



SAFETY DATA SHEET

1. Identification

Product identifier ZOVIRAX OPHTHALMIC OINTMENT

Other means of identification

Synonyms

ZOVIRAX OPHTHALMIC OINTMENT 3% * ZOVIRAX ACU ZIEDE * ZOVIRAX AUGENSALBE * ZOVIRAX MASC DO OCZU * ZOVIRAX OCNA MAST * ZOVIRAX OGONSALVA * ZOVIRAX ONGUENT OPHTHALMIQUE * 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

Recommended use of the chemical and restrictions on use

Recommended use 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.

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia
1061 Mountain Highway
Melbourne, Victoria 3155
Australia
Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS
(available 24hrs/7days: multi-language response)
Australia Toll Free +(61) 2 9037 2994
International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical

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

Label elements, including precautionary statements

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

Other hazards which do not result in classification

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

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
PHARMACEUTICAL GRADE PETROLATUM PETROLEUM JELLY VASELINE WHITE PETROLEUM JELLY WHITE PETROLEUM USP OHS18325 RTECS SE6780000 PETROLATO PETROLATO (PETROLIO) PETROLATOS Petrolatum PRETOLATO PÉTROLATUM VASELIINI VASELIN VASELINA	8009-03-8	97
ACYCLOVIR ACICLOVIR 248U74 CCI 22890 9-((2-HYDROXYETHOXY)METHYL)GUANINE ACYCLOGUANOSINE 2-AMINO-1,9-DIHYDRO-9-(2-HYDROXYETHOXY)METHYL-6H-PURIN-6-ON E	59277-89-3	3

4. First-aid measures

Description of necessary 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.

Personal protection for first-aid responders 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.

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

Medical attention and special treatment 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.

5. Fire-fighting measures

Extinguishing media

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

Unsuitable extinguishing media Water.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

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

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

Hazchem Code Not available.

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

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

6. Accidental release measures

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.

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.

Methods and materials 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. For waste disposal, see section 13 of the SDS.

7. Handling and storage

Precautions for safe handling No special control measures required for the normal handling of this product. Provide adequate ventilation. Avoid release to the environment.

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).

8. Exposure controls and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

GSK

Components	Type	Value
ACYCLOVIR (CAS 59277-89-3)	8 HR TWA	5000 mcg/m ³
	OHC	1

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	TWA	5 mg/m ³

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	TWA	5 mg/m ³	Mist.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	TWA	5 mg/m ³	Inhalable fraction.

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Appropriate engineering controls General ventilation normally adequate.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection	If contact is likely, safety glasses with side shields are recommended. Not normally needed.
Skin protection	
Hand protection	For prolonged or repeated skin contact use suitable protective gloves.
Other	Wear suitable protective clothing as protection against splashing or contamination.
Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
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.

9. 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.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Keep away from heat, sparks and open flame. Contact with incompatible materials.
Incompatible materials	Strong oxidising agents.

Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on possible 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 related to exposure None known. Direct contact with eyes may cause temporary irritation.

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

Components	Species	Test results
ACYCLOVIR (CAS 59277-89-3)		
Acute		
<i>Inhalation</i>		
LC50	Rat	> 15.1 mg/l, 4 hours
<i>Oral</i>		
LD50	Rat	> 20 g/kg
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)		
Acute		
<i>Oral</i>		
LD50	Rat	> 15 g/kg
Chronic		
<i>Oral</i>		
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/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 or skin sensitisation

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 No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. 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

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
ACYCLOVIR

2 year bioassay
Result: negative
Species: Mouse

PHARMACEUTICAL GRADE PETROLATUM

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

ACGIH Carcinogens

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

A2 Suspected human carcinogen.

A4 Not classifiable as a human carcinogen.

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.

Specific target organ toxicity - single exposure

None known.

Specific target organ toxicity - repeated exposure

None known.

Aspiration hazard

Not available.

Other information

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

12. Ecological information

Ecotoxicity

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
<i>Chronic</i>		
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.

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

Bioaccumulative potential No data available for this product.

Partition coefficient

n-octanol / water (log Kow)

ACYCLOVIR -1.2

Mobility in soil No data available for this product.

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.

Other adverse effects Not available.

13. Disposal considerations

Disposal methods 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.

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.

14. Transport information

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

15. Regulatory information

Safety, health and environmental regulations

National regulations

This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New Zealand 03 - 4747 - 000) or a doctor (at once)., If swallowed, do NOT induce vomiting.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

ACYCLOVIR (CAS 59277-89-3)

applies to all preparations in any concentration Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 5

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

1000 - 9999 TONNES See the regulation for additional information.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date 23-October-2014

Revision date 23-October-2014

References GSK Hazard Determination

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.

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