SAFETY DATA SHEET

GlaxoSmithKline

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

Material **VALTREX CAPLETS**

Synonyms VALTREX CAPLETS 500MG * VALTREX CAPLETS 1G * VALTREX TABLETS 500MG * VALTREX COMPRIMIDOS * VALTREX COMPRIMIDOS REVESTIDOS * VALTREX FILM TABLET * VALTREX FILMTABLETTEN * VALTREX POTAHOVANE TABLETY * VALTREX TABLETAS * VALTREX TABLETE * VALTREX TABLETES * VALTREX TABLETKI POWLEKANE * VALTREX TABLETTA * VALTREX TABLETTER * VALTREX TABLETTI * VALTREX TABLETY * NDC NO 0173-0933-56 * NDC NO 0173-0933-03 * NDC NO 0173-0565-01 * NDC NO 0173-0565-03 * NDC NO 0173-0565-02 * NDC NO 0173-0933-07 * NDC NO 0173-0933-06 * NDC NO 0173-0933-05 * VALACYCLOVIR HYDROCHLORIDE, FORMULATED PRODUCT

Company Name

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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

Ingredients	CAS RN	Percentage
VALACYCLOVIR HYDROCHLORIDE	124832-27-5	71 to 73
NON-HAZARDOUS INGREDIENTS	Unassigned	27 to 29

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

Health Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components. Caution - Pharmaceutical agent. Possible effects of overexposure in the workplace include: headache; nausea.

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.
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 Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
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 or foam extinguishers are recommended. Carbon dioxide or dry powder 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	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it 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.
STORAGE	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT	VALACYCLOVIR HYDROCHLORIDE
GSK Occupational Hazard Category	1
GSK Occupational Exposure Limit	5000 mcg/m3 (8 HR TWA)
Other Equipment or Procedures	None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Colour	Blue.
Physical Form	Tablet.

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

Oral Toxicity	Not expected to be toxic following ingestion.
Skin Effects	No studies have been conducted.
Eye Effects	No studies have been conducted.
Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: kidney. Assessment based upon information from animal studies.
Sensitisation	Potential for inducing allergic reactions via the dermal or respiratory route is not known.
Genetic Toxicity	Genetic toxicity is not expected under occupational exposure conditions based upon negative results in laboratory assays. No evidence of DNA damage occurred in the following assay(s): bacterial mutation assay (Ames).
Carcinogenicity	Not expected to produce cancer in humans under occupational exposure conditions based upon negative results in laboratory assays.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Pharmacological Effects	This preparation contains ingredient(s) with the following activity: a nucleoside analogue. This product is intended for the treatment of viral infection. Adverse effects of overexposure might include: headache; nausea.
*** Other Adverse Effects**	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

*** Summary**

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.

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.

IC50: > 100 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:
> 1000 mg/l, , Chaetomium globosum
> 1000 mg/l, , Aspergillus flavus
> 1000 mg/l, , Nostoc sp.
> 1000 mg/l, , Azotobacter chroococcum
> 1000 mg/l, , Pseudomonas fluorescens

*** Daphnid**

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

EC50: 340 mg/l, 48 Hours, Daphnia magna, Static test

NOEL: 56 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.

*** 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 unstable in water. Hydrolysis may be a significant depletion mechanism.

Half-Life, Neutral: 55.92 Hours, Measured

Half-Life, Acidic: 68.38 Days, Measured

Half-Life, Basic: 15.13 Hours, Measured

Hydrolysis Product(s) - By Products: ACYCLOVIR

*** Photolysis**

This material contains an active pharmaceutical ingredient that is unlikely to undergo photodegradation.

UV/Visible Spectrum: 264

*** 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: 0.08 %, 28 days, Modified Sturm test.

Aerobic - Inherent

Percent Degradation: 100 %, 14 days, Modified Zahn-Wellens, 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.

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.

US OSHA Standard (29 CFR Part 1910.1200)

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

Date Approved/Revised 04-Nov-2004 **SDS Version Number** 7

SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	
ECOLOGICAL INFORMATION	
HAZARDS IDENTIFICATION	Environment
REGULATORY INFORMATION	European Union Classification and Labelling Requirements
TOXICOLOGY INFORMATION	Other Adverse Effects

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.