

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material	RETROVIR SYRUP
Synonym(s)	RETROVIR SYRUP 50 MG/5 ML * RETROVIR/AZT ORAL SOLUTION 10 MG/ML * RETROVIR/AZT DRANK 50 MG/5 ML * RETROVIR JARABE * RETROVIR LOSUNG * RETROVIR ORAL SOLUTION * RETROVIR ORAL SUSPENSION * RETROVIR S SYRUP * RETROVIR SAFT * RETROVIR SCIROPPPO * RETROVIR SIROP * RETROVIR SOLUCAO ORAL * RETROVIR SOLUCION * RETROVIR SOLUCION ORAL * RETROVIR SOLUTION * RETROVIR SOLUTION BUVABLE * RETROVIR SURUP * RETROVIR SUSPENSION * RETROVIR SYROP * NDC NO 0173-0113-18 * ZIDOVUDINE, FORMULATED PRODUCT
Company Name	GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response

* 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
NON-HAZARDOUS INGREDIENTS	Unassigned	99	
ZIDOVUDINE	30516-87-1	1	

3. HAZARDS IDENTIFICATION

Fire and Explosion	This product is classified as non-flammable.
Health	Caution - Pharmaceutical agent. May produce mutagenic effects in human cells. Limited evidence of carcinogenic effect. Exposure might occur via skin; eyes; inhalation; ingestion. Health effects information is based on hazards of components.
Environment	No environmental hazards have been identified for this material.

4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation	Using appropriate personal protective equipment, move exposed subject to fresh air. If breathing is difficult or ceases, ensure and maintain ventilation. Give oxygen as appropriate. The exposed subject should be kept warm and at rest. Obtain medical attention in cases of known or possible over exposure, or with symptoms including chest pain, difficulty breathing, loss of consciousness or other adverse effects, which may be delayed.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of an anti-viral agent.
Medical Conditions Caused or Aggravated by Exposure	None for occupational exposure.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
Clean-up Methods	Spread an inert absorbent on the spill and place in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
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STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	ZIDOVUDINE
GSK Occupational Hazard Category	2
GSK Occupational Exposure Limit	350 mcg/m3 (8 HR TWA) CARCINOGEN
Other Equipment or Procedures	Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	
Physical Form	Syrup.

10. STABILITY AND REACTIVITY

Stability	This product is expected to be stable.
Conditions to Avoid	None for normal handling of this product.

11. TOXICOLOGY INFORMATION

Pharmacological Effects	This preparation contains ingredient(s) with the following activity: a nucleoside analogue; an anti-viral agent.
Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells.
Routes of Exposure	
Oral Toxicity	Not expected to be toxic following ingestion. Assessment based upon effects of individual components.
Inhalation Toxicity	No studies have been conducted.
Skin Effects	Irritation is not expected following direct contact. Assessment based upon effects of individual components.
Eye Effects	Irritation is not expected following direct contact with eyes. Assessment based upon effects of individual components.
Sensitisation	Sensitisation (allergic skin reaction) is not expected. Assessment based upon effects of individual components.
Genetic Toxicity	Possible human mutagen. Assessment based upon effects of individual components.
Carcinogenicity	Possible human carcinogen. Assessment based upon effects of individual components. Not expected to produce cancer in humans under occupational exposure conditions.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Other Adverse Effects	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary	No information is available about the potential of this product to produce adverse environmental effects. This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release.
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Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Activated Sludge Respiration	This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.
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IC50: > 1000 mg/l, 3 Hours, Activated sludge

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Microbial Growth Inhibition This material contains an active pharmaceutical ingredient that is not toxic to these microorganisms.

Minimum Inhibition Concentration: 250 mg/l, , Aspergillus flavus
> 1000 mg/l, , Azotobacter chroococcum
> 1000 mg/l, , Chaetomium globosum
> 1000 mg/l, , Nostoc sp.
> 1000 mg/l, , Pseudomonas fluorescens

Daphnid This material contains an active pharmaceutical ingredient that is not toxic to daphnids.

EC50: > 100 mg/l, 48 Hours, Daphnia magna, Static test

MOBILITY

Solubility This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

Volatility This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance.

Henry's Law Constant 3.50E-15 atm m³/mol, Estimated at 25 C

Adsorption This material contains an active pharmaceutical ingredient that is not likely to adsorb to soil or sediment if released directly to the environment. This material contains an active pharmaceutical ingredient that is not likely to adsorb to sludge or biomass if released directly to the environment.

Soil Sediment Sorption (log K_{oc}): 1.1, Estimated at pH 7

Sludge Biomass Distribution Coefficient (log K_d): 1.34 Measured at pH 7

Partitioning This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

Hydrolysis This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.

Half-Life, Neutral: > 1 Years, Measured

Photolysis This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water when exposed to light. Aqueous photolysis may be a significant depletion mechanism.

Half-Life, Aqueous: 9.04 Hours, Measured, pH 7 Buffer Solution

UV/Visible Spectrum: 266 nm

Biodegradation This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.

Aerobic - Ready

Percent Degradation: 0.23 %, 28 days, Modified Sturm test., Activated sludge

Aerobic - Ready

Percent Degradation: 50 %, 3 days, , Activated sludge

Aerobic - Inherent

Percent Degradation: 50 %, 3 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Bioaccumulation This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations	Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used. The recommended method of disposal is incineration.
Regulatory Requirements	Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information	Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.
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15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification	This product is classified as hazardous according to the OSHA Hazard Communication Standard.
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Other US Regulations

TSCA Status	Exempt
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16. OTHER INFORMATION

References	GSK Hazard Determination
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SDS Version Number	9
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SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	

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.