



SAFETY DATA SHEET

1. Identification

Product identifier BEECHAMS HOT FLAVORS (WITH PARACETAMOL AND PHENYLEPHRINE HCL)

Other means of identification

Synonyms

BEECHAM HONEY LEMON * BEECHAMS HOT LEMON * BEECHAMS HOT BLACKCURRANT * BEECHAMS HOT BLACKCURRANT POWDER * BEECHAMS FLU PLUS HOT LEMON SACHETS * BEECHAMS FLU-PLUS HOT SOLUTION * BEECHAMS COLD AND FLU HOT LEMON AND HONEY * BEECHAMS COLD AND FLU SACHETS HOT LEMON AND HONEY (UK) * BEECHAMS COLD AND FLU SACHETS - HOT LEMON * BEECHAMS HOT LEMON WITH HONEY * BEECHAMS HOT HONEY LEMON (EIRE AND MEXICO) * PANADOL COLD AND FLU HOT LEMON AND HONEY * PARACETAMOL, ASCORBIC ACID, PHENYLEPHRINE HCL, FORMULATED PRODUCT

Recommended use of the chemical and restrictions on use

Recommended use Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

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

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

2. Hazard(s) identification

Classification of the hazardous chemical

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

Label elements, including precautionary statements

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

Other hazards which do not result in classification

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

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Sucrose	57-50-1	55 - < 65
SUGAR		
CANE SUGAR		
BEET SUGAR		
CONFECTIONER'S SUGAR		
ALPHA-D-GLUCOPYRANOSIDE, BETA-D-FRUCTOFURANOSYL		
GRANULATED SUGAR		
SUCRALOX		

PARACETAMOL ACETAMIDE, N-(4-HYDROXYPHENYL)- ACETANILIDE, 4'-HYDROXY- 4'-HYDROXYACETANILIDE PANADOL PARACETAMOL TYLENOL PARA-ACETAMIDOPHENOL 4-ACETAMINOPHENOL PARA-HYDROXYACETANILIDE	103-90-2	10 - < 16
CITRIC ACID ANHYDROUS 60/120 CITIRIC ACID	77-92-9	6 - < 12
SODIUM CITRATE, ANHYDROUS CITREME	68-04-2	6 - < 12
SODIUM CITRATE DIHYDRATE 1,2,3-PROPANETRICARBOXYLIC ACID, 2-HYDROXY-, TRISODIUM SALT, DIHYDRATE CITRIC ACID, TRISODIUM SALT, DIHYDRATE SODIUM CITRATE, DIHYDRATE SODIUM CITRATE TRISODIUM CITRATE DIHYDRATE TRISODIUM CITRATE SODIUM CITRATE DIHYDRATE	6132-04-3	0 - < 12
LEMON FLAVOUR PFW 610399E	Unassigned	0 - < 3.5
Starch ARROWROOT STARCH CORN STARCH POTATO STARCH RICE STARCH	9005-25-8	0 - < 3.5
SODIUM CYCLAMATE SODIUM CYCLOHEXANESULPHAMATE SODIUM CYCLOHEXYL AMIDOSULPHATE SODIUM CYCLOHEXYL SULFAMATE SODIUM CYCLOHEXYL SULFAMIDATE CYCLAMATE SODIUM CYCLAMIC ACID SODIUM SALT CYCLOHEXYL SULPHAMATE SODIUM CYCLOHEXYL SULFAMATE SODIUM	139-05-9	1 - 2
SACCHARIN SODIUM SALT 1,2-BENZISOTHIAZOL-3(2H)-ONE, 1,1-DIOXIDE, SODIUM SALT SACCHARIN SODIUM SACCHARIN SOLUBLE SODIUM SACCHARIDE SODIUM SACCHARIN SODIUM SACCHARINATE SOLUBLE SACCHARIN	128-44-9	0.5 - < 1
L-ASCORBIC ACID VITAMIN C	50-81-7	0.5 - < 0.75

PHENYLEPHRINE HYDROCHLORIDE (-)-M-HYDROXY-ALPHA-((METHYLAMINO)METHYL)BENZYL ALCOHOL HYDROCHLORIDE ISOPHRIN HYDROCHLORIDE LEVOPHENYLEPHRINE HYDROCHLORIDE METAOXEDRINE HYDROCHLORIDE META-SYNEPHRINE HYDROCHLORIDE NEOPHRYN NEO-SYNEPHRINE HYDROCHLORIDE L-PHENYLEPHRINE HYDROCHLORIDE BENZENEMETHANOL, 3-HYDROXY-ALPHA-(METHYLAMINO)METHYL-, HYDROCHLORIDE, (R)-	61-76-7	0.15 - 0.2
Silicon dioxide Silica Silica gel Amorphous silica DIATOMACEOUS EARTH INFUSORIAL EARTH CAB-O-SIL M-5	7631-86-9	0 - < 0.05

Other components below reportable levels

< 10

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.

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

4. First-aid measures

Description of necessary first aid measures

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard. If dust from the material is inhaled, remove the affected person immediately to fresh air. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists. Take off contaminated clothing and wash before reuse.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.

Personal protection for first-aid responders In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. 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.

Symptoms caused by exposure Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort.

Medical attention and special treatment No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Alcohol resistant foam. Water spray. Water fog. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Carbon dioxide (CO ₂).

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

Special protective equipment and precautions for fire fighters	Firefighters should wear full protective clothing including self contained breathing apparatus. Wear suitable protective equipment. Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	In the event of fire, cool tanks with water spray. Move containers from fire area if you can do so without risk.
Hazchem Code	Not available.
General fire hazards	Assume that this product is capable of sustaining combustion.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials. Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Keep upwind. Wear appropriate personal protective equipment. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Wear a dust mask if dust is generated above exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ventilate closed spaces before entering them. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

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

Environmental precautions Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up Minimise dust generation and accumulation. Stop the flow of material, if this is without risk. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Collect spillage. Collect dust using a vacuum cleaner equipped with HEPA filter. Sweep up or vacuum up spillage and collect in suitable container for disposal. Following product recovery, flush area with water. Dike far ahead of spill for later disposal. Use water spray to reduce vapours or divert vapour cloud drift. Prevent product from entering drains. Prevent entry into waterways, sewer, basements or confined areas. For waste disposal, see section 13.

Other issues relating to spills and releases Clean up in accordance with all applicable regulations.

7. Handling and storage

Precautions for safe handling Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Minimise dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Do not get this material in contact with eyes. Do not get this material in contact with skin. Avoid breathing dust. Avoid contact with skin and eyes. Avoid prolonged exposure. Do not get this material on clothing. Provide adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Wash thoroughly after handling. Practice good housekeeping. Avoid release to the environment. Do not empty into drains.

Conditions for safe storage, including any incompatibilities CAUTION Keep away from heat, sparks and open flame. Store in a closed container away from incompatible materials. Store in original tightly closed container. Use appropriate container to avoid environmental contamination. Store in a cool, dry place out of direct sunlight. Store in a well-ventilated place. Guard against dust accumulation of this material. Keep away from food, drink and animal feeding stuffs. Keep out of the reach of children. Use care in handling/storage. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

GSK Components	Type	Value
L-ASCORBIC ACID (CAS 50-81-7)	8 HR TWA	5000 mcg/m3
	OHC	1
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m3
	OHC	1

GSK Components	Type	Value
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)	15 MIN STEL	200 mcg/m3
	8 HR TWA	30 mcg/m3
	OHC	3
Silicon dioxide (CAS 7631-86-9)	OHC	1
SODIUM CITRATE, ANHYDROUS (CAS 68-04-2)	8 HR TWA	5000 mcg/m3
	OHC	1

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)			
Components	Type	Value	Form
Silicon dioxide (CAS 7631-86-9)	TWA	2 mg/m3	Respirable dust.
Starch (CAS 9005-25-8)	TWA	10 mg/m3	Inhalable dust.
Sucrose (CAS 57-50-1)	TWA	10 mg/m3	Inhalable dust.

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)			
Components	Type	Value	Form
Silicon dioxide (CAS 7631-86-9)	TWA	2 mg/m3	Respirable fraction.
Starch (CAS 9005-25-8)	TWA	10 mg/m3	Inspirable dust.
Sucrose (CAS 57-50-1)	TWA	10 mg/m3	Inspirable dust.

US. ACGIH Threshold Limit Values		
Components	Type	Value
Starch (CAS 9005-25-8)	TWA	10 mg/m3
Sucrose (CAS 57-50-1)	TWA	10 mg/m3

UK. EH40 Workplace Exposure Limits (WELs)			
Components	Type	Value	Form
PARACETAMOL (CAS 103-90-2)	TWA	10 mg/m3	Inhalable dust.
Silicon dioxide (CAS 7631-86-9)	TWA	6 mg/m3	Inhalable dust.
		2.4 mg/m3	Respirable dust.
Starch (CAS 9005-25-8)	TWA	4 mg/m3	Respirable.
		10 mg/m3	Inhalable
Sucrose (CAS 57-50-1)	STEL	20 mg/m3	
	TWA	10 mg/m3	

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	General ventilation normally adequate. If engineering measures are not sufficient to maintain concentrations of dust particulates below the OEL (occupational exposure limit), suitable respiratory protection must be worn.
Individual protection measures, for example personal protective equipment (PPE)	
Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
Other	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
Respiratory protection	No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. An occupational/industrial hygiene monitoring method has been developed for this material.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Powder filled sachet.
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	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.

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Some components are soluble in water.

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

Incompatible materials Alkali metals.

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

11. Toxicological information

Information on possible routes of exposure

Ingestion Expected to be a low ingestion hazard.

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard. Inhalation of dusts may cause respiratory irritation.

Skin contact No adverse effects due to skin contact are expected.

Eye contact Dust in the eyes will cause irritation. Direct contact with eyes may cause temporary irritation.

Symptoms related to exposure Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort.

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

Product	Species	Test results
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BEECHAMS HOT FLAVORS (WITH PARACETAMOL AND PHENYLEPHRINE HCL)

Acute

Oral

LD50	Rat	> 2000 mg/kg
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Components	Species	Test results
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L-ASCORBIC ACID (CAS 50-81-7)

Acute

Oral

LD50	Rat	11.9 g/kg
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Subchronic

Oral

NOAEL	Rat	2000 mg/kg/day
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PARACETAMOL (CAS 103-90-2)

Acute

Oral

LD50	Rat	1944 mg/kg
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TD

Human	>= 150 mg/kg
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Subacute

Oral

NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
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Subchronic

Oral

NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous
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TD

Rat	>= 12500 ppm, 13 weeks dietary, continuous
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Other

LOAEL	Mouse	130 ppm, 61 weeks dietary, continuous
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NOAEL	Mouse	3200 ppm, 13 weeks dietary, continuous
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		0.3 %, 41 weeks dietary, continuous
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TD	Mouse	6100 ppm, 13 weeks dietary, continuous
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		1.25 %, 41 weeks dietary, continuous
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PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)

Acute

Oral

LD50	Rat	350 mg/kg
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Subacute

Oral

NOAEL	Mouse	2000 ppm, 14 Day Dietary study, highest dose tested.
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Rat	2000 ppm, 14 Day Dietary study, highest dose tested.
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Subchronic

Oral

LD	Mouse	5000 - 20000 ppm, 12 weeks dietary study
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Components	Species	Test results
	Rat	5000 - 20000 ppm, 12 weeks dietary study
LOAEL	Mouse	1250 ppm, 12 weeks dietary study
	Rat	1250 ppm, 12 weeks dietary study
SODIUM CYCLAMATE (CAS 139-05-9)		
Acute		
<i>Oral</i>		
LD50	Rat	1280 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		
L-ASCORBIC ACID		Acute dermal irritation; OECD 404 Result: Non-irritant Species: Rabbit Notes: EU SCC Review 1986-1990
PHENYLEPHRINE HYDROCHLORIDE		Supplier SDS Result: Non-irritant Species: Rabbit Notes: US Pharmacopeia
Irritation Corrosion - Skin: P.I.I. value		
PARACETAMOL		OECD 404, Literature data Result: Slight irritant Species: Rabbit
Serious eye damage/irritation	Dust in the eyes will cause irritation. Direct contact with eyes may cause temporary irritation.	
Eye		
L-ASCORBIC ACID		Acute ocular irritation; OECD 405 Result: Slight irritant Species: Rabbit Notes: EU SCC Review 1986-1990
PHENYLEPHRINE HYDROCHLORIDE		Clinical use Result: Pharmacological, cardiovascular effects. Species: Human
PARACETAMOL		OECD 405 Result: Slight irritant Species: Rabbit
PHENYLEPHRINE HYDROCHLORIDE		Supplier SDS Result: Irritant
Eye / Initial pain reaction score		
PARACETAMOL		Literature data
Respiratory or skin sensitisation		
Respiratory sensitisation	Due to partial or complete lack of data the classification is not possible.	
Skin sensitisation	This product is not expected to cause skin sensitisation.	
Sensitisation		
PHENYLEPHRINE HYDROCHLORIDE		Clinical use - Ophthalmology Result: Low incidence of contact hypersensitivity. Species: Human
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
PHENYLEPHRINE HYDROCHLORIDE		Ames Result: negative Notes: NTP Study report - Phenylephrine.
PARACETAMOL		Ames, Literature data Result: negative
PHENYLEPHRINE HYDROCHLORIDE		Chromosomal Aberration Assay In Vitro, CHO cells Result: negative Notes: NTP Study report - Phenylephrine.
PARACETAMOL		Chromosomal Aberration Assay In Vitro, Literature data Result: positive

Mutagenicity

PARACETAMOL

HPRT gene mutation in human lymphocytes, Literature data

Result: negative

In vivo Micronucleus, Literature data

Result: negative

Species: Mouse

PHENYLEPHRINE HYDROCHLORIDE

L5178Y mouse lymphoma thymidine kinase locus assay

Result: Equivocal

Notes: NTP Study report - Phenylephrine.

sister chromatid exchange

Result: positive

Notes: NTP Study report - Phenylephrine.

Carcinogenicity

Not classifiable as to carcinogenicity to humans. Health injuries are not known or expected under normal use.

L-ASCORBIC ACID

1000 - 2000 mg/kg/day

Result: negative

Species: Rat

Notes: UN SIDS Dossier

PHENYLEPHRINE HYDROCHLORIDE

133 - 270 mg/kg/day

Result: negative

Species: Mouse

Test Duration: 103 weeks

Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride.

24 - 50 mg/kg/day

Result: negative

Species: Rat

Test Duration: 103 weeks

Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride.

L-ASCORBIC ACID

< 6000 mg/kg/day

Result: negative

Species: Mouse

Notes: UN SIDS Dossier

PARACETAMOL

Literature data

Result: Equivocal. Increase in adenomas at toxic dose.

Species: Mouse

Literature data

Result: Equivocal. Liver and bladder neoplasms at toxic doses.

Species: Rat

Literature data

Result: negative

Species: Mouse

Literature data

Result: negative

Species: Rat

ACGIH Carcinogens

STARCH (CAS 9005-25-8)

A4 Not classifiable as a human carcinogen.

SUCROSE (CAS 57-50-1)

A4 Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

PARACETAMOL (CAS 103-90-2)

3 Not classifiable as to carcinogenicity to humans.

SACCHARIN SODIUM SALT (CAS 128-44-9)

3 Not classifiable as to carcinogenicity to humans.

SILICON DIOXIDE (CAS 7631-86-9)

3 Not classifiable as to carcinogenicity to humans.

SODIUM CYCLAMATE (CAS 139-05-9)

3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity

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

Specific target organ toxicity - single exposure

Causes damage to organs.

PHENYLEPHRINE HYDROCHLORIDE

Clinical use

Organ: Cardiovascular effects, some marked.

PARACETAMOL

Species: Human

Organ: Liver

Specific target organ toxicity - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Specific target organ toxicity - repeated exposure

L-ASCORBIC ACID

Species: Human

Organ: Red blood cells, kidneys.

Notes: EU SCC Review 1986-1990

Aspiration hazard

Not likely, due to the form of the product.

Other information

Caution - Pharmaceutical agent.

12. Ecological information**Ecotoxicity**

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
L-ASCORBIC ACID (CAS 50-81-7)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	1020 mg/l, 96 hours
PARACETAMOL (CAS 103-90-2)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Scenedesmus subspicatus)	134 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	50 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	814 mg/l, 96 hours Flow-through test
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Selenastrum capricornutum)	> 124 mg/l, 72 hours Measured
	NOEC	Algae	31 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	0.86 mg/l, 48 hours Measured
	NOEC	Daphnia	0.21 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	> 100 mg/l, 96 hours Measured
	NOEC	Rainbow trout (Adult Oncorhynchus mykiss)	100 mg/l, 96 hours
SACCHARIN SODIUM SALT (CAS 128-44-9)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	16700 mg/l, 96 hours
Silicon dioxide (CAS 7631-86-9)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes

Components	Species	Test results
SODIUM CITRATE, ANHYDROUS (CAS 68-04-2)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) 161 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus) 2031 mg/l, 96 hours Static test
		Golden ide/orfe (Adult Leuciscus idus) 590 - 1018 mg/l, 96 hours Static test
Microtox	EC50	Microtox 18.8 mg/l, 15 minutes

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

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

SACCHARIN SODIUM SALT 3 Days Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

L-ASCORBIC ACID 100 %, 15 days Zahn-Wellens
 PARACETAMOL 99 %, 5 days Modified Zahn-Wellens, Activated sludge
 PHENYLEPHRINE HYDROCHLORIDE 81 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge
 99 %, 7 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
 SODIUM CITRATE, ANHYDROUS 98 %, 2 days Modified Zahn-Wellens, Activated sludge
 Sucrose 69 % BOD5

Bioaccumulative potential

Partition coefficient

n-octanol / water (log Kow)

L-ASCORBIC ACID -2.15
 PARACETAMOL 0.36
 PHENYLEPHRINE HYDROCHLORIDE 0.49 (Measured).
 Sucrose -3

Bioconcentration factor

(BCF)

SACCHARIN SODIUM SALT 3 Estimated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

SACCHARIN SODIUM SALT 1.88 Estimated

Volatility

Henry's law

PARACETAMOL 0 atm m³/mol Estimated
 Sucrose < 0 atm m³/mol Estimated

Other adverse effects Not available.

13. Disposal considerations

Disposal methods

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

Residual waste

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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

15. Regulatory information

Safety, health and environmental regulations

National regulations

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

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

PARACETAMOL (CAS 103-90-2)

applies to all preparations in any concentration Use Warning Statement 97 and/or Warning Statement 98., Adults: Keep to the recommended dose. Don't take this medicine for longer than a few days at a time unless advised to by a doctor., Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor., If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 131 - 126; New Zealand 0800 - 764 - 766) or go to a hospital straight away even if you feel well

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

PARACETAMOL (CAS 103-90-2)

for therapeutic use Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 3

PARACETAMOL (CAS 103-90-2)

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Australia Medicines & Poisons Schedule 4

PARACETAMOL (CAS 103-90-2)

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

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

CITRIC ACID ANHYDROUS 60/120 (CAS 77-92-9)

1000 - 9999 TONNES See the regulation for additional information.

SILICON DIOXIDE (CAS 7631-86-9)

1000 - 9999 TONNES See the regulation for additional information.

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

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

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

Not listed.

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

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

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. Young people under 18 years old are not allowed to work with this product according to the EU Directive 94/33/EC on the protection of young people at work.

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
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)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

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

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

16. Other information

Issue date 14-August-2014

References

GSK Hazard Determination

Disclaimer

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.