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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>50-00-0</td>
<td>&lt;= 0.74 g/L</td>
</tr>
</tbody>
</table>

Inactivated bacterin - Mycoplasma hyopneumoniae 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
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 delayed
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
Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media
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.

General fire hazards
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.

Environmental precautions
Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

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

<table>
<thead>
<tr>
<th>US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053) Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde (CAS 50-00-0)</td>
<td>STEL</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>0.75 ppm</td>
</tr>
</tbody>
</table>
US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Formaldehyde (CAS 50-00-0)</em></td>
<td>STEL</td>
<td>0.3 ppm</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>0.1 ppm</td>
</tr>
</tbody>
</table>

US. NIOSH: Pocket Guide to Chemical Hazards

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Formaldehyde (CAS 50-00-0)</em></td>
<td>Ceiling</td>
<td>0.1 ppm</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>0.016 ppm</td>
</tr>
</tbody>
</table>

No biological exposure limits noted for the ingredient(s).

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

Hand protection

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

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 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.

9. Physical and chemical properties

Appearance

Liquid solution of inactivated bacterin.

Physical state

Liquid.

Form

Liquid.

Color

Clear to slightly turbid rose to brown.

Odor

Not available.

Odor threshold

Not available.

pH

6 - 8

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Vapor pressure

Not available.

Vapor density

Not 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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Formaldehyde (CAS 50-00-0)</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>Rat</td>
<td>270 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Inhalation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>Rat</td>
<td>0.578 mg/l, 4 hours</td>
</tr>
<tr>
<td><strong>Oral</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>100 mg/kg</td>
</tr>
</tbody>
</table>

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

**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 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 1910.1001-1053)

*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.

- 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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Formaldehyde (CAS 50-00-0)</td>
<td>Aquatic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Crustacea</td>
<td>EC50</td>
</tr>
<tr>
<td></td>
<td>Fish</td>
<td>LC50</td>
</tr>
</tbody>
</table>

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 Annex II of MARPOL 73/78 and the IBC Code

Not established.
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


*Formaldehyde (CAS 50-00-0)

- Cancer
- Skin sensitization
- Respiratory sensitization
- Eye irritation
- Skin irritation
- Respiratory tract irritation
- Acute toxicity
- Flammability

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

**SARA 302 Extremely hazardous substance**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS number</th>
<th>Reportable quantity (pounds)</th>
<th>Threshold planning quantity (pounds)</th>
<th>Threshold planning quantity, lower value (pounds)</th>
<th>Threshold planning quantity, upper value (pounds)</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Formaldehyde</td>
<td>50-00-0</td>
<td>100</td>
<td>500</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SARA 311/312 Hazardous chemical**

Classified hazard categories

- Respiratory or skin sensitization
- Carcinogenicity

**SARA 313 (TRI reporting)**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS number</th>
<th>% by wt.</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Formaldehyde</td>
<td>50-00-0</td>
<td>&lt;= 0.74 g/L</td>
</tr>
</tbody>
</table>

**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 (SDWA)**

Not regulated.

**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.
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

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
<td>Yes</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

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

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

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

HMIS® ratings
- Health: 2
- Flammability: 0
- Physical hazard: 0

NFPA ratings

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