SAFETY DATA SHEET

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

Material: RETROVIR CAPSULES

Synonym(s):
- RETROVIR CAPSULES 100 MG
- RETROVIR CAPSULES 250 MG
- RETROVIR CAPSULAS
- RETROVIR GELULES
- RETROVIR KAPSELI
- RETROVIR KAPSELN
- RETROVIR KAPSLAR
- RETROVIR KAPSUL
- RETROVIR KAPSULAS
- RETROVIR KAPSULKI
- RETROVIR-AZT CAPSULAS
- RETROVIR/AZT CAPSULES
- NDC NO 0173-0108-55
- NDC NO 0173-0108-56
- ZIDOVUDINE, FORMULATED PRODUCT

Company Name:
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Medical Emergency +1-612-221-3999, Ext 221
Information and Advice: US number, available 24 hours
Multi-language response

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Transport Emergency (non EU) +1-703-527-3887
US number, available 24 hours
Multi-language response

* 2. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS #</th>
<th>Percent</th>
<th>EC-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZIDOVUDINE</td>
<td>30516-87-1</td>
<td>43.6</td>
<td></td>
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</table>

Other components below reportable levels 56.4

3. HAZARDS IDENTIFICATION

Fire and Explosion: Expected to be non-combustible.
Health: Caution - Pharmaceutical agent.
- May produce mutagenic effects in human cells.
- Limited evidence of carcinogenic effect.
- Exposure might occur via skin; eyes; 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: Physical form suggests that risk of inhalation exposure is negligible.
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.

Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

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.

None for occupational exposure.

No specific antidotes are recommended.

Not expected for the product, although the packaging is combustible.

Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.

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.

Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

Wear protective clothing and equipment consistent with the degree of hazard.

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Collect and place it in a suitable, properly labelled container for recovery or disposal.

No specific decontamination or detoxification procedures have been identified for this product.

Avoid breaking or crushing capsules.

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

ZIDOVUDINE

GSK Occupational Hazard Category 2

GSK Occupational Exposure Limit 350 mcg/m3 (8 HR TWA) CARCINOGEN

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: Capsule.

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.
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.

ECOTOXICITY

Aquatic

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

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 Koc): 1.1, Estimated at pH 7
Sludge Biomass Distribution Coefficient (log Kd): 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, 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.

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.

Classification  This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations
TSCA Status  Exempt

16. OTHER INFORMATION

References  GSK Hazard Determination
SDS Version Number  9

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.