



SAFETY DATA SHEET

1. Identification

Product identifier ROTARIX LYOPHILIZED VACCINE

Other means of identification
Synonyms HUMAN ROTAVIRUS (HRV) VACCINE * LIVE ATTENUATED HUMAN ROTAVIRUS (HRV) VACCINE

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. Medicinal Product

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

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

CHEMTREC EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES:
Customer Number: CCN9484
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

| Chemical name | Common name and synonyms | CAS number | % |
|---|---|------------|----------------|
| SUCROSE | SUGAR CANE SUGAR BEET SUGAR CONFECTIONER'S SUGAR ALPHA-D-GLUCOPYRANOSIDE, BETA-D-FRUCTOFURANOSYL GRANULATED SUGAR SUCRALOX | 57-50-1 | 17.4 |
| HUMAN ROTAVIRUS, LIVE ATTENUATED, RIX4414 STRAIN | | | Not Applicable |
| Other components below reportable levels | | | > 80 |

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

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. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment. |

5. Fire-fighting measures

| | |
|--|---|
| Suitable extinguishing media | Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂). |
| 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 | Assume that this product is capable of sustaining combustion. |

6. Accidental release measures

| | |
|--|---|
| Personal precautions, protective equipment and emergency procedures | Keep unnecessary personnel away. 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. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS. |
| 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 at 2 to 8 °C (36 to 46 °F). Do not freeze. Dispose of properly if frozen. Store away from incompatible materials (see Section 10 of the SDS). |

8. Exposure controls/personal protection

| | |
|-------------------------------------|--|
| Occupational exposure limits | The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits. |
| GSK | Not established |

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

| Components | Type | Value | Form |
|-----------------------|------|---------------------|----------------------|
| SUCROSE (CAS 57-50-1) | PEL | 5 mg/m ³ | Respirable fraction. |

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

| Components | Type | Value | Form |
|------------|------|----------|-------------|
| | | 15 mg/m3 | Total dust. |

US. ACGIH Threshold Limit Values

| Components | Type | Value |
|-----------------------|------|----------|
| SUCROSE (CAS 57-50-1) | TWA | 10 mg/m3 |

US. NIOSH: Pocket Guide to Chemical Hazards

| Components | Type | Value | Form |
|-----------------------|------|----------|-------------|
| SUCROSE (CAS 57-50-1) | TWA | 5 mg/m3 | Respirable. |
| | | 10 mg/m3 | Total |

| | |
|--|--|
| Biological limit values | No biological exposure limits noted for the ingredient(s). |
| Exposure guidelines | |
| Appropriate engineering controls | General ventilation normally adequate. |
| 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 | Powder.Vial. |
| Color | Not available. |
| Odor | Not available. |
| Odor threshold | Not available. |
| pH | Not available. |
| Melting point/freezing point | Not available. |
| Initial boiling point and boiling range | Not available. |
| 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. |

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. DO NOT FREEZE - dispose of properly if frozen. |
| Possibility of hazardous reactions | Hazardous polymerization does not occur. |
| Conditions to avoid | 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. |
| Skin contact | Health injuries are not known or expected under normal use. |
| Eye contact | Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation. |
| Ingestion | Health injuries are not known or expected under normal use. May be harmful if swallowed. 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 | Expected to be a low hazard for usual industrial or commercial handling by trained personnel. |
| Skin corrosion/irritation | Health injuries are not known or expected under normal use. |
| Serious eye damage/eye irritation | Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation. |
| Respiratory or skin sensitization | |
| Respiratory sensitization | No studies have been conducted. |
| Skin sensitization | None known. This product is not expected to cause skin sensitization. |
| 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. Carcinogenic effects are not expected as a result of occupational exposure. |

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

| | |
|---|--|
| Reproductive toxicity | Contains no ingredient listed as toxic to reproduction |
| Specific target organ toxicity - single exposure | Not assigned. |
| Specific target organ toxicity - repeated exposure | Not assigned. |
| Aspiration hazard | Not established. |
| Chronic effects | Prolonged inhalation may be harmful. |

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.

Persistence and degradability Not available.

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

SUCROSE 69 % BOD5

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

SUCROSE -3

Mobility in soil Not available.

Mobility in general Not available.

Volatility

Henry's law

SUCROSE < 0 atm m³/mol Estimated

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 applicable.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

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.

Safe Drinking Water Act (SDWA) Not regulated.

International Inventories

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

*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 04-11-2014

Revision date 05-06-2017

Version # 07

Further information HMIS® is a registered trade and service mark of the NPCA.

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

NFPA ratings Health: 1
Flammability: 0
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.

Revision information This document has undergone significant changes and should be reviewed in its entirety.