# SAFETY DATA SHEET

## 1. Identification

| | |
|---|---|
| **Product identifier** | **POULVAC® MATERNAVAC 4®** |
| **Other means of identification** | |
| **Synonyms** | Poulvac Maternavac 4 * Bursal Disease – Newcastle Disease – Bronchitis – Reovirus Vaccine, Standard & Variant, Massachusetts Type, Killed Virus |
| **Recommended use** | Veterinary vaccine |
| **Recommended restrictions** | Not for human use |
| **Manufacturer/Importer/Supplier/Distributor information** | |
| **Company Name (USA)** | Zoetis Inc.<br>10 Sylvan Way<br>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<br>International CHEMTREC (24 hours): +1-703-527-3887 |
| **Company Name (CA)** | Zoetis Canada Inc.<br>16740 Trans-Canada Highway<br>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<br>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. 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 | % |
|---|---|---|---|
| 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 | |

**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

**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**

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 centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.

**Most important symptoms/effects, acute and delayed**

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.

**Indication of immediate medical attention and special treatment needed**

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.

**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**

Water fog. Foam. Dry chemical powder. 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.

**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. Ensure adequate ventilation. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective 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**

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

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

Store as directed by product packaging. @ 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**

| 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)**

| Components | Type | Value |
|---|---|---|
| Formaldehyde (CAS 50-00-0) | Ceiling | 1.3 mg/m3 |
| | | 1 ppm |
| | TWA | 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) | STEL | 0.3 ppm |
| | TWA | 0.1 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 Labor - Regulation respecting occupational health and safety)**

| 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** 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** Emulsion.

**Physical state** Liquid.

**Form** Liquid.

**Colour** Milky. White.

**Odour** Not available.

**Odour threshold** Not available.

**pH** Not available.

**Melting point/freezing point** Not available.

**Initial boiling point and boiling range** Not available.

**Flash point** Not available.

**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)** 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. |
| **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. Excessive heat. Keep away from heat, sparks and open flame. Protect from freezing. |
| **Incompatible materials** | Strong oxidising agents. |
| **Hazardous decomposition products** | 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<br>Severity: Moderate to Severe |
| **Eye contact** | Direct contact with eyes may cause temporary irritation. |
| Gentamicin | Species: Rabbit<br>Severity: Non-irritating |
| Formaldehyde | Species: Rabbit<br>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) | | |
| **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) |

| Components | Species | Test Results |
|---|---|---|
| **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) |
| 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<br>Severity: Non-irritating |
| Formaldehyde | Species: Rabbit<br>Severity: Severe |

**Respiratory or skin sensitisation**

**ACGIH sensitisation**

| | |
|---|---|
| FORMALDEHYDE (CAS 50-00-0) | Dermal sensitization<br>Respiratory sensitisation |

**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** 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.

**Skin sensitisation**

| | |
|---|---|
| Formaldehyde | Species: Guinea Pig<br>Severity: positive |

**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.

**Mutagenicity**

| | |
|---|---|
| Amphotericin B | Bacterial Mutagenicity (Ames)<br>Result: negative<br>Species: Salmonella , E. coli |
| Formaldehyde | In Vitro Bacterial Mutagenicity (Ames)<br>Result: positive<br>Species: Bacteria |
| Amphotericin B | In Vitro Chromosome Aberration<br>Result: negative<br>Species: Chinese Hamster Ovary (CHO) cells |
| Formaldehyde | In Vitro Chromosome Aberration<br>Result: positive<br>Species: Rodent |
| | In Vitro Sister Chromatid Exchange<br>Result: positive<br>Species: Rodent |
| | In Vivo Chromosome Aberration<br>Result: positive<br>Species: Not specified |
| Amphotericin B | In Vivo Micronucleus<br>Result: negative<br>Species: Mouse |

**Carcinogenicity** 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 carcinogenic.

**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<br>Fetotoxicity<br>Result: NOAEL<br>Species: Rabbit<br>Organ: Oral |
| Formaldehyde | 185 mg/kg/day Embryo / Fetal Development, Not teratogenic<br>Maternal toxicity<br>Species: Mouse<br>Organ: Oral |

**Developmental effects**

| | |
|---|---|
| Formaldehyde | 40 ppm Embryo / Fetal Development, Not Teratogenic<br>Maternal Toxicity<br>Species: Rat<br>Organ: Inhalation |
| Amphotericin B | 7.5 mg/kg/day Embryo / Fetal Development, Not teratogenic<br>Fetotoxicity<br>Result: NOAEL<br>Species: Rat<br>Organ: Oral |
| Gentamicin | 75 mg/kg/day Embryo / Fetal Development, Developmental toxicity<br>Result: LOAEL<br>Species: Rat<br>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** 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) | | | |
| **Aquatic** | | | |
| Crustacea | EC50 | Daphnia magna (Water Flea) | 42 mg/l, 24 Hours |
| | | Water flea (Daphnia pulex) | 4.3 - 7.8 mg/l, 48 hours |
| Fish | LC50 | Bluegill (Lepomis macrochirus) | 10 mg/l, 96 hours |
| | | Oncorhynchus mykiss (rainbow trout) | 118 ppm, 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. 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**

| 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

| | |
|---|---|
| **Issue date** | 12-December-2019 |
| **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. |