# SAFETY DATA SHEET



# 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 TABLETE \* VALTREX TABLETES \* VALTREX TABLETKI POWLEKANE \* VALTREX TABLETTA \* VALTREX TABLETTI \* VALTREX TABLETTY \* NDC NO 0173-0933-56 \* NDC NO 0173-0933-03 \* NDC NO 0173-0565-01 \* NDC NO 0173-0565-02 \* NDC NO 0173-0933-07 \* NDC NO 0173-0933-06 \* NDC NO 0173-0933-05 \* VALACYCLOVIR HYDROCHLORIDE, FORMULATED PRODUCT

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> 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.

**SDS Number** 110584

**Environment** No environmental hazards have been identified for this material. 4. FIRST-AID MEASURES Never attempt to induce vomiting. Do not attempt to give any solid or liquid Ingestion 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. Physical form suggests that risk of inhalation exposure is negligible. Inhalation **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 Treat according to locally accepted protocols. For additional guidance, refer **Medical Treatment** to the current prescribing information or to the local poison control information centre. **Medical Conditions** Refer to prescribing information for detailed description of medical **Caused or Aggravated** conditions caused by or aggravated by overexposure to this product. by Exposure **Antidotes** No specific antidotes are recommended.

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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.

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** 

Material VALTREX CAPLETS

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 > 1000 mg/l, , Chaetomium globosum Concentration: > 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 ACYCLOVIR

**Products** 

\* 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.