

SAFETY DATA SHEET



1. Identification

Product identifier Poulvac® Newcastle V4

Other means of identification

Synonyms Newcastle V4

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 Direct contact with eyes may cause temporary irritation. Allergic reactions are possible.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Potassium phosphate	7778-77-0	<1
Gentamicin	1403-66-3	##
Newcastle disease virus, strain V4	Not assigned	
Nystatin	1400-61-9	##

Composition comments ## Trace

4. First-aid measures

Description of necessary first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.
Skin contact	Wash off with soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Eye contact	Do not rub eyes. 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	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	For personal protection, see section 8 of the SDS. 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.
Symptoms caused by exposure	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Allergic reactions are possible. 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.
Medical attention and special treatment	Provide general supportive measures and treat symptomatically.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical 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	Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.
For emergency responders	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. Wear appropriate protective equipment and clothing during clean-up. Remove sources of ignition. Avoid release to the environment.

Large Spills: Contain the source of the spill if it is safe to do so. 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.

For waste disposal, see section 13 of the SDS.

7. Handling and storage

Precautions for safe handling Wear personal protective equipment. Avoid formation of dust and aerosols. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with eyes, skin, and clothing. 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 below -5°C (freeze). Store away from direct sunlight. Protect from heat and light. 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 No exposure limits noted for ingredient(s).
Biological limit values No biological exposure limits noted for the ingredient(s).
Exposure guidelines No exposure standards allocated.
Control banding approach Gentamicin: Zoetis OEB 2 (control exposure to the range of 100ug/m3 to < 1000ug/m3)

Nystatin: Zoetis OEB 3 (control exposure to the range of 10ug/m3 to < 100ug/m3)

Appropriate engineering controls Provide adequate general and local exhaust ventilation. 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. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

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 Freeze-dried preparation

Physical state Solid.

Form Solid.

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 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. Sunlight. Exposure to light. High temperatures.
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.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not known or expected under normal use.

Symptoms related to exposure Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Allergic reactions are possible. 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.

Acute toxicity Allergic reactions are possible.

Components	Species	Test results
Nystatin (CAS 1400-61-9)		
Acute		
Oral		
LD50	Rat	10000 mg/kg
Potassium phosphate (CAS 7778-77-0)		
Acute		
Oral		
LD50	Mouse	1700 mg/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	Due to partial or complete lack of data the classification is not possible. As with any protein, the pos exists.
Skin sensitisation	Due to partial or complete lack of data the classification is not possible. As with any protein, the possibility of allergic reactions exists.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	Due to partial or complete lack of data the classification is not possible.
Reproductive toxicity	Due to partial or complete lack of data the classification is not possible. This product is not expected to cause reproductive or developmental effects.
Specific target organ toxicity - single exposure	Due to partial or complete lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Due to partial or complete lack of data the classification is not possible.
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.

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.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
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 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.
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.

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).

This SDS replaces version: Issued December, 2017

Poison Schedule (Product) – Schedule 0

APVMA No. 42019

Australia Medicines & Poisons Appendix E

ALKALINE SALTS (CAS 7778-77-0)

Australia Medicines & Poisons Appendix F

ALKALINE SALTS (CAS 7778-77-0)

Nystatin (CAS 1400-61-9)

Australia Medicines & Poisons Appendix H

Nystatin (CAS 1400-61-9)

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 2

Nystatin (CAS 1400-61-9)

Australia Medicines & Poisons Schedule 3

Nystatin (CAS 1400-61-9)

Australia Medicines & Poisons Schedule 4

Gentamicin (CAS 1403-66-3)

Nystatin (CAS 1400-61-9)

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)

Not listed.

Importation of Ozone Depleting 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
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

02-February-2018

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: Synonyms
Composition / Information on Ingredients: Ingredients