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:

<table>
<thead>
<tr>
<th>Identity of chemical ingredients</th>
<th>CAS number and other unique identifiers</th>
<th>Concentration of ingredients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium phosphate</td>
<td>7778-77-0</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>##</td>
</tr>
<tr>
<td>Newcastle disease virus, strain V4</td>
<td>Not assigned</td>
<td>##</td>
</tr>
<tr>
<td>Nystatin</td>
<td>1400-61-9</td>
<td>##</td>
</tr>
</tbody>
</table>

Composition comments: ## Trace

Material name: Poulvac® Newcastle V4

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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
Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Suitable extinguishing media

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.
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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nystatin (CAS 1400-61-9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>10000 mg/kg</td>
</tr>
<tr>
<td>Potassium phosphate (CAS 7778-77-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Mouse</td>
<td>1700 mg/kg</td>
</tr>
</tbody>
</table>

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 possibility of allergic reactions 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 Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)
Not listed.

National Pollutant Inventory (NPI) substance reporting list
Not listed.

Prohibited Carcinogenic Substances
Not listed.

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 listed.

International regulations

Stockholm Convention
Not applicable.

Rotterdam Convention
Not applicable.

Kyoto protocol
Not applicable.

Montreal Protocol
Not applicable.

Basel Convention
Not applicable.
International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
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<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A “Yes” indicates that all components of this product comply with the inventory requirements administered by the governing country(s) of the product. 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