

Schering-Plough Animal Health Corporation
556 Morris Ave
Summit, NJ 07901

MATERIAL SAFETY DATA SHEET

Intervet Schering-Plough Animal Health urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector, Mycoplasma Hyopneumoniae Bacterin (Tradename = Circumvent PCV M)

SYNONYM(S): Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector, Mycoplasma Hyopneumoniae Bacterin (Tradename = Circumvent PCV M)
Circumvent PCV M

MSDS NUMBER: SP002582

EMERGENCY NUMBER(S): Rocky Mountain Poison Center (For Human Exposure):
(303) 595-4869

Animal Health Technical Services:
For Animal Adverse Events: Small Animals and Horses: (800) 224-5318
For Animal Adverse Events: Livestock: (800) 211-3573
For Animal Adverse Events: Poultry: (800) 219-9286

(908) 423-6000 (24/7/365) English Only
Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

INFORMATION: Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
For Livestock: (800) 211-3573
For Poultry: (800) 219-9286

MERCK MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Liquid
Off-white
Odor unknown
May be irritating to skin and eyes.
May cause allergic reactions in susceptible individuals (preservatives).

POTENTIAL HEALTH EFFECTS:

The toxicological properties of this material have not been fully characterized in humans and animals. Therefore, laboratory or process control systems and appropriate work practices should be in place to minimize the potential for inhalation exposure, skin contact, eye contact, or ingestion when working with this material.

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

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% in this mixture.

ADDITIONAL INFORMATION: This product contains a preservative or preservatives which may cause allergic-type reactions, including anaphylactic shock, in susceptible individuals.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

CLASS: Killed Virus, Inactivated bacterial vaccine

CHARACTERISTIC: Killed

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.

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

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	PERCENT
Killed baculovirus		Varies
Mycoplasma Hyopneumoniae Bacteria (Inactivated)		Varies
Preservative (Gentamicin)	1403-66-3	< 0.1
Preservative (Thimerosal)	54-64-8	< 0.1

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.

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 product is a vaccine. Accidental injection may cause local swelling, irritation or necrosis at the injection site.

Animal health workers, research workers, and veterinarians who use adjuvanted inactivated bacterins or viral vaccines are at risk for accidental self-inoculations or needle stick exposures. Victims should seek medical treatment at once and inform attending physicians the name(s) of the organism(s) contained in the inactivated bacterin or viral vaccine and type (if contained in the vaccine) of adjuvant used (i.e., oil, aluminum hydroxide, etc.). Adjuvants heighten the immune response by increasing the attraction of white blood cells (neutrophils, macrophages, and lymphocytes) to the vaccination sites.

These types of biologic products can cause adverse allergic or hypersensitivity reactions in humans, sometimes with serious consequences, who have accidentally self-inoculated themselves or have had needle-stick exposures.

Allergic or anaphylactic (Type 1 Hypersensitivities) reactions can be caused by the adjuvants, inactivated bacteria, inactivated viruses, or other bacterin or vaccine components to which accidental needle-stick exposed humans have been previously sensitized. These reactions usually occur shortly after inoculation and are characterized by difficulty in breathing, sometimes rapid skin eruptions, or rashes, and shaking.

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.

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. 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.

STORAGE:

Store between 2 and 7 deg C.

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

S* - Skin Notation

Fields in the above table(s) that do not contain data indicate that exposure limits are not available for those endpoints.

No exposure limits are available for the active ingredient(s) or any other hazardous ingredient in this formulation.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM:	Liquid
COLOR:	Off-white
ODOR:	Odor unknown
pH:	7.2 +/- 0.2 @ 2 - 7 deg C
SOLUBILITY:	
Water:	Not determined

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:

Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:

Heat. Do not freeze.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:

No dangerous decomposition is expected if used according to manufacturer's specifications.

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SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture(s). The information presented below is either for the base molecule or its salt forms. The form tested is indicated in the summary.

ACUTE TOXICITY DATA

INHALATION:

Gentamicin sulfate: LC50: > 0.20 mg/L (rat)

In an acute inhalation toxicity study, rats given 0.20 mg/L (maximum attainable concentration) exhibited labored breathing and eye closure during exposure to gentamicin sulfate. Nasal discharge was noted for several days followed by recovery.

SKIN:

Gentamicin sulfate was slightly irritating to the skin of rabbits (PII 1.0).

Thimerosal is a primary skin irritant.

EYE:

Gentamicin sulfate was slightly irritating to the eyes of rabbits. Eye irritation studies using Gentamicin Ophthalmic Solutions (0.1% and 0.3%) were performed in rabbits. The concentrations tested were non-irritating, no significant changes were observed in the cornea, iris or conjunctivae of any of the animals tested.

Administration of 8 ug thimerosal into rabbit eyes produced mild irritant effects.

ORAL:

Gentamicin sulfate: Oral LD50: > 5000 mg/kg (rat)

Thimerosal: Oral LD50: 75 mg/kg (rat); Oral LD50: 91 mg/kg (mouse).

DERMAL AND RESPIRATORY SENSITIZATION:

May cause sensitization based on data from similar drug class.

ADDITIONAL INFORMATION:

Gentamicin sulfate: Intravenous LD50: 96 mg/kg

Gentamicin sulfate: Intramuscular LD50: 371-384 mg/kg (rat)

Clinical signs included hypoactivity, increased water consumption, and irregular respiration.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:

A subacute (2-week) study was conducted in cynomolgus monkeys with intravenous injections of gentamicin sulfate at dose levels of 2.5 to 30 mg/kg/day. Mortality was observed at 30 mg/kg following administration of the first dose. Clinical observations including hypoactivity, labored breathing, reduced body weight, and renal toxicity resulted from treatment [NOEL: 2.5 mg/kg/day]. No adverse effects were observed in rats given gentamicin sulfate for 20 mg/kg/day for 24 days or in cats given 10 mg/kg/day for 40 days. Gentamicin sulfate administered to dogs at 6 mg/lb/day, 6 days weekly for 3 weeks, caused no detectable kidney damage. At higher doses impairment of equilibrium and renal function were observed in these species.

Oral subchronic (13-14 weeks) studies with gentamicin sulfate were conducted in rats and dogs. Dose levels ranged from 3.9 to 232.8 mg/kg/day in rats and 2 to 120 mg/kg in dogs. Soft stools and abnormal urinalysis (increased ketone bodies), both in the high dose group, were the only effects noted in rats [NOEL: 19.4 mg/kg/day]. In dogs, no adverse clinical reactions were noted and liver and kidney function were normal [NOEL: 120 mg/kg].

Varied, repeated animal studies dosing mice via intraperitoneal and oral exposure for dosing periods ranging from 6 days to 22 weeks with Thimerosal showed effects on blood, spleen, and brain on necropsy. Increases in humoral immune responses were noted in multiple organs including allergic reactions. Autoimmune reactions were observed in the kidney, ureter, bladder, and respiratory system.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:

In rats and guinea pigs, fetal renal abnormalities have been reported after administration of gentamicin to the dam. In guinea pigs, transient renal abnormalities were observed in the fetus after the administration of 4 mg/kg of gentamicin to the mother. In two reproduction studies, rats were administered 75 mg/kg gentamicin (10 to 15 times the human dose) in saline for 12 days from day 10 of gestation to delivery (intraperitoneal injection) or on days 7-11 and 14-18 of pregnancy (intramuscular injection). Adverse effects reported included lesions in the developing kidney, reduced rate of early nephrogenesis, general growth retardation, and alterations of the glomeruli and proximal tubules. Other animal reproduction studies in rats did not exhibit any evidence of impaired fertility or harm to the fetus following exposure to gentamicin sulfate. No adverse effects were observed in the offspring of rabbits given 0.8 to 3.6 mg/kg intramuscularly on gestation days 6 to 16.

Rats doses intraperitoneally with as low as 130 mg/kg thimerosal on days 6 through 18 of pregnancy showed effects on fertility: post implantation mortality.

In another study, rats dosed subcutaneously at doses as low as 104 mg/kg for one year showed uterine tumor development as well as tumors at the site of application.

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MUTAGENICITY / GENOTOXICITY:

Thimerosal was shown to be mutagenic in varied micronucleus tests, Chinese hamster ovary DNA damage and sex chromosome loss and nondisjunction assays.

CARCINOGENICITY:

This material or product has not been evaluated for carcinogenicity.

SECTION 12. ECOLOGICAL INFORMATION**ECOTOXICITY DATA**

There are no ecotoxicity 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**TSCA LISTING**

INGREDIENT	TSCA
Preservative (Thimerosal)	X

Substances not included in the table above are TSCA exempt or not regulated under TSCA.

U.S. STATE REGULATIONS

INGREDIENT	California Proposition 65	CARTK	NJRTK	CTR TK	MARTK
Preservative (Thimerosal)	D	X			

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
Preservative (Thimerosal)	X		X	

Check state requirements for ingredient listing.

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
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One Merck Drive
Whitehouse Station, NJ 08889

MERCK MSDS HELPLINE:

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

MSDS CREATION DATE:

13-May-2011

SUPERSEDES DATE:

13-May-2011

SIGNIFICANT CHANGES (US SUBFORMAT):

New regional format