MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Ingelvac® CircoFLEX - MycoFLEX™
Product No. : 129551000, APHIS # 49K5.R1
MSDS ID# : Not applicable
GHS Product Identifier: Not applicable

Synonyms:
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): (866) 638-2226

Non-emergency Telephone: (800) 821-7467

Intended Use: Recommended for the vaccination of healthy, susceptible swine 3 weeks of age or older as an aid in the prevention of lymphoid depletion, inflammation, and colonization of lymphoid tissue associated with Porcine Circovirus Type 2 (PCV2) and enzootic pneumonia of swine caused by *Mycoplasma hyopneumoniae.*

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Liquid solution of inactivated bacterin in two 250mL vials; one vial of Ingelvac® CircoFLEX and one vial of Ingelvac® MycoFLEX. Mix vials to 500mL. 2 mL per dose.
Color: Clear to yellow to slightly turbid rose to brown
Odor: No data available

WARNING!
For use in swine only.

Not for human use.
Allergic reactions can occur.

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 between 2 - 7° C.
Do not freeze.
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 incinerate.
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.

Description:

Recommended for the vaccination of healthy, susceptible swine 3 weeks of age or older as an aid in the prevention of lymphoid depletion, inflammation, and colonization of lymphoid tissue associated with Porcine Circovirus Type 2 (PCV2) and enzootic pneumonia of swine caused by *Mycoplasma hyopneumoniae.*

Shake well before using. Use entire contents when first opened. Using aseptic technique, inject a single 2 mL dose intramuscularly.

Acute effect: Rarely, severe allergic reactions may occur that require immediate veterinary care. Antidote: Epinephrine.

Precautions/Contraindications: Do not vaccinate within 21 days before slaughter.

Overdosage: None known.

ADVERSE REACTIONS TO PRODUCT: Anaphylactoid reactions may occur but are rare.

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 in eye may cause mild transient eye irritation.

Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions. May cause skin sensitization by contact.

Ingestion: Not expected to be an ingestion hazard with prescribed use. Ingestion may cause nausea and systemic effects.

Injection: Swelling at injection site may occur.

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

Target Organ(s): Gastrointestinal System, Respiratory System, Immune System

Potential Physical Effects: May cause skin sensitization.

OSHA Regulatory Status: Non-hazardous

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Inactivated baculo-expressed PCV2 ORf2	----	----	proprietary	----	----
Inactivated bacterin – *Mycoplasma hyopneumoniae*	----	----	proprietary	----	---
Additives	----	proprietary	proprietary	----	----
*Formaldehyde	2000018	50-00-0	≤ 0.74 g/L	23/24/25/ 34 40 43	---

The full texts for all R-Phrases are displayed in Section 16, if applicable.

* Used to inactivate virus and subsequently removed from solution. Concentration represents maximum remaining amount by percent weight which is below USDA allowable 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. If skin irritation or rash occurs, seek medical advice. Wash contaminated clothing before reuse.

Ingestion: Call a physician or poison control center immediately. 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 use in swine 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 (See Section 8).

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

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. Shake well before using. Use entire contents when first opened.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

For Industrial Exposures:

Exposure Limits:

Formaldehyde	ACGIH	8-HR TWA	0.3 ppm	Irritation, cancer
Formaldehyde	OSHA	Action	0.5 ppm	Cancer-suspect

		Level		agent
Formaldehyde	Austria	TWA	0.5 mg/m^3	Justifiably suspected of carcinogenic potential. Skin absorption. Sensitizer
Formaldehyde	Alberta	8-HR TWA	0.92 mg/m^3	Irritation
Formaldehyde	British Columbia	8-HR TWA	0.3 ppm	Capable of causing respiratory, dermal or conjunctival sensitization.
Formaldehyde	Ontario	8-HR TWA	1.5 mg/m^3	----
Formaldehyde	Quebec	Ceiling Exposure Value	3 mg/m^3	----
Formaldehyde	Belgium	15-minute STEL	0.38 mg/m^3	Irritant
Formaldehyde	Denmark	Ceiling	0.4 mg/m^3	----
Formaldehyde	Finland	8-HR Limit	0.37 mg/m^3	----
Formaldehyde	France	Short Term Limit	1 ppm	----
Formaldehyde	Germany	8-HR TWA	0.37 mg/m^3	
Formaldehyde	Greece	8-HR TWA	0.25 mg/m^3	----
Formaldehyde	Iceland	8-HR TWA	0.4 mg/ m^3	Allergenic substance
Formaldehyde	Ireland	8-HR TWA	2.5 mg/m^3	----
Formaldehyde	Italy	Ceiling limit	0.3 ppm	---
Formaldehyde	Netherlands	MAC TWA	1.5 mg/m^3	----
Formaldehyde	Norway	TLV	0.6 mg/m^3	Allergenic substance
Formaldehyde	Portugal	Ceiling Exposure limit	0.3 ppm	Sensitizer, suspected human carcinogen
Formaldehyde	Spain	15-minute STEL	0.37 mg/m^3	Sensitizer
Formaldehyde	Sweden	Level Limit Value (NGV)	0.6 mg/m^3	----
Formaldehyde	Switzerland	TWA	0.37 mg/m^3	Sensitizing substance
Formaldehyde	United Kingdom	TWA	2.5 mg/m^3	----

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.

Europe: Wear appropriate personal protective equipment according to the Council Directive 89/686/EEC (4) and the appropriate CEN standards.

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, shower

9 PHYSICAL AND CHEMICAL PROPERTIES

Color: Clear to yellow to slightly turbid rose to brown
Odor: No data available
Odor Threshold: No data available
Physical State: Liquid solution of inactivated bacterin in two 250mL vials; one vial of Ingelvac® CircoFLEX and one vial of Ingelvac® MycoFLEX. Mix vials to 500mL. 2 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

Stability: Stable

Conditions to Avoid: Temperatures below 2° C (35° F)

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: None known

Possibility of Hazardous Reactions: Will not occur.

11 TOXICOLOGICAL INFORMATION

Ingelvac® MycoFLEX™ and Ingelvac® CircoFLEX™ are considered nontoxic.

Listed Carcinogens: None

12 ECOLOGICAL INFORMATION

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

General Information: Dispose of in accordance with local, state, federal, national or international regulations.

Disposal Methods: Incinerate containers and unused contents. Do not empty into drains; dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by disposal.

RCRA Information: Not applicable

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

14 TRANSPORT INFORMATION

DOT: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

15 REGULATORY INFORMATION

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

One or more components of this product are **not** listed on the following inventories: TSCA, DSL, AICS, EINECS, IECSC, ENCS, PICCS, KECI, and NZIoC. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use. In the United States, this product is regulated by the USDA Animal and Plant Health Inspection Service (APHIS).

Canada CEPA Schedule 1 - Formaldehyde

US Regulations
CERCLA Hazardous Substance List (40 CFR 302.4): None

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

Section 311/312 (40 CFR 370): None

Section 313 Toxic Release Inventory (40 CFR 372): None

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): 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):
Formaldehyde (gas)
Massachusetts Right-To-Know List: Formaldehyde
Minnesota Hazardous Substances List: None
New Jersey Right-To-Know List: None
Pennsylvania Right-To-Know List: Formaldehyde
Rhode Island Right-To-Know List: Formaldehyde

European Regulations
Austria MAK List (Annex I): Formaldehyde
Denmark (Annex 3.6, April 2005): Formaldehyde
Germany (Dangerous Substances Ordinance 2004, Annex III): None
Norway (List of Dangerous Substance): None
Sweden (Sensitizers- Annex 3): Formaldehyde
Switzerland (Toxins List 1): Formaldehyde

16 OTHER INFORMATION

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

R23/24/25 – Harmful by inhalation, in contact with skin and if swallowed.
R40 - Limited evidence of a carcinogenic effect.
R43 - May cause sensitization by skin contact.
S(1/2) - Keep locked up and out of reach of children.
S24 - Avoid contact with skin.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S51 - Use only in well-ventilated areas.

ABBREVIATIONS:
BIV - Boehringer Ingelheim Vetmedica, Inc.
N/A - Not applicable
N/E - Not established
pph – parts per hour

References:

1. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
2. GHS Manual
3. Ingelvac® CircoFLEX - MycoFLEX™ Label

Prepared by: Boehringer Ingelheim Vetmedica, Inc.
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