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 OPHTHALMIC OINTMENT
Registration number	-
Synonyms	ZOVIRAX OPHTHALMIC OINTMENT 3% * ZOVIRAX ACU ZIEDE * ZOVIRAX AUGENSALBE * ZOVIRAX MASC DO OCZU * ZOVIRAX OCNA MAST * ZOVIRAX OGONSALVA * ZOVIRAX ONGUENT OPHTALMIQUE * ZOVIRAX OOGZALF * ZOVIRAX OYESALVE * ZOVIRAX POMADA OFTALMICA * ZOVIRAX POMATA OFTALMICO * ZOVIRAX POMMADE OPHTHALMIQUE * ZOVIRAX UNGUENTO OFTALMICO * ACYVIR EYE OINTMENT * ZOVIR EYE OINTMENT * ACYCLOVIR, FORMULATED PRODUCT
Issue date	23-October-2014
Version number	10
Revision date	23-October-2014

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.

2.3. Other hazards

This product will support combustion at elevated temperatures.
Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
PHARMACEUTICAL GRADE PETROLATUM	97	8009-03-8 232-373-2	-	649-254-00-X	
Classification: **DSD:** -					N
CLP: -					N
ACYCLOVIR	3	59277-89-3 261-685-1	-	-	
Classification: **DSD:** -					
CLP: -					

List of abbreviations and symbols that may be used above

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 In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center.

4.2. Most important symptoms and effects, both acute and delayed None known. Direct contact with eyes may cause temporary irritation.

4.3. Indication of any immediate medical attention and special treatment needed No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards This product will support combustion at elevated temperatures.

5.1. Extinguishing media

Suitable extinguishing media Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media Water.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

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 Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
6.2. Environmental precautions	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.
6.3. Methods and material for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Use water spray to reduce vapours or divert vapour cloud drift. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	No special control measures required for the normal handling of this product. Avoid prolonged exposure. Provide adequate ventilation. Avoid release to the environment.
7.2. Conditions for safe storage, including any incompatibilities	Keep away from heat, sparks and open flame. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
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

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.

Exposure guidelines

8.2. Exposure controls

Appropriate engineering controls	General ventilation normally adequate.

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. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.
Eye/face protection	If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166). Not normally needed.
Skin protection	
- Hand protection	For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust). Not normally needed.

Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. 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). No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.
Environmental exposure controls	
Hazard guidance and control recommendations	Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Ointment.
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	182 - 221 °C (359.6 - 429.8 °F) Closed cup (Estimation based on components).
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)	
Solubility (water)	Not available.
Solubility (other)	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	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Keep away from heat, sparks and open flame. Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Health injuries are not known or expected under normal use.

Eye contact Health injuries are not known or expected under normal use.

Ingestion Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms None known. Direct contact with eyes may cause temporary irritation.

11.1. Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

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
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)		
Acute		
Oral		
LD50	Rat	> 15 g/kg
Chronic		
Oral		
NOAEL	Rat	>= 3000 mg/kg, 2 years

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

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Irritation Corrosion - Skin

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

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.

Eye

ACYCLOVIR
Acute ocular irritation
Result: negative
Species: Rabbit

Respiratory sensitisation Not available.

Skin sensitisation Health injuries are not known or expected under normal use.

Sensitisation

ACYCLOVIR
Method not specified
Result: negative
Species: Guinea pig

Germ cell mutagenicity Health injuries are not known or expected under normal use.

Mutagenicity

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

Mutagenicity

ACYCLOVIR	Cytogenetic Analysis In Vivo, bone marrow Result: negative Species: Mouse Mouse lymphoma cell (L5178Y TK) Assay Result: positive

Carcinogenicity

ACYCLOVIR	2 year bioassay Result: negative Species: Mouse 2 year bioassay Result: negative Species: Rat
PHARMACEUTICAL GRADE PETROLATUM	>= 3000 mg/kg/day 2 year bioassay, oral administration Result: NOAEL Species: Rat Dermal application Result: negative Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

ACYCLOVIR (CAS 59277-89-3)	3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Health injuries are not known or expected under normal use.

Fertility effects - Males and females

ACYCLOVIR	0, 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 None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not available.

Mixture versus substance information No information available.

Other information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

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
Microtox	MIC	Aspergillus flavus	> 993 mg/l, 5 days
		Azotobacter chroococcum	> 993 mg/l, 5 days
		Chaetomium globosum	> 993 mg/l, 5 days

Components		Species	Test results
		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

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

12.2. Persistence and degradability No data is available on the degradability of this product.

Photolysis

Half-life (Photolysis-aqueous)

ACYCLOVIR 3.55 Hours Measured, pH 7 Buffer Solution

Hydrolysis

Half-life (Hydrolysis-neutral)

ACYCLOVIR > 1 years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ACYCLOVIR 50 %, < 1 day Modified Zahn-Wellens, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

ACYCLOVIR 0.7 %, 28 days Sturm test

12.3. Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol/water (log Kow)

ACYCLOVIR -1.2

12.4. Mobility in soil No data available.

Adsorption

Sludge/biomass distribution coefficient - log Kd

ACYCLOVIR 2.33 - 2.37 Estimated

Soil/sediment sorption - log Koc

ACYCLOVIR 2.6 - 2.64 Measured

Mobility in general Not available.

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). Avoid discharge into water courses or onto the ground.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

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. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

Special precautions Dispose in accordance with all applicable regulations.

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(10) 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

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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

Follow national regulation for work with chemical agents.

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

None.

Revision information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Transport Information: Agency Name and Packaging Type/Transport Mode Selection Regulatory Information: Risk Phrases - Class. GHS: Classification
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.