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MATERIAL SAFETY DATA SHEET

PRODUCT AND COMPANY IDENTIFICATION

Product Name: ULTRATM Duramune[®] DAP + 4L

Product No.: No data available

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

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 Telephone: (800) 821-7467

Intended Use: Vaccine

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Modified live virus in an injectable solution.

Color: Reddish-white Odor: Odorless







WARNING!

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

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Canine Distemper-			proprietary		
Adenovirus Type 2-					
Parvovirus-modified					
live virus					
Leptospira canicola-			proprietary		
Grippotyphosa-					
Icterohaemorragiae-					
Pomona-inactivated					
bacterin					
Proprietary Adjuvant			proprietary		

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 FIREFIGHTING 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 Firefighting Procedures: Wear self-contained breathing apparatus and protective clothing.

Unusual Fire & Explosion Hazards: None known

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Hazardous Combustion Products: Carbon monoxide, carbon dioxide

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. Store out of direct sunlight to protect product integrity. Shake well before using.

8 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:

Eve 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: Reddish white **Odor:** No data available

Odor Threshold: No data available

Physical State: Modified live virus in an injectable solution.

pH: No data available

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

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Conditions to Avoid: Exposure to light. Temperatures below 2° C (35° F).

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: None known

Possibility of Hazardous Reactions: Will not occur

TOXICOLOGICAL INFORMATION

ULTRATM Duramune[®] DAP + 4L is considered non-toxic.

Acute Toxicity: No data available

Chronic Health Effects: Possible hypersensitization (development of abnormal sensitivity).

Listed Carcinogens: None listed

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: No data available

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

14 TRANSPORT INFORMATION

<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.

Canada CEPA Schedule 1 - None listed

US Regulations

FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.

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

EU Symbol and R Phrase Definitions: None listed

ABBREVIATIONS:

BIV – Boehringer Ingelheim Vetmedica, Inc.

N/A – Not applicable

N/E – Not established

pph - parts per hour

References:

1. Duramune Adult 3 MSDS, Label and Package Insert. Fort Dodge Animal Health.

- 2. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
- 3. GHS Manual

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

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