

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 (US)	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 (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.
OSHA defined 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.
Hazard(s) not otherwise classified (HNOC)	None known.
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	%
Mineral oil, white		8042-47-5	60-80
Formaldehyde		50-00-0	<0.1

Material name: POULVAC® SE-ND-IB

Version #: 03 Revision date: 10-28-2019 Issue date: 09-10-2013

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Chemical name	Common name and synonyms	CAS number	%
Bronchitis Disease Virus		Not Assigned	
Gentamicin		1403-66-3	##
Newcastle Disease Virus, killed		Not Assigned	
Salmonella enteritidis		Not Assigned	

Composition comments ## Trace
 In accordance with 29 CFR 1910.1200, 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. If skin irritation or rash occurs: Get medical advice/attention.

Eye contact Remove contact lenses, if present and easy to do. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion If swallowed, do NOT induce vomiting. Rinse mouth. Call a physician or poison control center 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.

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 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.

General information 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

Suitable extinguishing media Foam. Dry chemicals. Carbon dioxide (CO2).

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. Mineral oil is combustible when exposed to heat or flame.

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 Cool containers exposed to heat with water spray and remove container, if no risk is involved.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards Combustible. Material will burn in a fire.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures 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.

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**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	2 ppm
	TWA	0.75 ppm

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Mineral oil, white (CAS 8042-47-5)	PEL	5 mg/m ³	Mist.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	0.3 ppm	
	TWA	0.1 ppm	
Mineral oil, white (CAS 8042-47-5)	TWA	5 mg/m ³	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	Ceiling	0.1 ppm	
	TWA	0.016 ppm	
Mineral oil, white (CAS 8042-47-5)	STEL	10 mg/m ³	Mist.
	TWA	5 mg/m ³	Mist.

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

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 protective 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.
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	Suspension
Physical state	Liquid.
Form	Liquid.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
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.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
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.
Oxidizing properties	Not oxidizing.

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, hot surfaces, sparks, open flames and other ignition sources. Do not allow material to freeze.
Incompatible materials	Strong oxidizing agents. This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.

Hazardous decomposition products

Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	No adverse effects due to inhalation are expected.
Skin contact	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
Mineral oil, white	Species: Rabbit Severity: Slight
Eye contact	Direct contact with eyes may cause temporary irritation.
Formaldehyde	Species: Rabbit Severity: Severe
Mineral oil, white	Species: Rabbit Severity: Slight

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. 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)		
Acute		
Inhalation		
LC50	Rat	0.48 mg/l, 4 Hours
Oral		
LD50	Rat	800 mg/kg
Chronic		
Inhalation		
LOAEL	Mouse	15 ppm, 2 years Tumors
	Rat	15 ppm, 9 days Respiratory system 6 ppm, 2 years Tumors
Mineral oil, white (CAS 8042-47-5)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Corrosivity		
Mineral oil, white	Species: Rabbit Severity: Slight	

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye Contact

Formaldehyde

Species: Rabbit
Severity: Severe

Mineral oil, white

Species: Rabbit
Severity: Slight**Respiratory or skin sensitization****ACGIH sensitization**

FORMALDEHYDE (CAS 50-00-0)

Dermal sensitization
Respiratory sensitization**Respiratory sensitization**

Based on available data, the classification criteria are not met. In the event of accidental injection, an allergic reaction may occur.

Skin sensitization

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.

Germ cell mutagenicity

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Formaldehyde

In Vitro Bacterial Mutagenicity (Ames)
Result: Positive
Species: BacteriaIn Vitro Chromosome Aberration
Result: Positive
Species: RodentIn Vitro Sister Chromatid Exchange
Result: Positive
Species: RodentIn Vivo Chromosome Aberration
Result: Positive
Species: Not specified**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. No data available to indicate product or any components present at greater than 0.1% are carcinogenic.

IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0)

1 Carcinogenic to humans.

Mineral oil, white (CAS 8042-47-5)

3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Formaldehyde (CAS 50-00-0)

Cancer

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

Developmental effects

Formaldehyde

185 mg/kg/day Embryo / Fetal Development, Not teratogenic
Maternal toxicity
Species: Mouse
Organ: Oral40 ppm Embryo / Fetal Development, Not Teratogenic
Maternal Toxicity
Species: Rat
Organ: Inhalation**Specific target organ toxicity - single exposure**

Not classified.

Specific target organ toxicity - repeated exposure

Not classified.

Aspiration hazard	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.
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Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
Aquatic		
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

DOT	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

US federal regulations	This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4)	
Formaldehyde (CAS 50-00-0)	Listed.
SARA 304 Emergency release notification	
Formaldehyde (CAS 50-00-0)	100 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Formaldehyde (CAS 50-00-0)

Cancer
Skin sensitization
Respiratory sensitization
Eye irritation
Skin irritation
respiratory tract irritation
Acute toxicity
Flammability**Superfund Amendments and Reauthorization Act of 1986 (SARA)****SARA 302 Extremely hazardous substance**

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
Formaldehyde	50-00-0	100	500		

SARA 311/312 Hazardous chemical No**SARA 313 (TRI reporting)**

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Formaldehyde (CAS 50-00-0)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Formaldehyde (CAS 50-00-0)

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations****California Proposition 65****WARNING:** This product can expose you to Formaldehyde, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.**California Proposition 65 - CRT: Listed date/Carcinogenic substance**

Formaldehyde (CAS 50-00-0)

Listed: January 1, 1988

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Formaldehyde (CAS 50-00-0)

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
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, including date of preparation or last revision

Issue date 09-10-2013

Revision date 10-28-2019

Version # 03

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