MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Solo-Jec® 7 (47P9.22)
Product No. : Not applicable
MSDS ID# : B479P.22A
GHS Product Identifier: Not applicable
Synonyms: Not applicable
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): (800)530-5432

Non-emergency Telephone: (800) 821-7467

Intended Use:
Solo-Jec® 7 is recommended for vaccination of healthy, susceptible dogs against disease caused by canine distemper, hepatitis, canine adenovirus type 1 and type 2, parainfluenza, parvovirus, *L canicola* and *icterohaemorrhagiae*.

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: 1 dose vial of desiccated vaccine cake (canine distemper, canine hepatitis, canine parainfluenza) and 1 mL vial of vaccine diluent (canine parvovirus vaccine-*leptospira canicola-icterohaemorrhagiae* bacterin*).*
Packages: Single 1 mL dose with a syringe; 25 boxes x 1 mL dose.
Color: Off white plug and clear liquid. After rehydration: tan to yellow liquid.
Odor: No data available

WARNING!

For use in dogs only.
Not for human use.
Severe 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.
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 dispose.
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.

Acute effect:
Swelling at injection site may occur. An occasional transitory corneal opacity may occur following administration of the vaccine. This disappears without having an untoward effect on the dog.

Precautions/Contraindications: Vaccine may be given subcutaneously or intramuscular. Contains a combination of antigenic, attenuated, strains of Canine Distemper, Parainfluenza, Hepatitis, and Parvovirus propagated in cell line tissue cultures. The diluent is Parvovirus Vaccine-Leptospira canicola-icterohaemorrhagiae bacterin. The infectious Canine Hepatitis (CAV-1) fraction cross protects against respiratory disease caused by CAV-2.
Do not vaccinate pregnant animals. **Do not use in ferrets or mink.** Protective immunity may not be completely established in all puppies vaccinated at less than 16 weeks of age because of maternal antibody interference. Only vaccinate healthy animals. Animals incubating any disease or stressed due to shipping, malnutrition, or parasitism may not achieve or maintain an adequate immune response. Use entire contents when first opened.

Overdosage: None known.

ADVERSE REACTIONS TO PRODUCT: Anaphylactoid reactions may occur but are rare.

<u>Potential Health Effects</u>

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 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): Immune 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
Desiccated Vaccine Cake: Canine Distemper, Canine Hepatitis, Canine Parainfluenza	----	----	proprietary	----	---
Diluent: Canine Parvovirus Vaccine-*Leptospira Canicola-Icterohaemorrhagiae* Bacterin	----	----	proprietary	----	---
Methiolate	2311067	54-64-8	.01	----	*
Gentamicin sulfate	2157789	1405-41-0	proprietary	----	*

The full texts for all R-Phrases are displayed in Section 16, if applicable.
* Preservative

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. Get medical attention if symptoms occur.

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 dogs 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. For large liquid spill: Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers.

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). Avoid freezing. Store out of direct sunlight to protect product integrity.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

For Industrial Exposures:

Exposure Limits: None

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

Color: No data available
Odor: Off white plug and clear liquid. After rehydration: tan to yellow liquid.
Odor Threshold: No data available
Physical State: Liquid; 1 dose vial of desiccated vaccine cake (canine distemper, canine hepatitis, canine parainfluenza) and 1 mL vial of vaccine diluent (canine parvovirus vaccine-*leptospira canicola-icterohaemorrhagiae* bacterin*).*
Packages: Single 1 mL dose with a syringe; 25 boxes x 1 mL dose.
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: Soluble in water
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), direct sunlight

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: None known

Possibility of Hazardous Reactions: Will not occur.

11 TOXICOLOGICAL INFORMATION

Specified Substances

Acute Toxicity: Product contains a combination of antigenic, attenuated strains of canine distemper, parainfluenza, hepatitis, and parvovirus propagated in cell line tissue cultures.

Gentamicin Sulfate	Oral LD_{50} (rat): > 5,000 mg/kg Oral LD_{50} (mouse): > 11,269 mg/kg Intramuscular LD_{50} (rat): 245 mg/kg
Methiolate	Oral LD_{50} (rat): 75 mg/kg Oral LD_{50} (mouse): 91 mg/kg Eye Irritation (rabbit): 8µg – Mild irritation

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: Methiolate: Class 3: severely water-endangering

13 DISPOSAL CONSIDERATIONS

General Information: Dispose of in accordance with local, state and federal 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 US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.
This material is **not** listed on the DSL or European Inventory.

Canada CEPA Schedule 1 - None

US Regulations
CERCLA Hazardous Substance List (40 CFR 302.4): None

SARA Title III
Section 302Extremely Hazardous Substance (40 CFR 355, Appendix A): 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): None
Massachusetts Right-To-Know List: None
Minnesota Hazardous Substances List: None
New Jersey Right-To-Know List: None
Pennsylvania Right-To-Know List: None
Rhode Island Right-To-Know List: None

European Regulations

Austria MAK List (Annex I): None
Denmark (Annex 3.6, April 2005): None
Germany (Dangerous Substances Ordinance 2004, Annex III): None
Norway (List of Dangerous Substance): None
Sweden (Sensitizers- Annex 3): None
Switzerland (Toxins List 1): None

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

Xi - Irritant
R43 - May cause sensitization by skin contact.
S24 - Avoid contact with skin.
S37 – Wear suitable gloves.

ABBREVIATIONS:
BIV - Boehringer Ingelheim Vetmedica, Inc.
N/A - Not applicable
N/E - Not established

References:

1. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
2. GHS Manual
3. Product Label, Solo-Jec™ 7, Pharma International Inc., Boehringer Ingelheim Vetmedica, Inc.
4. RTECS – Methiolate, OV8400000 Review Date, RTECS No. 200608.
5. Solo-Jec™ 7, Reference Page, http://bivetmedica.com/product_sites/SoloJec/reference.htm
6. Solo-Jec™ 7, Product Information Label, http://bivetmedica.com/product_sites/SoloJec/documents/SoloJec7_label.pdf

Revision Information: All sections of MSDS updated.
Prepared by: Boehringer Ingelheim Vetmedica, Inc.
Issue Date: 04/06/07
Supercedes Date: 3/29/05

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