

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	Ingelvac CircoFLEX
Product code:	A009935
Recommended use:	For active immunisation of pigs from two weeks of age and older as an aid in the prevention and control of porcine circovirus type 2 associated diseases caused by porcine circovirus type 2.
Company details:	Boehringer Ingelheim Animal Health New Zealand Limited
Address:	Level 3, Boehringer Ingelheim Building 2 Osterley Way Manukau City Auckland 2104 New Zealand
Telephone number:	Phone: +64 9 263 1400
Emergency telephone number:	Boehringer Ingelheim Freephone: 0800 800 822 National Poisons Centre : 0800 764 766 (0800 POISON) Fire Service, Ambulance : Dial 111
Date of issue:	17 May 2018
Date of review:	4 February 2020

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Liquid

Product components:

<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
Additives	Proprietary	0-100%
Inactivated baculo-expressed PCV2 ORf2	N/A	0-100%

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	Not classified as Hazardous according to the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001, New Zealand. Not classified as Dangerous Goods for transport according to the New Zealand Standard NZS 5433:2012 Transport of Dangerous Goods on Land.
Priority and secondary identifiers:	N/A
Risk and safety phrases:	N/A

SECTION 4: FIRST AID MEASURES

Necessary first aid measures:	<p>For advice, contact the National Poisons Centre on 0800 POISON (0800 764 766), or a doctor immediately. Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.</p> <p><u>Ingestion:</u> Do NOT induce vomiting. Wash out mouth thoroughly with water. Seek medical attention.</p> <p><u>Eyes:</u> If in eyes, hold eyelids apart and flush the eyes continuously with running water. Remove contact lenses. Continue flushing for several minutes until all contaminants are washed out completely. If symptoms develop, seek medical attention.</p> <p><u>Skin:</u> Wash affected area thoroughly with soap and water. If symptoms develop, seek medical attention. In case of self-injection, seek immediate medical attention.</p>
--------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

SAFETY DATA SHEET

Product Name: Ingelvac CircoFLEX

Page 2 of 5
Reviewed on: 4 February 2020

Workplace facilities:	<u>Inhalation:</u> Not a likely source of exposure. However if inhaled, remove affected person from contaminated area to fresh air. Keep at rest until recovered. If symptoms develop, seek medical attention.
Required instructions:	No special facilities required.
Notes for medical personnel:	Observe good work practices and avoid skin contact. Wash hands and exposed skin before meals and after use. Do not eat or drink while using. Launder protective clothing separately from other clothing, and before each reuse. Treat symptomatically. For animal injection only. Not for human use. Antidote: Epinephrine is indicated for anaphylactoid reactions.

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:	Non combustible
Fire hazard properties:	Under fire conditions this product may emit toxic and/or irritating fumes and gases including carbon monoxide and carbon dioxide.
Extinguishing media and methods:	Use foam, carbon dioxide, dry powder or water fog.
Hazchem code:	N/A
Recommended protective clothing:	Fire fighters should wear full protective clothing and self-contained breathing apparatus operated in positive pressure mode. Fight fire from safe location.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures:	Wear appropriate personal protective equipment and clothing. For a small liquid spill: Wipe up or soak up using an inert non-combustible absorbent material. Collect the material and place into a suitable labelled container for disposal. If contamination of sewers or waterways occurs, inform the local water and waste management authorities in accordance with local regulations. For a large liquid spill: Increase ventilation. If possible, contain the spill. Place inert absorbent material onto spillage. Collect the material and place into a suitable labelled container. Do not dilute material but contain. Dispose of waste according to the applicable local and national regulations. If contamination of sewers or waterways occurs, inform the local water and waste management authorities in accordance with local regulations.
------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:	Use only in a well ventilated area. Prevent the buildup of mists or vapours in the work atmosphere. Avoid contact with clothing, skin or eyes and accidental injection. Use entire contents when first opened. Sterilise all injection apparatus before use. Avoid the use of strong disinfectants. Inject a single 1mL dose irrespective of body weight. If possible, avoid injection during wet weather or dusty conditions. Maintain high standards of personal hygiene i.e. Washing hands prior to eating, drinking, smoking or using toilet facilities.
Approved handlers:	Not required
Conditions for safe storage:	Store in a cool, dry, well-ventilated area, out of direct sunlight. Store in suitable, labelled containers. Keep containers closed when not in use. Store away from incompatible materials. Ensure that storage conditions comply with applicable local and national regulations.

SAFETY DATA SHEET

Product Name: Ingelvac CircoFLEX

Page 3 of 5
Reviewed on: 4 February 2020

Store site requirements: Store at temperatures between 2 °C and 8 °C. Do not freeze. Protect from light.

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure standards: No exposure standards have been established for the mixture. However, over-exposure to some chemicals may result in enhancement of pre-existing adverse medical conditions and/or allergic reactions and should be kept to the least possible levels.

Application in the workplace: Prevent exposure by using engineering controls, personal protective equipment and work practices that prevent skin contact.

Engineering controls: None required, when used as intended. However, if there is risk of airborne exposure, use with good general ventilation. If mists or vapours are produced, local exhaust ventilation should be used.

Personal protection:

Respiratory Protection
None required, when used as intended. However, if engineering controls are not effective in controlling airborne exposure then an approved respirator with a replaceable vapor/mist filter should be used. Refer to relevant regulations for further information concerning respiratory protective requirements.¹

Eye Protection
Safety glasses with side shields, chemical goggles or full-face shield as appropriate should be used. Final choice of appropriate eye/ face protection will vary according to individual circumstances. Eye protection devices should conform to relevant regulations.²

Hand Protection
None required, when used as intended. However, where exposure to the contents is likely wear gloves of impervious material. Final choice of appropriate gloves will vary according to individual circumstances, i.e. methods of handling or according to risk assessments undertaken. Occupational protective gloves should conform to relevant regulations.³

Body Protection
Suitable protective workwear, e.g. cotton overalls buttoned at neck and wrist is recommended. Chemical resistant apron is recommended where large quantities are handled.

References:

1. Reference should be made to Australian Standards AS/ NZS 1715, Selection, Use and Maintenance of Respiratory Protective Devices; and AS/NZS 1716, Respiratory Protective Devices, in order to make any necessary changes for individual circumstances.
2. Eye protection should conform with Australian/New Zealand Standard AS/NZS 1337 - Eye Protectors for Industrial Applications.
3. Reference should be made to AS/NZS 2161.1: Occupational protective gloves - Selection, use and maintenance.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data:

Formulation type: Liquid
Appearance: Clear liquid in multi-dose vials: 10, 50, 100, 250 and 500 mL bottles
Odour: Odourless
Boiling Point: Not available
Vapour Pressure: Not available
Flammability: Non-combustible
Solubility in Water: Not available

SAFETY DATA SHEET

Product Name: Ingelvac CircoFLEX

Page 4 of 5
Reviewed on: 4 February 2020

SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:	Stable under normal conditions of use and storage. Reacts with incompatible materials.
Conditions to avoid:	Extremes of temperature and direct sunlight.
Material to avoid:	Strong oxidizing agents.
Hazardous decomposition products:	Under fire conditions this product may emit toxic and/or irritating fumes and gases including carbon monoxide and carbon dioxide.
Hazardous polymerization:	Will not occur.
Specific data:	N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Data:	No toxicity data available for this material.
	Ingestion Ingestion unlikely due to form of product. Ingestion of this product may irritate the gastric tract causing nausea and vomiting or other systemic effects.
	Inhalation Not a likely source of exposure. Inhalation of product vapours may cause irritation of the nose, throat and respiratory system.
	Skin May cause mild transient skin irritation. After injection, animals developing anaphylactic (life threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.
	Eye Unlikely due to form of product. May cause mild transient eye irritation.
	Respiratory sensitisation Not expected to be a respiratory sensitiser.
	Skin Sensitisation Not expected to be a skin sensitiser.
	Germ cell mutagenicity Not considered to be a mutagenic hazard.
	Carcinogenicity Not considered to be a carcinogenic hazard.
	Reproductive Toxicity Not considered to be toxic to reproduction.
	STOT-single exposure Not expected to cause toxicity to a specific target organ.
	STOT-repeated exposure Not expected to cause toxicity to a specific target organ.
	Aspiration Hazard Not expected to be an aspiration hazard.
	Other Information Possible hypersensitization (development of abnormal sensitivity).

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:	N/A
Data organisation :	Persistence and degradability Not available
	Mobility Not available
	Bioaccumulative Potential Not available
	Other Adverse Effects

SAFETY DATA SHEET

Product Name: Ingelvac CircoFLEX

Page 5 of 5
Reviewed on: 4 February 2020

	Not available
Environmental risk and safety phrases:	Do not discharge this material into waterways, drains and sewers.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :	The disposal of the spilled or waste material must be done in accordance with applicable local and national regulations. Used needles should be placed in a designated sharps container.
-------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

SECTION 14: TRANSPORT INFORMATION

Relevant information:	Not classified as dangerous for rail, road, air or sea transport.
Other requirements:	N/A

SECTION 15: REGULATORY INFORMATION

Regulatory status:	Registered pursuant to the ACVM Act 1997, No. A009935 See www.foodsafety.govt.nz for registration conditions
	Restricted Veterinary Medicine For use only under the authority or prescription of a veterinarian.
	Not classified as Hazardous according to the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001, New Zealand.
HSNO and ACVM controls:	Refer to Section 3

SECTION 16: OTHER INFORMATION

Additional information:	For product information visit the Boehringer Ingelheim website www.boehringer-ingelheim.co.nz While the information set forth is believed to be accurate as of the date hereof, BOEHRINGER INGELHEIM makes no warranty with respect hereto and disclaims all liability from reliance thereon.
--------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------