Chiron Corporation
Material Safety Data Sheet
Prepared to U.S. OSHA, CMA, ANSI and Canadian WHMIS, And European Union Standards

CHIRON

RABAVERT®

Section 1 – Chemical Product and Company

Manufacturer:
Chiron Corporation
4560 Horton St.
Emeryville, CA 94608

Emergency Phone:
CHEMTREC: 1-800-424-9300
International: 1-703-527-3887
Customer Service: 1 800 244-7668
1-510-655-8729

Trade Name: ***RabAvert® Rabies Vaccine***
Synonyms: Purified Chick Embryo Cell Vaccine (PCECV)
Chiron Product Codes: NDC Number: 53905-501-01

Section 2 – Composition and Information on Ingredients

RabAvert® Rabies Vaccine is supplied as two separate components: one vial containing the lyophilized vaccine and one vial containing Sterile Diluent for RabAvert (sterile water for injection). Refer to Package Insert (Prescribing Information) for description of this product. The constituents for each component are described in the following tables.

EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.
EU Classification: Not Applicable
EU Risk Phrases: Not Applicable

This product contains no hazardous components. This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200 (b)(5)(ii). Drugs are exempt from this requirement as determined by the Occupational Safety and Health Administration (OSHA) and cited in 29 CRF 1910.1200(b)(5)(ii) as follows:

(5)This section does not require labeling of the following chemicals:

(ii) any food, food additive, color additive, drug, cosmetic, or medical or veterinary device, including materials intended for use as ingredients in such products (e.g., flavors and fragrances) as such terms are defined in the Federal Food, Drug and Cosmetic Act (21 U.S.C. 302 et seq.) and regulations issued under that Act, when they are subject to the labeling requirements under that Act by the Food and Drug Administration.

CHEMICAL NAME	CAS #	EINECS #	% w/w	EU CLASSIFICATION FOR COMPONENTS
COMPONENT 1: LYOPHILIZED VACCINE				
Amphotericin B	1397-89-3	215-742-2	< 0.1	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
Chlortetracycline	57-62-5	200-341-7	< 0.1	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
Neomycin B Sulfate	119-04-0	204-292-2	< 0.1	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
Human Serum Albumin	70024-90-7	274-272-6	< 0.1	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
Ethylenediaminetetraacetic Acid, Disodium Dihydrate	6381-92-6	205-358-3	< 1	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
Potassium Glutamate	19473-49-5	243-094-0	< 2	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
Polygeline (processed bovine gelatin)	9000-70-8	232-554-6	< 25	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
"inactivated rabies virus"	NE	NE	Balance	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.

Section 2 – Composition and Information on Ingredients (Continued)

CHEMICAL NAME	CAS #	EINECS #	% w/w	EU CLASSIFICATION FOR COMPONENTS

COMPONENT 2: STERILE DILUENT FOR RABAVERT® (WATER FOR INJECTION)

Water for Injection (WFI)	N / A	N / A	100	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.

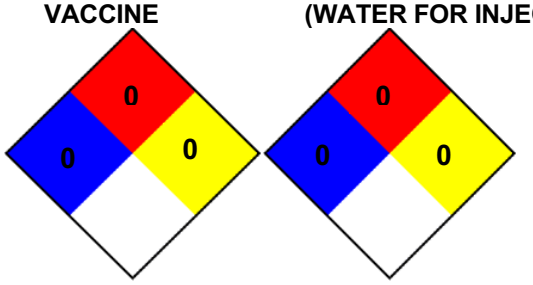
NE = Not Established. See Section 16 for Definitions of Terms Used.

NOTE: ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-1998 format. This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR. All European EU required information is also included.

Section 3 – Hazard Identification

Emergency Overview

LYOPHILIZED VACCINE **STERILE DILUENT FOR RABAVERT® (WATER FOR INJECTION)**



Chiron Corporation Laboratory Labeling Codes:

LYOPHILIZED VACCINE:

Health: 0 **Flammability: 0** **Instability: 0** **Special: None**

STERILE DILUENT FOR RABAVERT® (WATER FOR INJECTION): Not applicable.

Health: 0 **Flammability: 0** **Instability: 0** **Special: None**

Product Description: This product is supplied as two separate components. The Sterile Diluent for RabAvert is a clear, colorless liquid. The LYOPHILIZED VACCINE is a white, odorless solid. **Health Hazards:** None known. **Flammability Hazards:** None known. **Reactivity Hazards:** None known. **Emergency Response Recommendations:** This product poses no hazard if spilled and no unusual hazard if involved in a fire.

Numbering Guidelines: Based upon a nationally recognized color-coded 0–4 scale: Blue represents Health, Red represents flammability, Yellow represents instability (reactivity) and White represents a "special" hazard. 0 represents no hazard and 4 represents the most severe hazard for each category. Examples one might see in the "special" category include CA=potential carcinogen, COR=corrosive, I=irritant, T=toxic, OXY=Oxidizer, PF=Peroxide Former, W = Water reactive, SEN= sensitizing agent, REP=reproductive hazard and TER=harmful to the fetus

Symptoms of Overexposure: None known.

Inhalation: Unknown.

Contact with Skin or Eyes: Unknown.

Skin Absorption: Unknown.

Ingestion: Unknown.

Injection: Unknown.

Appropriate route of entry: Intramuscular injection:
See Package Insert (Prescribing Information) for Clinical Pharmacology, Indications and Usage, Contraindications, Warnings, Precautions, Adverse Reactions and Dosage and Administration.

Acute: Unknown.

Chronic: Unknown.

Target Organs: Unknown.

Section 4 – First Aid Measures

Persons who are exposed to this product should seek medical attention if any adverse health effects occur. Rescuers should be taken for medical attention if necessary. In the event medical attention is sought, the physician or health care professional should receive a copy of this product's label and this MSDS.

Skin: Wash affected area with soap and water. If irritation or allergic skin reaction should develop, seek medical attention.

Eyes: In case of contact, rinse immediately with plenty of water and seek medical attention if irritation develops.

Inhalation: If symptoms develop, remove to fresh air and obtain medical attention.

Ingestion: If swallowed, seek medical advice immediately and show package container or prescribing information.

Injection: In the event of accidental injection, wash the puncture site with soap and water and treat with a disinfectant. If accidental injection occurs with a needle or syringe that has been previously used for injection, the requirements of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) are applicable.

Medical conditions aggravated by exposure: No specific medical conditions are known to be aggravated by exposure to this product.

Recommendations to Physicians: This product is not expected to cause clinical symptoms. If such symptoms occur, treat the symptoms, while alleviating the cause.

Section 5 – Fire Fighting Measures

Flash Point: Not established nor applicable.

Autoignition Temperature: Not established nor applicable.

Flammable Limits (in air by volume, %):

UEL: Not established nor applicable.

LEL: Not established nor applicable.

Fire Extinguishing Materials: Use any extinguishing agent which is suitable for the surrounding fire.

Unusual Fire and Explosion Hazards:

LYOPHILIZED VACCINE: This component must be significantly preheated for ignition to become a hazard. When involved in a fire, this product may decompose and produce carbon oxides.

STERILE DILUENT FOR RABAVERT® (WATER FOR INJECTION): None.

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

Special Fire-Fighting Procedures: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained breathing Apparatus and full protective equipment.

LYOPHILIZED VACCINE: NFPA Rating: HEALTH = 1 FIRE = 1 INSTABILITY = 0 Special = 0

STERILE DILUENT FOR RABAVERT® (WATER FOR INJECTION): NFPA Rating: HEALTH = 0 FIRE = 1 INSTABILITY = 0 Special = 0

Section 6 - Accidental Release Measures

Spill and Leak Response: Spill area can be washed to a sanitary sewer. Absorb material and place in appropriate containers for disposal. Prevent from entering open drains and waterways. Use appropriate personal protective equipment during clean up.

Section 7 – Handling and Storage

Work Practices and Hygiene Practices: See Package Insert (Prescribing Information). This product should be used in accordance with normal clinical practice.

Storage: Protect from light.

Temperature:

Minimum: 2 degrees Centigrade (36 degrees Fahrenheit)

Maximum: 8 degrees Centigrade (46 degrees Fahrenheit)

Shelf Life: The vaccine may not be used after the expiration date given on package and vials.

Special Sensitivity: Avoid freezing as breakage of the diluent container might occur.

Handling/Storage Precautions: Use normal precautions for storage of a drug or biologic. After reconstitution the vaccine is to be used immediately.

Section 8 – Exposure Controls – Personal Protection

Refer to Package Insert (Prescribing Information) for description of this product.

This product contains no hazardous components. This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200 (b)(5)(ii). Drugs are exempt from this requirement as determined by the Occupational Safety and Health Administration (OSHA) and cited in 29 CRF 1910.1200(b)(5)(ii).

Ventilation and Engineering Controls: Special ventilation is not required.

Exposure Limits/Guidelines:

CHEMICAL NAME	CAS #	% w/w	EXPOSURE LIMITS IN AIR							
			ACGIH-TLV		OSHA-PEL		AIHA WEELs		NIOSH	OTHER
			TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	mg/m^3
COMPONENT 1: LYOPHILIZED VACCINE										
Amphotericin B	1397-89-3	< 0.1	NE	NE	NE	NE	NE	NE	NE	NE
Chlortetracycline	57-62-5	< 0.1	NE	NE	NE	NE	NE	NE	NE	NE
Neomycin B Sulfate	119-04-0	< 0.1	NE	NE	NE	NE	NE	NE	NE	NE
Human Serum Albumin	70024-90-7	< 0.1	NE	NE	NE	NE	NE	NE	NE	NE
Ethylenediaminetetra acetic Acid, Disodium Dihydrate	6381-92-6	< 1	NE	NE	NE	NE	NE	NE	NE	NE
Potassium Glutamate	19473-49-5	< 2	NE	NE	NE	NE	NE	NE	NE	NE
Polygeline (processed bovine gelatin)	9000-70-8	< 25	NE	NE	NE	NE	NE	NE	NE	NE
"inactivated rabies virus"		Balance	NE	NE	NE	NE	NE	NE	NE	NE
COMPONENT 2: STERILE DILUENT FOR RABAVERT® (WATER FOR INJECTION)										
Water for Injection	N/A	100	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established. See Section 16 for Definitions of Terms Used.

Respiratory Protection: Normal clinical practice.

Eye Protection: Normal clinical practice.

Hand Protection: Normal clinical practice.

Body Protection: Normal clinical practice.

Additional Protective Measures: Educate and train employees in the safe use and administration of this product.

Section 9 – Physical and Chemical Properties

FOR LYOPHILIZED VACCINE:

Relative Vapor Density (Air = 1): Not established.
Evaporation Rate (nBuAc = 1): Not established.
Specific Gravity: Not established.
Melting/Freezing Point: Not established.
Solubility in Water: Soluble.
Boiling Point: Not established.
Vapor Pressure, mm Hg @ 20°C: Not established.
pH: Not established.
Odor Threshold: Odorless.
Coefficient Water/Oil Distribution: Not established.
Appearance, Odor and Color: This component is a white, odorless, lyophilized solid.
How to Detect This Substance: To identify this material, an immunological assay would be required. The appearance is not unlike many other lyophilized proteinaceous materials.

Section 9 – Physical and Chemical Properties (Continued)

STERILE DILUENT FOR RABAVERT® (WATER FOR INJECTION):

Relative Vapor Density (Air = 1): Not established.
Evaporation Rate (nBuAc = 1): Not established.
Specific Gravity: 1.0
Melting/Freezing Point: 0°C (32°F)
Solubility in Water: Soluble (it is water)
Boiling Point: 100°C (212°F)
Vapor Pressure, mm Hg @ 20°C: Not established.
pH: Not established.
Odor Threshold: Odorless.
Coefficient Water/Oil Distribution: Not established.
Appearance, Odor and Color: This component is a clear, colorless, odorless liquid.
How to Detect This Substance: There are no good identity properties for this component (it is water).

Section 10 – Stability and Reactivity

Stability: Stable.

Decomposition Products: None known.

Incompatibility: Oxidizing agents, reducing agents, water reactive materials.

Hazardous Polymerization: Will not occur.

Conditions to Avoid: Exposure to or contact with incompatible chemicals.

Section 11 – Toxicological Information

Refer to Package Insert (Prescribing Information) for description of this product.
This product contains no hazardous components. This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200 (b)(5)(ii). Drugs are exempt from this requirement as determined by the Occupational Safety and Health Administration (OSHA) and cited in 29 CRF 1910.1200(b)(5)(ii).

Toxicity Data: No data available for this product.

RabAvert® Rabies Vaccine is FDA classified as Pregnancy Category C. Animal reproductive studies have not been conducted with RabAvert® Rabies Vaccine. It is not known whether RabAvert can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. The CDC has issued recommendations for use of rabies vaccine in pregnant women (ACIP 1999). This product should be given to a pregnant woman only if clearly needed. However, because of the potential consequences of inadequately treated rabies exposure and limited data that indicate fetal abnormalities have not been associated with rabies vaccination, pregnancy is not considered a contraindication to post-exposure prophylaxis. If there is substantial risk of exposure to rabies, pre-exposure prophylaxis may also be indicated during pregnancy. In such instances, consideration should be given to removing the pregnant woman from the high risk environment.

Cancer Agent: The components in this product are not found on the following lists: NTP, IARC, FEDERAL OSHA Z-List, and CAL-OSHA and therefore are not considered to be or suspected to be cancer causing agents by these agencies.

Irritancy: No skin irritation studies have been performed. The product may mildly irritate skin and eyes.

Sensitization:

LYOPHILIZED VACCINE: This component is produced in primary chick embryo fibroblast cell culture. History of anaphylaxis to the vaccine or any of the vaccine components constitutes a contraindication to pre-exposure vaccination with this vaccine. There is no contraindication to post-exposure treatment with this vaccine; please see package insert.

STERILE DILUENT FOR RABAVERT® (WATER FOR INJECTION): Not applicable.

Section 11 – Toxicological Information (Continued)

Reproductive Information: Listed below is information concerning the effects of this product on the reproductive system.

Mutagenicity: Unknown; no studies have been performed.

Embryotoxicity: Unknown; no studies have been performed.

Teratogenicity: Unknown; no studies have been performed.

Reproductive Toxicity: Unknown; no studies have been performed.

ACGIH Biological Exposure Indices: There are currently no ACGIH Biological Exposure Indices (BEIs) determined for the components of this product.

Section 12 – Ecological Information

All Work Practices Should be Aimed at Minimizing Environmental Releases

Ecological Note: No data available for this product.

Environmental Stability: The components of this product are relatively stable in the environment.

Effect of Material on Plants and Animals: The toxicological properties have not been fully investigated.

Effect of Chemical on Aquatic Life: The toxicological properties have not been fully investigated.

Section 13 – Disposal Considerations

Waste Disposal: This product contains no hazardous material. Place in containers and dispose of in accordance with existing federal, state and local environmental regulations.

Section 14 – Transport Information

U.S. Department of Transportation Regulations: This product does not meet the definition of a "hazardous material" (49 CFR 171.8) and therefore is not subject to the U.S. DOT regulations.

Transport Canada, Transportation of Dangerous Goods Regulations: This product is not classified as dangerous goods, per regulations of Transport Canada, but must be labeled as emergency biopharmaceutical and be accompanied by a Letter of Authorization allowing its shipment into the country.

International Air Transport Association (IATA): This product does not meet the definition of dangerous goods, and is therefore exempt from IATA/ICAO regulations.

International Maritime Organization (IMO): This product is not Dangerous Goods, per the IMO.

European Agreement Concerning The International Carriage Of Dangerous Goods By Road (ADR): This product is not classified as Dangerous Goods, under regulations of the United Nations Economic Commission for Europe.

Section 15 – Regulatory Information

U.S. Regulations:

SARA Reporting Requirements: The constituents in this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

SARA 302 Extremely Hazardous Threshold Planning Quantity (TPQ): Not applicable.

SARA 304 Extremely Hazardous Reportable Quantity (RQ): Not applicable.

CERCLA: Not applicable.

TSCA: This product is regulated by the Food and Drug Administration; it is exempt from the requirements of TSCA.

Other U.S. Federal Regulations: Not applicable.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): The constituents in this product's components are not on the California Proposition 65 lists.

Canadian Regulations:

Canadian DSL/NDSL Inventory Status: Some constituents in this product are listed on the DSL/NDSL Inventory.

Other Canadian Regulations: Not applicable.

Canadian Environmental Protection Act (CEPA) Priority Substances Lists: The constituents of this product are not on the CEPA Priority Substances Lists.

Canadian WHMIS Classification and Symbols: Not applicable.

Section 15 – Regulatory Information (Continued)

European Union Information for Product:

EU Labeling and Classification: This product does not meet the criteria of hazardous according to current European Union Guidelines.

EU Classification: Not applicable.
EU Risk Phrases: Not applicable.
EU Safety Phrases: Not applicable.
EU Hazard Symbol: Not applicable

Section 16 – Other Information

This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200 (b)(5)(ii). Drugs are exempt from this requirement as determined by the Occupational Safety and Health Administration (OSHA) and cited in 29 CRF 1910.1200(b)(5)(ii) as follows:

(5)This section does not require labeling of the following chemicals:

(ii) any food, food additive, color additive, drug, cosmetic, or medical or veterinary device, including materials intended for use as ingredients in such products (e.g., flavors and fragrances) as such terms are defined in the Federal Food, Drug and Cosmetic Act (21 U.S.C. 302 et seq.) and regulations issued under that Act, when they are subject to the labeling requirements under that Act by the Food and Drug Administration.

Prepared by:	CHEMICAL SAFETY ASSOCIATES, Inc. PO Box 3519, La Mesa, CA 91944-3519 800/441-3365
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Glossary:

ACGIH = American Conference of Governmental Industrial Hygienists
AIHA = American Industrial Hygiene Association
BEI = Biological Exposure Index
CAS Number = Chemical Abstract Service Registry Number
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHEMTREC = Chemical Transportation Emergency Center
DOT = Department of Transportation
EU = European Union
EINECS = European Inventory of Existing Chemical Substances
ELINCS = European List of New Chemical Substances
EPA = Environmental Protection Agency
HEPA = High Efficiency Particulate Air (Filter)
IARC = International Agency for Research on Cancer
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association
IMO = International Maritime Organization
LC_{50} = Lethal Concentration at 50 % of test population (gases and vapors)
LD_{50} = Lethal Dose at 50 % of test population
LEL = Lower Explosive Limit
MSDS = Material Safety Data Sheet
NA = Not Applicable, except in Section 14 where NA = North America
NADA = New Animal Drug Application
NAIF = No Applicable Information Found
NCI = National Cancer Institute
NE = Not Established

NIOSH = National Institute for Occupational Safety and Health
NOS = Not Otherwise Specified
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Limit (OSHA)
RCRA = Resource Conservation and Recovery Act
RQ = Reportable Quantity
RTECS = Registry of Toxic Effects of Chemical Substances
SARA = Superfund Amendments and Reauthorization Act
STEG = Lilly Short Term Exposure Guideline
STEL = Short Term Exposure Limit
TD_{LO} = Toxic Dose (lowest) that caused a symptom
TLV = Threshold Limit Value (ACGIH)
TPQ = Threshold Planning Quantity
TSCA = Toxic Substances Control Act
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted
UEL = Upper Explosive Limit
UN = United Nations
WEEL = Workplace Environmental Exposure Level (AIHA)