

Schering-Plough Saude Animal Ind e Com. Ltda  
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Brasil

## MATERIAL SAFETY DATA SHEET

Schering-Plough 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:** Coccidiosis Vaccines

**SYNONYM(S):** Coccivac-B  
Coccivac-T  
Coccivac-D

**MSDS NUMBER:** SP000831

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

**INFORMATION:** + 55 (11) 4613-4000 (Coopers Brasil Ltda. - Cotia)

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

### SECTION 2. HAZARDS IDENTIFICATION

#### EMERGENCY OVERVIEW

Yellow-brown  
Liquid  
Odor unknown

Causes cancer.  
Mutagen.  
Toxic by inhalation, skin absorption or if swallowed.  
May cause impaired fertility.  
May cause developmental effects.  
May cause sensitization by inhalation or skin contact.  
May be irritating to eyes, skin or respiratory tract.  
Prolonged exposure may cause serious health effects.

*May cause effects to:*  
respiratory system  
gastrointestinal tract  
liver  
kidney  
reproductive system  
fetus

## SECTION 2. HAZARDS IDENTIFICATION

Toxic to fish and aquatic organisms.  
May cause long-term adverse effects in the aquatic environment.

### 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).

Potassium dichromate is corrosive to any tissue with which it comes into contact. Acute inhalation of the dust or mist can produce irritation of the nose, eyes, and respiratory tract, sneezing, throat redness, nasal septum lesions, or bronchospasm. Potassium dichromate can be absorbed by any exposure route and may cause systemic effects. Acute effects that may result from ingestion include abdominal and esophageal pain, vomiting, gastrointestinal bleeding, respiratory distress, cyanosis, coma, and death. Potassium dichromate is a common skin sensitizer following repeated exposure. Chronic skin contact may produce allergic contact dermatitis with deep ulcers. Long-term inhalation exposure to potassium dichromate may cause chronic rhinitis, coughing, wheezing, dyspnea, asthma, perforation of the nasal septum, and mucous membrane injury. Hexavalent chromium, class of compounds to which potassium dichromate belongs, have been shown to cause liver and kidney damage with chronic occupational exposure.

Epidemiological studies have consistently shown excess risks for lung cancer in workers involved in chromate or chromate pigment production. The epidemiological studies do not clearly implicate specific chromium compounds, but implicate the class of hexavalent chromium {chromium [VI]} compounds, to which potassium dichromate belongs. IARC has concluded that there is sufficient evidence in humans for the carcinogenicity of hexavalent chromium compounds. Hexavalent chromium compounds have also been shown to be consistently genotoxic in various studies and assays, and causes developmental and reproductive effects in animals.

### LISTED CARCINOGENS

Potassium dichromate: IARC has classified potassium dichromate as a Group 1 (carcinogenic to humans).

Chromium [VI] Compounds: ACGIH has classified chromium [VI] compounds as Group A1 (confirmed human carcinogen), and NTP has classified the compounds as Group K (known to be a human carcinogen).

## 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.

### CHEMICAL COMPOSITION

CHEMICAL NAME	CAS NUMBER	PERCENT
Potassium dichromate.	7778-50-9	<3
Eimeria acervulina.		Varies
Eimeria brunetti.		Varies
Eimeria hagani.		Varies
Eimeria maxima.		Varies
Eimeria mivati.		Varies
Eimeria necatrix.		Varies
Eimeria tenella.		Varies
Eimeria adenoides.		Varies
Eimeria dispersa.		Varies
Eimeria gallopavonis.		Varies
Eimeria meleagridis.		Varies

### 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

<b>INHALATION:</b>	Remove to fresh air. Administer artificial respiration if breathing has ceased. IMMEDIATELY consult a physician.
<b>SKIN CONTACT:</b>	In case of skin contact, IMMEDIATELY flush exposed skin thoroughly with plenty of water. While wearing protective gloves, remove any contaminated clothing, including shoes and continue to wash skin thoroughly with soap and water for at least 15 minutes. Get IMMEDIATE medical attention. Treat symptomatically.
<b>EYE CONTACT:</b>	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.
<b>INGESTION:</b>	Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. IMMEDIATELY consult a physician. Do not attempt to give anything by mouth to a seizing, drowsy or unconscious person. If alert, rinse mouth and drink a glass of water.

#### 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<sub>2</sub>), 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.

##### ENVIRONMENTAL PRECAUTIONS:

This product is toxic to aquatic organisms. Do not allow product to reach ground water, water course, sewage or drainage systems.

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

Chromium [VI] Compounds:	ACGIH TLV (TWA): 0.05mg/m <sup>3</sup>	OSHA PEL (STEL/CEIL): 0.1 mg/m <sup>3</sup>
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## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>FORM:</b>	Liquid
<b>COLOR:</b>	Yellow-brown
<b>ODOR:</b>	Odor unknown
<b>SOLUBILITY:</b>	
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:**

None known.

**HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:**

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

**SECTION 11. TOXICOLOGICAL INFORMATION**

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

**ACUTE TOXICITY DATA****SKIN:**

Potassium Dichromate: Dermal LD50: 14 mg/kg (rabbit)

A single application of 0.5% potassium dichromate (0.175% chromium(VI)) to the shaved skin of rats resulted in increased levels of serotonin in the liver, decreased activities of acetylcholinesterase and cholinesterase in the plasma and erythrocytes, increased levels of acetylcholine in the blood, and increased glycoprotein hexose in the serum. These effects may indicate alterations in carbohydrate metabolism.

**ORAL:**

Potassium Dichromate: Oral LD50: 25 mg/kg (rat)

**SENSITIZATION:**

Potassium dichromate has been shown to be sensitizing to mice and guinea pigs in various studies.

**ADDITIONAL INFORMATION:**

Potassium dichromate produced kidney effects (inflammation) in rabbits and kidney damage in dogs when administered subcutaneously at doses of 0.8-2 mg or 17 mg, respectively.

**REPEAT DOSE TOXICITY DATA****SUBCHRONIC / CHRONIC TOXICITY:**

Mice were given drinking water containing 25, 50, & 100 mg/l of chromium as potassium dichromate for 1 yr. Body weight increases were observed in low- and mid-dose groups; however, no increases were observed in the high-dose group. Decreases in hemoglobin and red blood cells, and decreases in cholesterol and increases in glutamic-pyruvic transaminase were observed; however, these effects were not dose-related.

Significant increased incidences of pulmonary lesions (lung abscesses, bronchopneumonia, giant cells, & granulomata) found in rats exposed chronically to a finely ground, mixed chromium roast material that resulted in airborne concentrations of 1.6-2.1 mg chromium(VI)/m<sup>3</sup>. In the same study, guinea pigs were exposed chronically to the chromium roast material along with mists of potassium dichromate that also resulted in 1.6-2.1 mg chromium(VI)/m<sup>3</sup>. Significant increased incidences of alveolar and interstitial inflammation, alveolar hyperplasia, and interstitial fibrosis were observed. Similarly, rabbits were also exposed and had pulmonary lesions similar to those seen in the rats and guinea pigs.

**REPRODUCTIVE / DEVELOPMENTAL TOXICITY:**

Common reproductive effects observed in mice and rats administered doses ranging from 45 to 180 chromium/kg/day as potassium dichromate in drinking water before or during gestation include significant reductions in the number of follicles at different stages of maturation, reductions in the number of ova/mice, significant increases in the estrus cycle duration, decreases in the number of corpora lutea, histological alterations in the ovaries (e.g. proliferated, dilated, and congested blood vessels, pyknotic nuclei in follicular cells, and atretic follicles), decreases in implantations, increases in preimplantation and postimplantation loss, increases in resorptions, decreases in litter size, and placental weight decreases. Fetal effects observed at doses of 98 mg chromium (VI)/kg/day and greater included increased numbers of sub-dermal hemorrhagic patches, kinky short tails, decreased fetal body weights, decreased crown-rump length, reduction in ossification in caudal, parietal, and interparietal bones. The severity of the reproductive and fetal effects appeared to be dose-related.

**MUTAGENICITY / GENOTOXICITY:**

Chromium [VI] compounds, to which potassium dichromate belongs, have been shown to be consistently genotoxic, inducing a wide variety of effects such as DNA damage, gene mutation, sister chromatid exchange, chromosomal aberrations, cell transformation, and dominant lethal mutations.

Potassium dichromate has been shown to induce mutations in the Ames Salmonella assay, in yeast, and in mammalian cells, including crossing over in microbes and sister chromatid exchanges, increased chromosome aberrations, inhibition of DNA synthesis and repair, and induction of dominant lethal mutations in mice.

**CARCINOGENICITY:**

This material or product has not been evaluated for carcinogenicity.

In rats, potassium dichromate by bronchial implantation did not produce an increase in lung tumors. However, epidemiological studies from around the world have consistently shown excess risks of lung cancer in workers involved in chromate and chromate pigment production. The studies do not clearly implicate specific chromium compounds, but implicate the class of compounds, chromium [VI] compounds, to which potassium dichromate belongs. IARC has concluded that there is sufficient evidence in humans for the carcinogenicity of chromium [VI] compounds.

**SECTION 12. ECOLOGICAL INFORMATION**

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

Coccidiosis Vaccines

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Latest Revision Date: 21-Mar-2008

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## ECOTOXICITY DATA

### INGREDIENT ECOTOXICITY

Potassium dichromate: 48-hr LC50 (daphnid): 0.02-2.7mg/L  
96-hr LC50 (rainbow trout): 12.3-27.7 mg/L  
72-hr EC50 (green algae): 0.066-1.3 mg/L

## ENVIRONMENTAL DATA

There are no environmental data available for the ingredients in the mixture(s).

## SECTION 13. DISPOSAL CONSIDERATIONS

### MATERIAL WASTE:

This material is classified as a hazardous or special waste and should be disposed of in accordance with applicable federal, state/provincial, and/or local regulations.

### PACKAGING AND CONTAINERS:

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

### SPECIAL ENVIRONMENTAL HANDLING PROCEDURES:

This product contains materials that are harmful to the environment. Do not allow product to reach ground water, water courses, sewage or drainage systems.

## SECTION 14. TRANSPORT INFORMATION

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

### ADR CLASSIFICATION:

Proper Shipping Name: Environmentally hazardous substance, solid, n.o.s. (potassium dichromate)  
Hazard Class: 9  
UN Number: UN 3077  
Packing Group: III  
Classification Code: M7

### ADDITIONAL INFORMATION:

Although this material is regulated only under the ADR, both the IATA and IMO have special provisions that allow the shipper to transport materials under the shipping name "Environmentally hazardous substance, solid, n.o.s." if the material is being transported under both ADR and either IATA or IMO regulations.

## SECTION 15. REGULATORY INFORMATION

### TSCA LISTING

CHEMICAL NAME	TSCA
Potassium dichromate.	Listed.

### EUROPEAN UNION REGULATIONS:

The classification presented below is based on the active ingredient(s) and individual hazardous ingredients in the product formulation.

Indication of Danger: T - Toxic.  
N - Dangerous For The Environment.



**Risk Phrases:**

R45 - May cause cancer.

R46 - May cause heritable genetic damage.

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.

R48/20 - Harmful: danger of serious damage to health by prolonged exposure through inhalation.

R42/43 - May cause sensitization by inhalation and skin contact.

R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Safety Phrases:**

S45 - In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).

S53 - Avoid exposure - obtain special instructions before use.

Covexin-9 S63 - In case of accident by inhalation: remove casualty to fresh air and keep at rest.

S29 - Do not empty into drains.

S60 - This material and its container must be disposed of as hazardous waste.

S 1/2 - Keep locked-up and out of the reach of children.

S24/25 - Avoid contact with skin and eyes.

S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

**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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