# 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.<br><br>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<br>232-373-2 | - | 649-254-00-X | |
| **Classification:** **DSD:** - | | | | | N |
| **CLP:** - | | | | | N |
| ACYCLOVIR | 3 | 59277-89-3<br>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 ($CO_2$).

**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.<br><br>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.<br><br>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 |

**Ireland. Occupational Exposure Limits**

| Components | Type | Value | Form |
|---|---|---|---|
| PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8) | TWA | 5 mg/m3 | Inhalable fraction. |

| | |
|---|---|
| **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

**Mutagenicity**

| | |
|---|---|
| ACYCLOVIR | Chromosomal Aberration Assay In Vitro, human lymphocytes<br>Result: Equivocal<br>Cytogenetic Analysis In Vivo, bone marrow<br>Result: negative<br>Species: Mouse<br>Mouse lymphoma cell (L5178Y TK) Assay<br>Result: positive |

**Carcinogenicity**

| | |
|---|---|
| ACYCLOVIR | 2 year bioassay<br>Result: negative<br>Species: Mouse<br>2 year bioassay<br>Result: negative<br>Species: Rat |
| PHARMACEUTICAL GRADE PETROLATUM | >= 3000 mg/kg/day 2 year bioassay, oral administration<br>Result: NOAEL<br>Species: Rat<br>Dermal application<br>Result: negative<br>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<br>Result: NOAEL = 25 mg/kg/day; LOAEL = 50 mg/kg/day (decreased implantation efficiency, no effect on litter size)<br>Species: Rat |

**Reproductivity**

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

| Components | | Species | Test results |
|---|---|---|---|
| | | 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 |

* 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<br>Composition / Information on Ingredients: Ingredients<br>Physical & Chemical Properties:<br>Transport Information: Agency Name and Packaging Type/Transport Mode Selection<br>Regulatory Information: Risk Phrases - Class.<br>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. |