

SAFETY DATA SHEET



1. Identification

Product identifier	Poulvac Maternavac® IBD-Reo
Other means of identification	
Synonyms	POULVAC® * Poulvac Maternavac IBD-Reo * Bursal Disease-Reovirus Vaccine, Standard and Variant, Killed Virus
Recommended use	Veterinary vaccine
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (USA)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	productsupport@zoetis.com
Product Support	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(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.

Label elements

Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.

Precautionary statement

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 None known.

Supplemental information Direct contact with eyes may cause temporary irritation. In the event of accidental injection, an allergic reaction may occur.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Adjuvant		Mixture	
Amphotericin B		1397-89-3	##
Bursal Disease Virus		Not assigned	*
Formaldehyde		50-00-0	##
Gentamicin		1403-66-3	##
Reovirus		Not assigned	*

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

Composition comments ## Trace
* Non-hazardous Ingredients

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 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. 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.
General information	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.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
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. For personal protection, see section 8 of the SDS.
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Methods and materials for containment and cleaning up

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

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

Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapour. Avoid accidental injection. 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 out of direct sunlight in dark, dry conditions. @ 2 - 7°C (36 - 45°F). Do not freeze. Store in original tightly closed container. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS).

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

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

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

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)	Ceiling	1 ppm
	TWA	0.3 ppm

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

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

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

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

Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	3 mg/m3
		2 ppm

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

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

Gentamicin: Zoetis OEB 2 (control exposure to the range of 100ug/m3 to < 1000ug/m3)

Appropriate engineering controls	Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. 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.
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 Opaque liquid.

Physical state Liquid.

Form Liquid.

Colour Pale yellow - Red White.

Odour Odourless.

Odour threshold Not available.

pH 6 - 8

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Non-flammable

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.

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) miscible

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity 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. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
Incompatible materials	Strong oxidising agents. 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.
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 Expected to be a low ingestion hazard.

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

Components	Species	Test results
Amphotericin B (CAS 1397-89-3)		
Acute		
Intraperitoneal		
LD50	Mouse	27.7 mg/kg
	Rat	> 5000 mg/kg
Intravenous		
LD50	Mouse	1.2 mg/kg
Oral		
LD50	Rat	> 5000 mg/kg
Subacute		
Intravenous		
LOAEL	Dog	37 mg/kg/day, 30 days (Kidney) 16.5 mg/kg/day, 2 months (Kidney)
Subchronic		
Oral		
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)		
Acute		
Dermal		
LD50	Rabbit	270 mg/kg
Inhalation		
LC50	Mouse	0.414 mg/l, 4 hours
	Rat	0.48 mg/l, 4 hours
Oral		
LD50	Rat	100 mg/kg
Chronic		
Inhalation		
LOAEL	Mouse	15 ppm, 2 years Tumours
	Rat	15 ppm, 90 days Respiratory system
		6 ppm, 2 years Tumours
Gentamicin (CAS 1403-66-3)		
Acute		
Intramuscular		
LD50	Mouse	167 mg/kg
	Rat	463 mg/kg
Oral		
LD50	Rat	6600 mg/kg
Subcutaneous		
LD50	Rat	710 mg/kg
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		
Gentamicin	Species: Rabbit Severity: Non-irritating	
Formaldehyde	Species: Rabbit Severity: Severe	
Respiratory or skin sensitisation		
ACGIH sensitisation		
FORMALDEHYDE (CAS 50-00-0)	Dermal sensitization Respiratory sensitisation	
Canada - British Columbia OELs: Respiratory or skin sensitiser		
Formaldehyde (CAS 50-00-0)	Capable of causing respiratory, dermal or conjunctival sensitization.	
Canada - Manitoba OELs Hazard: Dermal sensitization		
Formaldehyde (CAS 50-00-0)	Dermal sensitization	
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	Not a respiratory sensitizer.	
Skin sensitisation	This product contains formaldehyde which is considered to be a skin sensitizer. This product is not expected to cause skin sensitisation.	
Skin sensitisation		
Formaldehyde	Species: Guinea Pig Severity: positive	

Germ cell mutagenicity

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

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%.

ACGIH Carcinogens

Formaldehyde (CAS 50-00-0)

A2 Suspected human carcinogen.

Canada - Alberta OELs: Carcinogen category

Formaldehyde (CAS 50-00-0)

Suspected human carcinogen.

Canada - Manitoba OELs: carcinogenicity

Formaldehyde (CAS 50-00-0)

Suspected 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

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

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** Not classified.

**Specific target organ toxicity -
 repeated exposure** Not classified.

Aspiration hazard Not an aspiration hazard.

Further 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)	EC50	Daphnia magna (Water Flea)	42 mg/l, 24 Hours
	LC50	Oncorhynchus mykiss (Rainbow Trout)	118 ppm, 96 Hours
Aquatic			
	Crustacea	Water flea (Daphnia pulex)	4.3 - 7.8 mg/l, 48 hours
	Fish	Striped bass (Morone saxatilis)	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.

Hazardous waste code None known.

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**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.

Ontario. Toxic Substances. Toxic Reduction Act, 2009. Regulation 455/09 (July 1, 2011)

Formaldehyde (CAS 50-00-0)

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 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

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Version No. 01

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
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Transport Information: Material Transportation Information