SAFETY DATA SHEETS

This SDS packet was issued with item: 078705782

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

078779223

Boehringer Ingelheim MATERIAL SAFETY DATA SHEET

PRODUCT AND COMPANY IDENTIFICATION

Product Name: Entervene[®] D **Product No.:** RM1000221 **GHS Product Identifier:** Not applicable **Synonyms:** No data available

Molecular Formula: Mixture, not applicable Molecular Weight: Mixture, not applicable CAS Number: Mixture, not applicable Chemical Family: Vaccine

Manufacturer:

Boehringer Ingelheim Vetmedica, Inc. 800 5th Street NW PO Box 518 Fort Dodge, IA 50501 Telephone: (515) 955-4600 **Transporation 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 Telephone:** (800) 821-7467

Intended Use: Indicated for vaccination of healthy calves as an aid in the prevention of clinical disease due to *Salmonella Dublin*.

HAZARDS IDENTIFICATION

Emergency Overview

2

Physical State: Live bacterial culture in an injectable solution. **Color:** Brownish-red **Odor:** Odorless



WARNING! For use in calves and cows 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. Store out of direct sunlight. 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/exposure 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. In case of contact with eyes, flush with gently flowing fresh water thoroughly. Wash skin thoroughly with soap and water after handling. 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.

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): Skin

OSHA Regulatory Status: Non-hazardous (exempt)

Environment: No data available

COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Bacterial (Salmonella			proprietary		
Dublin) live culture					
Various adjuvents			40 - 50%		
Water	231-791-2	7732-18-5	Balance		

Components not listed are not hazardous or are below reportable limits.

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 animal injection only. Not for human use.

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

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear appropriate personal protective equipment (See Section 8).

Spill Cleanup Methods: STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED: Absorb or cover with dry earth, sand or other non-combustible material. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

Environmental Precautions: Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

7 HANDLING AND STORAGE

Handling: HANDLING SIGNIFICANT QUANTITIES OF PRODUCT: Avoid contact with eyes, skin or clothing. Avoid accidental injection. Wash hand thoroughly after handling.

Storage: Store at 2°-7°C (35°-45°F). Do not freeze. Shake well before using.

EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits: None Established.

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 mixture is likely wear:

Eye Protection: Wear safety glasses with side shields (or goggles).

Hand Protection: Wear suitable gloves.

Skin Protection: Wear lab coat, apron or appropriate clothing to prevent skin contact.

Hygiene Measures: Eye bath, washing facilities

PHYSICAL AND CHEMICAL PROPERTIES

Color: Brownish-red **Odor:** Odorless **Odor Threshold:** No data available Physical State: Live bacterial culture in an injectable solution. **pH:** 5 - 8 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: Easily soluble in cold water, hot water, methanol, n-octanol, acetone, diethyl ether 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

Entervene D is considered non-toxic.

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: No specific disposal method required. 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

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<u>DOT</u>: 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: Non-controlled

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.

US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4): None listed.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): None listed.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): None listed.

SARA Title III

Section 302Extremely Hazardous Substance (40 CFR 355, Appendix A): None listed.

Section 311/312 (40 CFR 370): Not Regulated.

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

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): None listed.

Massachusetts Right-To-Know List: None listed. Minnesota Hazardous Substances List: None listed. New Jersey Right-To-Know List: None listed. Pennsylvania Right-To-Know List: None listed. Rhode Island Right-To-Know List: None listed.

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

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

ABBREVIATIONS:

BIV – Boehringer Ingelheim Vetmedica, Inc.

- N/A Not applicable
- N/E Not established
- pph parts per hour

References:

- 1. Entervene D MSDS and Label. Fort Dodge Animal Health.
- 2. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
- 3. GHS Manual

Revision Information: New MSDS

Prepared by: Boehringer Ingelheim Vetmedica, Inc. **Issue Date:** 08/9/2010

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SAFETY DATA SHEET

1. Identification

Product identifier	Entervene® D
Other means of identification	None.
Recommended use	Indicated for vaccination of healthy calves as an aid in the prevention of clinical disease due to Salmonella Dublin
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/	Distributor information
Manufacturer	Boehringer Ingelheim Animal Health
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	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials. Keep at a temperature between 2 - 7°C Do not freeze.
Disposal	Dispose of waste and residues in accordance with local authority requirements.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures		
Chemical name	CAS number	%
Various adjuvents		40 - 50
Bacterial (Salmonella Dublin) live culture		Proprietary
Water	7732-18-5	Balance

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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	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
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	Direct contact with eyes may cause temporary irritation. 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 calves and cows only. Treat symptomatically. 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.
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 oxides, nitrogen oxides, sulfur oxides.
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. 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. 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	Avoid prolonged exposure. Use care in handling/storage.	
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from foodstuffs. Store material between 2°C and 7°C. Do not freeze. Protect from direct sunlight.	
8. Exposure controls/personal protection		

No exposure limits noted for ingredient(s). **Occupational exposure limits Biological limit values** No biological exposure limits noted for the ingredient(s). Appropriate engineering Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates controls 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 Wear safety glasses with side shields (or goggles). Skin protection

Skin protection	
Other	Wear suitable protective clothing.
Respiratory protection	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.
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	
Physical state	Liquid.
Form	Injectable liquid.
Color	Brownish-red.
Odor	Odorless.
Odor threshold	Not available.
pH	5 - 8
Melting point/freezing point	Not available.
Initial boiling point and boiling	Not available.
range	
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or exp	losive 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)	Easily soluble in cold and hot water
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	Contact with incompatible materials. High temperatures.
Incompatible materials	Strong oxidizing agents. Strong acids. Strong bases.
Hazardous decomposition products	No hazardous decomposition products are known.
11. Toxicological informat	ion

Information on likely routes of exposure

Inhalation	No adverse effects due to inhalation are expected.
Skin contact	No adverse effects due to skin contact are expected.

Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Expected to be a low ingestion hazard.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. Ingestion of a large quantity may cause vomiting, nausea, dizziness, drowsiness and other systemic effects.
Information on toxicological effe	ects
Acute toxicity	Not expected to be acutely toxic.
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.
Respiratory or skin sensitizatior	1
Respiratory sensitization	Not a respiratory sensitizer.
Skin sensitization	This product is not expected to cause skin sensitization.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Not listed. NTP Report on Carcinogens Not listed.	Evaluation of Carcinogenicity d Substances (29 CFR 1910.1001-1053)
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not an aspiration hazard.
Chronic effects	None known.
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.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.
13. Disposal consideration	าร
Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
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 g	oods.

ΙΑΤΑ

Not regulated as dangerous goods.

Entervene® D

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
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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 1910.1001-1053)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous No chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

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

Not regulated.

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

Not regulated.

Safe Drinking Water Act Not regulated.

(SDWA)

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act Not listed.

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

Not listed.

US. Rhode Island RTK

Not regulated.

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

Country(s) or region	Inventory name	On inventory (yes/no)*
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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	22-July-2015
Revision date	-
Version #	01
Further information	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the American Coatings Association (ACA).
HMIS® ratings	Health: 1 Flammability: 1 Physical hazard: 0
NFPA ratings	
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