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	ZYLORIC TABLETS
Registration number	-
Synonyms	ZYLORIC TABLETS 100 MG * ZYLORIC TABLETS 300 MG * ZYLOPRIM COMPRIMIDOS * ZYLOPRIM TABLETAS * ALLOPURINOL, FORMULATED PRODUCT
Issue date	15-April-2013
Version number	06
Revision date	15-April-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 (by country / geographic region):

Africa / EU / Israel / Middle East (English / European languages):	+44 (0) 1235 239 670
Asia Pacific (except China):	+65 3158 1074
China:	+86 10 5100 3039
Middle East / Africa (Arabic-speaking countries):	+44 (0) 1235 239 671
US:	+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.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
ALLOPURINOL	33 - < 56	315-30-0 206-250-9	-	-	
Classification:	**DSD:** Xn;R22, R43, N;R50/53				
	CLP: Acute Tox. 4;H302, Skin Sens. 1;H317, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				
Starch	10 - < 20	9005-25-8 232-679-6	-	-	
Classification:	**DSD:** -				
	CLP: -				
Polyvinylpyrrolidone	1 - < 3	9003-39-8 -	-	-	
Classification:	**DSD:** R52/53				
	CLP: Aquatic Chronic 3;H412				
MAGNESIUM STEARATE	< 1	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				
Other components below reportable levels	30 - < 40				

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).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

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. 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).

4.2. Most important symptoms and effects, both acute and delayed Prolonged exposure may cause chronic effects.

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 No unusual fire or explosion hazards noted.

5.1. Extinguishing media

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

Unsuitable extinguishing media None known.

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	In the event of fire, cool tanks with water spray. Water runoff can cause environmental damage.

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. Wear appropriate personal protective equipment. 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 MSDS.
6.2. Environmental precautions	Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material for containment and cleaning up	Stop the flow of material, if this is without risk. Collect spillage. Prevent product from entering drains. Following product recovery, flush area with water.
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. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.
7.2. Conditions for safe storage, including any incompatibilities	Store in a cool, dry place out of direct sunlight.
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	Note
ALLOPURINOL (CAS 315-30-0)	OHC	2	Skin Sensitiser

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

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Open handling is not recommended. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Consider segregating operations, use of enclosures and sealed transfer systems.

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.

Individual protection measures, such as 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	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. Glove selection must take into account any solvents and other hazards present. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Wear appropriate chemical resistant clothing. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. (EN 14605 for splashes, EN ISO 13982 for dust)
Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. 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	Not available.
Hygiene measures	When using, do not eat, drink or smoke. Do not get in eyes. An eye wash station should be available. Do not get this material in contact with skin. Wear appropriate clothing to avoid skin contact. Handle in accordance with good industrial hygiene and safety practices. Wash hands before breaks and immediately after handling the product. Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Consider control procedures for maintenance, cleaning and emergencies. Entry to the working area should be controlled. Doors with interlocks may be needed for materials airlocks and locker rooms. Only equipment and supplies necessary for job activities should be taken into working area. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices. An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
Environmental exposure controls	
GSK environmental hazard category	4
Hazard guidance and control recommendations	Contain spills and prevent releases and observe national regulations on emissions. Environmental manager must be informed of all major releases. Avoid release to the aquatic environment. Very toxic and potential for long-term adverse effects. Wastewaters containing this material must be converted to non-hazardous forms and/or rendered biodegradable prior to discharge.

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 applicable.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not applicable.
Evaporation rate	Not applicable.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not applicable.

Vapour density	Not applicable.
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 applicable.
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	Heat, flames and sparks. Contact with incompatible materials.
10.5. Incompatible materials	Peroxides. Acids. Phenols.
10.6. Hazardous decomposition products	No hazardous decomposition products are known. 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	Due to lack of data the classification is not possible. Inhalation of dusts may cause respiratory irritation.
Skin contact	May cause an allergic skin reaction. Avoid contact with the skin.
Eye contact	Due to lack of data the classification is not possible. 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
ALLOPURINOL (CAS 315-30-0)		
Acute		
Oral		
LD50	Rat	> 7500 mg/kg
Chronic		
Oral		
NOAEL	Rat	12 mg/kg/day
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: P.I.I. value

ALLOPURINOL	0
MAGNESIUM STEARATE	0

Serious eye damage/eye irritation	Due to lack of data the classification is not possible.
Respiratory sensitisation	Due to lack of data the classification is not possible.
Skin sensitisation	May cause an allergic skin reaction.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
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. Not classifiable as to carcinogenicity to humans.

IARC Monographs. Overall Evaluation of Carcinogenicity

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

Reproductive toxicity	Due to lack of data the classification is not possible.
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	May cause damage to organs through prolonged or repeated exposure.
Aspiration hazard	Not available.
Mixture versus substance information	Not available.
Other information	Not available.

SECTION 12: Ecological information

12.1. Toxicity Very toxic to aquatic life with long lasting effects. Accumulation in aquatic organisms is expected.

Components		Species	Test results
ALLOPURINOL (CAS 315-30-0)			
Acute			
	IC50	Activated sludge	1100 mg/l, 3 hours
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	0.45 mg/l, 72 hours, Measured
	NOEC	Green algae (Scenedesmus subspicatus)	0.157 mg/l, 72 hours, Measured
Crustacea	EC50	Water flea (Daphnia magna)	130 mg/l, 48 hours, Measured
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours, Measured
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	> 100 mg/l, 96 hours, Static renewal test
	NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	100 mg/l, 96 hours, Static renewal test
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 No data is available on the degradability of this product.

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE	17 Hours Estimated

UV/visible spectrum wavelength

ALLOPURINOL	257 nm
MAGNESIUM STEARATE	210 nm

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ALLOPURINOL	2 %, 28 days 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)

MAGNESIUM STEARATE	95 %, 22 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days

12.3. Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol/water (log Kow)

ALLOPURINOL	0.33

Bioconcentration factor (BCF)

ALLOPURINOL	1 Estimated
MAGNESIUM STEARATE	> 9999 Estimated

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

ALLOPURINOL	< 1.25 OECD 121
MAGNESIUM STEARATE	5.86 Estimated

Mobility in general

Volatility

Henry's law

ALLOPURINOL	0 atm m^3/mol Estimated

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

12.7. Additional information 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. 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. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

ADR

14.1. UN number	UN3077
14.2. UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (ALLOPURINOL, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III

14.5. Environmental hazards	No
Tunnel restriction code	E
Labels required	9
14.6. Special precautions for user	May be able to ship as an Excepted or Limited Quantity. May not be subject to ADR; See SP 601.

IATA

14.1. UN number	UN3077
14.2. UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (ALLOPURINOL, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	Not available.
Labels required	Not available.
ERG Code	9L
14.6. Special precautions for user	May be able to ship as an Excepted or Limited Quantity. ID 8000, Consumer Commodity, may apply. See Packing Instruction Y963.

IMDG

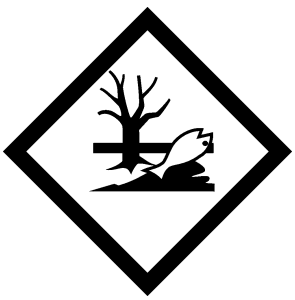
14.1. UN number	UN3077
14.2. UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (ALLOPURINOL, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	Yes
Labels required	Not available.
EmS	F-A, S-F
14.6. Special precautions for user	May be able to ship as an Excepted or Limited Quantity.

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.

ADR; IATA; IMDG

Marine pollutant



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.

Always applicable.

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

Not regulated.

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	R22 Harmful if swallowed. R36/37/38 Irritating to eyes, respiratory system and skin. R43 May cause sensitisation by skin contact. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. H302 Harmful if swallowed. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.

H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

Revision information

Product and Company Identification: Business Units
Composition/Information on Ingredients:
Physical & Chemical Properties:
Ecological Information: GSK Environmental Hazard Assessment Concentration
Transport Information: Agency Name and Packaging Type/Transport Mode Selection
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. The information in the sheet was written based on the best knowledge and experience currently available.