

SAFETY DATA SHEET



1. Identification

Product identifier	Poulvac® i N + B
Other means of identification	
Synonyms	Poulvac® ND-IB * Newcastle Disease virus - Infectious Bronchitis Disease virus, inactivated vaccine * Newcastle-Bronchitis Vaccine, 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	1-888-963-8471
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 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	%
Gentamicin		1403-66-3	##
Inactivated IB Virus, strain Massachusetts M41		Not assigned	
Newcastle disease virus		Not assigned	
Oil vehicle		Mixture	

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

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	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. Show this safety data sheet to the doctor in attendance.

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. 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.

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.

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. 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 No exposure limits noted for ingredient(s).

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 Emulsion.

Physical state Liquid.

Form Liquid.

Colour Milky. 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)	Insoluble
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. High temperatures. Keep away from heat, sparks and open flame. 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	No adverse effects due to inhalation are expected.
Skin contact	Prolonged skin contact may cause temporary irritation.
Eye contact	Direct contact with eyes may cause temporary irritation.
Gentamicin	Species: Rabbit Severity: Non-irritating

Ingestion Health injuries are not known or expected under normal use.

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 Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
Gentamicin (CAS 1403-66-3)		
<u>Acute</u>		
Intramuscular		
LD50	Mouse	167 mg/kg

Components	Species	Test Results
	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
	Severity: Non-irritating	
Respiratory or skin sensitisation		
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	Based on available data, the classification criteria are not met. In the event of accidental injection, an allergic reaction may occur.	
Germ cell mutagenicity	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.	
Carcinogenicity	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.	
Reproductive toxicity	Based on available data, the classification criteria are not met.	
Developmental effects		
Gentamicin	75 mg/kg/day Embryo / Fetal Development, Developmental toxicity	Result: LOAEL
	Species: Rat	Organ: Intramuscular
Specific target organ toxicity - single exposure	Due to partial or complete lack of data the classification is not possible.	
Specific target organ toxicity - repeated exposure	Due to partial or complete lack of data the classification is not possible.	
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	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.	
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 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 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	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.
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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 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

Country(s) or region	Inventory name	On inventory (yes/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. 02

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Revision information This document has undergone significant changes and should be reviewed in its entirety.