SAFETY DATA SHEETS

This SDS packet was issued with item:

078377584

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

078377121 078705493



MATERIAL SAFETY DATA SHEET

PRODUCT AND COMPANY IDENTIFICATION

Product Name: CaliberTM 7 Product No.: Not applicable MSDS ID#: B7410.02

GHS Product Identifier: 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 **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: Recommended for the vaccination of healthy, susceptible sheep and cattle, including bred and/or lactating beef and dairy cattle, as an aid in the reduction of diseases caused by *Clostridium chauvoei*, *Cl. Septicum*, *Cl. novyi*, *Cl. sordellii and Clostridium perfringens* Types C and D.

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Deactivated bacterin/toxoids in liquid saline solution, packaged in 20mL bottle.

Color: Brown opaque **Odor:** No data available







DANGER!

Contains a component that may cause cancer.

Allergic reactions can occur.

In vaccines, chronic exposure potential is not expected.

For use in sheep and cattle only.

Not for human use.

Precautionary Statements

Prevention:

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Use personal protective equipment as required.

Response:

If exposed or concerned: Get medical advice/attention.

Storage:

Store locked up.

Disposal:

Dispose of contents/container according to applicable federal and local regulations.

Additional 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.

Injection: Swelling at injection site may occur.

Chronic Health Effects: Possible hypersensitization (development of abnormal sensitivity). Contains formaldehyde and phenol. Formaldehyde has a carcinogenic potential and is a known skin and respiratory sensitizer. Phenol has been shown to be mutagenic or fetotoxic in animals. In vaccines, the chronic exposure potential is negligible.

Target Organ(s): Skin

3

OSHA Regulatory Status: Hazardous (Exempt)

Environment: No data available

COMPOSITION / INFORMATION ON INGREDIENTS

| Chemical Name | EC No. | CAS- No. | Concentration | Classification | Notes |
|--|-----------|----------|---------------|---|-------|
| Clostridium chauvoei bacterin-toxoid - deactivated | | | proprietary | | |
| Clostridium septicum bacterin-toxoid - deactivated | | | proprietary | | |
| Clostridium novyi bacterin-toxoid - deactivated | | | proprietary | | |
| Clostridium sordellii bacterin-toxoid - deactivated | | | proprietary | | |
| Clostridium perfringens Type C bacterin-toxoid - deactivated | | | proprietary | | |
| Clostridium perfringens Type D bacterin-toxoid - deactivated | | | proprietary | | |
| Formaldehyde | 200-001-8 | 50-00-0 | 0.5 % | T; C; C3 R23/24/25, R34, R40, R43 | * |
| Phenol | 203-632-7 | 108-95-2 | 0.5 % | T, C; M3 R23/24/25, R34, R48/20/21/22, R68 | * |

^{*} Used to inactivate virus and subsequently removed from solution. Concentration represents maximum remaining amount by percent weight which is below USDA allowable 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, nitrogen oxides

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:

| Chemical Name | Source | Type | Exposure Limits | Notes |
|---------------|--------|----------|------------------------|------------------|
| Formaldehyde | ACGIH | Ceiling | 0.3 ppm | Sensitizer, |
| | | Exposure | | Suspected |
| | | Limit | | cancer hazard, |
| | | | | Upper |
| | | | | respiratory and |
| | | | | eye irritation |
| Formaldehyde | OSHA | Action | 0.5 ppm | Cancer-suspect |
| | | Level | | agent |
| Formaldehyde | OSHA | TWA | 0.75 ppm | |
| Formaldehyde | OSHA | STEL | 2 ppm | |
| Phenol | ACGIH | TWA | 5 ppm | Upper |
| | | | | respiratory |
| | | | | irritation; Lung |
| | | | | damage; CNS |
| | | | | Impairment |
| Phenol | OSHA | PEL | 5 ppm | Skin |
| | | | _ | designation |

Where lower governmentally imposed exposure limits exist, such limits should take precedence.

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: Brown opaque **Odor:** No data available

9

Odor Threshold: No data available

Physical State: Deactivated bacterin/toxoids in liquid saline solution, packaged in 20mL bottle.

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: Nitrogen oxides

Possibility of Hazardous Reactions: Will not occur.

TOXICOLOGICAL INFORMATION

CaliberTM 7 is considered non-toxic.

Specified Substances

Acute Toxicity

11

| Chemical Name | Test Results | | | | |
|---------------|---|--|--|--|--|
| Formaldehyde | Administration into the eye (rabbit): 750 ug, Severe Irritant | | | | |
| | Administration onto the skin (rabbit): 2 mg/24 h, Severe Irritant | | | | |
| | Oral LD50 (rat): 800 mg/kg | | | | |
| | Dermal LD50 (rabbit): 630 mg/kg | | | | |
| | Inhalation LC50 (rat): 0.48 mg/l/4 hours | | | | |
| Phenol | Administration into the eye (rabbit): 5 mg, Severe Irritant | | | | |
| | Administration onto the skin (rabbit): 500 mg/24 h, Severe | | | | |
| | Irritant | | | | |
| | Oral LD50 (rat): 317 mg/kg | | | | |
| | Dermal LD50 (rabbit): 630 mg/kg | | | | |
| | Inhalation LC50 (rat): 316 mg/m3/4h | | | | |

Chronic Toxicity – Possible hypersensitization (development of abnormal sensitivity). Contains formaldehyde and phenol. Formaldehyde has a carcinogenic potential and is a known skin and respiratory sensitizer. Phenol has been shown to be mutagenic or fetotoxic in animals. In vaccines, the chronic exposure potential is negligible.

Listed Carcinogens:

| Chemical Name | IARC | NTP | OSHA | ACGIH |
|---------------|--------------|------------|----------------|-----------------|
| Formaldehyde | 1: | Known | Cancer suspect | A2: |
| | Carcinogenic | carcinogen | agent | Suspected Human |
| | to humans | | | Carcinogen |

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: Phenol: ID No: 170; Class 2: water-endangering. Formaldehyde: ID No: 112;

Class 2: water-endangering.

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

Caliber TM 7 September 7, 2011

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: D/2/A, 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 - Formaldehyde

US Regulations

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

CERCLA Hazardous Substance List (40 CFR 302.4):

| Component | Reportable Quantity |
|--------------|---------------------|
| Formaldehyde | 100lbs |
| Phenol | 1000lbs |

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

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):

| Component | Reportable Quantity Code | Reportable Quantity |
|--------------|-----------------------------|------------------------|
| Formaldehyde | В | 100lbs |
| Phenol | С | 1000lbs |

SARA Title III

Section 302 Extremely Hazardous Substances (40 CFR 355, Appendix A):

| Component | Reportable Quantity |
|--------------|---------------------|
| Formaldehyde | 100lbs |
| Phenol | 1000lbs |

| Sec | tion 311/312 (40 CFR | 370): | | | | |
|-----|----------------------|-------|-------------------|------|----------|------------------------|
| | Acute (Immediate) | | Chronic (Delayed) | Fire | Reactive | Pressure Generating |

Section 313 Toxic Release Inventory (40 CFR 372):

| Component | CAS No | Weight % |
|--------------|---------|-----------|
| Formaldehyde | 50-00-0 | 0.5 - 0.9 |

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):

Formaldehyde (gas)

Massachusetts Right-To-Know List: Formaldehyde, Phenol Minnesota Hazardous Substances List: Formaldehyde, Phenol New Jersey Right-To-Know List: Formaldehyde, Phenol Pennsylvania Right-To-Know List: Formaldehyde, Phenol Rhode Island Right-To-Know List: Formaldehyde, Phenol

European Regulations

Austria MAK List (Annex I): Formaldehyde, Phenol

Denmark (Annex 3.6): Formaldehyde

Germany (Dangerous Substances Ordinance 2004, Annex III): Formaldehyde

Norway (List of Dangerous Substance): Formaldehyde, Phenol

Sweden (Annex 3): Formaldehyde

Switzerland (Toxins List 1): Formaldehyde, Phenol

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

T – Toxic

C – Corrosive

C3 – Carcinogen category 3

M3 – Mutagen category 3

R23/24/25 – Toxic by inhalation, in contact with skin and if swallowed.

R34 – Causes burns.

R40 – Limited evidence of a carcinogenic effect.

R43 – May cause sensitization by skin contact.

R48/20/21/22 – Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.

R68 – Possible risks of irreversible effects.

ABBREVIATIONS:

BIV – Boehringer Ingelheim Vetmedica, Inc.

N/A – Not applicable

N/E – Not established

pph – parts per hour

ppm – parts per million

References:

1. CaliberTM 7 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: 09/07/2011 **Revision Information:** New

Disclaimer: The information provided herein is offered by Boehringer Ingelheim Vetmedica, Inc. ("BIV") in good faith as accurate as of the date hereof, but without guarantee. This information includes information which has been generated by other parties and provided to BIV, and which BIV has not independently verified. The information provided herein relates only to the specific product designated, and may not be valid where such product is used in combination with any other materials or in any process. The information provided herein is offered solely for your consideration, investigation and verification, and Boehringer Ingelheim Vetmedica, Inc. ("BIV") expressly disclaims all liability for reliance thereon. BIV EXPRESSLY DISCLAIMS ALL WARRANTIES OF EVERY KIND AND NATURE (INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE) WITH RESPECT TO THE USE OR SUITABILITY OF THE PRODUCT. In addition, since the conditions of use and suitability of the product for particular uses are beyond BIV's control, ALL RISKS OF USE OF THE PRODUCT ARE THEREFORE ASSUMED BY THE USER, AND BIV EXPRESSLY DISCLAIMS ANY AND ALL LIABILITY AS TO ANY RESULTS OBTAINED OR ARISING FROM ANY USE OF THE PRODUCT. Use or transmission of the information contained herein in any other format than the format as presented is strictly prohibited. Nothing herein shall be construed as permission or recommendation for the use of the product in a manner that might infringe an existing patent. BIV neither represents nor warrants that the format, content or product formulas contained in this document comply with the laws of any other country except the United States of America.

© Copyright 2011 Boehringer Ingelheim Vetmedica, Inc. All rights reserved.



SAFETY DATA SHEET

1. Identification

Product identifier Caliber™ 7

Other means of identification None.

Recommended use For the vaccination of healthy, susceptible sheep and cattle as an aid in the reduction diseases.

Recommended restrictions None known.

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 Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Avoid breathing mist or vapor. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection.

Response If on skin: Wash with plenty of water. If exposed or concerned: Get medical advice/attention. 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 None.

3. Composition/information on ingredients

Mixtures

| Chemical name | CAS number | % |
|---------------|------------|-----|
| Formaldehyde* | 50-00-0 | 0.5 |
| Phenol* | 108-95-2 | 0.5 |

Caliber™ 7 SDS US

928642 Version #: 02 Revision date: 30-May-2018 Issue date: 22-July-2015

| Clostridium chavoei bacterin-toxoid - deactivated | Proprietary |
|--|-------------|
| Clostridium novyi bacterin-toxoid - deactivated | Proprietary |
| Clostridium perfringens Type C bacterin-toxoid - deactivated | Proprietary |
| Clostridium perfringens Type D bacterin-toxoid - deactivated | Proprietary |
| Clostridium septicum bacterin-toxoid - deactivated | Proprietary |
| Clostridium sordellii bacterin-toxoid - deactivated | Proprietary |

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

Indication of immediate medical attention and special May cause an allergic skin reaction. Dermatitis. Rash. Ingestion of a large quantity may cause vomiting, nausea, dizziness, drowsiness and other systemic effects. Prolonged exposure may cause chronic effects.

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. Not for human use. For use in cattle and swine only. Persons developing anaphylactic (life threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

General information

treatment needed

IF exposed or concerned: Get medical advice/attention. 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

Unsuitable extinguishing

media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

None known.

Specific hazards arising from

the chemical

During fire, gases hazardous to health may be formed.

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

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

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. Wear appropriate protective equipment and clothing during clean-up. Avoid breathing mist or vapor. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. 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.

Never return spills to original containers for re-use. 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

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Provide adequate ventilation. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Should be handled in closed systems, if possible. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Persons susceptible to allergic reactions should not handle this product.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Store away from foodstuffs. Store in the dark at 2°C to 7°C (35°F to 45°F). Avoid freezing. Shake Well. Protect from direct sunlight. Store away from incompatible materials, see Section 10 of the SDS.

8. Exposure controls/personal protection

Occupational exposure limits

| Components | Туре | Value | |
|---------------------------------|--------------------------------|-----------|--|
| Formaldehyde* (CAS 50-00-0) | STEL | 2 ppm | |
| | TWA | 0.75 ppm | |
| US. OSHA Table Z-1 Limits for A | ir Contaminants (29 CFR 1910.1 | 000) | |
| Components | Туре | Value | |
| Phenol* (CAS 108-95-2) | PEL | 19 mg/m3 | |
| | | 5 ppm | |
| US. ACGIH Threshold Limit Valu | es | | |
| Components | Туре | Value | |
| Formaldehyde* (CAS 50-00-0) | STEL | 0.3 ppm | |
| | TWA | 0.1 ppm | |
| Phenol* (CAS 108-95-2) | TWA | 5 ppm | |
| US. NIOSH: Pocket Guide to Che | mical Hazards | | |
| Components | Type | Value | |
| Formaldehyde* (CAS 50-00-0) | Ceiling | 0.1 ppm | |
| | TWA | 0.016 ppm | |
| Phenol* (CAS 108-95-2) | Ceiling | 60 mg/m3 | |
| | | 15.6 ppm | |
| | TWA | 19 mg/m3 | |
| | | 5 ppm | |

Biological limit values

| ACGIH Biological Exposure Indices | | | | | |
|-----------------------------------|----------|------------------------|---------------------|---------------|--|
| Components | Value | Determinant | Specimen | Sampling Time | |
| Phenol* (CAS 108-95-2) | 250 mg/g | Phenol with hydrolysis | Creatinine in urine | * | |

^{* -} For sampling details, please see the source document.

Exposure guidelines

US - California OELs: Skin designation

Phenol* (CAS 108-95-2)

Can be absorbed through the skin.

 Caliber™ 7
 SDS US

 928642
 Version #: 02
 Revision date: 30-May-2018
 Issue date: 22-July-2015
 3 / 9

US - Minnesota Haz Subs: Skin designation applies

Phenol* (CAS 108-95-2) Skin designation applies.

US - Tennessee OELs: Skin designation

Phenol* (CAS 108-95-2) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

Phenol* (CAS 108-95-2) Can be absorbed through the skin.

US. NIOSH: Pocket Guide to Chemical Hazards

Phenol* (CAS 108-95-2) Can be absorbed through the skin.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Phenol* (CAS 108-95-2) Can be absorbed through the skin.

Appropriate engineering

controls

Good general ventilation 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. Not normally needed.

Individual protection measures, such as personal protective equipment

Eye/face protection Chemical respirator with organic vapor cartridge and full facepiece.

Skin protection

Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove Hand protection

supplier. Wear protective gloves.

Skin protection

Other Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended. Wear

protective aloves.

Chemical respirator with organic vapor cartridge and full facepiece. Respiratory protection

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. 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. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance

Physical state

Liquid. Deactivated bacterin/toxoids in liquid saline solution, packaged in 20mL bottle. **Form**

Color Opaque Brown Odor Not available. **Odor threshold** Not available. Ha Not available. Melting point/freezing point Not available. Initial boiling point and boiling

range

Not available.

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

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

(%)

Not available. Explosive limit - lower (%) Explosive limit - upper (%) Not available. Not available. Vapor pressure Vapor density Not available. Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Explosive properties Not explosive. **Oxidizing properties** Not oxidizing.

10. Stability and reactivity

ReactivityThe 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. Excessive heat. Keep from freezing.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

InhalationProlonged inhalation may be harmful.Skin contactMay cause an allergic skin reaction.

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

May cause an allergic skin reaction. Dermatitis. Rash. Ingestion of a large quantity may cause vomiting, nausea, dizziness, drowsiness and other systemic effects. Prolonged exposure may

cause chronic effects.

Information on toxicological effects

Acute toxicity Not expected to be acutely toxic.

| Components | Species | Test Results | |
|--------------------------|---------|--------------|--|
| Formaldehyde* (CAS 50-00 | 0-0) | | |
| <u>Acute</u> | | | |
| Dermal | | | |
| LD50 | Rat | 270 mg/kg | |

Inhalation
LC50 Rat 0.578 mg/l, 4 hours

Oral

LD50 Rat 100 mg/kg

Phenol* (CAS 108-95-2)

<u>Acute</u> Dermal

LD50 Rat 525 mg/kg

Oral

LD50 Rat 317 mg/kg

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

irritation

928642

Respiratory or skin sensitization

ACGIH sensitization

Version #: 02

FORMALDEHYDE (CAS 50-00-0) Dermal sensitization

Revision date: 30-May-2018

Caliber™ 7 SDS US

Issue date: 22-July-2015

Respiratory sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization May cause an allergic skin reaction.

Germ cell mutagenicityNo data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Carcinogenicity May cause cancer. 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.

Phenol* (CAS 108-95-2) 3 Not classifiable as to carcinogenicity to humans.

NTP Report on Carcinogens

Formaldehyde* (CAS 50-00-0) Known To Be Human Carcinogen.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)
Formaldehyde* (CAS 50-00-0)

Cancer

Reproductive toxicityThis 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 Prolonged inhalation may be harmful. Prolonged exposure may cause 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.

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

Partition coefficient n-octanol / water (log Kow)

Formaldehyde* (CAS 50-00-0) 0.35 Phenol* (CAS 108-95-2) 1.46

Mobility in soil Expected to be slightly to moderately mobile in soil.

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 instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of

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

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

928642

Not regulated as dangerous goods.

Version #: 02 Revision date: 30-May-2018

Caliber™ 7 SDS US

Issue date: 22-July-2015

IATA

Not regulated as dangerous goods.

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.

CERCLA Hazardous Substance List (40 CFR 302.4)

Formaldehyde* (CAS 50-00-0) Listed. Phenol* (CAS 108-95-2) Listed.

SARA 304 Emergency release notification

Formaldehyde* (CAS 50-00-0) 100 LBS Phenol* (CAS 108-95-2) 1000 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Formaldehyde* (CAS 50-00-0)

Skin sensitization Respiratory sensitization

Eye irritation Skin irritation

respiratory tract irritation

Acute toxicity Flammability

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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) |
|---------------|------------|------------------------------------|--|--|--|
| Formaldehyde* | 50-00-0 | 100 | 500 | | |
| Phenol* | 108-95-2 | 1000 | | 500 | 10000 |

SARA 311/312 Hazardous

chemical

Classified hazard Respiratory or skin sensitization

Yes

Carcinogenicity categories

SARA 313 (TRI reporting)

| Chemical name | CAS number | % by wt. | |
|---------------|------------|----------|--|
| Formaldehyde* | 50-00-0 | 0.5 | |

Other federal regulations

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

Formaldehyde* (CAS 50-00-0)

Phenol* (CAS 108-95-2)

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

Formaldehyde* (CAS 50-00-0)

Safe Drinking Water Act Not regulated.

(SDWA)

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

Phenol* (CAS 108-95-2) Low priority

US state regulations

US. Massachusetts RTK - Substance List

Formaldehyde* (CAS 50-00-0)

Phenol* (CAS 108-95-2)

US. New Jersey Worker and Community Right-to-Know Act Formaldehyde* (CAS 50-00-0)

Phenol* (CAS 108-95-2)

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

Formaldehyde* (CAS 50-00-0) Phenol* (CAS 108-95-2)

US. Rhode Island RTK

Formaldehyde* (CAS 50-00-0) Phenol* (CAS 108-95-2)

California Proposition 65



WARNING: This product can expose you to Formaldehyde*, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Carcinogenic substance

Formaldehyde* (CAS 50-00-0) Listed: January 1, 1988

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Formaldehyde* (CAS 50-00-0) Phenol* (CAS 108-95-2)

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) No Existing Chemicals List (ECL) Korea Nο New Zealand Inventory New Zealand Νo **Philippines** Philippine Inventory of Chemicals and Chemical Substances No (PICCS)

Taiwan Taiwan Chemical Substance Inventory (TCSI) No United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory Nο

16. Other information, including date of preparation or last revision

Issue date 22-July-2015 **Revision date** 30-May-2018

Version #

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).

Health: 2* **HMIS®** ratings

Flammability: 0 Physical hazard: 0

^{*}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).

NFPA ratings



Disclaimer

The information provided herein is offered by Boehringer Ingelheim Vetmedica, Inc. ("BIVI") in good faith as accurate as of the date hereof, but without guarantee. This information includes information which has been generated by other parties and provided to BIVI, and which BIVI has not independently verified. The information provided herein relates only to the specific product designated, and may not be valid where such product is used in combination with any other materials or in any process. The information provided herein is offered solely for your consideration, investigation and verification, and Boehringer Ingelheim Vetmedica, Inc. ("BIVI") expressly disclaims all liability for reliance thereon. BIVI EXPRESSLY DISCLAIMS ALL WARRANTIES OF EVERY KIND AND NATURE (INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE) WITH RESPECT TO THE USE OR SUITABILITY OF THE PRODUCT. In addition, since the conditions of use and suitability of the product for particular uses are beyond BIVI's control, ALL RISKS OF USE OF THE PRODUCT ARE THEREFORE ASSUMED BY THE USER, AND BIVI EXPRESSLY DISCLAIMS ANY AND ALL LIABILITY AS TO ANY RESULTS OBTAINED OR ARISING FROM ANY USE OF THE PRODUCT. Use or transmission of the information contained herein in any other format than the format as presented is strictly prohibited. Nothing herein shall be construed as permission or recommendation for the use of the product in a manner that might infringe an existing patent. BIVI neither represents nor warrants that the format, content or product formulas contained in this document comply with the laws of any other country except the United States of America. Boehringer Ingelheim cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.