

MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Ingelvac® CircoFLEX™

Product No. : N/A

MSDS ID# : N/A

GHS Product Identifier: Not applicable

Synonyms: Not applicable

Molecular Formula: Mixture, not applicable

Molecular Weight: Not applicable

CAS Number: Mixture, not applicable

Chemical Family: Vaccine

Manufacturer:

Boehringer Ingelheim Vetmedica, Inc.

2621 North Belt Hwy

St. Joseph, MO 64506-2002

Emergency Telephone:

Transportation Emergency: (800) 424-9300

Medical Emergency (24HR): (800)530-5432

Intended Use:

Vaccination of healthy, susceptible pigs 3 weeks of age or older as an aid in the reduction of lymphoid depletion, inflammation and colonization of lymphoid tissue, viremia, nasal shedding of virus associated with Porcine Circovirus Type 2 (PCV2).

Non-emergency Telephone: (800) 821-7467

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Liquid; Multi-dose vials: 10, 50, 100, 250, and 500 mL bottles. 1 mL per dose

Color: Clear-yellowish

Odor: None



WARNING!

For swine injection only.

Not for human use.

Precautionary Statements:

Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.

Keep only in original container.

Keep at a temperature not exceeding 7° C.

Fire-fighting: Use foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Avoid contact with eyes, skin and clothing.

Wash thoroughly with soap and water after handling.

Wear suitable gloves and eye/face protection.

Spills: Cover with absorbent or contain. Collect and dispose.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed, seek medical advice immediately and show this container or label.

This material and its container must be disposed of in a safe way.

Keep out of reach of children.

Keep away from food, drink, and animal feedstuffs.

Acute effect:

Swelling at injection site may occur.

Precautions/Contraindications:

Use entire contents when first opened. Do not vaccinate within 21 days before slaughter.

Overdosage: None known

ADVERSE REACTIONS TO PRODUCT: Anaphylactoid reactions may occur.

Potential Health Effects

Inhalation: Not expected to be an inhalation hazard with prescribed use.

Eye Contact: Not expected to be a hazard to the eye with prescribed use. Exposure to liquid may cause mild transient eye irritation.

Skin Contact: Not expected to be a hazard to the skin with prescribed use. Exposure to liquid may cause mild transient skin irritation.

Ingestion: Not expected to be an ingestion hazard with prescribed use. Ingestion may cause vomiting, nausea or other systemic effects.

Injection: Swelling at injection site may occur.

Chronic Health Effects: Possible hypersensitization (development of abnormal sensitivity).

Target Organ(s): Immune System

Potential Physical Effects: None known. This is an inactivated vaccine and there should be no danger of reversion to virulence or potential for it to combine with field strains.

OSHA Regulatory Status: Non-hazardous, exempt

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Inactivated baculo-expressed PCV2 ORf2	----	----	proprietary	----	----
Additives	----	proprietary	proprietary	----	----

The components not listed are non-hazardous or below required disclosure limits.

4 FIRST AID MEASURES

General: Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

Inhalation: Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

Eye Contact: Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

Skin Contact: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Call a physician or poison control center. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Injection: In case of accidental injection, wash the site thoroughly. Contact a physician immediately.

Note to Physician: For animal injection only. Not for human use.

Antidote: Epinephrine is indicated for anaphylactoid reactions.

5 FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish with foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known

Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing.

Unusual Fire & Explosion Hazards: None known

Hazardous Combustion Products: Carbon monoxide, carbon dioxide

Flammability Class: 0

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear appropriate personal protective equipment.

Spill Cleanup Methods: Small liquid spill: Wipe up or use a non-combustible material like vermiculite, earth or sand to soak up the product and place into container for later disposal. For large liquid spill: Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers.

Environmental Precautions: Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

7 HANDLING AND STORAGE

Handling: Avoid contact with eyes, skin and clothing. Avoid accidental injection. Wash thoroughly with soap and water after handling. Use only with adequate ventilation.

Storage: Keep container closed. Store at 2°-7° C (35°-45° F). Do not freeze. Use entire contents when first opened.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

For Industrial Exposures:

Exposure Limits:

Chemical Name	Source	Type	Exposure Limits	Notes
Inactivated baculo-expressed PCV2 ORf2	----	----	N/A	----
Additives	----	----	N/A	----

Engineering Controls: Not generally required when handling vials or containers. Good 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.

Respiratory Protection: Not generally required when handling vials or containers. 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. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA standard 63 FR 1152, January 8, 1998. Respirator type: NIOSH approved organic vapor respirator.

PERSONAL PROTECTIVE EQUIPMENT: Not generally required when handling containers. If containers are compromised or exposure to the active ingredient or mixture is likely wear:

Eye Protection: Wear safety glasses with side shields (or goggles).

Hand Protection: Wear suitable gloves.

Skin Protection: Wear protective clothing appropriate for the risk of exposure.

Hygiene Measures: Eye bath, washing facilities

9	PHYSICAL AND CHEMICAL PROPERTIES
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Color: Clear-yellowish

Odor: None

Odor Threshold: No data available

Physical State: Multi-dose vials: 10, 50, 100, 250, and 500 mL bottles. 1 mL per dose.

pH: No data available

Melting Point: No data available

Freezing Point: No data available

Boiling Point: No data available

Flash Point: No data available

Flammability Limit – Upper (%): No data available

Flammability Limit – Lower (%): No data available

Evaporation rate: No data available

Vapor Pressure: No data available

Vapor Density (Air=1): No data available

Specific Gravity: No data available

Solubility: No data available

Partition Coefficient (n-Octanol/water): No data available

Autoignition Temperature: Not applicable

Decomposition Temperature: No data available

10	STABILITY AND REACTIVITY
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Stability: Stable

Conditions to Avoid: None known

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: None known

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

11	TOXICOLOGICAL INFORMATION
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Specified Substances

Acute Toxicity

Chemical Name	Test Results
Inactivated baculo-expressed PCV2 ORf2	None available

Listed Carcinogens: None

12	ECOLOGICAL INFORMATION
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Ecotoxicity: No data available

Persistence and degradability: No data available

Mobility in soil: No data available

Other adverse effects: No data available

Germany WGK: Proprietary Additive: Class: 1: slightly water-endangering

13	DISPOSAL CONSIDERATIONS
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General Information: Dispose of in accordance with local, state and federal regulations.

Disposal Methods: No specific disposal method required. Do not empty into drains; dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by storage disposal.

RCRA Information: Not applicable

Container: Since emptied containers retain product residue, follow label warnings even after container is emptied.

14	TRANSPORT INFORMATION
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DOT: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

15	REGULATORY INFORMATION
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Canadian Controlled Products Regulations: This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

WHMIS Classification: Noncontrolled, exempt

Inventory Status

Inactivated baculo-expressed PCV2 ORf2 is not listed on the following inventories: AICS (Australia), TSCA (United States), DSL (Canada), IECSC (China), EINECS (Europe), ENCS (Japan), KECI (Korea), ERMA (New Zealand), and PICCS (Philippines).

Proprietary additives are listed on the following inventories: AICS (Australia), IECSC (China), KECI (Korea), ERMA (New Zealand), and PICCS (Philippines). One additive is not listed on EINECS (Europe) but is listed as a common nomenclature of ingredients employed in cosmetic products (INCI) as amended by Decision 2006/257/EC (OJ (L97)1, 5 Apr 2006). One additive is not listed on TSCA, but it is classified under the TSCA polymer exemption. It is not listed on the DSL (Canada) but is regulated under the Food & Drugs Act. One additive is not listed on ENCS (Japan).

Canada CEPA Schedule 1 - None

US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4): None

SARA Title III

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): None

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): None

Massachusetts Right-To-Know List: None

Minnesota Hazardous Substances List: None

New Jersey Right-To-Know List: None

Pennsylvania Right-To-Know List: None

Rhode Island Right-To-Know List: None

European Regulations

Austria MAK List (Annex I): None

Denmark (Annex 3.6, April 2005): None

Germany (Dangerous Substances Ordinance 2004, Annex III): None

Norway (List of Dangerous Substance): None

Sweden (Sensitizers- Annex 3): None

Switzerland (Toxins List 1): None

16	OTHER INFORMATION
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Hazard Ratings

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	1	0	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	1	0	0	N/A

*- Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

This product has been reviewed and is classified and labeled as follows in full accord with EC Directive 67/548 and all other current applicable amending Directives, including, but not limited to, 91/155/EC, 1999/45/EC, 2001/58/EC and 2001/59/EC.

Not classified as hazardous

Handle in accordance with good industrial hygiene and safety practice.

References:

1. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
2. Control of Porcine Circovirus Diseases (PCVDS) towards improved Food Quality and Safety, www.pcvd.org.
3. GHS Manual
4. Ingelvac®, CircoFLEX™ Product Label, Boehringer Ingelheim Vetmedica, Inc.
5. Launch of Joint PCVD Discussion Forum; www.thepigsite.com.
6. RTECS
7. Swine Health Fact Sheet, Circovirus Infection in Swine; October 2002.

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

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Supercedes Date: New MSDS

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