degradability** No data available for this product.

**Bioaccumulative potential** No data available for this product.

**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. Disposal considerations**

**Disposal instructions** Avoid release to the environment. Do not dispose of waste into sewer. Do not contaminate ponds, waterways or ditches with chemical or used container. 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.

**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** 12-December-2019  
**Revision date** 10-April-2024  
**Version No.** 02

**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: Synonyms

Hazard identification: Other hazards

Composition/information on ingredients: Component information

Accidental release measures: Personal precautions, protective equipment and emergency procedures

Accidental release measures: Methods and materials for containment and cleaning up

Handling and storage: Conditions for safe storage, including any incompatibilities

Exposure controls/personal protection: Respiratory protection

Stability and reactivity: Incompatible materials

Disposal considerations: Waste from residues / unused products

Other information: References

Other information: Further information

Other information: List of abbreviations