SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	ZOVIRAX TABLETS
Registration number	-
Synonyms	ZOVIRAX TABLETS 400 MG * ZOVIRAX TABLETS 800 MG * ZOVIRAX COMPRESSE * ZOVIRAX COMPRIMES * ZOVIRAX COMPRIMIDOS * ZOVIRAX TABLETAS * ZOVIRAX TABLETES * ZOVIRAX TABLETKI * ZOVIRAX TABLETTA * ZOVIRAX TABLETTER * ZOVIRAX TABLETTI * ZOVIRAX TABLETY * ZOVIRAX WELLSTAT PAC TABLETS * ZOVIRAX ZOSTAB PAC TABLETS * ACYVIR TABLETS * ZOV800 TABLETS * ZOVIR TABLETS * ACYCLOVIR, FORMULATED PRODUCT
Issue date	17-December-2013
Version number	10
Revision date	17-December-2013
Supersedes date	03-May-2013

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	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.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Supplemental label information None.

2.3. Other hazards

Caution - Pharmaceutical agent.
See section 11 for additional information on health hazards.
Expected to be non-combustible.
No information is available about the potential of this product to produce adverse environmental effects.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
ACYCLOVIR	70 - < 80	59277-89-3 261-685-1	-	-	
Classification: **DSD:** -					
CLP: -					
MAGNESIUM STEARATE	1 - < 3	557-04-0 209-150-3	-	-	
Classification: **DSD:** Xi;R36/37/38					
CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335					
Polyvinylpyrrolidone	1 - < 3	9003-39-8 -	-	-	
Classification: **DSD:** R52/53					
CLP: Aquatic Chronic 3;H412					
Other components below reportable levels	10 - < 20				

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. IF exposed or concerned: Get medical advice/attention.

4.1. Description of first aid measures

Inhalation If not breathing, give artificial respiration. If breathing is difficult, trained personnel should give oxygen. Get medical attention immediately.

Skin contact Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Remove and isolate contaminated clothing and shoes. Get medical attention if symptoms occur.

Eye contact In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Get medical attention if irritation develops and persists.

Ingestion Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person. If swallowed, rinse mouth with water (only if the person is conscious). Get medical attention if symptoms occur.

4.2. Most important symptoms and effects, both acute and delayed Not available.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards Expected to be non-combustible.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder.

Unsuitable extinguishing media Carbon dioxide extinguishers may be ineffective.

5.2. Special hazards arising from the substance or mixture Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting 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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Wear protective clothing and equipment consistent with the degree of hazard. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.
6.2. Environmental precautions	Prevent further leakage or spillage if safe to do so. For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
6.3. Methods and material for containment and cleaning up	Collect and place it in a suitable, properly labelled container for recovery or disposal. Stop the flow of material, if this is without risk. Following product recovery, flush area with water. No specific decontamination or detoxification procedures have been identified for this product.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid prolonged exposure. Avoid breaking or crushing tablets.
7.2. Conditions for safe storage, including any incompatibilities	Store away from incompatible materials (see Section 10 of the MSDS). No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.
7.3. Specific end use(s)	Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK Components	Type	Value
ACYCLOVIR (CAS 59277-89-3)	8 HR TWA	5000 mcg/m3
	OHC	1
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1

Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived No Effect Level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

8.2. Exposure controls

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. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them. No special engineering controls are required. Local exhaust ventilation (LEV) is recommended. Only authorised personnel may enter the working area.

Individual protection measures, such as personal protective equipment

General information	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eye/face protection	Wear approved safety glasses with side shields or cover goggles if eye contact is possible. (eg. EN 166)
Skin protection	
- Hand protection	Glove selection must take into account any solvents and other hazards present. Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Wear appropriate chemical resistant clothing. (EN 14605 for splashes, EN ISO 13982 for dust)

Respiratory protection	If respiratory protective equipment (RPE) is used, the type of RPE will depend upon air concentrations present, required protection factor as well as hazards, physical properties and warning properties of substances present. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	An eye wash station should be available. Wear appropriate clothing to avoid skin contact. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Environmental exposure controls

GSK environmental hazard category	1
Hazard guidance and control recommendations	Not available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Solid.
Form	Tablet.
Colour	Not available.
Odour	Not available.
Odour 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.
Vapour pressure	Not available.
Vapour 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.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	This product is expected to be stable.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	None for normal handling of this product.
10.5. Incompatible materials	None known.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Ingestion Based on available data, the classification criteria are not met.

Inhalation Based on available data, the classification criteria are not met. Inhalation of dusts may cause respiratory irritation.

Skin contact Based on available data, the classification criteria are not met. Dust or powder may irritate the skin.

Eye contact Based on available data, the classification criteria are not met. Dust or powder may irritate eye tissue.

Symptoms Not available.

11.1. Information on toxicological effects

Acute toxicity Based on available data, the classification criteria are not met.

Components	Species	Test results
ACYCLOVIR (CAS 59277-89-3)		
Acute		
Inhalation		
LC50	Rat	> 15.1 mg/l, 4 hours
Oral		
LD50	Rat	> 20 g/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
Polyvinylpyrrolidone (CAS 9003-39-8)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg

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

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Irritation Corrosion - Skin

ACYCLOVIR: Acute dermal irritation, Tested at 5% in a cream; Irritation Index 0.02
Result: negative
Species: Rabbit

Irritation Corrosion - Skin: P.I.I. value

MAGNESIUM STEARATE: 0

Serious eye damage/eye irritation Based on available data, the classification criteria are not met. Dust or powder may irritate eye tissue.

Eye

ACYCLOVIR: Acute ocular irritation
Result: negative
Species: Rabbit

Respiratory sensitisation Due to lack of data the classification is not possible.

Skin sensitisation Based on available data, the classification criteria are not met.

Sensitisation

ACYCLOVIR: Method not specified
Result: negative
Species: Guinea pig

Germ cell mutagenicity Based on available data, the classification criteria are not met. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Germ cell mutagenicity

Mutagenicity

ACYCLOVIR: Ames Assay
Result: negative
C3H/T10 1/2 Cell Transformation Assay
Result: negative

Mutagenicity

ACYCLOVIR

Chromosomal Aberration Assay In Vitro, Positive response only with levels much above equivalent of human therapeutic dose
Result: positive
Species: Hamster
Chromosomal Aberration Assay In Vitro, human lymphocytes
Result: Equivocal
Cytogenetic Analysis In Vivo, bone marrow
Result: negative
Species: Mouse
Mouse lymphoma cell (L5178Y TK) Assay
Result: positive

Carcinogenicity Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

ACYCLOVIR

2 year bioassay
Result: negative
Species: Mouse
2 year bioassay
Result: negative
Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

ACYCLOVIR (CAS 59277-89-3) 3 Not classifiable as to carcinogenicity to humans.
Polyvinylpyrrolidone (CAS 9003-39-8) 3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Based on available data, the classification criteria are not met.

Reproductive toxicity

Fertility effects - Males and females

ACYCLOVIR

Subcutaneous injection
Result: NOAEL = 25 mg/kg/day; LOAEL = 50 mg/kg/day (decreased implantation efficiency, no effect on litter size)
Species: Rat

Reproductivity

ACYCLOVIR

Embryo-foetal development - Oral, sub-cutaneous administration
Result: NOAEL = 50 mg/kg/day; no adverse foetal effects
Species: Rabbit
Embryo-foetal development - Oral, sub-cutaneous administration
Result: NOAEL = 50 mg/kg/day; no adverse foetal effects
Species: Rat

Specific target organ toxicity - single exposure Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Not available.

Mixture versus substance information Not available.

Other information Not available.

SECTION 12: Ecological information

12.1. Toxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test results
ACYCLOVIR (CAS 59277-89-3)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 100 mg/l, 3 hours, OECD 209
Algae	EC50	Green algae (Selenastrum capricornutum)	> 99 mg/l, 96 hours, Static test, OECD 201
Crustacea	EC50	Water flea (Daphnia magna)	> 93 mg/l, 48 hours, Static test, OECD 202
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	> 95 mg/l, 96 hours, Static renewal test, OECD 203

Components		Species	Test results
Microtox	MIC	Aspergillus flavus	> 993 mg/l, 5 days
		Azotobacter chroococcum	> 993 mg/l, 5 days
		Chaetomium globosum	> 993 mg/l, 5 days
		Nostoc sp.	> 993 mg/l, 5 days
		Pseudomonas fluorescens	> 993 mg/l, 5 days
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	> 10 mg/l, 7 days, 7 day static renewal, EPA 1002
	NOEC	Water flea (Ceriodaphnia dubia)	10 mg/l, 7 days
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
Microtox	EC50	Microtox	12.5 mg/l, 15 minutes
Polyvinylpyrrolidone (CAS 9003-39-8)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours, Static test
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	84 mg/l, 48 hours, Static test
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours, Static test

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

12.2. Persistence and degradability

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

ACYCLOVIR	3.55 Hours Measured, pH 7 Buffer Solution

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE	17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE	210 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

ACYCLOVIR	> 1 years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ACYCLOVIR	50 %, < 1 day Modified Zahn-Wellens, Activated sludge
MAGNESIUM STEARATE	77 %, 28 days BOD
Polyvinylpyrrolidone	0 %, 28 days Modified MITI test, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

ACYCLOVIR	0.7 %, 28 days Sturm test
MAGNESIUM STEARATE	95 %, 22 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days

12.3. Bioaccumulative potential Not available.

Partition coefficient n-octanol/water (log Kow)

ACYCLOVIR	-1.2

Bioconcentration factor (BCF)

MAGNESIUM STEARATE	> 9999 Estimated

12.4. Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

ACYCLOVIR	2.33 - 2.37 Estimated

Soil/sediment sorption - log Koc

ACYCLOVIR	2.6 - 2.64 Measured
MAGNESIUM STEARATE	5.86 Estimated

12.5. Results of PBT and vPvB assessment	Not available.
12.6. Other adverse effects	Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Observe all local and national regulations when disposing of this product. 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.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.
National regulations	Not available.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R36/37/38 Irritating to eyes, respiratory system and skin. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H412 Harmful to aquatic life with long lasting effects.
Revision information	Composition / Information on Ingredients: Disclosure Overrides SECTION 8: Exposure controls/personal protection: - Other Regulatory Information: United States
Training information	Follow training instructions when handling this material.
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.