

1. Identification

Product identifier

DARAPRIM TABLETS

Other means of identification

Synonyms

DARAPRIM TABLETS 25 MG * DARAPRIM COMPRIMES * DARAPRIM COMPRIMIDOS *
DARAPRIM TABLETAS * DARAPRIM TABLETKI * DARAPRIM TABLETTEN * NDC NO
0173-0201-55 * PYRIMETHAMINE, FORMULATED PRODUCT

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.

Recommended restrictions

No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

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

Label elements

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

Hazard(s) not otherwise classified (HNOC)

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

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
PYRIMETHAMINE	2,4-DIAMINO-5-(4'-CHLOROPHENYL)-6-ET HYLPYRIMIDINE * 2,4-DIAMINO-5-P-CHLOROPHENYL-6-ETH YLPYRIMIDINE * 5-(4'-CHLOROPHENYL)-2,4-DIAMINO-6-ET HYLPYRIMIDINE * 5-(4-CHLOROPHENYL)-6-ETHYL-2,4-PYRI MIDINEDIAMINE * 5-(P-CHLOROPHENYL)-6-ETHYL-2,4-DIAM INOPYRIMIDINE * PYRAMETHAMINE * PYRIMETHAMIN * RTECS UV8140000 * 63U50 * GR 99352X * PYRIMETHAMIN-	58-14-0	< = 20
STARCH	ARROWROOT STARCH * CORN STARCH * POTATO STARCH * RICE STARCH	9005-25-8	< 15

Chemical name	Common name and synonyms	CAS number	%
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	< 1
Other components below reportable levels			> 68

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. 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 center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching) gastrointestinal distress, nausea, vomiting, convulsions, respiratory depression, decrease in blood pressure.
Indication of 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 center.
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.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	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.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust from the spilled material. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Collect dust using a vacuum cleaner equipped with HEPA filter. Minimize dust generation and accumulation. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Provide appropriate exhaust ventilation at places where dust is formed. Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes. Practice good housekeeping.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
PYRIMETHAMINE (CAS 58-14-0)	8 HR TWA	7 mcg/m3	
	OHC	4	REPRODUCTIVE HAZARD

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
STARCH (CAS 9005-25-8)	PEL	5 mg/m3 15 mg/m3	Respirable fraction. Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3
STARCH (CAS 9005-25-8)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
STARCH (CAS 9005-25-8)	TWA	5 mg/m3 10 mg/m3	Respirable. Total

Biological limit values

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

Exposure guidelines

Appropriate engineering controls

General ventilation normally adequate. 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.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

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

Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. No personal respiratory protective equipment normally required.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Tablet.
Color	Not available.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor 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 Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

Incompatible materials Acids. Peroxides. Phenols.

Hazardous decomposition products None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information**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.

Symptoms related to the physical, chemical and toxicological characteristics Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching) gastrointestinal distress, nausea, vomiting, convulsions, respiratory depression, decrease in blood pressure.

Information on toxicological effects

Acute toxicity May be harmful if swallowed.

Components	Species	Test Results
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
PYRIMETHAMINE (CAS 58-14-0)		
Acute		
<i>Oral</i>		
LD50	Rat	440 mg/kg

* 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	
PYRIMETHAMINE	Acute dermal irritation; OECD 404 Result: Minimal irritant
Irritation Corrosion - Skin: P.I.I. value	
MAGNESIUM STEARATE	0
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.
Eye	
PYRIMETHAMINE	Acute ocular irritation; OECD 405 Result: Mild IRE Assay Result: Negative; not likely to be a severe irritant
Eye / Kay and Calandra class - Intact	
MAGNESIUM STEARATE	4 Recovery Period: 2 days
Respiratory or skin sensitization	
Respiratory sensitization	No studies have been conducted.
Skin sensitization	Knowledge about sensitization hazard is incomplete.
Germ cell mutagenicity	Health injuries are not known or expected under normal use. May cause genetic defects.
Mutagenicity	
PYRIMETHAMINE	Ames Assay, GLP assay Result: Negative Chromosomal Aberration Assay In Vitro Result: Positive GreenScreen Assay Result: Positive In vivo Micronucleus Result: Positive Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay Result: Positive SAR, DEREK, Lhasa, UK Result: Plausible structural alert identified Sister Chromatid Exchange Result: Positive
Carcinogenicity	Carcinogenic effects are not expected as a result of occupational exposure.
PYRIMETHAMINE	18 month bioassay Result: Negative Species: Mouse 18 month bioassay Result: Negative Species: Rat 25 mg/kg Intraperitoneal Result: Positive Species: Mouse
IARC Monographs. Overall Evaluation of Carcinogenicity	
PYRIMETHAMINE (CAS 58-14-0)	3 Not classifiable as to carcinogenicity to humans.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	
Not listed.	
Reproductive toxicity	Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. Possible risk of harm to the unborn child. May cause harm to breastfed babies.
Reproductivity	
PYRIMETHAMINE	SAR / QSAR, DEREK, Lhasa, UK Result: Plausible Teratogenicity, Literature data Result: Adverse developmental effects; oral doses of 1-2 mg/kg/day Species: Rat
Specific target organ toxicity - single exposure	Not assigned.
Specific target organ toxicity - repeated exposure	May cause damage to organs.

Specific target organ toxicity - repeated exposure

PYRIMETHAMINE

Clinical use

Organ: bone marrow; blood; central nervous system

Aspiration hazard

Not available.

Further 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
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
PYRIMETHAMINE (CAS 58-14-0)			
<i>Acute</i>			
	IC50	Activated sludge	> 3200 mg/l, 3 hours Nominal
	NOEC	Activated sludge	10, 3 hours
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Chlorella pyrenoidosa)	20 mg/l, 48 hours
Crustacea	EC50	Water flea (Daphnia magna)	4.8 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Juvenile Oncorhynchus mykiss)	5.9 mg/l, 48 hours Static test

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

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

PYRIMETHAMINE 6 Months Measured, Deionized Water

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE 77 %, 28 days BOD

PYRIMETHAMINE 2 %, 28 days Modified MITI (II) Test., Activated sludge

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

PYRIMETHAMINE 2.7 (Measured).

Bioconcentration factor (BCF)

MAGNESIUM STEARATE > 9999 Estimated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE 5.86 Estimated

Mobility in general

Volatility

Henry's law

PYRIMETHAMINE 0 atm m³/mol, 25 C Estimated

Distribution

Octanol/water distribution coefficient log DOW

PYRIMETHAMINE

2.44, pH 7.4

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions	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.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	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

DOT	Not regulated as a dangerous good.
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	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.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes
	Delayed Hazard - Yes
	Fire Hazard - No
	Pressure Hazard - No
	Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

STARCH (CAS 9005-25-8)

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

STARCH (CAS 9005-25-8)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Developmental toxin

PYRIMETHAMINE (CAS 58-14-0)

Listed: January 29, 1999

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)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
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, including date of preparation or last revision

Issue date 11-21-2014

Revision date 11-21-2014

Version # 08

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 2*
Flammability: 0
Physical hazard: 0

NFPA ratings
Health: 2
Flammability: 0
Instability: 0

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: Undisclosed Ingredient Statement
Physical & Chemical Properties:
Toxicological Information:
Ecological Information: Mobility
Transport Information:
Regulatory Information: United States
GHS: Classification