SAFETY DATA SHEETS

This SDS packet was issued with item:

078033082

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

078033090 078847808

Boehringer Ingelheim

SAFETY DATA SHEET

1. Identification

Product identifier Naramune-2™

Other means of identification

Product code APHIS Code - 14M1.20, Family Code - 104

For vaccination of healthy susceptible dogs and puppies against Canine Upper Respiratory Recommended use

Infection (Canine Cough) caused by canine parainfluenza and Bordetella bronchiseptica

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Boehringer Ingelheim Animal Health Manufacturer

Address 2621 North Belt Hwy

St. Joseph, MO 64506-2002

For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Transportation emergency

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. Not classified. **Health hazards OSHA** defined hazards Not classified.

Label elements

None. **Hazard symbol** 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 Not applicable.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Bordetella bronchiseptica — Avirulent bacterium		Proprietary
Canine parainfluenza virus - Attenuated live virus		Proprietary

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

SDS US Naramune-2™ 940359 Version #: 01 Revision date: -Issue date: 18-October-2017

Wash off with soap and water. Get medical attention if irritation develops and persists. Skin contact

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Rinse mouth. Get medical attention if symptoms occur. Ingestion Direct contact with eyes may cause temporary irritation. Most important

symptoms/effects, acute and

delaved

Indication of immediate medical attention and special treatment needed

Not for human use. For use in dogs only.

General information

Persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention. If anaphylactoid reactions occur, epinephrine may be used as an antidote.

5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

Move containers from fire area if you can do so without risk.

equipment/instructions 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 Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. 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. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Store in original tightly closed container. Keep at a temperature between 2 - 7°C (33 - 45° F). Protect from freezing. Store away from foodstuffs. Protect from direct sunlight. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

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

Appropriate engineering

controls

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 Wear safety glasses with side shields (or goggles).

Skin protection

Wear appropriate chemical resistant gloves. Hand protection

Naramune-2™ SDS US Skin protection

Wear suitable protective clothing. Other

Respiratory protection In case of insufficient ventilation, wear suitable respiratory equipment.

Wear appropriate thermal protective clothing, when necessary. Thermal hazards

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.

Lyophilized modified live virus and avirulent live bacterium supplied as a solid plug with a solution **Form**

of liquid diluent.

Color White plug; After rehydration: Cloudy liquid

Not available. Odor Not available. Odor threshold Not available. pН Not available. Melting point/freezing point Initial boiling point and boiling Not available.

range

Not available. Flash point **Evaporation rate** Not available. Flammability (solid, gas) Not available. Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

(%)

Not available.

Not available. Vapor pressure Vapor density Not available. Not available. Relative density

Solubility(ies)

Not available. Solubility (water) **Partition coefficient** Not available.

(n-octanol/water) **Auto-ignition temperature**

Not available. Not available. **Decomposition temperature** Not available.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Material is stable under normal conditions. **Chemical stability**

Possibility of hazardous

reactions

Viscosity

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Strong oxidizing agents. Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

11. Toxicological information

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. May cause skin sensitization in

hypersensitive individuals.

SDS US Naramune-2™

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

In case of accidental injection, wash the site thoroughly. Contact a physician immediately.

Information on toxicological effects

Acute toxicity This product is considered nontoxic.

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation. **Serious eye damage/eye** Direct contact with eyes may cause temporary irritation.

irritation

Respiratory or skin sensitization

Respiratory sensitizationThis product is not expected to cause respiratory sensitization. **Skin sensitization**May cause skin sensitization in hypersensitive individuals.

Germ cell mutagenicityNo 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.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

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 Due to partial or complete lack of data the classification is not possible.

Chronic effects Possible hypersensitization (development of abnormal sensitivity).

12. Ecological information

Ecotoxicity No ecotoxicity data noted for the ingredient(s).

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil This product has not been tested.

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 considerations

Disposal instructionsDispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste codeThe 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

Version #: 01

DOT

Not regulated as dangerous goods.

IATA

940359

Not regulated as dangerous goods.

Revision date: -

Naramune-2™ SDS US

Issue date: 18-October-2017

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

US federal regulations 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)

Hazard categories 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

US. New Jersey Worker and Community Right-to-Know Act

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

Naramune-2™ SDS US 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)

Taiwan Taiwan Chemical Substance Inventory (TCSI)

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 18-October-2017

Revision date - 01

HMIS® ratings Health: 1

Flammability: 1 Physical hazard: 0

NFPA ratings



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Naramune-2™ SDS US

No



MATERIAL SAFETY DATA SHEET

PRODUCT AND COMPANY IDENTIFICATION

Product Name: Naramune-2TM **Product No.:** Not applicable **MSDS ID#:** B14M1.20

GHS Product Identifier: Not applicable

Molecular Formula: Mixture, not applicable Molecular Weight: Mixture, not applicable CAS Number: Mixture, not applicable

Chemical Family: Vaccine

Manufacturer:

Boehringer Ingelheim Vetmedica, Inc. 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 Telephone: (800) 821-7467

Intended Use: For vaccination of healthy susceptible dogs and puppies against Canine Upper Respiratory Infection (Canine Cough) caused by canine parainfluenza and *Bordetella bronchiseptica*.

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Lyophilized modified live virus and avirulent live bacterium supplied as a solid

plug with a solution of liquid diluent.

Color: White plug; After rehydration: Cloudy liquid

Odor: No data available







WARNING!

Allergic reactions can occur.

For use in dogs only.

Not for human use.

Precautionary Statements

Keep only in original container.

Keep at a temperature between 2 - 7°C.

Do not freeze.

Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.

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.

If swallowed, seek medical advice immediately and show this container or label.

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.

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.

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 parainfluenza			proprietary		
virus - Attenuated live					
virus					
Bordetella			proprietary		

bronchiseptica -			
Avirulent bacterium			

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.

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. 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:

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: White plug: After rehydration: Cloudy liquid

Odor: No data available

9

Odor Threshold: No data available

Physical State: Lyophilized modified live virus and avirulent live bacterium supplied as a solid

plug with a solution of liquid diluent.

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

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

Naramune-2TM is considered non-toxic.

Specified Substances

Acute Toxicity: No data available

Chronic Toxicity – 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: 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

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: Non-controlled, 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.

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 302 Extremely Hazardous Substances (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	1	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	1	1	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. Naramune-2TM MSDS and Label

- 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.

Issue Date: 10/12/2011 **Revision Information:** New

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