

# SAFETY DATA SHEET



## 1. Identification

**Product identifier** POULVAC® SE-ND-IB

**Other means of identification**

**Synonyms** Newcastle-Bronchitis Vaccine-Salmonella Enteritidis Bacterin, Mass. Type, 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 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** Combustible.

**Supplemental information** This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Oil, Mineral		8042-47-5	60-80
Formaldehyde		50-00-0	<0.1
Bronchitis Disease Virus		Not assigned	
Gentamicin		1403-66-3	##
Newcastle Disease Virus, killed		Not assigned	
Salmonella enteritidis		Not assigned	

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

**Composition comments**      ## Trace  
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. If skin irritation or rash occurs: Get medical advice/attention.
<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>	If swallowed, do NOT induce vomiting. 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. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
<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>	Provide general supportive measures and treat symptomatically. Symptoms may be delayed. 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>	Foam. Dry chemicals. Carbon dioxide (CO2).
<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. Mineral oil is combustible when exposed to heat or flame.
<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>	Cool containers exposed to heat with water spray and remove container, if no risk is involved.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	Combustible. Material will burn in a fire.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained.
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**Methods and materials for containment and cleaning up**

Ensure adequate ventilation. Remove sources of ignition. Wear appropriate protective equipment and clothing during clean-up. Avoid release to the environment.

Large Spills: Stop the flow of material, if this is without risk. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. 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. Avoid discharge into drains, water courses or onto the ground.

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

Wear appropriate personal protective equipment. Avoid accidental injection. Avoid contact with eyes, skin, and clothing. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Observe good industrial hygiene practices. Wash hands thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment.

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

Store out of direct sunlight in dark, dry conditions. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze. Store away from incompatible materials (see Section 10 of the SDS). Keep away from heat and sources of ignition.

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

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	0.3 ppm	
	TWA	0.1 ppm	
Oil, Mineral (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.

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

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	Ceiling	1.3 mg/m3	
	TWA	1 ppm	
Oil, Mineral (CAS 8042-47-5)	STEL	0.9 mg/m3	
	TWA	0.75 ppm	
Oil, Mineral (CAS 8042-47-5)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.

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

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	Ceiling	1 ppm	
	TWA	0.3 ppm	
Oil, Mineral (CAS 8042-47-5)	TWA	1 mg/m3	Mist.

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

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	0.3 ppm	
	TWA	0.1 ppm	
Oil, Mineral (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.

**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 Labor - Regulation respecting occupational health and safety)**

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	Ceiling	3 mg/m3	
		2 ppm	
Oil, Mineral (CAS 8042-47-5)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.

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

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm
Oil, Mineral (CAS 8042-47-5)	15 minute	10 mg/m3
	8 hour	5 mg/m3

<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.

**Individual protection measures, such as personal protective equipment**

<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear protective 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>	No personal respiratory protective equipment normally required.
<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.
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**9. Physical and chemical properties**

<b>Appearance</b>	Suspension
<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Non-flammable
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.

<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit – upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</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. High temperatures. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Do not allow material to freeze.
<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 product's decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	No adverse effects due to inhalation are expected.
<b>Skin contact</b>	No adverse effects due to skin contact are expected. Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.
Formaldehyde	Species: Rabbit Severity: Moderate Severe
Oil, Mineral	Species: Rabbit Severity: Slight
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
Formaldehyde	Species: Rabbit Severity: Severe
Oil, Mineral	Species: Rabbit Severity: Slight
<b>Ingestion</b>	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. 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
Formaldehyde (CAS 50-00-0)		
<b>Acute</b>		
<b>Inhalation</b>		
LC50	Rat	0.48 mg/l, 4 Hours
<b>Oral</b>		
LD50	Rat	800 mg/kg 100 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
Oil, Mineral (CAS 8042-47-5)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	> 5000 mg/kg
<b>Skin corrosion/irritation</b>		
	Prolonged skin contact may cause temporary irritation.	
<b>Corrosivity</b>		
Oil, Mineral	Species: Rabbit Severity: Slight	
<b>Serious eye damage/eye irritation</b>		
	Direct contact with eyes may cause temporary irritation.	
<b>Eye contact</b>		
Formaldehyde	Species: Rabbit Severity: Severe	
Oil, Mineral	Species: Rabbit Severity: Slight	
<b>Respiratory or skin sensitisation</b>		
<b>ACGIH sensitisation</b>		
FORMALDEHYDE (CAS 50-00-0)	Dermal sensitization Respiratory sensitisation	
<b>Canada - British Columbia OELs: Respiratory or skin sensitiser</b>		
Formaldehyde (CAS 50-00-0)	Capable of causing respiratory, dermal or conjunctival sensitization.	
<b>Canada - Manitoba OELs Hazard: Dermal sensitization</b>		
Formaldehyde (CAS 50-00-0)	Dermal sensitization	
<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. 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>	Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
<b>ACGIH Carcinogens</b> Formaldehyde (CAS 50-00-0) Oil, Mineral (CAS 8042-47-5)	A1 Confirmed human carcinogen. A4 Not classifiable as a 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) Oil, Mineral (CAS 8042-47-5)	Confirmed human carcinogen. Not classifiable as a 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) Oil, Mineral (CAS 8042-47-5)	1 Carcinogenic to humans. 3 Not classifiable as to carcinogenicity 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>	Based on available data, the classification criteria are not met. 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>	Due to partial or complete lack of data the classification is not possible.

**Further information** The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

## 12. Ecological information

**Ecotoxicity** 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. Avoid release to the environment.

Components	Species	Test Results	
Formaldehyde (CAS 50-00-0)			
<b>Aquatic</b>			
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 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 dispose of waste into sewer. 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 (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**

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
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
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** Draft version.

**Revision date** Draft version.

**Version No.** 00

**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.