SAFETY DATA SHEET



1. Identification

Product identifier Poulvac® Newcastle iK Vaccine

Other means of identification

Poulvac Newcastle iK * Newcastle disease vaccine **Synonyms**

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 (02) 8876 0444 Fax

Email productsupport.au@zoetis.com 1800 814 883 (all hours)

Emergency Phone

Police and Fire Brigade Dial 000

Dial Poisons Information Centre (13 1126 from anywhere in Australia) If ineffective

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

Warning Signal word

Causes serious eye irritation. Hazard statement(s)

Precautionary statement(s)

Wash thoroughly after handling. Wear eye protection/face protection. Prevention

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present Response

and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Store away from incompatible materials. Storage

Dispose of waste and residues in accordance with local authority requirements. Disposal

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.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other Concentration o unique identifiers 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

Inhalation

responders

Description of necessary first aid measures

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. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove **Eve contact**

contact lenses, if present and easy to do. Continue rinsing.

Call a physician or poison control centre immediately. Only induce vomiting at the instruction of Ingestion

medical personnel. Never give anything by mouth to an unconsious person. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware Personal protection for first-aid

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. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred Symptoms caused by exposure

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

Methods and materials for containment and cleaning up Avoid discharge into drains, water courses or onto the ground.

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	Туре	Value	
Formaldehyde (CAS 50-00-0)	STEL	2.5 mg/m3	
		2 ppm	
	TWA	1.2 mg/m3	
		1 ppm	
Mineral oil, white (CAS 8042-47-5)	TWA	5 mg/m3	

US. ACGIH Threshold Limit Valu Components	es 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	Туре	Value	
Formaldehyde (CAS 50-00-0)	STEL	2.5 mg/m3	
		2 ppm	
	TWA	2.5 mg/m3	

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

in the Work Area (Br G)			
Components	Туре	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.

2 ppm

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 Not available.

Material name: Poulvac® Newcastle iK Vaccine

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 pressureNot available.Vapour densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water)Not available.Partition coefficientNot available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other physical and chemical parameters

Explosive properties Not explosive. **Oxidising properties** Not oxidising.

10. Stability and reactivity

ReactivityThe 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

May be harmful if swallowed. However, ingestion is not likely to be a primary route of

Mineral oil, white Species: Rabbit Severity: Slight

occupational exposure.

Ingestion

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

Components

Expected to be a low hazard for usual industrial or commercial handling by trained

personnel.

Species

Formaldehyde (CAS 50-00-0)

Test Results

<u>Acute</u>

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.

Not an aspiration hazard. **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.

Species **Test Results**

Components Formaldehyde (CAS 50-00-0) Aquatic EC50 42 mg/l, 24 Hours Daphnia magna (Water Flea) Crustacea Fish LC50 Oncorhynchus mykiss (rainbow trout) 118 ppm, 96 Hours

Material name: Poulvac® Newcastle iK Vaccine

SDS AUSTRALIA

Components Species Test Results

Acute

Crustacea EC50 Water flea (Daphnia pulex) >= 4.3 - <= 7.8 mg/l, 48 hours

Fish LC50 Bluegill (Lepomis macrochirus) 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 methodsAvoid 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

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 Deleting 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.

Resricted 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 Industrial Chemicals (AICIS)

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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 date02-February-2018Revision date19-December-2022

Key abbreviations or acronyms

used

AICIS: Australian Inventory of Industrial Chemicals.

DisclaimerZoetis 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 informationThis document has undergone significant changes and should be reviewed in its entirety.