

SAFETY DATA SHEETS

This SDS packet was issued with item:

078705733

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

078705717 078705725



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Ingelvac® MycoFLEX™

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

Emergency Telephone:

Transportation Emergency: (800) 424-9300

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

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*.

Non-emergency Telephone: (800) 821-7467

2 HAZARDS IDENTIFICATION

Emergency Overview

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 – <i>Mycoplasma hyopneumoniae</i>	----	----	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.

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: 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 Level	0.5 ppm	Cancer-suspect 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
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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

Melting Point: No data available

Freezing Point: No data available

Boiling Point: No data available

Flash Point: No data available

Flammability Limit – Upper (%): No data available

Flammability Limit – Lower (%): No data available

Evaporation rate: No data available

Vapor Pressure: No data available

Vapor Density (Air=1): No data available

Specific Gravity: No data available

Solubility: No data available

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

Autoignition Temperature: Not applicable

Decomposition Temperature: No data available

10	STABILITY AND REACTIVITY
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Stability: Stable

Conditions to Avoid: 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
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Ingelvac® MycoFLEX™ is considered nontoxic.

Listed Carcinogens: None

12	ECOLOGICAL INFORMATION
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Ecotoxicity: No data available

Persistence and degradability: No data available

Mobility in soil: No data available

Other adverse effects: No data available

Germany WGK: Not applicable

13	DISPOSAL CONSIDERATIONS
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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
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DOT: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

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

WHMIS Classification: Noncontrolled, exempt

Inventory Status

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 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
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Hazard Ratings

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	1	0	0

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

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

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™ Label

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

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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	Not for human use.
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

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.
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. 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 1910.1001-1050)

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

US. ACGIH Threshold Limit Values

Components	Type	Value
*Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

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

Biological limit values	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.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity 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.

Components	Species	Test Results
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*Formaldehyde (CAS 50-00-0)

Acute**Inhalation**

LC50	Rat	0.48 mg/l, 4 Hours
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Oral

LD50	Rat	100 mg/kg
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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 1910.1001-1050)	
*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.
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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 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.

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 quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
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*Formaldehyde	50-00-0	100	500		
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SARA 311/312 Hazardous chemical Yes

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 (SDWA) Not regulated.

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

*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)

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).

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 -
Version # 01
HMIS® ratings Health: 2
Flammability: 0
Physical hazard: 0

NFPA ratings**Disclaimer**

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