

SAFETY DATA SHEET



Revision date: 14-Mar-2014

Version: 2.1

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Clostridium chauvoei-septicum-haemolyticum-novyi-sordellii-perfringens Types C&D Bacterin-Toxoid

Trade Name: UltraChoice® 8
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary Vaccine

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison Control Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Liquid solution in multiple-dose vials

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1
Carcinogenicity: Category 1A

EU Classification:

EU Indication of danger: Harmful
Carcinogenic: Category 3

EU Symbol: Xn

EU Risk Phrases:
R40 - Limited evidence of a carcinogenic effect
R43 - May cause sensitization by skin contact.

Label Elements

Signal Word: Danger
Hazard Statements: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction
H350 - May cause cancer

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Precautionary Statements:

- P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
- P284 - Wear respiratory protection
- P272 - Contaminated work clothing should not be allowed out of the workplace
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
- P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
- P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
- P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
- P362 - Take off contaminated clothing and wash before reuse
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards
Short Term:

May cause eye, skin and respiratory tract irritation. In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.
 Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|--------------|------------|-----------------------|--|--|-------|
| Formaldehyde | 50-00-0 | 200-001-8 | T; R23/24/25 C; R34 Carc.Cat.3; R40 R43 | Acute Tox. 3 (H301) Skin Corr. 1B (H314) Skin Sens. 1 (H317) Carc. 1A (H350) Acute Tox. 3 (H331) | < 0.2 |
| Saponin | 8047-15-2 | 232-462-6 | Not Listed | Not Listed | ## |

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3. COMPOSITION/INFORMATION ON INGREDIENTS

| | | | | | |
|----------------------------|-----------|------------|------------|------------|----|
| Aluminum potassium sulfate | 7784-24-9 | Not Listed | Not Listed | Not Listed | ## |
|----------------------------|-----------|------------|------------|------------|----|

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|--------------------------------|--------------|-----------------------|-------------------|--------------------|------|
| Clostridium haemolyticum | NOT ASSIGNED | Not Listed | Not Listed | Not Listed | * |
| Clostridium sordellii | NOT ASSIGNED | Not Listed | Not Listed | Not Listed | * |
| Clostridium novyi | NOT ASSIGNED | Not Listed | Not Listed | Not Listed | * |
| Clostridium chauvoei | NOT ASSIGNED | Not Listed | Not Listed | Not Listed | * |
| Clostridium perfringens type D | NOT ASSIGNED | Not Listed | Not Listed | Not Listed | * |
| Clostridium septicum | NOT ASSIGNED | Not Listed | Not Listed | Not Listed | * |
| Clostridium perfringens type C | NOT ASSIGNED | Not Listed | Not Listed | Not Listed | * |
| Water, purified | 7732-18-5 | 231-791-2 | Not Listed | Not Listed | >90% |

Additional Information:

* Proprietary

Trace

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation:

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure:

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure:

None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:

None

5. FIRE-FIGHTING MEASURES

Extinguishing Media:

Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment. Wash thoroughly after handling. Prevent environmental releases. Avoid accidental injection.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store under refrigeration in closed container. Do not freeze. Keep container tightly closed when not in use.

Storage Temperature: 2-7°C

Incompatible Materials: This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Formaldehyde

| | |
|---------------------------------------|-----------------------|
| ACGIH Ceiling Threshold Limit: | 0.3 ppm |
| ACGIH - Sensitizer Designation | Sensitizer |
| Australia STEL | 2 ppm |
| | 2.5 mg/m ³ |
| Australia TWA | 1 ppm |
| | 1.2 mg/m ³ |
| Austria OEL - MAKs | 0.5 ppm |
| | 0.6 mg/m ³ |
| Bulgaria OEL - TWA | 1.0 mg/m ³ |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---|---|
| Czech Republic OEL - TWA | 0.5 mg/m ³ |
| Estonia OEL - TWA | 0.5 ppm |
| | 0.6 mg/m ³ |
| Finland OEL - TWA | 0.3 ppm |
| | 0.37 mg/m ³ |
| France OEL - TWA | 0.5 ppm |
| Germany (DFG) - MAK | 0.3 ppm |
| | 0.37 mg/m ³ no irritation should occur during mixed exposure |
| Greece OEL - TWA | 2 ppm |
| | 2.5 mg/m ³ |
| Hungary OEL - TWA | 0.6 mg/m ³ |
| Ireland OEL - TWAs | 2 ppm |
| | 2.5 mg/m ³ |
| Japan - OELs - Ceilings | 0.2 ppm |
| | 0.24 mg/m ³ |
| Latvia OEL - TWA | 0.5 mg/m ³ |
| Lithuania OEL - TWA | 0.5 ppm |
| | 0.6 mg/m ³ |
| Netherlands OEL - TWA | 0.15 mg/m ³ |
| Vietnam OEL - TWAs | 0.5 mg/m ³ |
| OSHA - Final PELs - TWAs: | 0.75 ppm |
| OSHA - Specifically Regulated Chemicals | 2 ppm |
| | 0.5 ppm |
| | 0.75 ppm |
| Poland OEL - TWA | 0.5 mg/m ³ |
| Romania OEL - TWA | 1 ppm |
| | 1.20 mg/m ³ |
| Slovakia OEL - TWA | 0.3 ppm |
| | 0.37 mg/m ³ |
| Slovenia OEL - TWA | 0.5 ppm |
| | 0.62 mg/m ³ |
| Sweden OEL - TWAs | 0.3 ppm |
| | 0.37 mg/m ³ |
| Switzerland OEL -TWAs | 0.3 ppm |
| | 0.37 mg/m ³ |

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Exposure monitoring may be necessary to determine requirements.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Wear impervious gloves if skin contact is possible.

Eyes:

Safety glasses or goggles

Skin:

Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection:

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|---|--|--------------------------|--------------------|
| Physical State: | Liquid Solution in multiple-dose vials | Color: | No data available. |
| Odor: | No data available. | Odor Threshold: | No data available. |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |
| Solvent Solubility: | No data available | | |
| Water solubility: | Components are soluble in water | | |
| Water Solubility: | No data available | | |
| pH: | 7.0 +/- 1.5 | | |
| Melting/Freezing Point (°C): | No data available | | |
| Boiling Point (°C): | >100 | | |
| Partition Coefficient: (Method, pH, Endpoint, Value) | No data available | | |
| Decomposition Temperature (°C): | No data available. | | |
| Evaporation Rate (Gram/s): | No data available | | |
| Vapor Pressure (kPa): | Expected to be negligible | | |
| Vapor Density (g/ml): | No data available | | |
| Relative Density: | No data available | | |
| Specific Gravity: | 1.0 +/-0.2 | | |
| Viscosity: | No data available | | |
| Flammability: | | | |
| Autoignition Temperature (Solid) (°C): | No data available | | |
| Flammability (Solids): | No data available | | |
| Flash Point (Liquid) (°C): | Non-flammable | | |
| Upper Explosive Limits (Liquid) (% by Vol.): | No data available | | |
| Lower Explosive Limits (Liquid) (% by Vol.): | No data available | | |
| Polymerization: | Will not occur | | |

10. STABILITY AND REACTIVITY

| | |
|---|--|
| Reactivity: | No data available |
| Chemical Stability: | Stable under normal conditions of use. |
| Possibility of Hazardous Reactions | |
| Oxidizing Properties: | No data available |
| Conditions to Avoid: | Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze. |
| Incompatible Materials: | This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals. |
| Hazardous Decomposition Products: | None expected under normal conditions. |

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. The information included in this section describes the potential hazards of the individual ingredients.

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11. TOXICOLOGICAL INFORMATION

Acute Toxicity: (Species, Route, End Point, Dose)

Formaldehyde

Rat Oral LD50 800 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Formaldehyde

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Moderate Severe
Skin Sensitization Positive

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Formaldehyde

90 Day(s) Dog Inhalation Not Specified Lungs
90 Day(s) Rat Inhalation Not Specified Lungs
90 Day(s) Monkey Inhalation Not Specified Lungs
90 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Formaldehyde

Embryo / Fetal Development Mouse Oral 185 mg/kg/day Not teratogenic, Maternal toxicity
Embryo / Fetal Development Rat Inhalation 40 ppm Not Teratogenic, Maternal Toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Formaldehyde

In Vitro Bacterial Mutagenicity (Ames) Bacteria Positive
In Vitro Chromosome Aberration Rodent Positive
In Vitro Sister Chromatid Exchange Rodent Positive
In Vivo Chromosome Aberration Not specified Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors
2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

Carcinogen Status: See below

Formaldehyde

IARC: Group 1 (Carcinogenic to Humans)
NTP: Known Human Carcinogen
OSHA: Listed

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15. REGULATORY INFORMATION



Formaldehyde

| | |
|---|------------------------------------|
| CERCLA/SARA 313 Emission reporting | 0.1 % |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 100 lb 45.4 kg |
| CERCLA/SARA - Section 302 Extremely Hazardous TPQs | 500 lb |
| CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs | 100 lb |
| California Proposition 65 | carcinogen initial date 1/1/88 gas |
| OSHA - Specifically Regulated Chemicals | 2 ppm 0.5 ppm 0.75 ppm |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 2 Schedule 6 |
| EU EINECS/ELINCS List | 200-001-8 |

Saponin

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 232-462-6 |

Clostridium haemolyticum

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Clostridium sordellii

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Clostridium novyi

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Aluminum potassium sulfate

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | Not Listed |

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15. REGULATORY INFORMATION

Clostridium chauvoei

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Clostridium perfringens type D

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Clostridium septicum

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Clostridium perfringens type C

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Water, purified

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | 231-791-2 |

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H301 - Toxic if swallowed
H314 - Causes severe skin burns and eye damage
H317 - May cause an allergic skin reaction
H331 - Toxic if inhaled
H350 - May cause cancer

Carcinogenic: Category 3

T - Toxic
C - Corrosive

R34 - Causes burns.
R40 - Limited evidence of a carcinogenic effect
R43 - May cause sensitization by skin contact.
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.

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Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet