SAFETY DATA SHEETS

This SDS packet was issued with item:

078344173

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

078408775 078423211

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078344165

MSD Animal Health
Breakspear Road South
Harefield, Uxbridge
Middlesex, England UB9 6LS

SAFETY DATA SHEET

MSD Animal Health urges each user or recipient of this SDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

SDS NAME: **COVEXIN**

SYNONYM(S): COVEXIN 8
TASVAX 8
6+HAEN (US)
7+HAEN
Clostridium chauvoei, C. septicum, C. haemolyticum, C. novyi, C. tetani, C. perfringens Type B, C.& D

SDS Number: SP000714

EMERGENCY NUMBER(S): +1 (908) 423-6000 (24/7/365) English Only

MSD Security Control Center (908) 820-6921 (24 Hours)

EU Transportation Emergencies - Carechem24:
+44 (0)208 762 8322 (24 hours/7 days/week)

INFORMATION: (0 11 44) 1895 62 6000 (MSD Animal Health- Harefield)

MERCK SDS HELPLINE: +1 (908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SDS EMAIL: spmsds@spcorp.com

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Light brown to amber
Liquid
Odor unknown
May be irritating to eyes, skin or respiratory tract.
May cause allergic reactions in susceptible individuals.
May cause effects to:
gastrointestinal tract
liver
kidney

POTENTIAL HEALTH EFFECTS:

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. However, there are data to describe the toxicological properties of the individual ingredients. The following summary is based upon available information about the individual ingredients of the mixture(s), or of the expected properties of the mixture(s). Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) are presented.

This product is a vaccine for use in animals. Pathogenic clostridial bactrial strains may cause infection to damaged skin. Local irritation to the eyes, skin, or respiratory tract may occur following direct contact or inhalation of the product. As with any vaccine, exposure may cause hypersensitvity reactions.

Potassium aluminum sulfate dodecahydrate, an ingredient in this product, is an astringent (causes contraction of the tissues). Alum compounds are mucous membrane irritants. Inhalation of dust or mist causes irritation to the eyes, nose, mouth, and respiratory tract. Prolonged dermal contact may cause a numbing sensation in the fingers. Ingestion of alum compounds may cause cramping, nausea, vomiting and bleeding and inflammation of the mucous membrane of the stomach and intestine. Alum compounds have also been reported to cause liver damage following acute and chronic exposure, as well as, liver and renal necrosis in animal studies.

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by IARC or EU Directive 90/394 (Annex I) in this mixture.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Vaccine

CHEMICAL FORMULA: Mixture.

The formulations for these products are proprietary information. These formulations have the same hazardous profile; however, the presence of hazardous ingredients may vary by formulation. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

The product(s) may contain preservatives, as listed, in concentrations less than 1%.

This formulation may contain some sodium hydroxide for pH adjustment.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	EC NUMBER	EU CLASSIFICATION	PERCENT
C. perfringens B 1240 (Inactivated)				Varies
C. perfringens B 3424 (Inactivated)				Varies
C. septicum toxoid (inactivated)				Varies
C. tetani toxoid (inactivated)				Varies
Potassium aluminium sulfate dodecahydrate	7784-24-9	233-141-3		< 10
C. novyi Type B toxoid (inactivated)				Varies
C. chauvoei whole cell culture (inactivated)				Varies
C. perfringens Type D toxoid (inactivated)				Varies

INGREDIENT	CAS NUMBER	EC NUMBER	EU CLASSIFICATION	PERCENT
C. haemolyticum toxoid (inactivated)				Varies
C. perfringens Type C toxoid (inactivated)				Varies
Preservative (Thimerosal)	54-64-8	200-210-4	T;R23/24/25 Xn;R48/20/21/22 N;R50/53	<1

Fields in the above table that do not contain data indicate that the substance(s) have not been listed or classified according to EU criteria.

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

See section 15 for EU hazard classification symbols and risk and safety phrases.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

NOTE TO PHYSICIAN: This product is a vaccine. Accidental injection may cause local swelling, irritation or necrosis at the injection site. This preparation contains a preservative or antibiotic or both which may cause allergic reactions in susceptible individuals.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO_2), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:
Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

SPILL RESPONSE / CLEANUP:
Notify Emergency Spill Response Team if spill is greater than one liter or worker is uncomfortable with clean up procedure.

For small spills, treat with disinfectant such as diluted (5% v/v) chlorine bleach. Use protective gloves, lab coat and eye protection. For larger spills, leave room, closing door behind. Allow aerosols to settle for at least 15 minutes. Re-enter room and absorb spilled liquid with paper towels. Wash contaminated area with disinfectant such as diluted (5% v/v) chlorine bleach. Place all spill residue in a double plastic bag and seal. Dispose of spill residue in accordance with federal, state, and local waste disposal regulations.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

HANDLING:

Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

CONDITIONS FOR SAFE STORAGE, INCLUDING ANY IMCOMPATIBILITIES

STORAGE:
Store between 2 and 8 deg C. Do not freeze. Store out of direct sunlight.

SPECIFIC END USE(S)
Refer to Section 1 for identified use(s).

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

EXPOSURE CONTROLS
The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	In laboratories and small-scale operations, respirators are not normally required; however, appropriate respiratory protection may be required in situations where exposure (e.g. spills, process upsets, or non-routine maintenance) may exceed any available recommended exposure limit. Consult your site safety staff for guidance. In manufacturing and large-scale operations, powered air purifying respirators (PAPRs) or positive-pressure air supplied respirators with full-face coverage may be required dependent on the level of exposure. Appropriate respiratory protection is required in situations where exposure (e.g. spills, process upsets, or non-routine maintenance) may exceed any available recommended exposure limit. Consult your site safety staff for guidance.
Skin Protection:	Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.
Eye Protection:	Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

Body Protection:

In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

EXPOSURE LIMIT VALUES:

INGREDIENT	CAS NUMBER	EU	Austria	Belgium	Denmark	France
Preservative (Thimerosal)	54-64-8		STEL 0.1 mg/m^3 S* MAK 0.01 mg/m^3		TWA 0.05 mg/m^3 S*	

INGREDIENT	CAS NUMBER	Germany	Ireland	Italy	Netherlands
Preservative (Thimerosal)	54-64-8	S*			

INGREDIENT	CAS NUMBER	Norway	Portugal	Spain	Switzerland	UK:
Preservative (Thimerosal)	54-64-8	STEL 0.06 mg/m^3 TWA 0.02 mg/m^3			S* MAK 0.01 mg/m^3	

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Liquid
COLOR: Light brown to amber
ODOR: Odor unknown
SOLUBILITY:
Water: Miscible

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under conditions specified in Section 7 of this SDS. No hazardous reactions known.

CONDITIONS AND MATERIALS TO AVOID:
None known.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
No dangerous decomposition is expected if used according to manufacturer's specifications.

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture(s).

ACUTE TOXICITY DATA

INHALATION:
Potassium aluminum sulfate dodecahydrate: Irritating to mucous membrane and respiratory tract.

SKIN:
Potassium aluminum sulfate dodecahydrate: Irritating.

EYE:
Potassium aluminum sulfate dodecahydrate: Irritating.

ORAL:
Potassium aluminum sulfate dodecahydrate: Oral LD50: 4210 to 6207 mg/kg (mouse); 1930 mg/kg (rat)

REPEAT DOSE TOXICITY DATA

MUTAGENICITY / GENOTOXICITY:
Rats administered anhydrous potassium aluminum sulfate for up to 21 days at oral dose levels as high as 764 mg/kg/day exhibited an increased incidence of chromosome aberrations in bone marrow cells.

CARCINOGENICITY:
Mice administered anhydrous potassium aluminum sulfate at concentrations up to 10% in their diet for 20 months did not exhibit an increase in tumor incidences nor were there any other signs of toxicity noted.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

There are no ecototoxicity data available for this product or its components.

ENVIRONMENTAL DATA

There are no environmental data available for this material.

SECTION 13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT METHODS

MATERIAL WASTE:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION

The following classification is based on available data and is in accordance with European Union criteria.

EUROPEAN UNION REGULATIONS:

Based on available data, this material or product does not require labelling according to the EC directives.

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

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DEPARTMENT ISSUING MSDS:
Global Safety & the Environment
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889

MERCK SDS HELPLINE:
+1 (908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

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