

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 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. 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 (%)
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.
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	IF exposed or concerned: Get medical advice/attention. 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. 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. 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	Treat symptomatically. 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 (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	Cool containers exposed to heat with water spray and remove container, if no risk is involved.
Hazchem Code	None.
General fire hazards	Material will burn in a fire. Combustible.
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. 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.

Contain the source of the spill if it is safe to do so. Absorb spillage with non-combustible, absorbent material. 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 contact with eyes, skin, and clothing. Avoid breathing mist or vapour. Wash thoroughly after handling. When using, do not eat, drink or smoke. Wear personal protective equipment. 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. Store in original tightly closed container. Keep away from heat, sparks and open flame. 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
	TWA	2 ppm 1.2 mg/m ³ 1 ppm
Mineral oil, white (CAS 8042-47-5)	TWA	5 mg/m ³

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 ³	
	TWA	2 ppm 1.2 mg/m ³ 1 ppm	
Mineral oil, white (CAS 8042-47-5)	TWA	5 mg/m ³	Mist.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	0.3 ppm	
	TWA	0.1 ppm	

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Mineral oil, white (CAS 8042-47-5)	TWA	5 mg/m ³	Inhalable fraction.

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	2.5 mg/m ³
	TWA	2 ppm
		2.5 mg/m ³
		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 ³	
Mineral oil, white (CAS 8042-47-5)	TWA	0.3 ppm	Respirable fraction.
		5 mg/m ³	

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.

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. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.

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

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 and open flame. High temperatures.

Incompatible materials Strong oxidising agents.

Hazardous decomposition products No hazardous decomposition products are known. 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 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
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Formaldehyde (CAS 50-00-0)

Acute

Dermal

LD50	Rabbit	270 mg/kg
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Inhalation

LC50	Mouse	0.414 mg/l, 4 hours
	Rat	0.48 mg/l, 4 hours

Oral

LD50	Rat	100 mg/kg
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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
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Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

Mineral oil, white	Species: Rabbit Severity: Slight
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Serious eye damage/irritation Direct contact with eyes may cause temporary irritation.

Eye contact

Formaldehyde	Species: Rabbit Severity: Severe
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Mineral oil, white	Species: Rabbit Severity: Slight
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Respiratory or skin sensitisation

ACGIH sensitisation

FORMALDEHYDE (CAS 50-00-0)	Dermal sensitization Respiratory sensitisation
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Respiratory sensitisation Due to partial or complete lack of data the classification is not possible. In the event of accidental in 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
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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 Due to partial or complete lack of data the classification is not possible. No data available to indicate product or any components present at greater than 0.1% are carcinogenic.

ACGIH Carcinogens

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

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

IARC Monographs. Overall Evaluation of Carcinogenicity

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

1 Carcinogenic to humans.
3 Not classifiable as to carcinogenicity 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 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)	EC50	Daphnia magna (Water Flea)	42 mg/l, 24 Hours
	LC50	Oncorhynchus mykiss (Rainbow Trout)	118 ppm, 96 Hours
Aquatic			
	Crustacea	Water flea (Daphnia pulex)	4.3 - 7.8 mg/l, 48 hours
Fish	LC50	Striped bass (Morone saxatilis)	10.302 - 16.743 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. 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 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 (23/12/2011).

This SDS replaces version: Issued December, 2017

Australia Medicines & Poisons Appendix E

FORMALDEHYDE (ALSO SEE PARAFORMALDEHYDE) (CAS 50-00-0)
HYDROCARBONS, LIQUID (CAS 8042-47-5)

Australia Medicines & Poisons Appendix F

FORMALDEHYDE (IN NAIL HARDENER COSMETICS) (CAS 50-00-0)

Australia Medicines & Poisons Schedule 10

FORMALDEHYDE (EXCLUDING ITS DERIVATIVES) (CAS 50-00-0)

Australia Medicines & Poisons Schedule 2

FORMALDEHYDE (EXCLUDING ITS DERIVATIVES) (CAS 50-00-0)

Australia Medicines & Poisons Schedule 5

HYDROCARBONS, LIQUID, INCLUDING KEROSENE, DIESEL (DISTILLATE), MINERAL TURPENTINE, WHITE PETROLEUM SPIRIT, TOLUENE, XYLENE AND LIGHT MINERAL AND PARAFFIN OILS (BUT EXCLUDING THEIR DERIVATIVES) (CAS 8042-47-5)

Australia Medicines & Poisons Schedule 6

FORMALDEHYDE (EXCLUDING ITS DERIVATIVES) (CAS 50-00-0)

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
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.