# SAFETY DATA SHEET

## 1. Identification

**Product identifier** **RELENZA**

**Other means of identification** Not available.

**Synonym(s)** RELENZA ROTADISK 5 MG/25MG * RELENZA DISKHALER 5 MG/25 * ZANAMIVIR, FORMULATED PRODUCT

**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**

**Hazardous components**

| Chemical name | Common name and synonyms | CAS number | % |
|---|---|---|---|
| ZANAMIVIR | GR121167X<br>GG167<br>5-ACETYLAMINO-4-GUANIDINO-2,6-ANHYI<br>ACID<br>D-GLYCERO-D-GALACTO-NON-2-ENONIC<br>ACID,<br>5-(ACETYLAMINO)-4-((AMINOIMINOMETHY<br>(2R,3R,4S)-3-(ACETYLAMINO)-4-((AMINO(II<br>ACID<br>(4S,5R,6R)-5-ACETYLAMINO-4-GUANIDINC<br>ACID<br>5-GUANIDINO-NEU-5-AC-2-EN<br>1042 (GW ACN) | 139110-80-8 | 20 |
| 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** In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

**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** Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

**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.

**Most important symptoms/effects, acute and delayed** The following adverse effects have been noted with therapeutic use of this material: dizziness; bronchospasm; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing).

**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 centre.

**General information** 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 fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

**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** In the event of fire, cool tanks with water spray.

**Specific methods** Cool containers exposed to flames with water until well after the fire is out.

## 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures** Keep unnecessary personnel away. For personal protection, see section 8 of the MSDS.

**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 MSDS.

**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 away from incompatible materials (see Section 10 of the MSDS).

## 8. Exposure controls/personal protection

**Occupational exposure limits**

**GSK**

| Components | Type | Value |
|---|---|---|
| ZANAMIVIR (CAS 139110-80-8) | 8 HR TWA | 1000 mcg/m3 |
| | OHC | 2 |

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls** An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection** If contact is likely, safety glasses with side shields are recommended.

| | |
|---|---|
| **Hand protection** | The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present. |
| **Other** | Not normally needed. |
| **Respiratory protection** | No personal respiratory protective equipment normally required. |
| **Thermal hazards** | Wear appropriate thermal protective clothing, when necessary. |
| **General hygiene considerations** | An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. 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. |

## 9. Physical and chemical properties

| | |
|---|---|
| **Appearance** | |
| **Physical state** | Solid. |
| **Form** | Powder. |
| **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)** | 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. |
| **Possibility of hazardous reactions** | No dangerous reaction known under conditions of normal use. |
| **Conditions to avoid** | Contact with incompatible materials. |
| **Incompatible materials** | Strong oxidizing agents. |
| **Hazardous decomposition products** | Irritating and/or toxic fumes and gases may be emitted upon the products decomposition. |

## 11. Toxicological information

**Information on likely routes of exposure**

| | |
|---|---|
| **Ingestion** | Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. |
| **Inhalation** | Health injuries are not known or expected under normal use. Inhalation of dusts may cause respiratory irritation. |
| **Skin contact** | Health injuries are not known or expected under normal use. Dust or powder may irritate the skin. |
| **Eye contact** | Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation. |
| **Symptoms related to the physical, chemical and toxicological characteristics** | The following adverse effects have been noted with therapeutic use of this material: dizziness; bronchospasm; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing).<br>No specific target organ effects have been identified. |

**Information on toxicological effects**

**Acute toxicity** Health injuries are not known or expected under normal use.

| Components | Species | Test Results |
|---|---|---|
| ZANAMIVIR (CAS 139110-80-8) | | |
| **Acute** | | |
| *Inhalation* | | |
| LCLo | Rat | > 0.3 mg/l, 4 hr |
| *Oral* | | |
| LD50 | Rat | > 2000 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.

**Irritation Corrosion - Skin**

ZANAMIVIR
Acute dermal irritation; OECD 404, Primary dermal irritation index = 0
Result: Negative
Species: Rabbit

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

**Eye**

ZANAMIVIR
Acute ocular irritation; OECD 405, Overall mean score = 0.7
Result: Negative
Species: Rabbit

**Respiratory sensitization** Not available.

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

**Maximisation assay (Magnusson and Kligman)**

RELENZA
Result:

**Sensitization**

ZANAMIVIR
Maximisation assay (Magnusson and Kligman)
Result: Negative
Species: Guinea pig

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

ZANAMIVIR
Ames Assay, GLP assay
Result: Negative
Bacterial High Throughput Fluctuation Test
Result: Negative
Chromosomal Aberration Assay In Vitro, human lymphocytes
Result: Negative
Micronucleus Assay, GLP assay; tested to MTD of 90 mg/kg (intravenous)
Result: Negative
Species: Mouse
Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay
Result: Negative
Yeast Mutation Assay
Result: Negative

**Carcinogenicity** This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Health injuries are not known or expected under normal use.

**Carcinogenicity**

ZANAMIVIR

2 year bioassay, Maximum dose = 105 mg/kg/day (inhalation)
Result: Negative
Species: Mouse
2 year bioassay, Maximum dose = 53.1 mg/kg/day (inhalation)
Result: Negative
Species: Rat

**Reproductive toxicity** This product is not expected to cause reproductive or developmental effects.

ZANAMIVIR

Embryo-foetal development - Intravenous
Result: NOAEL (maternal and foetal) = 90 mg/kg/day (intraveous; maximum dose)
Species: Rabbit
Embryo-foetal development - Intravenous
Result: NOAEL (maternal and foetal) = 90 mg/kg/day (intraveous; maximum dose)
Species: Rat
Fertility and general reproductive performance
Result: NOAEL / fertility = 90 mg/kg/day (intravenous; maximum dose)
Species: Rat
Pre- and Post-natal development
Result: NOAEL (maternal and foetal) = 90 mg/kg/day (intraveous; maximum dose)
Species: Rat

**Specific target organ toxicity - single exposure** None known.

**Specific target organ toxicity - repeated exposure** None known.

**Aspiration hazard** Not available.

## 12. Ecological information

**Ecotoxicity** Not expected to be harmful to aquatic organisms.

| Components | | Species | Test Results |
|---|---|---|---|
| ZANAMIVIR (CAS 139110-80-8) | | | |
| **Aquatic** | | | |
| *Acute* | | | |
| Activated Sludge Respiration | IC50 | Residential sludge | > 1000 mg/l, 3 hours, OECD 209 |
| Crustacea | EC50 | Water flea (Daphnia magna) | > 1000 mg/l, 48 hours, Static test, OECD 202 |
| | NOEC | Water flea (Daphnia magna) | > 1000 mg/l, 48 hours, Static test |
| *Chronic* | | | |
| Crustacea | EC50 | Water flea (Ceriodaphnia dubia) | > 100 mg/l, 8 days, Static renewal test, EPA 1002 |
| | LOEC | Daphnia | > 100 mg/l, 8 days |
| | NOEC | Daphnia | 100 mg/l, 8 days |

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

**Persistence and degradability**

**Hydrolysis**

**Half-life (Hydrolysis-neutral)**

ZANAMIVIR > 1 Years Measured

**Biodegradability**

**Percent degradation (Aerobic biodegradation-soil)**

ZANAMIVIR 6 - 36 %, 64 days

**Bioaccumulative potential**

**Partition coefficient n-octanol / water (log Kow)**

ZANAMIVIR -7.082 (Calculated).

**Mobility in soil**

**Adsorption**

**Soil/sediment sorption - log Koc**

ZANAMIVIR 0.82 - 1.18, pH 6-8.2

**Mobility in general**

**Volatility**

**Henry's law**

| | |
|---|---|
| ZANAMIVIR | 0 atm m^3/mol Calculated, 20 C |

**Other adverse effects** Not available.

## 13. Disposal considerations

| | |
|---|---|
| **Disposal instructions** | Collect and reclaim or dispose in sealed containers at licensed waste disposal site. |
| **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). |
| **Contaminated packaging** | Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied. |

## 14. Transport information

**DOT**

Not regulated as a dangerous good.

**IATA**

Not regulated as a dangerous good.

**IMDG**

Not regulated as a dangerous good.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

## 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.

**US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

| | |
|---|---|
| **Hazard categories** | Immediate Hazard - No<br>Delayed Hazard - No<br>Fire Hazard - No<br>Pressure Hazard - No<br>Reactivity Hazard - No |
| **SARA 302 Extremely hazardous substance** | No |
| **SARA 311/312 Hazardous chemical** | No |

**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. |
| **Food and Drug Administration (FDA)** | Not regulated. |

**US state regulations**

**US. Massachusetts RTK - Substance List**

Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**

Not regulated.

**US. Pennsylvania RTK - Hazardous Substances**

Not regulated.

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**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** | 10-04-2013 |
| **Revision date** | 10-04-2013 |
| **Version #** | 15 |
| **Further information** | This material has not been assessed for HMIS or NFPA ratings. |
| **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** | Product and Company Identification: Business Units<br>Composition / Information on Ingredients: Ingredients<br>Physical & Chemical Properties:<br>Toxicological Information:<br>Ecological Information:<br>Transport Information: |