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® MycoFLEXTM

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

^{*} 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° - 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	3 mg/m^3	
		Exposure		
		Value		
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	
	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 mg/m^3	substance
Formaldehyde	Italy	Ceiling		
Formaidenyde	Italy	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	0.3 ppm	Sensitizer,
		Exposure		suspected
		limit		human
				carcinogen
Formaldehyde	Spain	15-minute STEL	0.37 mg/m^3	Sensitizer
Formaldehyde	Sweden	Level Limit	0.6 mg/m^3	
		Value		
		(NGV)		
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

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® MycoFLEXTM 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

^{*-} 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® MycoFLEXTM Label

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

Issue Date: 08/14/07

Supercedes Date: New MSDS

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Boehringer Ingelheim

SAFETY DATA SHEET

1. Identification

Product identifier Ingelvac MycoFLEX®

Other means of identification

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

Recommended use Veterinary Vaccine **Recommended restrictions** Not for human use. Manufacturer/Importer/Supplier/Distributor information

Boehringer Ingelheim Vetmedica, Inc. Manufacturer

Address 2621 North Belt Hwy

St. Joseph, MO 64506-2002

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

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



Danger Signal word

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

Precautionary statement

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

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

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

Wash contaminated clothing before reuse.

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

Store locked up.

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

Hazard(s) not otherwise

classified (HNOC)

937513 Version #: 01

None known.

Supplemental information Contains formaldehyde. May produce an allergic reaction.

3. Composition/information on ingredients

Revision date: -

Mixtures

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

SDS US Ingelvac MycoFLEX®

Issue date: 11-April-2017

1/7

Inactivated bacterin -Mycoplasma hyopneumoniae

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.

Proprietary

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.

Eye contact Ingestion

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

Most important

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

symptoms/effects, acute and delaved

May cause an allergic skin reaction. Dermatitis. Rash. Ingestion of a large quantity may cause vomiting, nausea, dizziness, drowsiness and other systemic effects.

Indication of immediate 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

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

None known.

Specific hazards arising from the chemical

Special protective equipment

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

monoxide and carbon dioxide.

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

No unusual fire or explosion hazards noted.

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.

Ingelvac MycoFLEX® SDS US

937513 Version #: 01 Revision date: -Issue date: 11-April-2017

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Components	Туре	Value	
*Formaldehyde (CAS 50-00-0)	STEL	2 ppm	
,	TWA	0.75 ppm	
US. ACGIH Threshold Limit Val	ues		
Components	Туре	Value	
*Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Туре	Value
*Formaldehyde (CAS 50-00-0)	Ceiling	0.1 ppm
00 00 0)	TWA	0.016 ppm

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

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.

Individual protection measures, such as personal protective equipment

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

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.

General hygiene considerations

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.

Issue date: 11-April-2017

9. Physical and chemical properties

Appearance Liquid solution of inactivated bacterin.

Physical state Liquid. **Form** Liquid.

Color Clear to slightly turbid rose to brown.

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

6 - 8

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

range

937513 Version #: 01

Not available.

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

Revision date: -

Ingelvac MycoFLEX® SDS US

3/7

Upper/lower flammability or explosive limits

Flammability limit - lower Not available.

(%)

Flammability limit - upper

(%)

Not available.

Not available. Vapor pressure Not available. Vapor density Relative density Not available.

Solubility(ies)

Not available. Solubility (water) Partition coefficient Not available.

(n-octanol/water)

Not available. **Auto-ignition temperature Decomposition temperature** Not available. Not available. Viscosity

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.

Temperatures below 2°C. Conditions to avoid Strong oxidizing agents. Incompatible materials

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 Inhalation

LC50 Rat 0.48 mg/l, 4 Hours

Oral

LD50 Rat 100 mg/kg

Skin corrosion/irritation May cause an allergic skin reaction.

Serious eye damage/eye

Direct contact with eyes may cause temporary irritation.

irritation

Respiratory or skin sensitization

ACGIH sensitization

FORMALDEHYDE (CAS 50-00-0) Dermal sensitization Respiratory sensitization

Exposure to formaldehyde may cause respiratory sensitization in some individuals or aggravate Respiratory sensitization pre-existing asthmatic conditions.

Ingelvac MycoFLEX® SDS US

937513 Version #: 01 Revision date: -Issue date: 11-April-2017 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.

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

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

potential is negligible.

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 1910.1001-1050) *Formaldehyde (CAS 50-00-0)

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

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity**

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

LC50 Fish 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.

No data available for this product. Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

*Formaldehyde (CAS 50-00-0)

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

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

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

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Ingelvac MycoFLEX® SDS US

937513 Version #: 01 Revision date: -Issue date: 11-April-2017 **IMDG**

Not regulated as dangerous goods.

Transport in bulk according to

Not established.

Annex II of MARPOL 73/78 and

the IBC Code

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

*Formaldehyde (CAS 50-00-0) Cancer

Skin sensitization Respiratory sensitization

Eye irritation Skin irritation

respiratory tract irritation

Acute toxicity Flammability

CERCLA Hazardous Substance List (40 CFR 302.4)

*Formaldehyde (CAS 50-00-0) LISTED

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Chemical name CAS number Reportable Threshold Threshold Threshold Threshold quantity planning quantity, planning quantity, planning quantity,

(pounds) (pounds) lower value upper value (pounds)

*Formaldehyde 50-00-0 100 500

SARA 311/312 Hazardous Yes

chemical

SARA 313 (TRI reporting)

Chemical nameCAS number% by wt.*Formaldehyde50-00-0<= 0.74 g/L</td>

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)

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US state regulations WARNING: This product contains chemical(s) known to the State of California to cause cancer.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

*Formaldehyde (CAS 50-00-0)

US. Massachusetts RTK - Substance List

Revision date: -

*Formaldehyde (CAS 50-00-0)

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

*Formaldehyde (CAS 50-00-0)

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

*Formaldehyde (CAS 50-00-0)

US. Rhode Island RTK

*Formaldehyde (CAS 50-00-0)

International Inventories

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
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

^{*}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 date 11-April-2017

Revision date - 01

HMIS® ratings Health: 2

Flammability: 0 Physical hazard: 0

NFPA ratings



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Ingelvac MycoFLEX® SDS US

937513 Version #: 01 Revision date: - Issue date: 11-April-2017

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).