SAFETY DATA SHEET



SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation

PIRITEZE SYRUP

of the mixture

Registration number

PIRITEZE SYRUP 1 MG/ML (UK) * CETIRIZINE DIHYDROCHLORIDE, FORMULATED **Synonyms**

PRODUCT

Issue date 15-September-2014

Version number

Revision date 15-September-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

Fmail Address: msds@gsk.com Website: www.gsk.com

1.4. Emergency telephone

number

TRANSPORT EMERGENCIES::

UK In-country toll call: +(44)-870-8200418 International toll call: +1 703 527 3887

available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

Supplemental label information None.

2.3. Other hazards This product is non-flammable.

Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3,2. Mixtures

Material name: PIRITEZE SYRUP

General information

| Chemical name | | % | CAS-No. / EC No. | REACH Registration No. | INDEX No. | Note |
|--------------------|---------|-------------------|-----------------------|------------------------|--------------|------|
| D-SORBITOL | | 38,0 - 39,0 | 50-70-4 | - | - | |
| Classification: | DSD: | _ | 200-061-5 | | | |
| Ciassification. | CLP: | | | | | |
| | | | | | | |
| GLYCERIN | | 17,0 - 18,0 | 56-81-5 200-289-5 | - | - | |
| Classification: | DSD: | - | | | | |
| | CLP: | - | | | | |
| Propylene glycol | | 4,0 - 5,0 | 57-55-6 200-338-0 | - | - | |
| Classification: | DSD: | - | | | | |
| | CLP: | - | | | | |
| METHYL PARABEN | | <1,0 | 99-76-3 202-785-7 | - | - | |
| Classification: | DSD: | R52/53 | | | | |
| | CLP: | Skin Irrit. 2;H31 | 5 | | | |
| SODIUM ACETATE AN | IHYDROL | JS <1,0 | 127-09-3 204-823-8 | - | - | |
| Classification: | DSD: | - | | | | |
| | CLP: | - | | | | |
| ACETIC ACID | | <0,1 | 64-19-7 200-580-7 | - | 607-002-00-6 | # |
| Classification: | DSD: | R10, C;R35 | | | | В |
| | CLP: | Flam. Liq. 3;H22 | 26, Skin Corr. 1A;H31 | 4 | | |
| CETIRIZINE DIHYDRO | CHLORI | DE <0,1 | 83881-52-1 | - | - | |
| Classification: | DSD: | Xn;R22 | | | | |
| | CLP: | Acute Tox. 4;H3 | 02 | | | |
| PROPYL PARABEN | | <0,1 | 94-13-3 202-307-7 | - | - | |
| Classification: | DSD: | - | | | | |
| | CLP: | - | | | | |

Other components below reportable levels 35,0 - 40,0

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. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

Material name: PIRITEZE SYRUP

SDS MALTA

4.1. Description of first aid measures

Inhalation

Move to fresh air. Call a physician if symptoms develop or persist. If breathing is difficult, trained personnel should give oxygen. Under normal conditions of intended use, this material is not

expected to be an inhalation hazard.

Skin contact Take off contaminated clothing and wash before reuse. Immediately flush skin with plenty of water.

Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large Ingestion

amount does occur, call a poison control centre immediately. Do not induce vomiting without

medical advice.

4.2. Most important symptoms and effects, both acute and

delayed

The following adverse effects have been noted with therapeutic use of this material: irritability;

somnolence; abdominal pain; sore throat; nausea.

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.

Water. Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2).

SECTION 5: Firefighting measures

General fire hazards This product is non-flammable.

5.1. Extinguishing media

Suitable extinguishing

media

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

Special fire fighting

Move containers from fire area if you can do so without risk.

procedures

Specific methods

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

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8.

For emergency responders

Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions

Avoid 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. 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.

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

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s) Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Material name: PIRITEZE SYRUP

Occupational exposure limits

| Components | Туре | Value | |
|---|----------|-------------|--|
| CETIRIZINE DIHYDROCHLORIDE (CAS 83881-52-1) | OHC | 2 | |
| D-SORBITOL (CAS 50-70-4) | OHC | 1 | |
| PROPYL PARABEN (CAS 94-13-3) | 8 HR TWA | 5000 mcg/m3 | |
| • | OHC | 1 | |
| SODIUM ACETATE ANHYDROUS (CAS 127-09-3) | OHC | 1 | |

Malta. OELs. Occupational Exposure Limit Values (L.N. 227. of Occupational Health and Safety Authority Act (CAP. 424), Schedules I and V)

| Components | Туре | Value |
|------------------|------|----------|
| ACETIC ACID (CAS | TWA | 25 mg/m3 |
| 64-19-7) | | |

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU Components Type Value

64-19-7)

TWA

10 ppm

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

Recommended monitoring procedures

ACETIC ACID (CAS

Follow standard monitoring procedures.

Derived no-effect level (DNEL) Not available.

Predicted no effect Not available.

concentrations (PNECs)

8.2. Exposure controls

Appropriate engineering controls

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

10 ppm

25 mg/m3

assessment. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

General information Personal protection equipment should be chosen according to the CEN standards and in

discussion with the supplier of the personal protective equipment. Follow all local regulations if

personal protective equipment (PPE) is used in the workplace.

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended. (eg.

EN 166)

Skin protection

- Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Select

suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min

permeation time).

- Other Not normally needed. Wear suitable protective clothing as protection against splashing or

contamination. (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. 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 Always observe good personal hygiene measures, such as washing after handling the material

and before eating, drinking, and/or smoking. Routinely wash work clothing and protective

equipment to remove contaminants.

Environmental exposure controls

Hazard guidance and control recommendations

Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Material name: PIRITEZE SYRUP

Appearance

Physical stateLiquid.FormSyrup.

Colour Not available.
Odour Not available.
Odour threshold Not available.
pH Not available.
Melting point/freezing point Not available.
Initial boiling point and boiling Not available.

range

Flash point Expected to be non-flammable based on components present.

Not available.

Evaporation rateNot available.Flammability (solid, gas)Not available.Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Flammability limit - upper Not available.

(%)

Vapour pressureNot available.Vapour densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Not available.
Solubility (other) Not available.

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.Explosive propertiesNot available.Oxidizing propertiesNot available.

9.2. Other information No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. ReactivityThe 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 avoidContact with incompatible materials.

10.5. Incompatible materials Strong oxidising agents.

10.6. Hazardous Irritating and/or toxic fun

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 cause discomfort if swallowed. However, ingestion is not likely to be a primary route of

occupational 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.

Symptoms The following adverse effects have been noted with therapeutic use of this material: irritability;

somnolence; abdominal pain; sore throat; nausea.

11.1. Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Material name: PIRITEZE SYRUP

SDS MALTA

Species Test results Components

ACETIC ACID (CAS 64-19-7)

Acute

Inhalation

LCLo Rat 39,6 mg/l 4-hour exposure

Oral

LD50 Rat 3310 mg/kg

CETIRIZINE DIHYDROCHLORIDE (CAS 83881-52-1)

Acute

Oral

LD50 Rat 365 mg/kg

D-SORBITOL (CAS 50-70-4)

Acute

Oral LD50

Rat 15,9 g/kg

GLYCERIN (CAS 56-81-5)

Acute

Oral

LD50 > 2000 mg/kg Rat

METHYL PARABEN (CAS 99-76-3)

Acute

Oral

LD50 Mouse > 8 g/kg

PROPYL PARABEN (CAS 94-13-3)

Acute

Oral

LD50 Rat

> 2000 mg/kg

Skin corrosion/irritation Health injuries are not known or expected under normal use. Health injuries are not known or expected under normal use. Serious eye damage/eye

irritation

Respiratory sensitisation Not available. Skin sensitisation None known.

No data available to indicate product or any components present at greater than 0.1% are Germ cell mutagenicity

mutagenic or genotoxic.

Mutagenicity

CETIRIZINE DIHYDROCHLORIDE Ames

Result: negative

Notes: FDA Approval Package

Chromosomal Aberration Assay In Vitro, human lymphocytes

Result: negative

Notes: FDA Approval Package

In vivo Micronucleus Result: negative Species: Mouse

Notes: FDA Approval Package

In vivo Micronucleus Result: negative Species: Rat

Mouse Lymphoma Cell (L5178Y) Mutation Assay

Result: negative

Notes: FDA Approval Package

Not classifiable as to carcinogenicity to humans. Carcinogenicity

CETIRIZINE DIHYDROCHLORIDE 16 mg/kg/day, Species-specific

Result: Increase in benign tumours

Species: Mouse Organ: Liver

Notes: FDA Approval Package

Material name: PIRITEZE SYRUP

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

Carcinogenicity

CETIRIZINE DIHYDROCHLORIDE

20 mg/kg/day Result: negative Species: Rat

Notes: FDA Approval Package

Reproductive toxicity

Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did

not produce this adverse effect.

Reproductivity

CETIRIZINE DIHYDROCHLORIDE 135 mg/kg/day Embryo-foetal development

Result: Maternal toxicity; adverse foetal effects

Species: Rabbit

Notes: FDA Approval Package

25 mg/kg/day Embryo-foetal development Result: Maternal NOAEL, Foetal NOAEL

Species: Rat

Notes: FDA Approval Package

45 mg/kg/day Embryo-foetal development Result: Maternal NOAEL, Foetal NOAEL

Species: Rabbit

Notes: FDA Approval Package

64 mg/kg/day Female Fertility / Early Embryonic Developmen

t Result: negative Species: Mouse

75 - 225 mg/kg/day Embryo-foetal development Result: Maternal toxicity; adverse effects on offspring.

Species: Rat

Notes: FDA Approval Package

96 mg/kg/day Embryo-foetal development Result: Maternal NOAEL, Foetal NOAEL

Species: Mouse

Notes: FDA Approval Package

Specific target organ toxicity -

single exposure

Not assigned.

Specific target organ toxicity -

repeated exposure

None known.

Aspiration hazard Not likely, due to the form of the product.

Mixture versus substance

information

No information available.

Other information Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity Not expected to be harmful to aquatic organisms.

| | Species | Test results |
|----------|--|--|
| 7) | | |
| | | |
| | | |
| EC50 | Water flea (Daphnia magna) | 47 mg/l, 24 hours Static test |
| EC50 | Fathead minnow (Adult Pimephales promelas) | 79 mg/l, 96 hours Static test |
| | Mosquito fish (Adult Gambusia affinis) | 251 mg/l, 96 hours Static test |
| EC50 | Microtox | 11 mg/l, 15 minutes |
| 99-76-3) | | |
| | | |
| | | |
| EC50 | Water flea (Daphnia magna) | 11,2 mg/l, 48 hours |
| LC50 | Medaka, high-eyes (Oryzias latipes) | 59,5 mg/l, 96 hours |
| | | |
| NOEC | Water flea (Daphnia magna) | 0,2 mg/l, 21 days OECD 211 |
| 5-6) | | |
| | | |
| IC50 | Activated sludge | > 1000 mg/l, 3 hours |
| | EC50 EC50 99-76-3) EC50 LC50 NOEC | EC50 Water flea (Daphnia magna) EC50 Fathead minnow (Adult Pimephales promelas) Mosquito fish (Adult Gambusia affinis) EC50 Microtox 99-76-3) EC50 Water flea (Daphnia magna) LC50 Medaka, high-eyes (Oryzias latipes) NOEC Water flea (Daphnia magna) |

Material name: PIRITEZE SYRUP

| omponents | | Species | Test results |
|-------------------|----------------|--|-----------------------------------|
| Aquatic | | | |
| Acute | | | |
| Algae | EC50 | Green algae (Selenastrum capricornutum) | 19000 mg/l, 14 days |
| | NOEC | Green algae (Selenastrum capricornutum) | 15000 mg/l, 14 days |
| Crustacea | EC50 | Daphnia | 43500 mg/l, 48 hours |
| | NOEC | Daphnia | 28500 mg/l, 48 hours |
| Fish | EC50 | Fathead minnow (Adult Pimephales promelas) | 51400 mg/l, 96 hours Static test |
| | | Rainbow trout (Adult Oncorhyncus mykiss) | 51600 mg/l, 96 hours Static test |
| | NOEC | Fathead minnow (Adult Pimephales promelas) | 41000 mg/l, 96 hours Static test |
| | | Rainbow trout (Adult Oncorhyncus mykiss) | 42000 mg/l, 96 hours Static test |
| Microtox | EC50 | Microtox | 51400 mg/l, 30 minutes |
| ODIUM ACETATE ANH | DROUS (CAS 127 | -09-3) | |
| Chronic | | | |
| Other | LC50 | Pseudomonas putida | 7200 mg/l, 18 hours |
| Aquatic | | | |
| Acute | | | |
| Crustacea | EC50 | Water flea (Daphnia magna) | 7170 mg/l, 24 hours Static test |
| Fish | EC50 | Bluegill sunfish (Adult Lepomis macrochirus) | 5000 mg/l, 24 hours Static test |
| | | Fathead minnow (Adult Pimephales promelas) | 13330 mg/l, 120 hours Static test |
| Microtox | EC50 | Microtox | 22500 mg/l, 15 minutes |

12.2. Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

Propylene glycol 1,3 - 2,3 years Estimated

Half-life (Photolysis-atmospheric)

ACETIC ACID 22 Days Estimated Propylene glycol 32 Hours Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ACETIC ACID 95 %, 5 days Zahn-Wellens, Activated sludge 62 %, 5 days BOD5, Activated sludge Propylene glycol 79 %, 20 Days BOD20, Activated sludge

SODIUM ACETATE ANHYDROUS 100 %, 5 days Modified Zahn-Wellens, Activated sludge 97,4 % Coupled Unit test (OECD 303A), Activated sludge

Percent degradation (Aerobic biodegradation-ready)

ACETIC ACID 99 %, 30 days Closed Bottle test, Activated sludge

METHYL PARABEN 89 %, 28 days, OECD 301B

Percent degradation (Anaerobic biodegradation)

Propylene glycol 100 %, 9 days

12.3. Bioaccumulative potential

Partition coefficient

n-octanol/water (log Kow)

-0,24ACETIC ACID -2,2 **D-SORBITOL** -1,76 **GLYCERIN** METHYL PARABEN 1,96 PROPYL PARABEN 3,04 Propylene glycol -1,35

Material name: PIRITEZE SYRUP

Bioconcentration factor (BCF)

1 Estimated **D-SORBITOL** Propylene glycol < 1 Estimated

SODIUM ACETATE ANHYDROUS < 10 Measured, Leuciscus idus, golden ide/orfe

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

ACETIC ACID 0,81 - 2,36 Measured **D-SORBITOL** 0.3 Estimated

Mobility in general

Volatility

Henry's law ACETIC ACID **D-SORBITOL**

0 atm m3/mol Measured, 25 C 0 atm m³/mol Estimated 0 atm m³/mol Estimated Propylene glycol

Distribution

Octanol/water distribution coefficient log DOW

PROPYL PARABEN 3,04

Not available.

12.5. Results of PBT

and vPvB assessment

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).

Empty containers should be taken to an approved waste handling site for recycling or disposal. Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is

The Waste code should be assigned in discussion between the user, the producer and the waste EU waste code

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

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 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.

MARPOL73/78 and the IBC Code

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

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended Not listed.

Material name: PIRITEZE SYRUP SDS MALTA Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

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

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at

work

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

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

ACETIC ACID (CAS 64-19-7)

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

ACETIC ACID (CAS 64-19-7)

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.

Follow national regulation for work with chemical agents. **National regulations** No Chemical Safety Assessment has been carried out 15.2. Chemical safety

assessment

SECTION 16: Other information

Not available. List of abbreviations

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

R10 Flammable.

R22 Harmful if swallowed. R35 Causes severe burns.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic

environment.

H226 Flammable liquid and vapour.

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

Revision information Product and Company Identification: Product and Company Identification

Composition / Information on Ingredients: Undisclosed Ingredient Statement

Physical & Chemical Properties:

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.

Material name: PIRITEZE SYRUP