

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Poulvac Pabac IV</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	Poulvac® i P Vaccine * Poulvac I Pabac IV * Pasteurella Multocida Bacterin * Poulvac® i Pabac IV
<b>Recommended use of the chemical and restrictions on use</b>	
<b>Recommended use</b>	Veterinary vaccine
<b>Restrictions on use</b>	Not for human use
<b>Details of manufacturer or importer</b>	
<b>Company Name (AU)</b>	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA
<b>Tel</b>	1800 814 883
<b>Fax</b>	(02) 8876 0444
<b>Email</b>	productsupport.au@zoetis.com
<b>Emergency Phone</b>	1800 814 883 (all hours)
<b>Police and Fire Brigade</b>	Dial 000
<b>If ineffective</b>	Dial Poisons Information Centre (13 1126 from anywhere in Australia)

## 2. Hazard(s) identification

### Classification of the hazardous chemical

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>Environmental hazards</b>	Not classified.

### Label elements, including precautionary statements

<b>Hazard symbol(s)</b>	None.
<b>Signal word</b>	None.
<b>Hazard statement(s)</b>	The mixture does not meet the criteria for classification.
<b>Precautionary statement(s)</b>	
<b>Prevention</b>	Observe good industrial hygiene practices.
<b>Response</b>	Wash hands after handling.
<b>Storage</b>	Store away from incompatible materials.
<b>Disposal</b>	Dispose of waste and residues in accordance with local authority requirements.

**Other hazards which do not result in classification** 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

### Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Formaldehyde	50-00-0	<0.05
Mineral oil, white	8042-47-5	*
Pasteurella multocida	Not assigned	*

**Composition comments** \*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

## 4. First-aid measures

### Description of necessary 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. Take care to avoid accidental self-injection as this product contains mineral oil and is an irritant. It can cause pain and prolonged swelling (6-24 months) at the injection site and in the draining lymph nodes.

**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** 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.

**Personal protection for first-aid responders** IF exposed or concerned: Get medical advice/attention. You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call. 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. For personal protection, see section 8 of the SDS.

**Symptoms caused by exposure** 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.

**Medical attention and special treatment** 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. Self Injection: In all instances of accidental self injection contact a doctor as soon as possible. Further information on treatment is available from Poisons Information Centre - Phone 131 126. Accidental self injection may lead to an inflammatory response. Medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. Check your tetanus immunisation status.

The recommendations following self inoculation for medical management or surgical intervention are as follows: Category 1 injury (superficial skin exposure) Simply wash the contaminated area in warm soapy water. If vaccine material is splashed onto mucosal surfaces (e. g. eyes) there is greater risk and topical corticosteroids should be considered here. Category 2 injury (simple needle-stick injuries without injection) Allow the wound to bleed freely and do not squeeze or interfere with the injection site. Clean the wound thoroughly with soap and water, and keep it clean and dry. Treat symptomatically (e.g. ensure appropriate tetanus cover; prescribe topical corticosteroids and oral antibiotics to prevent opportunistic infection). If unsure whether or not product has been injected, monitor for 24 hours. If pain and swelling subside, injection is unlikely to have occurred. If pain and swelling persist after 24 hours, treatment should be as per Category 3. Category 3 injury (injection of vaccine material) Acute pain and inflammation is usually evident within 24 hours. Perform early surgery and drainage to remove the oil based vaccine material before it spreads or elicits a severe granulomatous reaction. Category 4 injury (lesion that has progressed to necrosis or granulomatous ulceration) Perform surgical debridement to remove any residual vaccine material. Skin grafting may ultimately be required.

## 5. Fire-fighting measures

### Extinguishing media

**Suitable extinguishing media** Foam. Dry chemicals. Carbon dioxide (CO<sub>2</sub>).

**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 fire fighters** 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>Hazchem code</b>	None.
<b>General fire hazards</b>	Combustible. Material will burn in a fire.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

<b>For non-emergency personnel</b>	Keep unnecessary personnel away.
<b>For emergency responders</b>	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

**Methods and materials for containment and cleaning up** Ensure adequate ventilation. Remove sources of ignition. Wear appropriate protective equipment and clothing during clean-up. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. 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.

## 7. Handling and storage

**Precautions for safe handling** Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. 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 in a well-ventilated place. Keep away from heat and sources of ignition. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls and personal protection

**Control parameters** Follow standard monitoring procedures.

### Occupational exposure limits

#### Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	2.5 mg/m <sup>3</sup>
		2 ppm
	TWA	1.2 mg/m <sup>3</sup>
Mineral oil, white (CAS 8042-47-5)		1 ppm
	TWA	5 mg/m <sup>3</sup>

#### Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	2.5 mg/m <sup>3</sup>	
		2 ppm	
	TWA	1.2 mg/m <sup>3</sup>	
Mineral oil, white (CAS 8042-47-5)		1 ppm	
	TWA	5 mg/m <sup>3</sup>	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 <sup>3</sup>	Inhalable fraction.

**UK. EH40 Workplace Exposure Limits (WELs)**

Components	Type	Value	
Formaldehyde (CAS 50-00-0)	STEL	2.5 mg/m <sup>3</sup>	
	TWA	2 ppm	
		2.5 mg/m <sup>3</sup>	
		2 ppm	

**Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)**

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	TWA	0.37 mg/m <sup>3</sup>	
Mineral oil, white (CAS 8042-47-5)	TWA	0.3 ppm	Respirable fraction.
		5 mg/m <sup>3</sup>	

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls** General ventilation normally adequate.

**Individual protection measures, for example personal protective equipment (PPE)**

**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.

**Hygiene measures** 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**

**Physical state** Liquid.

**Form** Liquid.

**Colour** Not available.

**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 physical and chemical parameters

**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. Keep away from heat, sparks, flame and all other sources of ignition.

**Incompatible materials** Strong oxidising agents.

**Hazardous decomposition products** No hazardous decomposition products are known.

### 11. Toxicological information

#### Information on possible routes of exposure

**Inhalation** Health injuries are not known or expected under normal use.

**Skin contact** Prolonged skin contact may cause temporary irritation.

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 exposure** 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.

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

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
Mineral oil, white (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>		
Mineral oil, white	Species: Rabbit	Severity: Slight
<b>Serious eye damage/irritation</b>	Direct contact with eyes may cause temporary irritation.	
<b>Eye contact</b>		
Formaldehyde	Species: Rabbit	Severity: Severe
Mineral oil, white	Species: Rabbit	Severity: Slight
<b>Respiratory or skin sensitisation</b>		
<b>ACGIH sensitisation</b>		
FORMALDEHYDE (CAS 50-00-0)	Dermal sensitization Respiratory sensitisation	
<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.	
<b>Germ cell mutagenicity</b>	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.	
<b>Mutagenicity</b>		
Formaldehyde	In Vitro Bacterial Mutagenicity (Ames) Result: positive Species: Bacteria	

**Mutagenicity**  
Formaldehyde

In Vitro Chromosome Aberration  
Result: positive  
Species: Rodent

In Vitro Sister Chromatid Exchange  
Result: positive  
Species: Rodent

In Vivo Chromosome Aberration  
Result: positive  
Species: Not specified

**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.

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

A4 Not classifiable as a human carcinogen.

**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.

**Reproductive toxicity** Based on available data, the classification criteria are not met.

**Developmental effects**

Formaldehyde

185 mg/kg/day Embryo / Fetal Development, Not teratogenic  
Maternal toxicity  
Species: Mouse  
Organ: Oral

40 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** Based on available data, the classification criteria are not met.

**Other information** The antigens included in this product are non-infectious. All have been prepared from modified 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)			
<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
<b>Persistence and degradability</b>	No data available for this product.		
<b>Bioaccumulative potential</b>	No data available for this product.		
<b>Mobility in soil</b>	No data available for this product.		
<b>Other adverse effects</b>	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

<b>Disposal methods</b>	Avoid release to the environment. Do not contaminate ponds, waterways or ditches with chemical or used container. 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.
<b>Residual waste</b>	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).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

<b>ADG</b>	Not regulated as dangerous goods.
<b>RID</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not established.

### 15. Regulatory information

#### Safety, health and environmental regulations

**National regulations** This Safety Data Sheet was prepared in accordance with the Australia Model Code of Practice for the preparation of safety data sheets for hazardous chemicals.

APVMA approval number: 60278

This SDS replaces version: Issued September 2014

**Australia Medicines & Poisons Appendix A**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix B**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix D**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix E**

Formaldehyde (CAS 50-00-0)  
Mineral oil, white (CAS 8042-47-5)

**Australia Medicines & Poisons Appendix F**

Formaldehyde (CAS 50-00-0)

**Australia Medicines & Poisons Appendix G**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix H**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix I**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix J**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix K**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 10**

Formaldehyde (CAS 50-00-0)



**Australia Medicines & Poisons Schedule 2**

Formaldehyde (CAS 50-00-0)

**Australia Medicines & Poisons Schedule 3**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 4**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 5**

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

**Australia Medicines & Poisons Schedule 6**

Formaldehyde (CAS 50-00-0)

**Australia Medicines & Poisons Schedule 7**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 8**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 9**

Poisons schedule number not allocated.

**Australia National Pollutant Inventory (NPI): Threshold quantity**

Formaldehyde (CAS 50-00-0)

10 TONNES/YR Threshold Category: 1

**High Volume Industrial Chemicals (HVIC)**

Formaldehyde (CAS 50-00-0)

10000 - 99999 TONNES See the regulation for additional information.

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

1000 - 9999 TONNES See the regulation for additional information.

**Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)**

Not listed.

**National Pollutant Inventory (NPI) substance reporting list**

Not listed.

**Prohibited Carcinogenic Substances**

Not regulated.

**Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)**

Not listed.

**Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)**

Not listed.

**Restricted Carcinogenic Substances**

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

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

<b>Issue date</b>	29-August-2019
<b>Disclaimer</b>	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.
<b>Revision information</b>	Product and Company Identification: Synonyms Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Multiple Properties GHS: Classification