

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078377758

N/A



# MATERIAL SAFETY DATA SHEET

## 1 PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Ingelvac® AR4

**Product No.:** Not applicable

**MSDS ID#:** B7060.00

**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 swine against atrophic rhinitis  
caused by toxigenic *Bordetella*  
*bronchiseptica* and *Pasteurella multocida*  
toxigenic Type D and protects against toxin  
produced by *Pasteurella multocida* toxigenic  
Type A.

## 2 HAZARDS IDENTIFICATION

### Emergency Overview

**Physical State:** Inactivated bacterin-toxoid supplied in liquid saline solution in 100mL bottles.

**Color:** White, cream or light tan 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 swine 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. Formaldehyde has a carcinogenic potential and is a known skin and respiratory sensitizer. In vaccines, the chronic exposure potential is negligible.

**Target Organ(s):** Skin

**OSHA Regulatory Status:** Hazardous (Exempt)

**Environment:** No data available

### 3 COMPOSITION / INFORMATION ON INGREDIENTS

| Chemical Name   | EC No.    | CAS- No. | Concentration | Classification                          | Notes |
|---|-----------|----------|---------------|---|-------|
| <i>Bordetella bronchiseptica</i><br>(inactivated bacterin-toxoid) | ----      | ----     | proprietary   | ----                                    | ---   |
| <i>Pasteurella multocida</i><br>(inactivated bacterin-toxoid)     | ----      | ----     | proprietary   | ----                                    | ---   |
| Formaldehyde  | 200-001-8 | 50-00-0  | <= 0.2%       | T; C; C3<br>R23/24/25, R34,<br>R40, R43 | *     |

\* 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 Exposure Limit | 0.3 ppm         | Sensitizer, Suspected 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    | ----  |

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:

**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

## 9 PHYSICAL AND CHEMICAL PROPERTIES

**Color:** White, cream or light tan opaque

**Odor:** No data available

**Odor Threshold:** No data available

**Physical State:** Inactivated bacterin-toxoid supplied in liquid saline solution in 100mL bottles.

**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.

## 11 TOXICOLOGICAL INFORMATION

Ingelvac® AR4 is considered non-toxic.

### Specified Substances

#### Acute Toxicity

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

**Chronic Toxicity** – Possible hypersensitization (development of abnormal sensitivity). Contains formaldehyde. Formaldehyde has a carcinogenic potential and is a known skin and respiratory sensitizer. In vaccines, the chronic exposure potential is negligible.

#### Listed Carcinogens:

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

**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              |

**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 | B                        | 100lbs              |

**SARA Title III****Section 302 Extremely Hazardous Substances (40 CFR 355, Appendix A):**

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

**Section 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 | <= 0.2   |

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

Formaldehyde (gas)

**Massachusetts Right-To-Know List:** Formaldehyde**Minnesota Hazardous Substances List:** Formaldehyde**New Jersey Right-To-Know List:** Formaldehyde**Pennsylvania Right-To-Know List:** Formaldehyde**Rhode Island Right-To-Know List:** Formaldehyde**European Regulations****Austria MAK List (Annex I):** Formaldehyde**Denmark (Annex 3.6):** Formaldehyde**Germany (Dangerous Substances Ordinance 2004, Annex III):** Formaldehyde**Norway (List of Dangerous Substance):** Formaldehyde**Sweden (Annex 3):** Formaldehyde**Switzerland (Toxins List 1):** Formaldehyde

|           |                          |
|-----------|--------------------------|
| <b>16</b> | <b>OTHER INFORMATION</b> |
|-----------|--------------------------|

**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

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.

**ABBREVIATIONS:**

BIV – Boehringer Ingelheim Vetmedica, Inc.

N/A – Not applicable

N/E – Not established

pph – parts per hour

ppm – parts per million

**References:**

1. Ingelvac® AR4 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

**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.



# MATERIAL SAFETY DATA SHEET

## 1 PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Ingelvac® AR4  
**Product No.:** Not applicable  
**MSDS ID#:** B7060.00  
**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 swine against atrophic rhinitis  
caused by toxigenic *Bordetella*  
*bronchiseptica* and *Pasteurella multocida*  
toxigenic Type D and protects against toxin  
produced by *Pasteurella multocida* toxigenic  
Type A.

## 2 HAZARDS IDENTIFICATION

### Emergency Overview

**Physical State:** Inactivated bacterin-toxoid supplied in liquid saline solution in 100mL bottles.  
**Color:** White, cream or light tan 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 swine 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. Formaldehyde has a carcinogenic potential and is a known skin and respiratory sensitizer. In vaccines, the chronic exposure potential is negligible.

**Target Organ(s):** Skin

**OSHA Regulatory Status:** Hazardous (Exempt)

**Environment:** No data available

### 3 COMPOSITION / INFORMATION ON INGREDIENTS

| Chemical Name   | EC No.    | CAS- No. | Concentration | Classification                          | Notes |
|---|-----------|----------|---------------|---|-------|
| <i>Bordetella bronchiseptica</i><br>(inactivated bacterin-toxoid) | ----      | ----     | proprietary   | ----                                    | ---   |
| <i>Pasteurella multocida</i><br>(inactivated bacterin-toxoid)     | ----      | ----     | proprietary   | ----                                    | ---   |
| Formaldehyde  | 200-001-8 | 50-00-0  | ≤ 0.2%        | T; C; C3<br>R23/24/25, R34,<br>R40, R43 | *     |

\* 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 Exposure Limit | 0.3 ppm         | Sensitizer, Suspected 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    | ----  |

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:

**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

|          |   |
|----------|---|
| <b>9</b> | <b>PHYSICAL AND CHEMICAL PROPERTIES</b> |
|----------|---|

**Color:** White, cream or light tan opaque

**Odor:** No data available

**Odor Threshold:** No data available

**Physical State:** Inactivated bacterin-toxoid supplied in liquid saline solution in 100mL bottles.

**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.

## 11 TOXICOLOGICAL INFORMATION

Ingelvac® AR4 is considered non-toxic.

### Specified Substances

#### Acute Toxicity

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

**Chronic Toxicity** – Possible hypersensitization (development of abnormal sensitivity). Contains formaldehyde. Formaldehyde has a carcinogenic potential and is a known skin and respiratory sensitizer. In vaccines, the chronic exposure potential is negligible.

#### Listed Carcinogens:

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

**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              |

**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 | B                        | 100lbs              |

**SARA Title III****Section 302 Extremely Hazardous Substances (40 CFR 355, Appendix A):**

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

**Section 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 | <= 0.2   |

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

Formaldehyde (gas)

**Massachusetts Right-To-Know List:** Formaldehyde**Minnesota Hazardous Substances List:** Formaldehyde**New Jersey Right-To-Know List:** Formaldehyde**Pennsylvania Right-To-Know List:** Formaldehyde**Rhode Island Right-To-Know List:** Formaldehyde**European Regulations****Austria MAK List (Annex I):** Formaldehyde**Denmark (Annex 3.6):** Formaldehyde**Germany (Dangerous Substances Ordinance 2004, Annex III):** Formaldehyde**Norway (List of Dangerous Substance):** Formaldehyde**Sweden (Annex 3):** Formaldehyde**Switzerland (Toxins List 1):** Formaldehyde

|           |                          |
|-----------|--------------------------|
| <b>16</b> | <b>OTHER INFORMATION</b> |
|-----------|--------------------------|

**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

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.

**ABBREVIATIONS:**

BIV – Boehringer Ingelheim Vetmedica, Inc.

N/A – Not applicable

N/E – Not established

pph – parts per hour

ppm – parts per million

**References:**

1. Ingelvac® AR4 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

**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.