MSD is a tradename of Merck & Co., Inc., with headquarters in Whitehouse Station, N.J., U.S.A.

SAFETY DATA SHEET

This SDS was created in accordance with Regulation EC 1907/2006 and all amendments. 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 THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

PRODUCT IDENTIFIER

SDS NAME: **Coccivac-D2**

SYNONYM(S): Coccivac-D2
Coccidiosis Vaccine (Coccivac-D2)

SDS Number: SP002402

REACH REGISTRATION NUMBER Not available

RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

IDENTIFIED USE(S): Animal Vaccine

USE(S) ADVISED AGAINST: None known.

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

EU SUPPLIER/MANUFACTURER: MSD Animal Health
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

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

SDS EMAIL: mercksds@merck.com

EMERGENCY TELEPHONE NUMBER

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

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

SECTION 2. HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to EC Directive 1272/2008:
Based on available data, this mixture does not meet the criteria to be classified as hazardous according to EC DIrective 1272/2008.

Classification according to EC Directives 67/548/EEC (substances) or 1999/45/EC (mixtures):
Based on available data, this preparation does not meet the criteria to be classified as hazardous according to EC DIrective 1999/45/EC.

COLOR: Red
FORM: Liquid
ODOR: Odorless

LABEL ELEMENTS

Based on available data, this mixture does not meet the criteria to be classified as hazardous in accordance with Directive 1272/2008.

OTHER HAZARDS

Health-Related Hazards:

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.

LISTED CARCINOGENS

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

Environmental-Related Hazards:

This substance has not been fully tested to meet the criteria for listing as a PBT or a vPvB.

Other Hazards:

No other information known.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

SUBSTANCE

CLASS: Parasite (Eimeria)

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.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	EC NUMBER	REACH REGISTRATION NUMBER	EU CLASSIFICATION	GHS CLASSIFICATION	PERCENT	REASON FOR LISTING
Eimeria acervulina		Not available	Not available			Varies	Active Ingredient
Eimeria maxima		Not available	Not available			Varies	Active Ingredient
Eimeria mivati		Not available	Not available			Varies	Active Ingredient
Eimeria tenella		Not available	Not available			Varies	Active Ingredient
Eimeria necatrix		Not available	Not available			Varies	Active Ingredient
Eimeria brunetti		Not available	Not available			Varies	Active Ingredient
Gentamicin Sulfate (Preservative)	1405-41-0	215-778-9	Not available	Repr. Cat.2;R61	Repr. 1B (H360D)	<0.001	Caution - Substance Not Fully Tested

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 16 for definitions of risk phrases and GHS classifications.

SECTION 4. FIRST AID MEASURES

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.

FIRST AID RESPONDER PROTECTION: Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves with appropriate personal protective equipment. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. DO NOT use mouth-to-mouth method if victim ingested or inhaled the substance.

MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

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.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

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

SECTION 5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO2), extinguishing powder or water spray.

UNSUITABLE EXTINGUISHING MEDIA:
None known.

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

SPECIAL FIRE HAZARDS:
None known.

ADVICE FOR FIREFIGHTERS

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

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

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

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

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

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:
Refrigerate at 4 to 7 deg C.

SPECIAL PRECAUTIONS:
Avoid self-inoculation or needle sticks.

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

This formulation contains a Risk Group 1 biological agent. Special containment devices or equipment such as a biological safety cabinet are generally not required for handling agents assigned to Biosafety Level 1.

CONTROL PARAMETERS

EXPOSURE LIMIT VALUES:

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

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):

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.
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.

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.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

FORM:	Liquid
COLOR:	Red
ODOR:	Odorless
ODOR THRESHOLD:	Not determined
pH:	Not determined
BOILING POINT / RANGE:	Not determined
MELTING POINT / RANGE:	Not determined
DECOMPOSITION TEMPERATURE:	Not determined
VAPOR PRESSURE:	Not determined
VAPOR DENSITY:	Not determined
SPECIFIC GRAVITY:	Not determined
SOLUBILITY:	
Water:	Not determined
PARTITION COEFFICIENT (log Pow):	Not determined
VISCOSITY:	Not determined
EVAPORATION RATE:	Not determined
FLAMMABILITY DATA:	
Flash Point:	Not determined (liquids) or not applicable (solids).
Flammability (solid, gas):	Not determined
UEL:	Not determined
LEL:	Not determined
Autoignition Temperature:	Not determined

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:
Extremes of temperature. Do not freeze.

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

SUSCEPTIBILITY TO DISINFECTANTS:
Ammonia. Bleach.

SURVIVAL OUTSIDE THE HOST:
Vaires by conditions. If stored in a refrigerator, has a 1 year expiration.

SECTION 11. TOXICOLOGICAL INFORMATION

The toxicological properties of the mixture(s) 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).

LIKELY ROUTES OF EXPOSURE:
Skin, eye, inhalation, and ingestion.

ACUTE TOXICITY DATA

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

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

EYE:
Gentamicin sulfate was slightly irritating to the eyes of rabbits.

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

ASPIRATION:
No data available.

DERMAL AND RESPIRATORY SENSITIZATION:
No data available.

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. Contains Gentamicin sulfate which is an aminoglycoside. Aminoglycosides are associated with significant nephrotoxicity and neurotoxicity, the latter manifested by ototoxiciy, numbness, and convulsions.

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].

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.

Aminoglycosides can cause fetal harm as they can cross the placenta, however, it is not known whether fetal harm or effects on the reproductive capacity can be caused by exposure to gentamicin sulfate by pregnant women.

MUTAGENICITY / GENOTOXICITY:
No data available.

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

Classification according to EC Directive 1272/2008:
Based on available data, this mixture does not meet the criteria to be classified as hazardous according to EC DIrective 1272/2008..

Classification criteria have not been met for the following endpoints due to lack of data, inconclusive data, technical impossibility to obtain the data, or data which are conclusive although insufficient for classification (available information to support classification criteria is given in Section 4 or Section 11 of this data sheet):
Inhalation toxicity. Dermal toxicity. Eye damage or irritation. Oral toxicity. Skin sensitization. Skin corrosion or irritation. Respiratory sensitization. Mutagenicity. Carcinogenicity. Reproductive toxicity. Specific target organ toxicity (STOT) - Single Exposure. Specific target organ toxicity (STOT) - Repeated Exposure. Aspiration hazard.

See Section 4 for human health symptoms and effects.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

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

PERSISTENCE AND DEGRADABILITY

Biodegradation Results: No data available.

BIOACCUMULATIVE POTENTIAL

Partition Coefficient (log Pow) Results: No data available.

MOBILITY IN SOIL

Soil Adsorption/Desorption Results: No data available.

PBT and vPvB ASSESSMENT

This substance has not been assessed.

OTHER ADVERSE EFFECTS

ENVIRONMENTAL FATE AND EFFECTS: No data available.

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.

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

SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Germany, Water Endangering Classes (WGK)

INGREDIENT	Annex 1	Annex 2 - Water Hazard Classes	Annex 3
Eimeria acervulina	Not listed.	Not listed.	Not listed.
Eimeria maxima	Not listed.	Not listed.	Not listed.
Eimeria mivati	Not listed.	Not listed.	Not listed.
Eimeria tenella	Not listed.	Not listed.	Not listed.
Eimeria necatrix	Not listed.	Not listed.	Not listed.
Eimeria brunetti	Not listed.	Not listed.	Not listed.
Gentamicin Sulfate (Preservative)	Not listed.	Not listed.	Not listed.

Ozone Depleting Substance(s)

INGREDIENT	Listing
Eimeria acervulina	Not listed.
Eimeria maxima	Not listed.

Eimeria mivati	Not listed.
Eimeria tenella	Not listed.
Eimeria necatrix	Not listed.
Eimeria brunetti	Not listed.
Gentamicin Sulfate (Preservative)	Not listed.

Persistent Organic Pollutants

INGREDIENT	Listing
Eimeria acervulina	Not listed.
Eimeria maxima	Not listed.
Eimeria mivati	Not listed.
Eimeria tenella	Not listed.
Eimeria necatrix	Not listed.
Eimeria brunetti	Not listed.
Gentamicin Sulfate (Preservative)	Not listed.

EU Import and Export Restrictions

INGREDIENT	Requires PIC Notification	Requires Export Notification	Export Ban
Eimeria acervulina	Not listed.	Not listed.	Not listed.
Eimeria maxima	Not listed.	Not listed.	Not listed.
Eimeria mivati	Not listed.	Not listed.	Not listed.
Eimeria tenella	Not listed.	Not listed.	Not listed.
Eimeria necatrix	Not listed.	Not listed.	Not listed.
Eimeria brunetti	Not listed.	Not listed.	Not listed.
Gentamicin Sulfate (Preservative)	Not listed.	Not listed.	Not listed.

SEVESO II EU Directive

INGREDIENT	Listing
Eimeria acervulina	Not listed.
Eimeria maxima	Not listed.
Eimeria mivati	Not listed.
Eimeria tenella	Not listed.
Eimeria necatrix	Not listed.
Eimeria brunetti	Not listed.
Gentamicin Sulfate (Preservative)	Not listed.

REACH

INGREDIENT	Subject to Authorization	Candidate List for Authorization	Potential Substances of High Concern	Restrictions
Eimeria acervulina	Not listed.	Not listed.	Not listed.	Not listed.
Eimeria maxima	Not listed.	Not listed.	Not listed.	Not listed.
Eimeria mivati	Not listed.	Not listed.	Not listed.	Not listed.
Eimeria tenella	Not listed.	Not listed.	Not listed.	Not listed.
Eimeria necatrix	Not listed.	Not listed.	Not listed.	Not listed.
Eimeria brunetti	Not listed.	Not listed.	Not listed.	Not listed.
Gentamicin Sulfate (Preservative)	Not listed.	Not listed.	Not listed.	Not listed.

CHEMICAL SAFETY ASSESSMENT

A Chemical Safety Assessment has not been done.

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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DEFINITIONS (referred to under Sections 2 and 3):

CLP Classifications:	• Based on available data, this mixture does not meet the criteria to be classified as hazardous according to EC DIrective 1272/2008.
Risk Phrases:	• Based on available data, this preparation does not meet the criteria to be classified as hazardous according to EC DIrective 1999/45/EC.

GLOSSARY:
IARC - International Agency for Research on Cancer, IARC Group 1 or 2A.
NTP - National Toxicology Program
ACGIH - American Conference of Governmental Industrial Hygienists
ADR - International Carriage of Dangerous Goods by Road
API - Active Pharmaceutical Ingredient
CAS - Chemical Abstract Service
CLP - Classification, Labeling and Packaging
DOT - Department of Transportation
EC - European Council
ETAC - Estimated Target Airborne Concentration
GHS - Globally Harmonized System
HEPA - High Efficiency Particulate Arresting
HHC - Health Hazard Category
HPA - Hypothalamic Pituitary Adrenal
IATA - International Air Transport Association
IMO - International Maritime Organization
IP - Intraperitoneal Injection
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%
LOEL - Lowest Observed Effect Level
NEL - No Effect Level
NOAEL - No Adverse Effect Level
NOEL - No Observe Effect Level
OEG - Occupational Exposure Guideline
PBT - Persistent BioaccumulativeToxic
PG - Packing Group
PIC - Prior Informed Consent
PPE - Personal Protective Equipment
REACH - Registration, Evaluation, Authorization and Restriction of Chemical Substances
RPE - Respiratory Protective Equipment
SCBA - Self Contained Breathing Apparatus
STOT - Specific Target Organ Toxicity
TSCA - Toxic Substances Control Act
TWA - Time Weighted Average
UN - United Nations
vPvB - Very Persistent andVery Bioaccumulative
WGK - Water Hazard Class (Germany)