

SAFETY DATA SHEET



1. Identification

Product identifier	Poulvac E. Coli
Other means of identification	
Synonyms	POULVAC® * Escherichia Coli Vaccine, Live Culture
Recommended use of the chemical and restrictions on use	
Recommended use	Veterinary vaccine
Restrictions on use	Not for human use
Details of manufacturer or importer	
Company Name (AU)	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA
Tel	1800 814 883
Fax	(02) 8876 0444
Email	australia.animalhealth@zoetis.com
Emergency Phone	1800 814 883 (all hours)
Police and Fire Brigade	Dial 000
If ineffective	Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.

Label elements, including precautionary statements

Hazard symbol(s)	None.
Signal word	None.
Hazard Statement(s)	The mixture does not meet the criteria for classification.
Precautionary Statement(s)	
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 which do not result in classification None known.

Supplemental information May cause hypersensitivity reactions in susceptible individuals. Direct contact with eyes may cause temporary irritation. May cause skin irritation.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Ammonium sulfate	7783-20-2	<3
Potassium phosphate	7778-77-0	<3
Escherichia coli, live	Not assigned	
Sucrose	57-50-1	

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	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Call a physician or poison control centre immediately. Do not induce vomiting without advice from poison control center.
Personal protection for first-aid responders	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.
Symptoms caused by exposure	Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. Allergic reactions are possible. Dermatitis. Rash. Coughing.
Medical attention and special treatment	Treat symptomatically.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water spray. Alcohol resistant foam. 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 fire fighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Use water spray to cool unopened containers.

Hazchem Code None.

General fire hazards No unusual fire or explosion hazards noted.

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.
For emergency responders	Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Keep unnecessary personnel away. Ventilate the contaminated area. Avoid the generation of dusts during clean-up. Do not breathe dust. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

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

Methods and materials for containment and cleaning up Ensure adequate ventilation.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

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 Use only in well-ventilated areas. Wear personal protective equipment. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with eyes, skin, and clothing. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Avoid release to the environment. Use care in handling/storage.

Conditions for safe storage, including any incompatibilities Store in a well-ventilated place. @ 2 - 7°C (36 - 45°F). Store in original tightly closed container. 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	Form
Sucrose (CAS 57-50-1)	TWA	10 mg/m ³	Inhalable dust.

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

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	TWA	10 mg/m ³	Inspirable dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
Sucrose (CAS 57-50-1)	TWA	10 mg/m ³

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Sucrose (CAS 57-50-1)	STEL	20 mg/m ³
	TWA	10 mg/m ³

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

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. 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 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. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure.

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

Powder.

Physical state

Solid.

Form

Solid.

Colour

Pale yellow to Reddish white

Odour

Odourless.

Odour threshold

Not available.

pH

6 - 8

Melting point/freezing point

Not available.

Initial boiling point and boiling range

100 °C (212 °F)

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

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.

Incompatible materials Strong oxidising agents.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information

Information on possible routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact No adverse effects due to skin contact are expected. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. May cause skin irritation.

Eye contact Direct contact with eyes may cause temporary irritation.

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. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. Allergic reactions are possible. Dermatitis. Rash. Coughing.

Acute toxicity May be harmful if swallowed.

Components	Species	Test results
------------	---------	--------------

Sucrose (CAS 57-50-1)

Acute

Oral

LD50

Rat

29.7 g/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

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

Respiratory or skin sensitisation

Respiratory sensitisation Not a respiratory sensitizer.

Skin sensitisation This product is not expected to cause skin sensitisation.
Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity
 Sucrose

Bacterial Mutagenicity (Ames)
 Result: negative
 Species: Salmonella

Carcinogenicity Due to partial or complete lack of data the classification is not possible.

ACGIH Carcinogens

Sucrose (CAS 57-50-1)

A4 Not classifiable as a human carcinogen.

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

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

Other information The antigens included in this product are non-infectious. All have been prepared from attenuated preparations of microorganisms. May cause hypersensitivity reactions in susceptible individuals.

12. Ecological information

Ecotoxicity 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
Ammonium sulfate (CAS 7783-20-2)		
Aquatic		
Crustacea	EC50	Water flea (Ceriodaphnia dubia) 52 - 67 mg/l, 48 hours
Fish	LC50	Rainbow trout, donaldson trout (Oncorhynchus mykiss) 35.2 - 43.8 mg/l, 96 hours

Persistence and degradability

Bioaccumulative potential

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 methods Avoid release to the environment. 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.

Residual waste 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. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

ADG

Not regulated as dangerous goods.

RID

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 applicable.

15. Regulatory information**Safety, health and environmental regulations**

National regulations This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

APVMA No. 80300

Australia Medicines & Poisons Appendix E

ALKALINE SALTS (CAS 7778-77-0)

Australia Medicines & Poisons Appendix F

ALKALINE SALTS (CAS 7778-77-0)

Australia Medicines & Poisons Schedule 10

ALKALINE SALTS, BEING THE CARBONATE, SILICATE OR PHOSPHATE SALTS OF SODIUM OR POTASSIUM ALONE OR IN ANY COMBINATION (CAS 7778-77-0)

Australia Medicines & Poisons Schedule 5

ALKALINE SALTS, BEING THE CARBONATE, SILICATE OR PHOSPHATE SALTS OF SODIUM OR POTASSIUM ALONE OR IN ANY COMBINATION, EXCEPT WHEN SEPARATELY SPECIFIED IN THESE SCHEDULES (CAS 7778-77-0)

Australia Medicines & Poisons Schedule 6

ALKALINE SALTS, BEING THE CARBONATE, SILICATE OR PHOSPHATE SALTS OF SODIUM OR POTASSIUM ALONE OR IN ANY COMBINATION, EXCEPT WHEN SEPARATELY SPECIFIED IN THESE SCHEDULES (CAS 7778-77-0)

High Volume Industrial Chemicals (HVIC)

Ammonium sulfate (CAS 7783-20-2)

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

Country(s) or region	Inventory name	On inventory (yes/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
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	06-December-2016
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	Product and Company Identification: Physical States Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Multiple Properties