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	PIRITON SYRUP
Registration number	-
Synonyms	PIRITON SYRUP 2MG/5ML * PIRITON SIROP * FORMULA CODE B066 * CHLORPHENIRAMINE MALEATE, FORMULATED PRODUCT
Issue date	03-March-2014
Version number	04
Revision date	03-March-2014

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Medicinal Product This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

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 Not applicable.

2.3. Other hazards 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
ETHANOL	5 - < 10	64-17-5 200-578-6	-	603-002-00-5	
Classification: **DSD:** F;R11, Xi;R36 **CLP:** Flam. Liq. 2;H225, Eye Irrit. 2;H319					
CHLORPHENIRAMINE MALEATE	0.04	113-92-8 204-037-5	-	-	
Classification: **DSD:** Xn;R22, Xi;R41 **CLP:** Acute Tox. 4;H302, Eye Dam. 1;H318					
Other components below reportable levels	90 - 100				

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 Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

4.1. Description of first aid measures

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

Skin contact Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if irritation develops and persists.

Eye contact Rinse immediately with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Ingestion Get medical advice/attention if you feel unwell. Rinse mouth thoroughly. Do not induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed 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 Combustible liquid.

5.1. Extinguishing media

Suitable extinguishing media Alcohol resistant 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 Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. 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 discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Large Spills: Stop the flow of material, if this is without risk. 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. Use water spray to reduce vapours or divert vapour cloud drift. 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 in original containers for re-use.

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

No special control measures required for the normal handling of this product. Avoid prolonged exposure.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from heat and sources of ignition. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the MSDS).

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
CHLORPHENIRAMINE MALEATE (CAS 113-92-8)	8 HR TWA	10 mcg/m3
	OHC	4

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
ETHANOL (CAS 64-17-5)	TWA	1920 mg/m3 1000 ppm	
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.
Sucrose (CAS 57-50-1)	STEL	20 mg/m3	
	TWA	10 mg/m3	

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

No particular ventilation requirements. 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

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

Wear safety glasses with side shields (or goggles). (eg. EN 166) Eye wash fountains are required.

Skin protection

- Hand protection

The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other

Wear suitable protective clothing. (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. Respiratory protective equipment (RPE) is not required for normal handling of this product. 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

Wear appropriate thermal protective clothing, when necessary.

Hygiene measures

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

Environmental exposure controls

Hazard guidance and control recommendations	Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid.
Form	Syrup.
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	64 - 66 °C (147.2 - 150.8 °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)	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	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. 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 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	May be harmful if swallowed.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.
Eye contact	Direct contact with eyes may cause temporary irritation.

Symptoms Narcosis. Direct contact with eyes may cause temporary irritation.

11.1. Information on toxicological effects

Acute toxicity May be harmful if swallowed.

Components	Species	Test results
CHLORPHENIRAMINE MALEATE (CAS 113-92-8)		
Acute		
Oral		
LD50	Rat	306 - 351 mg/kg
ETHANOL (CAS 64-17-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
Chronic		
Oral		
LOAEL	Monkey	40 %, 48 months, % ingested calories
Subacute		
Oral		
LOEL	Rat	16.9 g/kg, 4 weeks, Dietary - Dose given as g/kg/day
		6 %, 4 weeks, percent in diet - continuous
Subchronic		
Inhalation		
LOEL	Rat	2 ml, 36 weeks, haematological parameters
NOAEL	Guinea pig	3000 ppm, No adverse effects
	Rat	86 mg/m3, 90 Day, Daily dosing
Oral		
LOAEL	Rat	5000 mg/kg/day, 10 weeks, Liver toxicity
		80 ml/kg, 85 Day, Daily dose - Liver toxicity
		10.2 g/kg, 12 weeks, Dosed in drinking water - Continuous
		7.7 g/kg, 12 weeks, Dosed in drinking water - continuous

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

Skin corrosion/irritation Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.

Corrosivity

ETHANOL — OECD 404
Result: Negative; not considered a significant irritant
Species: Rabbit

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

ETHANOL — OECD 405
Result: Severe
Species: Rabbit

Respiratory sensitisation Due to partial or complete lack of data the classification is not possible.

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

Maximisation assay (Magnusson and Kligman)

CHLORPHENIRAMINE MALEATE — Result: negative
Species: Guinea pig

Sensitisation

ETHANOL — OECD 406
Result: negative
Species: Guinea pig

Germ cell mutagenicity

Germ cell mutagenicity

Mutagenicity

ETHANOL

Ames
Result: negative
Chromosomal Aberration Assay In Vitro, CHO cells
Result: negative
Dominant lethal assay
Result: positive
Species: Mouse
Dominant lethal assay
Result: positive
Species: Rat
Gene mutation and repair
Result: negative
Species: Bacteria
Gene mutation and repair
Result: positive
Species: Bacteria
In vitro cytogenetics assay
Result: positive
In vitro cytogenetics assay
Result: positive
Species: Aspergillus niger
L5178Y mouse lymphoma thymidine kinase locus assay
Result: Weakly positive
Yeast mutation
Result: negative
Yeast mutation
Result: positive
in vitro micronucleus assay
Result: negative
in vivo cytogenetics assay
Result: negative
Species: Hamster
in vivo cytogenetics assay
Result: negative
Species: Rat
in vivo cytogenetics assay
Result: positive
Species: Mouse
sister chromatid exchange
Result: positive

Carcinogenicity

Contains a material (ethanol) classified as a carcinogen by external agencies.

ETHANOL

Epidemiology, causation linked to excessive consumption.
Species: Human
Organ: oral cavity, larynx, pharynx, oesophagus, liver
Neonatal, inadequate study
Result: negative
Species: Rat
inadequate study
Result: Increase in liver sarcomas
Species: Mouse
inadequate study
Result: Time to tumour reduced
Species: Mouse
Test Duration: 80 weeks
inadequate study
Result: negative
Species: Hamster
Test Duration: 807 Day
inadequate study
Result: negative
Species: Mouse
Test Duration: 1020 Day
inadequate study
Result: negative
Species: Rat
inadequate study
Result: negative
Species: Rat
Test Duration: 78 weeks

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

Reproductive toxicity

Reproductivity

ETHANOL

0.3 - 4.1 g/kg Embryo-foetal development - Oral, daily dose
Species: Monkey
Organ: facial anomolies, nervous system dysfunction
1 - 2 g/kg Embryo-foetal development - Oral, daily dose
Result: embryolethality
Species: Rat
1.8 g/kg Embryo-foetal development - Oral, daily dose
Result: Increased abortion
Species: Monkey
5 g/kg Embryo-foetal development - Oral, daily dose - intravenous
Result: reduced foetal body weight; no malformations or other variations
Species: Monkey
7 - 17 g/kg Embryo-foetal development - Oral, daily dose - gavage
Species: Rat
Organ: skeletal malformations, dilated renal pelves
Embryo-foetal development - Oral, 15-30% in diet
Result: resorptions, neural defects, cardiac malformations
Species: Mouse
Embryo-foetal development - Oral, Causation is linked to excessive consumption.
Species: Human
Organ: growth deficiency, CNS dysfunction, facial defects, major organ malformation
Embryofetal Development, in utero - 36% total calories
Species: Rat
Organ: gonadal growth and development
Fertility, Female, 10% in drinking water
Result: negative
Species: Rat
Fertility, Female, 20-25% total calories
Result: negative
Species: Rat
Fertility, Male, 5-6% v/v liquid diet
Species: Mouse
Organ: significant effects on testes and seminal vesicles
Test Duration: 70 Day

Specific target organ toxicity - single exposure Narcotic effects.

Specific target organ toxicity - repeated exposure May cause damage to organs through prolonged or repeated exposure by ingestion.

Aspiration hazard May be harmful if swallowed and enters airways.

Mixture versus substance information No information available.

Other information None known.

SECTION 12: Ecological information

12.1. Toxicity No information is available about the potential of this product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment. The product contains a substance which may cause long-term adverse effects in the environment.

Components		Species	Test results
CHLORPHENIRAMINE MALEATE (CAS 113-92-8)			
Aquatic			
Acute			
Algae	EC50	Algae	0.1 - 1 mg/l, 96 hours, QSAR Estimate
Crustacea	EC50	Daphnia	0.1 - 1 mg/l, 48 hours, QSAR Estimate
Fish	EC50	Fish	1 - 10 mg/l, 96 hours, QSAR Estimate

Components		Species	Test results
ETHANOL (CAS 64-17-5)			
Aquatic			
Acute			
Algae	EC50	Blue-green algae (Microcystis aeruginosa)	1450 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	9190 mg/l, 48 hours, Static test
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	14200 mg/l, 96 hours, Flow-through test
		Rainbow trout (Adult Salmo gairdneri)	13000 mg/l, 96 hours, Static test

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

12.2. Persistence and degradability

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

ETHANOL 1 - 36.6 years Measured

Half-life (Photolysis-atmospheric)

ETHANOL 4 - 5.9 Days Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ETHANOL 37 - 86 %, 5 days BOD5, Activated sludge

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

CHLORPHENIRAMINE MALEATE 3.38 (measured)

ETHANOL -0.31

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

ETHANOL 1.2 Calculated

Mobility in general

Volatility

Henry's law

ETHANOL 0.000005 atm m3/mol Measured

Distribution

Octanol/water distribution coefficient log DOW

CHLORPHENIRAMINE MALEATE 1.15 (calculated)

Octanol/water distribution coefficient pH

CHLORPHENIRAMINE MALEATE 7

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).

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.

Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

General Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others, including fully exempted). Be sure to review all applicable agency packaging exceptions, packing instructions and special provisions to identify available options.

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(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

ETHANOL (CAS 64-17-5)

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

ETHANOL (CAS 64-17-5)

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

Not listed.

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	R11 Highly flammable. R22 Harmful if swallowed. R36 Irritating to eyes. R41 Risk of serious damage to eyes. H225 Highly flammable liquid and vapour. H302 Harmful if swallowed. H318 Causes serious eye damage. H319 Causes serious eye irritation.
Revision information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Transport Information: Material Transportation Information 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.