SAFETY DATA SHEET

1. Identification

Product identifier: RABIPUR RABIES VACCINE

Other means of identification:

Synonyms: RABAERT VACCINE, SUSPENSION FOR INJECTION (US) * RABIPUR (LYOPHILISATE), RABIES VACCINE, SUSPENSION FOR INJECTION (EU) * RABAERT RABIES VACCINE * PURIFIED CHICK EMBRYO CELL VACCINE (PCECV)

Recommended use: Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions: No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer:

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249

Email Address: msds@gsk.com
Website: www.gsk.com

EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES:
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards
Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements
Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)
Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>INACTIVATED RABIES VIRUS</td>
<td>Unassigned</td>
<td></td>
<td>&lt; 75</td>
</tr>
</tbody>
</table>
**4. First-aid measures**

**Inhalation**
Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

**Skin contact**
Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

**Eye contact**
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

**Ingestion**
If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.

**Most important symptoms/effects, acute and delayed**
None known.

**Indication of immediate medical attention and special treatment needed**
No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

**General information**
In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

**5. Fire-fighting measures**

**Suitable extinguishing media**

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
During fire, gases hazardous to health may be formed.

**Special protective equipment and precautions for firefighters**
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Fire fighting equipment/instructions**
Move containers from fire area if you can do so without risk.

**Specific methods**
Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Avoid prolonged exposure. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store in a well-ventilated place. Store at 2 to 8 °C (36 to 46 °F). Do not freeze. To maintain product quality, do not store in heat or direct sunlight. Dispose of properly if frozen. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

<table>
<thead>
<tr>
<th>GSK Components</th>
<th>Type</th>
<th>Value</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHYLENEDIAMINETETRACETIC ACID, DISODIUM SALT, DIHYDRATE (CAS 6381-92-6)</td>
<td>8 HR TWA</td>
<td>3000 mcg/m³</td>
<td></td>
</tr>
<tr>
<td>NEOMYCIN SULFATE (CAS 1405-10-3)</td>
<td>OHC</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>NEOMYCIN SULFATE (CAS 1405-10-3)</td>
<td>8 HR TWA</td>
<td>2000 mcg/m³</td>
<td></td>
</tr>
<tr>
<td>NEOMYCIN SULFATE (CAS 1405-10-3)</td>
<td>OHC</td>
<td>1</td>
<td>SKIN SENSITISER</td>
</tr>
<tr>
<td>NEOMYCIN SULFATE (CAS 1405-10-3)</td>
<td>1</td>
<td>REPRODUCTIVE HAZARD</td>
<td></td>
</tr>
</tbody>
</table>

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

General ventilation normally adequate.

Appropriate engineering controls

Individual protection measures, such as personal protective equipment

Eye/face protection

Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Other

Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection

No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state

Solid.

Form

Vial. Freeze dried powder. (Lyophilized.) and Vial. Diluent.

Color

White

Odor

Odourless.
Odor threshold Not available.

pH Not available.

Melting point/freezing point 32 °F (0 °C)

Initial boiling point and boiling range 212 °F (100 °C)

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Specific gravity 1

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Do not freeze. Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard. Literature search Result: May cause irritation

NEOMYCIN SULFATE

Skin contact Health injuries are not known or expected under normal use.

Eye contact Health injuries are not known or expected under normal use.

Ingestion Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics None known.

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.
**NEOMYCIN SULFATE (CAS 1405-10-3)**

**Acute**

**Oral**

LD50 Mouse > 8000 mg/kg

* Estimates for product may be based on additional component data not shown.

**Skin corrosion/irritation** Health injuries are not known or expected under normal use.

**Corrosivity**

NEOMYCIN SULFATE Literature search

**Result:** Irritant

**Serious eye damage/eye irritation** Health injuries are not known or expected under normal use.

**Eye**

NEOMYCIN SULFATE Literature search

**Result:** Irritant

**Respiratory or skin sensitization**

**Respiratory sensitization** Not established.

NEOMYCIN SULFATE Literature search

**Result:** Positive

**Skin sensitization** This product is not expected to cause skin sensitization.

NEOMYCIN SULFATE Literature search

**Result:** Positive

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Carcinogenicity** Not classifiable as to carcinogenicity to humans.

NEOMYCIN SULFATE 25 mg/kg/day, Auditory toxicity, no evidence of carcinogenicity.

Species: Rat

Observation Period: 104 weeks

IARC Monographs. Overall Evaluation of Carcinogenicity

Not available.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

**Reproductive toxicity** Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

**Reproductivity**

NEOMYCIN SULFATE 100 mg/kg/day Embryo-foetal development, Intra-muscular administration.

Result: Auditory toxicity in offspring.

Species: Rat

Notes: Shepherd's Catalogue of Teratogenic Agents.

25 mg/kg/day 3-generation study, Dietary study.

Result: NOAEL (maximum dose)

Species: Rat

Notes: WHO Food Additive Series

25 mg/kg/day, Dietary study.

Result: No adverse foetal effects observed.

Species: Rat

Notes: WHO Food Additive Series

4 g/l Embryo-foetal development, Administered in drinking water.

Result: No malformations.

Species: Mouse

Notes: Shepherd's Catalogue of Teratogenic Agents.
Reproductivity

NEOMYCIN SULFATE

Embryo-foetal development
Result: No malformations.
Species: Rabbit
Notes: Reprotox

Specific target organ toxicity - single exposure
None known.

Specific target organ toxicity - repeated exposure
None known.

NEOMYCIN SULFATE
Organ: Auditory system, kidneys.

Aspiration hazard
Not likely, due to the form of the product.

Chronic effects
None known.

Further information
Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE (CAS 6381-92-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Aquatic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>Water flea (Daphnia magna)</td>
</tr>
<tr>
<td>NOEC</td>
<td>Water flea (Daphnia magna)</td>
<td>4.1 mg/l, 48 hours Static test</td>
</tr>
<tr>
<td>Fish</td>
<td>EC50</td>
<td>Bluegill sunfish (Adult Lepomis macrochirus)</td>
</tr>
<tr>
<td></td>
<td>Channel catfish (Adult Ictalurus punctatus)</td>
<td>164 mg/l, 96 hours Static test</td>
</tr>
<tr>
<td></td>
<td>Fathead minnow (Adult Pimephales promelas)</td>
<td>75.9 mg/l, 96 hours Static test</td>
</tr>
<tr>
<td>NEOMYCIN SULFATE (CAS 1405-10-3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Aquatic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>MIC</td>
<td>Bacteria</td>
</tr>
</tbody>
</table>

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)
ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE 37 %, 14 days Zahn-Wellens, Activated sludge

Percent degradation (Aerobic biodegradation-ready)
ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE 28 %, 28 days Sturm test

Percent degradation (Aerobic biodegradation-soil)
ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE 13 - 45 %, 15 weeks

Bioaccumulative potential

Bioconcentration factor (BCF)
ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE 0.8 - 1.8 Measured, Lepomis macrochirus, bluegill sunfish

Mobility in soil
Not available.

Mobility in general
Not available.

Other adverse effects
Not available.
13. Disposal considerations

Disposal instructions: Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

Local disposal regulations: Dispose in accordance with all applicable regulations.

Hazardous waste code: The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products: Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.

Contaminated packaging: Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT: Not regulated as a dangerous good.

IATA: Not regulated as dangerous goods.

IMDG: Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not established.

15. Regulatory information

US federal regulations:


SARA 304 Emergency release notification: Not regulated.


Superfund Amendments and Reauthorization Act of 1986 (SARA):

Hazard categories: Immediate Hazard - Yes

SARA 302 Extremely hazardous substance: Not listed.

SARA 311/312 Hazardous chemical: No

SARA 313 (TRI reporting): Not regulated.

Other federal regulations:

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List: Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)
Not listed.

US. Massachusetts RTK - Substance List
Not regulated.

US. New Jersey Worker and Community Right-to-Know Act
Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law
Not listed.

US. Rhode Island RTK
Not regulated.

US. California Proposition 65
WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Developmental toxin
NEOMYCIN SULFATE (CAS 1405-10-3) Listed: October 1, 1992

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A “Yes” indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A “No” indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 06-02-2015
Revision date 10-12-2015
Version # 02

Further information
Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 1*
Flammability: 1
Physical hazard: 0

NFPA ratings
Health: 1
Flammability: 1
Instability: 0

References
GSK Hazard Determination

Disclaimer
The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.