

SAFETY DATA SHEET



1. Identification

Product identifier	Poulvac® Newcastle iK Vaccine	
Other means of identification		
Synonyms	Poulvac Newcastle iK * Newcastle disease vaccine	
Recommended use of the chemical and restrictions on use		
Recommended use	Veterinary vaccine	
Restrictions on use	Not available.	
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	productsupport.au@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	Serious eye damage/eye irritation	Category 2A
Environmental hazards	Not classified.	

Label elements, including precautionary statements

Hazard symbol(s)



Exclamation
mark

Signal word	Warning
Hazard statement(s)	Causes serious eye irritation.

Precautionary statement(s)

Prevention	Wash thoroughly after handling. Wear eye protection/face protection.
Response	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.

Supplemental information

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.

Other hazards which do not result in classification	None known.
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3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Mineral oil, white	8042-47-5	50-80
Formaldehyde	50-00-0	<0.1
Newcastle Disease Virus, killed	Not assigned	

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	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. 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.
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. Continue rinsing.
Ingestion	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. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. For personal protection, see section 8 of the SDS. 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.

Symptoms caused by exposure Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Exposure may cause temporary irritation, redness, or 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. Keep victim under observation. Symptoms may be delayed. Self Injection: This product contains mineral oil. In the event of accidental self-administration, it can cause significant pain and prolonged swelling for 6 to 24 months at the injection site, perhaps also involving the draining lymph nodes. Medical or surgical intervention may be required, especially if the site of injection involves a finger joint or tendon sheath. Accidental self-injection of this vaccine may result in cross- reaction with, and a false positive test results for human tuberculosis. Cases of accidental self-injection should also be reported to Zoetis on 1800 814 883.

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 (CO₂).

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 Cool containers exposed to heat with water spray and remove container, if no risk is involved.

Hazchem code None.

General fire hazards Combustible. Material will burn in a fire.

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.

For emergency responders Keep unnecessary personnel away. Ensure adequate ventilation. 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 Avoid release to the environment. Remove sources of ignition. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. 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 Avoid accidental injection. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Refrigeration recommended. 2 - 8°C (36 - 46°F). Do not freeze. Keep away from heat, sparks and open flame. Store in original tightly closed container. Use care in handling/storage. 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 ³
		2 ppm
	TWA	1.2 mg/m ³
Mineral oil, white (CAS 8042-47-5)		1 ppm
	TWA	5 mg/m ³

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/m3	Inhalable fraction.

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	2.5 mg/m3	
	TWA	2 ppm 2.5 mg/m3 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/m3	
		0.3 ppm	
Mineral oil, white (CAS 8042-47-5)	TWA	5 mg/m3	Respirable fraction.

Biological limit values

No biological exposure limits noted for the ingredient(s).

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. Provide eyewash station.

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

In case of insufficient ventilation, wear suitable respiratory equipment. 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. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely.

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**

Oily. Suspension.

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	
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	Keep away from heat, sparks and open flame. High temperatures. Contact with incompatible materials.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

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	Prolonged skin contact may cause temporary irritation. Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.
Formaldehyde	Species: Rabbit Severity: Moderate to Severe
Mineral oil, white	Species: Rabbit Severity: Slight
Eye contact	Causes serious eye 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 Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. 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)		
Acute		
Dermal		
LD50	Rabbit	270 mg/kg
Inhalation		
LC50	Mouse	0.414 mg/l, 4 hours
	Rat	0.48 mg/l, 4 hours
Oral		
LD50	Rat	100 mg/kg
Chronic		
Inhalation		
LOAEL	Mouse	15 ppm, 2 years Tumours
	Rat	15 ppm, 90 days Respiratory system
		6 ppm, 2 years Tumours
Mineral oil, white (CAS 8042-47-5)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.		
Corrosivity		
Mineral oil, white	Species: Rabbit	Severity: Slight
Serious eye damage/irritation Causes serious eye irritation.		
Eye contact		
Formaldehyde	Species: Rabbit	Severity: Severe
Mineral oil, white	Species: Rabbit	Severity: Slight
Respiratory or skin sensitisation		
ACGIH sensitisation		
Formaldehyde (CAS 50-00-0)	Dermal sensitisation	Respiratory sensitisation
Respiratory sensitisation Due to partial or complete lack of data the classification is not possible. In the event of accidental injection, an allergic reaction may occur.		
Skin sensitisation Due to partial or complete lack of data the classification is not possible. This product contains formaldehyde which is considered to be a skin sensitizer. In the event of accidental injection, an allergic reaction may occur.		
Skin Sensitisation		
Formaldehyde	Species: Guinea Pig	Severity: positive

Germ cell mutagenicity

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity
Formaldehyde

In Vitro Bacterial Mutagenicity (Ames)

Result: positive
Species: Bacteria

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

No data available to indicate product or any components present at greater than 0.1% are carcinogenic. Due to partial or complete lack of data the classification is not possible.

ACGIH Carcinogens

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

A1 Confirmed human carcinogen.
A2 Suspected human carcinogen.
A4 Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0)

1 Carcinogenic to humans.

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.

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

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 killed or inactivated preparations of microorganisms.

12. Ecological information**Ecotoxicity**

Avoid release to the environment. 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.

Components**Species****Test Results**

Formaldehyde (CAS 50-00-0)

Aquatic

Crustacea

EC50

Daphnia magna (Water Flea)

42 mg/l, 24 Hours

Fish

LC50

Oncorhynchus mykiss (rainbow trout)

118 ppm, 96 Hours

Components	Species	Test Results
<i>Acute</i>		
Crustacea	EC50	Water flea (<i>Daphnia pulex</i>) >= 4.3 - <= 7.8 mg/l, 48 hours
Fish	LC50	Bluegill (<i>Lepomis macrochirus</i>) 8.7 mg/l, 96 hours
Persistence and degradability	No data is available on the degradability of this product.	
Bioaccumulative potential	No data available for this product. Not expected to bioaccumulate.	
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. Dispose of contents/container in accordance with local/regional/national/international regulations. 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.
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.
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 established.

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. APVMA Approval No.: 59138 Poison Schedule (Product): Schedule 0
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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 Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Formaldehyde (CAS 50-00-0)

2000 TONNES/YR Threshold Category: 2B

400 TONNES/YR Threshold Category: 2A

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

Australia

Inventory name

Australian Inventory of Industrial Chemicals (AICIS)

On inventory (yes/no)*

No

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

Issue date	02-February-2018
Revision date	19-December-2022
Key abbreviations or acronyms used	AICIS: Australian Inventory of Industrial Chemicals.
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	This document has undergone significant changes and should be reviewed in its entirety.