

MATERIAL SAFETY DATA SHEET



Revision date: 10-Sep-2013

Version: 2.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Poulvac Pabac IV

Trade Name: POULVAC®, PABAC®
Synonyms: Pasteurella Multocida Bacterin
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use: Veterinary Vaccine

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison Control Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Liquid

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

EU Classification:

EU Indication of danger: Not classified

Label Elements

Signal Word: Not Classified

Other Hazards

Short Term: In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection. May cause eye and skin irritation

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

PZ01791

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Mineral oil, white	8042-47-5	232-455-8	Not Listed	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Pasteurella multocida	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	Not Listed	*
Sorbitan sesquioleate	8007-43-0	232-360-1	Not Listed	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Description of First Aid Measures

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** No data available
- Medical Conditions Aggravated by Exposure:** None known

Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** Where parenteral oil-adjuvanted vaccine exposure has occurred, the patient should be promptly evaluated for the development of vasospasm and/or compartment syndrome.

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

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Fire / Explosion Hazards: Not flammable.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Additional Information:

This product is a nonflammable aqueous solution.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid accidental injection. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Mineral oil, white

ACGIH Threshold Limit Value (TWA)	5 mg/m ³
ACGIH Threshold Limit Value (STEL)	10 mg/m ³ (oil mist)

Sodium chloride

Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	No data available.
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
No data available			
Decomposition Temperature (°C):	No data available.		
Evaporation Rate (Gram/s):	No data available		
Vapor Pressure (kPa):	No data available		
Vapor Density (g/ml):	No data available		
Relative Density:	No data available		
Viscosity:	No data available		
Flammability:			
Autoignition Temperature (Solid) (°C):		No data available	
Flammability (Solids):		No data available	
Flash Point (Liquid) (°C):		Non-flammable	
Upper Explosive Limits (Liquid) (% by Vol.):		No data available	
Lower Explosive Limits (Liquid) (% by Vol.):		No data available	
Polymerization:		Will not occur	

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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11. TOXICOLOGICAL INFORMATION

General Information:

Toxicological properties of the formulation have not been fully investigated. The information included in this section describes the potential hazards of the individual ingredients. The antigens included in this product are non-infectious. All have been prepared from modified or inactivated preparations of microorganisms.

Acute Toxicity: (Species, Route, End Point, Dose)

Mineral oil, white

Rat Oral LD50 > 5000 mg/kg

Polysorbate 80

Rat Oral LD50 25 g/kg

Sodium chloride

Rat Oral LD50 3000 mg/kg

Mouse Oral LD50 4000 mg/kg

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Mineral oil, white

Skin Irritation Rabbit Slight

Eye Irritation Rabbit Slight

Sorbitan sesquioleate

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

Sodium chloride

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Mild

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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12. ECOLOGICAL INFORMATION

Environmental Overview:	The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Mobility in Soil:	No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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.
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14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Pasteurella multocida

CERCLA/SARA 313 Emission reporting
California Proposition 65
EU EINECS/ELINCS List

Not Listed
Not Listed
Not Listed

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15. REGULATORY INFORMATION

Mineral oil, white	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-455-8
Sodium chloride	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3
Polysorbate 80	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Sorbitan sesquioleate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-360-1
Water for injection	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Data Sources:	The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.
Reasons for Revision:	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Prepared by:	Toxicology and Hazard Communication Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material 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.

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End of Safety Data Sheet