SAFETY DATA SHEETS

This SDS packet was issued with item:

078393723

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

078392848

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

SAFETY DATA SHEET

Schering-Plough 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: **PILIGUARD PINKEYE +7**

SYNONYM(S): PILIGUARD PINKEYE+7; M.bovis/Clostridial Combination Vaccine

MSDS NUMBER: SP001020

EMERGENCY NUMBER(S): Schering-Plough Security Control Center (908) 820-6921 (24 hours)

+31 (0) 485-587777 (Intervet Schering-Plough Animal Health - Boxmeer, Netherlands)

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

INFORMATION: +31 (0) 485-587600 (Intervet Schering-Plough Animal Health - Boxmeer, Netherlands)

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

SCHERING-PLOUGH SDS EMAIL: spmsds@spcorp.com

The brand-names or trademarks indicated by CAPITAL LETTERS in this [M]SDS are the property of, licensed to, promoted or distributed by Schering-Plough Corporation, its subsidiaries or related companies.

SECTION 2. HAZARDS IDENTIFICATION

This preparation has not been classified as dangerous according to EC Directive 1999/45/EC.

EMERGENCY OVERVIEW

Clear, Light yellow
Viscous solution
Odor unknown
May cause allergic reactions in susceptible individuals (preservatives).

POTENTIAL HEALTH EFFECTS:

This product is a vaccine for use in animals. This vaccine is not pathogenic to humans or animals. Local irritation to the eyes, skin, or respiratory tract may occur following direct contact or inhalation of the product. Accidental injection may cause local swelling, irritation or necrosis at the injection site. As with any vaccine, exposure may cause hypersensitivity reactions.

Aluminum hydroxide salts are relatively insoluble. Most effects reported are associated with aluminum, rather than to aluminum hydroxide specifically. Oral ingestion of aluminum may cause gastrointestinal effects including nausea, vomiting, and diarrhea; constipation may occur after chronic oral ingestion of aluminum and aluminum hydroxide. Aluminum containing dusts or fumes may cause pulmonary effects including fibrosis, emphysema, and pneumothorax (air in chest cavity).

LISTED CARCINOGENS

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

ADDITIONAL INFORMATION: This product contains a preservative which may cause allergic-type reactions, including anaphylactic shock, in susceptible individuals. Individuals allergic or sensitive to antibiotics similar to in this formulation may also be sensitive to this product.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Vaccine

CLASS: Inactivated multivalent bacterial vaccine

CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. 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.

This formulation may contain some hydrochloric acid and/or sodium hydroxide for pH adjustment.

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

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	EU NUMBER	EU CLASSIFICATION	PERCENT
Moraxella Bovis Bacterin, FLA 64 (Inactivated)				Varies
Moraxella Bovis Bacterin, EPP 63 (Inactivated)				Varies
Moraxella Bovis Bacterin, SAH 38 (Inactivated)				Varies
C. sordellii toxoid (inactivated)				Varies
C. novyi Type B toxoid (inactivated)				Varies
C. chauvoei whole cell culture (inactivated)				Varies
C. perfringens Type C toxoid (inactivated)				Varies
C. perfringens Type D toxoid (inactivated)				Varies
C. septicum 3204 (Inactivated)				Varies
C. septicum 368 (Inactivated)				Varies
C. novyi Type B cells (inactivated)				Varies
Aluminum Hydroxide	21645-51-2	244-492-7		30 - 40
Preservative (Thimerosal)	54-64-8	200-210-4		<1
Preservative (Gentamicin)				<1

Fields in the above table that do not contain data for EU Number or EU Classification indicate that the substances 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.

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.

SECTION 4. FIRST AID MEASURES

NOTE TO PHYSICIAN: This material is a M.bovis/Clostridium combination vaccine. Accidental injection may cause extensive necrosis. This preparation contains preservatives (gentamicin sulfate and thimerosal) which may cause allergic reactions in susceptible individuals. Treat supportively and symptomatically.

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 (CO2), extinguishing powder or water spray.

THERMAL DECOMPOSITION PRODUCTS:
Carbon oxides (COx).

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:
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

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

SECTION 7. HANDLING AND STORAGE

HANDLING:
Keep containers adequately sealed during material transfer, transport, or when not in use.

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.

STORAGE:
Store in a cool, dry, well ventilated area.

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: Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional 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
Aluminum Hydroxide	21645-51-2		STEL = 10 mg/m^3 MAK = 5 mg/m^3			

INGREDIENT	CAS NUMBER	Germany	Ireland	Italy	Netherlands
Aluminum Hydroxide	21645-51-2	MAK = 1.5 mg/m^3 MAK = 4 mg/m^3			

INGREDIENT	CAS NUMBER	Norway	Portugal	Spain	Switzerland	UK:
Aluminum Hydroxide	21645-51-2				MAK = 3 mg/m^3	

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Viscous solution
COLOR: Clear, Light yellow
ODOR: Odor unknown
SOLUBILITY:
Water: Not determined

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

CONDITIONS AND MATERIALS TO AVOID:
Oxidizers. Strong acids and bases. Open flames and high temperatures.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
Carbon oxides (COx).

SECTION 11. TOXICOLOGICAL INFORMATION

The toxicological properties of this material have not been fully characterized in humans or animals. The information presented below pertains to the following individual ingredients, and not to the mixture(s).

ACUTE TOXICITY DATA

This material or product has not been tested for acute toxicity.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Rats fed 6 to 10 mg of aluminum (as aluminum hydroxide) daily showed significant impairment of growth by the third and fourth week. Dietary administration of 14,470 ppm for 28 days to rats produced no adverse effects.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Pregnant rats or mice given aluminum hydroxide at doses of 192-768 mg/kg/day or 66.5-300 mg/kg/day, respectively, during organogenesis produced no teratogenic effects.

MUTAGENICITY / GENOTOXICITY:
Aluminum compounds were negative in standard mutagenic assays.

CARCINOGENICITY:
This material or product has not been evaluated for carcinogenicity.

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 product or its components.

SECTION 13. DISPOSAL CONSIDERATIONS

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. See recommended safety phrases below.

Safety Phrases:
S 2 - Keep out of reach of children.
S37 - Wear suitable gloves.

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).

The brand-names or trademarks indicated by CAPITAL LETTERS in this [M]SDS are the property of, licensed to, promoted or distributed by Schering-Plough Corporation, its subsidiaries or related companies.

DEPARTMENT ISSUING MSDS:

Global Safety and Environmental Affairs
Occupational and Environmental Toxicology
Schering Corporation
556 Morris Avenue
Summit, NJ 07901 USA

SCHERING-PLOUGH SDS HELPLINE:

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

MSDS CREATION DATE: 14-Mar-2002
SUPERSEDES DATE: 13-Jun-2002

SIGNIFICANT CHANGES (EU SUBFORMAT): New regional format