# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

078705717

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078705725 078705733



## MATERIAL SAFETY DATA SHEET

### PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Ingelvac® MycoFLEX<sup>TM</sup>

**Product No.:** Not applicable **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

**Intended Use:** Recommended for the vaccination of healthy, susceptible swine 3 weeks of age or older as an aid in the reduction of enzootic pneumonia of swine caused by *Mycoplasma hyopneumoniae*.

**Emergency Telephone:** 

Transportation Emergency: (800) 424-9300

Medical Emergency (24HR): (866) 638-2226

Non-emergency Telephone: (800) 821-7467

### HAZARDS IDENTIFICATION

### **Emergency Overview**

2

**Physical State:** Liquid solution of inactivated bacterin supplied in 10 mL, 50 mL, 100 mL, 250 mL, and 500 mL high density plastic bottles.

Color: Clear 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 reduction of enzootic pneumonia of swine caused by *Mycoplasma hyopneumoniae*.

Shake well before using. Use entire contents when first opened. Using aseptic technique, inject a single 1 mL dose intramuscularly. The duration of immunity is at least 26 weeks.

**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

Potential Physical Effects: Can cause skin sensitization.

OSHA Regulatory Status: Nonhazardous, exempt

**Environment:** No data available

### 3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Inactivated bacterin –			proprietary		
Mycoplasma					
hyopneumoniae					
*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.

### 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.

**Antidote:** Epinephrine is indicated for anaphylactoid reactions.

### 5 FIRE-FIGHTING MEASURES

<sup>\*</sup> Used to inactivate virus and subsequently removed from solution. Concentration represents maximum remaining amount by percent weight which is below USDA allowable limits.

**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:** Store at  $2^{\circ}$ - $7^{\circ}$  C ( $35^{\circ}$ - $45^{\circ}$  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 <sup>3</sup>	Justifiably suspected of carcinogenic potential. Skin absorption. Sensitizer

Formaldehyde	Alberta	8-HR TWA	$0.92 \text{ mg/m}^3$	Irritation
Formaldehyde	British Columbia	8-HR TWA	0.3 ppm	Capable of
				causing
				respiratory,
				dermal or
				conjunctival
				sensitization.
Formaldehyde	Ontario	8-HR TWA	$1.5 \text{ mg/m}^3$	
Formaldehyde	Quebec	Ceiling	$3 \text{ mg/m}^3$	
		Exposure		
		Value		
Formaldehyde	Belgium	15-minute STEL	$0.38 \text{ mg/m}^3$	Irritant
Formaldehyde	Denmark	Ceiling	$0.4 \text{ mg/m}^3$	
Formaldehyde	Finland	8-HR Limit	$0.37 \text{ mg/m}^3$	
Formaldehyde	France	Short Term Limit	1 ppm	
Formaldehyde	Germany	8-HR TWA	$0.37 \text{ mg/m}^3$	
Formaldehyde	Greece	8-HR TWA	$0.25 \text{ mg/m}^3$	
	Iceland	8-HR TWA	$\frac{0.23 \text{ mg/m}}{0.4 \text{ mg/m}^3}$	Allamania
Formaldehyde	Iceiana	6-ΠΚ Ι W A	0.4 mg/ m	Allergenic substance
Formaldehyde	Ireland	8-HR TWA	$2.5 \text{ mg/m}^3$	substance 
Formaldehyde	Italy	Ceiling		
Formaidenyde	Italy	limit	0.3 ppm	
Formaldehyde	Netherlands	MAC TWA	$1.5 \text{ mg/m}^3$	
Formaldehyde	Norway	TLV	$0.6 \text{ mg/m}^3$	Allergenic
				substance
Formaldehyde	Portugal	Ceiling	0.3 ppm	Sensitizer,
		Exposure		suspected
		limit		human
				carcinogen
Formaldehyde	Spain	15-minute STEL	$0.37 \text{ mg/m}^3$	Sensitizer
Formaldehyde	Sweden	Level Limit	$0.6 \text{ mg/m}^3$	
		Value		
		(NGV)		
Formaldehyde	Switzerland	TWA	$0.37 \text{ mg/m}^3$	Sensitizing
				substance
Formaldehyde	United Kingdom	TWA	$2.5 \text{ mg/m}^3$	

**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

### PHYSICAL AND CHEMICAL PROPERTIES

Color: Clear to slightly turbid rose to brown

Odor: No data available

Odor Threshold: No data available

Physical State: Liquid solution of inactivated virus supplied in 10 mL, 50 mL, 100 mL, 250 mL,

and 500 mL high density plastic bottles.

**pH:** 6.0 - 8.0

9

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<sup>TM</sup> is 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: Not applicable

### 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

### 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**

This material is **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 Jersev 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

<sup>\*-</sup> 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® MycoFLEX<sup>TM</sup> Label

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

**Issue Date:** 08/14/07

Supercedes Date: New MSDS

**Disclaimer:** The information provided herein is offered by Boehringer Ingelheim Vetmedica, Inc. ("BIV") in good faith as accurate as of the date hereof, but without guarantee. This information includes information which has been generated by other parties and provided to BIV, and which BIV has not independently verified. The information provided herein relates only to the specific product designated, and may not be valid where such product is used in combination with any other materials or in any process. The information provided herein is offered solely for your consideration, investigation and verification, and Boehringer Ingelheim Vetmedica, Inc. ("BIV") expressly disclaims all liability for reliance thereon. BIV EXPRESSLY DISCLAIMS ALL WARRANTIES OF EVERY KIND AND NATURE (INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE) WITH RESPECT TO THE USE OR SUITABILITY OF THE PRODUCT. In addition, since the conditions of use and suitability of the product for particular uses are beyond BIV's control, ALL RISKS OF USE OF THE PRODUCT ARE THEREFORE ASSUMED BY THE USER, AND BIV EXPRESSLY DISCLAIMS ANY AND ALL LIABILITY AS TO ANY RESULTS OBTAINED OR ARISING FROM ANY USE OF THE PRODUCT. Use or transmission of the information contained herein in any other format than the format as presented is strictly prohibited. Nothing herein shall be construed as permission or recommendation for the use of the product in a manner that might infringe an existing patent. BIV neither represents nor warrants that the format, content or product formulas contained in this document comply with the laws of any other country except the United States of America.

© Copyright 2001 Boehringer Ingelheim Vetmedica, Inc. All rights reserved.

# Boehringer Ingelheim

### SAFETY DATA SHEET

### 1. Identification

Product identifier Ingelvac MycoFLEX®

Other means of identification

**Product code** APHIS Code- 2775.02, Family Code - 273

**Recommended use** Veterinary Vaccine **Recommended restrictions** None known.

Manufacturer/Importer/Supplier/Distributor information

**Manufacturer** Boehringer Ingelheim Vetmedica, Inc.

Address 2621 North Belt Hwy

St. Joseph, MO 64506-2002

Transportation emergency For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or

Night

Within USA and Canada: 1-800-424-9300

Outside USA and Canada: +1 703-527-3887 (collect calls accepted)

Medical Emergency

(24HR):

(866)638-2226

**Non-Emergency calls:** (800) 821-7467

2. Hazard(s) identification

Physical hazards Not classified.

**Health hazards** Sensitization, skin Category 1

Carcinogenicity Category 1

OSHA defined hazards Not classified.

Label elements



Signal word Danger

**Hazard statement** May cause cancer. May cause an allergic skin reaction.

Precautionary statement

**Prevention** Avoid breathing mist or vapor. Contaminated work clothing must not be allowed out of the

workplace. Wear protective gloves. Obtain special instructions before use.

**Response** If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention.

Wash contaminated clothing before reuse.

Storage Store away from incompatible materials. Keep at a temperature between 2 - 7°C Do not freeze.

Store locked up.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

None known.

**Supplemental information** Contains formaldehyde. May produce an allergic reaction.

### 3. Composition/information on ingredients

#### **Mixtures**

Chemical name	CAS number	%
*Formaldehyde	50-00-0	<= 0.74 g/L
Inactivated bacterin - Mycoplasma hyopneumoniae		Proprietary

Ingelvac MycoFLEX® SDS US

#### **Composition comments**

\* Used to inactivate bacterin and subsequently removed from solution. Concentration represents maximum remaining amount by percent weight which is below USDA allowable limits.

#### 4. First-aid measures

Inhalation

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact

Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders. Seek medical attention and take along these instructions.

Eve contact

Rinse with water. Get medical attention if irritation develops and persists.

Ingestion

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and

May cause an allergic skin reaction. Dermatitis. Rash. Ingestion of a large quantity may cause

delayed Indication of immediate vomiting, nausea, dizziness, drowsiness and other systemic effects.

medical attention and special treatment needed

Not for human use. For use in animals only. Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. Persons developing anaphylactic (life threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

**General information** 

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

### 5. Fire-fighting measures

Suitable extinguishing media Unsuitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

None known.

Specific hazards arising from

the chemical

During fire, gases hazardous to health may be formed. Combustion products may include: carbon monoxide and carbon dioxide.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

equipment/instructions

Move containers from fire area if you can do so without risk.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

No unusual fire or explosion hazards noted. General fire hazards

### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

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.

**Environmental precautions** 

Avoid discharge into drains, water courses or onto the ground.

### 7. Handling and storage

Precautions for safe handling

Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Shake well before using. Avoid accidental injection.

Conditions for safe storage, including any incompatibilities Keep away from food, drink and animal feedingstuffs. Store at 2°-7° C (35°-45° F). Do not freeze.

### 8. Exposure controls/personal protection

#### Occupational exposure limits

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Components	Type	Value
*Formaldehyde (CAS 50-00-0)	STEL	2 ppm
33 33 37	TWA	0.75 ppm

Ingelvac MycoFLEX® SDS US **US. ACGIH Threshold Limit Values** Components Value Type \*Formaldehyde (CAS STEL 0.3 ppm 50-00-0) **TWA** 0.1 ppm **US. NIOSH: Pocket Guide to Chemical Hazards** Components Value **Type** \*Formaldehyde (CAS Ceiling 0.1 ppm 50-00-0)

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**TWA** 

Appropriate engineering

controls

Not generally required when handling vials or containers. 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.

0.016 ppm

### Individual protection measures, such as personal protective equipment

Not generally required when handling containers. If containers are compromised or exposure to Eye/face protection

the mixture is likely: Wear safety glasses with side shields (or goggles).

Skin protection

Not generally required when handling containers. If containers are compromised or exposure to Hand protection

the mixture is likely: Wear suitable gloves.

Other Not generally required when handling containers. If containers are compromised or exposure to

the mixture is likely: Wear lab coat, apron or appropriate clothing to prevent skin contact.

Not generally required when handling vials or containers. If engineering controls do not maintain Respiratory protection

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 29 CFR 1910.134. Respirator type: NIOSH

approved organic vapor respirator.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Always observe good personal hygiene measures, such as washing after handling the material General hygiene considerations

and before eating, drinking, and/or smoking. Routinely wash work clothing and protective

equipment to remove contaminants.

#### 9. Physical and chemical properties

Liquid solution of inactivated bacterin. **Appearance** 

Physical state Liquid. **Form** Liquid.

Clear to slightly turbid rose to brown. Color

Not available. Odor **Odor threshold** Not available.

6 - 8

Melting point/freezing point Not available. Initial boiling point and boiling Not available.

range

Not available. Flash point Not available. **Evaporation rate** Not applicable. Flammability (solid, gas)

Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

Flammability limit - upper

Not available.

(%)

Vapor pressure Not available. Vapor density Not available.

Ingelvac MycoFLEX® SDS US

937513 Version #: 02 Revision date: 12-February-2018 Issue date: 11-April-2017 Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.

(n-octanol/water)

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

### 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 Temperatures below 2°C.

Incompatible materials Strong oxidizing agents.

**Hazardous decomposition** 

products

No hazardous decomposition products are known.

### 11. Toxicological information

Information on likely routes of exposure

**Inhalation** May cause inhalation hypersensitivity (occupational asthma) in sensitive individuals.

**Skin contact** May cause an allergic skin reaction.

**Eye contact**Direct contact with eyes may cause temporary irritation.

Ingestion

Ingestion may cause irritation and stomach discomfort.

Symptoms related to the physical, chemical and toxicological characteristics

May cause an allergic skin reaction. Dermatitis. Rash. Ingestion of a large quantity may cause

vomiting, nausea, dizziness, drowsiness and other systemic effects.

Information on toxicological effects

Acute toxicity May cause an allergic skin reaction.

Components Species Test Results

\*Formaldehyde (CAS 50-00-0)

Acute Dermal

LD50 Rat 270 mg/kg

Inhalation

LC50 Rat 0.578 mg/l, 4 hours

Oral LD50

Oral

**Skin corrosion/irritation** May cause an allergic skin reaction.

Rat

Serious eye damage/eye

irritation

Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

**ACGIH** sensitization

FORMALDEHYDE (CAS 50-00-0)

Dermal sensitization

Respiratory sensitization

**Respiratory sensitization** Exposure to formaldehyde may cause respiratory sensitization in some individuals or aggravate

pre-existing asthmatic conditions.

**Skin sensitization** May cause an allergic skin reaction.

**Germ cell mutagenicity**No data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Carcinogenicity Contains a component that is listed as an IARC 1 (Known Human Carcinogen), a NTP Known

Carcinogen and an ACGIH A2 (Suspected Human Carcinogen). In vaccines, the chronic exposure

100 mg/kg

potential is negligible.

Ingelvac MycoFLEX® SDS US

IARC Monographs. Overall Evaluation of Carcinogenicity

\*Formaldehyde (CAS 50-00-0) 1 Carcinogenic to humans.

NTP Report on Carcinogens

\*Formaldehyde (CAS 50-00-0) Known To Be Human Carcinogen.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

\*Formaldehyde (CAS 50-00-0)

Cancer

**Reproductive toxicity**This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity -

single exposure

No data available.

Specific target organ toxicity -

repeated exposure

No data available.

Aspiration hazard Not classified, however droplets of the product may be aspirated into the lungs through ingestion

or vomiting and may cause a serious chemical pneumonia.

**Chronic effects** Possible hyper sensitization (development of abnormal sensitivity).

12. Ecological information

**Ecotoxicity** 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.

Components Species Test Results

\*Formaldehyde (CAS 50-00-0)

**Aquatic** 

Crustacea EC50 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.

Partition coefficient n-octanol / water (log Kow)

\*Formaldehyde (CAS 50-00-0) 0.35

Mobility in soil Diluent and end-product expected to be slightly to moderately mobile in soil.

Other adverse effects This product contains one or more substances identified as hazardous air pollutants (HAPs) per

the US Federal Clean Air Act (see section 15).

13. Disposal considerations

**Disposal instructions**This material and its container must be disposed of in a safe way. Burn container and all unused

contents. Do not discharge into drains, water courses or onto the ground. Do not contaminate

water, food, or feed by disposal.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

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** Empty containers should be taken to an approved waste handling site for recycling or disposal.

Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

**IMDG** 

Not regulated as dangerous goods.

Transport in bulk according to Not established.

Annex II of MARPOL 73/78 and

the IBC Code

Ingelvac MycoFLEX® SDS US

937513 Version #: 02 Revision date: 12-February-2018 Issue date: 11-April-2017

### 15. Regulatory information

**US federal regulations** 

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

One or more components are not listed on TSCA.

Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use. FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED

VETERINARIANS.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)** 

\*Formaldehyde (CAS 50-00-0) Listed.

SARA 304 Emergency release notification

\*Formaldehyde (CAS 50-00-0) 100 LBS OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

\*Formaldehyde (CAS 50-00-0)

Skin sensitization Respiratory sensitization

Eve irritation Skin irritation

respiratory tract irritation

Acute toxicity Flammability

#### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### SARA 302 Extremely hazardous substance

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
*Formaldehyde	50-00-0	100	500		

SARA 311/312 Hazardous

chemical

**Classified hazard** Respiratory or skin sensitization

Yes

categories Carcinogenicity

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
*Formaldehyde	50-00-0	<= 0.74 g/L

#### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

\*Formaldehyde (CAS 50-00-0)

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

\*Formaldehyde (CAS 50-00-0)

Safe Drinking Water Act Not regulated. (SDWA)

### **US** state regulations

#### **US. Massachusetts RTK - Substance List**

\*Formaldehyde (CAS 50-00-0)

#### US. New Jersey Worker and Community Right-to-Know Act

\*Formaldehyde (CAS 50-00-0)

#### US. Pennsylvania Worker and Community Right-to-Know Law

\*Formaldehyde (CAS 50-00-0)

#### **US. Rhode Island RTK**

\*Formaldehyde (CAS 50-00-0)

### **California Proposition 65**



WARNING: This product can expose you to \*Formaldehyde, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Ingelvac MycoFLEX®

937513 Version #: 02 

### California Proposition 65 - CRT: Listed date/Carcinogenic substance

\*Formaldehyde (CAS 50-00-0)

Listed: January 1, 1988

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

\*Formaldehyde (CAS 50-00-0)

#### **International Inventories**

Country/o) or region

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)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

<sup>\*</sup>A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

### 16. Other information, including date of preparation or last revision

Issue date11-April-2017Revision date12-February-2018

Version # 02

HMIS® ratings Health: 2

Flammability: 0 Physical hazard: 0

**NFPA** ratings



#### Disclaimer

The information provided herein is offered by Boehringer Ingelheim Vetmedica, Inc. ("BIVI") in good faith as accurate as of the date hereof, but without guarantee. This information includes information which has been generated by other parties and provided to BIVI, and which BIVI has not independently verified. The information provided herein relates only to the specific product designated, and may not be valid where such product is used in combination with any other materials or in any process. The information provided herein is offered solely for your consideration, investigation and verification, and Boehringer Ingelheim Vetmedica, Inc. ("BIVI") expressly disclaims all liability for reliance thereon. BIVI EXPRESSLY DISCLAIMS ALL WARRANTIES OF EVERY KIND AND NATURE (INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE) WITH RESPECT TO THE USE OR SUITABILITY OF THE PRODUCT. In addition, since the conditions of use and suitability of the product for particular uses are beyond BIVI's control, ALL RISKS OF USE OF THE PRODUCT ARE THEREFORE ASSUMED BY THE USER, AND BIVI EXPRESSLY DISCLAIMS ANY AND ALL LIABILITY AS TO ANY RESULTS OBTAINED OR ARISING FROM ANY USE OF THE PRODUCT. Use or transmission of the information contained herein in any other format than the format as presented is strictly prohibited. Nothing herein shall be construed as permission or recommendation for the use of the product in a manner that might infringe an existing patent. BIVI neither represents nor warrants that the format, content or product formulas contained in this document comply with the laws of any other country except the United States of America.

Ingelvac MycoFLEX® SDS US

937513 Version #: 02 Revision date: 12-February-2018 Issue date: 11-April-2017

On inventory (vec/pe)\*

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).