



SAFETY DATA SHEET

1. Identification

| | |
|--------------------------------------|---|
| Product identifier | RETROVIR SYRUP |
| Other means of identification | Not available. |
| Synonym(s) | RETROVIR SYRUP 50 MG/5 ML * RETROVIR/AZT ORAL SOLUTION 10 MG/ML * RETROVIR ORAL SOLUTION * RETROVIR ORAL SUSPENSION * RETROVIR S SYRUP * NDC NO 0173-0113-18 * ZIDOVUDINE, 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

ViiV Healthcare
Five Moore Drive
Research Triangle Park
North Carolina, USA
27709-3398
US General Information (normal business hours): +1-877-844-8872 (+1 877 ViiVUSA)
Email Address: msds@gsk.com
Website: www.viivhealthcare.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 | % |
|---------------|---|------------|----|
| GLYCERIN | GLYCEROL GLYCERIN ANHYDROUS GLYCERINE GLYCERITOL GLYCYL ALCOHOL 1,2,3-PROPANETRIOL PROPANETRIOL GLYROL GLYSANIN TRIHIDROXYPROPANE 1,2,3-TRIHIDROXYPROPANE OSMOGLYN | 56-81-5 | 10 |

| Hazardous components | | | |
|--|--|-------------------|----------|
| Chemical name | Common name and synonyms | CAS number | % |
| ZIDOVUDINE | 3'-AZIDO-3'-DEOXYTHYMIDINE 509U81 AZIDOTHYMIDINE ERYTHRO-3'-THYMIDINE GR 63367X ZDV | 30516-87-1 | 1 |
| CITRIC ACID ANHYDROUS | BETA-HYDROXYTRICARBALLYLIC ACID ANHYDROUS CITRIC ACID 2-HYDROXY-1,2,3-PROPANETRICARBOXY ACID CITIRIC ACID | 77-92-9 | 0.35 |
| SODIUM BENZOATE | BENZOIC ACID, SODIUM SALT BENZOATE OF SODA SODIUM BENZOIC ACID C7H6NaO2 OHS20965 RTECS DH6650000 GR 33388B 427 (GW ACN) | 532-32-1 | 0.2 |
| Other components below reportable levels | | | 99.0 |

*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 not breathing, give artificial respiration. If breathing is difficult, trained personnel should give oxygen. |
| 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 | Prolonged exposure may cause chronic effects. The following adverse effects have been noted with therapeutic use of this material: anaemia; headache; nausea; vomiting; anorexia. |
| 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 | Alcohol resistant foam. Water fog. Dry chemical powder. Carbon dioxide (CO2). |
| Unsuitable extinguishing media | Do not use water jet as an extinguisher, as this will spread the fire. |
| 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. |

6. Accidental release measures

| | |
|--|--|
| Personal precautions, protective equipment and emergency procedures | Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate personal protective equipment. 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 MSDS. |
|--|--|

Methods and materials for containment and cleaning up

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Use water spray to reduce vapors or divert vapor cloud drift. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills in original containers for re-use. 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**

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapor. Avoid prolonged exposure. Avoid contact during pregnancy/while nursing. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection**Occupational exposure limits****GSK****Components****Type****Value****Note**

CITRIC ACID ANHYDROUS (CAS 77-92-9)

8 HR TWA

5000 mcg/m3

OHC

1

SODIUM BENZOATE (CAS 532-32-1)

8 HR TWA

5000 mcg/m3

OHC

1

ZIDOVUDINE (CAS 30516-87-1)

8 HR TWA

350 mcg/m3

OHC

2

CARCINOGEN

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**Components****Type****Value****Form**

GLYCERIN (CAS 56-81-5)

PEL

5 mg/m3

Respirable fraction.

15 mg/m3

Total dust.

US. ACGIH Threshold Limit Values**Components****Type****Value****Form**

GLYCERIN (CAS 56-81-5)

TWA

10 mg/m3

Mist.

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**

Chemical goggles 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

Wear appropriate chemical resistant clothing.

Respiratory protection

No personal respiratory protective equipment normally required.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

When using, do not eat, drink or smoke. 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. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

9. Physical and chemical properties**Appearance**

| | |
|---|----------------|
| Physical state | Liquid. |
| Form | Syrup. |
| 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 | Adverse effects might occur with repeated ingestion. |
| Inhalation | Health injuries are not known or expected under normal use. |
| Skin contact | Health injuries are not known or expected under normal use. |
| Eye contact | Health injuries are not known or expected under normal use. |

Symptoms related to the physical, chemical and toxicological characteristics

The following adverse effects have been noted with therapeutic use of this material: anaemia; headache; nausea; vomiting; anorexia.
Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells; lymph nodes; spleen; thymus. Assessment based upon information from animal studies.

Information on toxicological effects

Acute toxicity Adverse effects might occur with repeated ingestion.

| Components | Species | Test Results |
|-------------------------------------|---------|-----------------------------|
| CITRIC ACID ANHYDROUS (CAS 77-92-9) | | |
| Acute | | |
| <i>Oral</i> | | |
| LD50 | Rat | 3000 mg/kg |
| GLYCERIN (CAS 56-81-5) | | |
| Acute | | |
| <i>Oral</i> | | |
| LD50 | Rat | > 2000 mg/kg |
| ZIDOVDINE (CAS 30516-87-1) | | |
| Acute | | |
| <i>Oral</i> | | |
| LD50 | Rat | 3083 - 3683 mg/kg |
| Subchronic | | |
| <i>Oral</i> | | |
| LOEL | Monkey | 35 mg/kg/day, 6 month study |

* 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
ZIDOVDINE

Acute dermal irritation, Primary Irritation Index: 0; abraded and non-abraded sites
Result: Negative
Species: Rabbit

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

Eye
ZIDOVDINE

Acute ocular irritation
Result: Moderate Irritant
Species: Rabbit

Respiratory sensitization Not available.

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

Germ cell mutagenicity The ingredient zidovudine has caused genetic toxicity in laboratory studies.

ZIDOVDINE

Ames Assay, GLP assay
Result: Positive
Chromosomal Aberration Assay In Vitro, human lymphocytes
Result: Positive
GreenScreen Assay
Result: Positive (+ S9 only)
Micronucleus Assay
Result: Positive
Species: Mouse
Micronucleus Assay
Result: Positive
Species: Rat
Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay
Result: Positive
Sister Chromatid Exchange
Result: Positive

Carcinogenicity Contains a material (zidovudine) classified as a carcinogen by external agencies.

ZIDOVDINE

2 year bioassay, vaginal tumours in females at doses of 24X the equivalent of human therapeutic dose; no effect in males
Result: Positive
Species: Rat

Carcinogenicity
ZIDOVDINE

2 year bioassay, vaginal tumours in females at doses of 3X or more the equivalent of human therapeutic dose; no effect in males
Result: Positive
Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

ZIDOVDINE (CAS 30516-87-1)

2B Possibly carcinogenic to humans.

Reproductive toxicity

The ingredient zidovudine has caused adverse effects on the development of unborn offspring in animal studies.

ZIDOVDINE

Embryo-foetal development - Oral
Result: Foetal and maternal NOAEL = 150 mg/kg/day; with 500 mg/kg/day evidence of foetal toxicity (increased incidence of resorptions); no foetal malformations with any dose up to maximum of 450 mg/kg/day
Species: Rabbit
Embryo-foetal development - Oral
Result: Foetal and maternal NOAEL = 50 mg/kg/day; with 150 mg/kg/day or more evidence of foetal toxicity (increased incidence of resorptions); no foetal malformations with any dose up to maximum of 450 mg/kg/day
Species: Rat
Fertility
Result: Negative
Species: Rat
Peri- and Post-natal development
Result: NOAEL = 450 mg/kg/day (maximum dose)
Species: Rat

Specific target organ toxicity - single exposure

None known.

Specific target organ toxicity - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

ZIDOVDINE

Repeat dose non-clinical studies
Organ: bone marrow; blood; lymph nodes; spleen; thymus

Aspiration hazard

Not available.

Chronic effects

May cause damage to organs through prolonged or repeated exposure.

12. Ecological information

Ecotoxicity

| Components | Species | Test Results |
|--|---------|---|
| CITRIC ACID ANHYDROUS (CAS 77-92-9) | | |
| Aquatic | | |
| <i>Acute</i> | | |
| Crustacea | EC50 | Water flea (Daphnia magna) 120 mg/l, 72 hours, Static test |
| Fish | EC50 | Bluegill sunfish (Adult Lepomis macrochirus) 1516 mg/l, 96 hours, Static test |
| | | Golden ide/orfe (Adult Leuciscus idus) 440 - 760 mg/l, 96 hours, Static test |
| Microtox | EC50 | Microtox 14 mg/l, 15 minutes |
| SODIUM BENZOATE (CAS 532-32-1) | | |
| Aquatic | | |
| <i>Acute</i> | | |
| Crustacea | EC50 | Water flea (Daphnia magna) > 100 mg/L, 96 hours, Static test |
| Fish | EC50 | Fathead minnow (Juvenile Pimephales promelas) 484 mg/L, 96 hours, Flow-through test |
| ZIDOVDINE (CAS 30516-87-1) | | |
| Aquatic | | |
| <i>Acute</i> | | |
| Activated Sludge Respiration | IC50 | Residential sludge > 1000 mg/l, 3 hours, OECD 209 |
| Crustacea | EC50 | Water flea (Daphnia magna) > 100 mg/l, 48 hours, Static test, OECD 202 |
| Microtox | MIC | Aspergillus flavus 250 mg/l |

| Components | | Species | Test Results |
|----------------|------|----------------------------|---|
| | | Azotobacter chroococcum | > 1000 mg/l |
| | | Chaetomium globosum | > 1000 mg/l |
| | | Nostoc sp. | > 1000 mg/l |
| | | Pseudomonas fluorescens | > 1000 mg/l |
| <i>Chronic</i> | | | |
| Crustacea | LOEC | Water flea (Daphnia magna) | 40 mg/l, 21 days, Static renewal test, OECD 211 |
| | NOEC | Water flea (Daphnia magna) | 16 mg/l, 21 days, Static renewal test |

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

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

ZIDOVDINE 9.04 Hours Measured, pH 7 Buffer Solution

UV/visible spectrum wavelength

ZIDOVDINE 266 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

ZIDOVDINE > 1 Years Measured

Biodegradability

Percent degradation (Anaerobic biodegradation)

SODIUM BENZOATE 93 %, 7 days Other degradation test system, Mixed Residential/Industrial

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

GLYCERIN -1.76

ZIDOVDINE 0.06

SODIUM BENZOATE 1.89

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

ZIDOVDINE 1.34 Measured, pH 7

Soil/sediment sorption - log Koc

SODIUM BENZOATE 1.16 Calculated

ZIDOVDINE 1.1, pH 7 Estimated

Mobility in general

Volatility

Henry's law

CITRIC ACID ANHYDROUS < 0 atm m³/mol Calculated, 25 °C

ZIDOVDINE 0 atm m³/mol, 25 C Estimated

Other adverse effects Not available.

13. Disposal considerations

| | |
|--|--|
| Disposal instructions | Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international 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). |
| 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 This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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 - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
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

GLYCERIN (CAS 56-81-5)

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

GLYCERIN (CAS 56-81-5)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

ZIDOVDINE (CAS 30516-87-1) Listed: December 18, 2009

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 |

| Country(s) or region | Inventory name | On inventory (yes/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 | 08-19-2013 |
| Revision date | 08-19-2013 |
| Version # | 11 |
| 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. The information in the sheet was written based on the best knowledge and experience currently available. |
| Revision Information | Product and Company Identification: Business Units Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Multiple Properties Transport Information: |