

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

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	%
SUCROSE	SUGAR * CANE SUGAR * BEET SUGAR * CONFECTIONER'S SUGAR * ALPHA-D-GLUCOPYRANOSIDE, BETA-D-FRUCTOFURANOSYL * GRANULATED SUGAR * SUCRALOX	57-50-1	55 - < 65

Chemical name	Common name and synonyms	CAS number	%
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)MET HYL)-, 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

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

4. 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.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort.
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 centre.
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. 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.

5. Fire-fighting measures

Suitable extinguishing media	Alcohol resistant foam. Water spray. Water fog. Dry chemical powder.
Unsuitable extinguishing media	Carbon dioxide (CO2).
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	In the event of fire, cool tanks with water spray. 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. Cool containers exposed to flames with water until well after the fire is out.
General fire hazards	Assume that this product is capable of sustaining combustion.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. 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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Minimize dust generation and accumulation. 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. Prevent entry into waterways, sewer, basements or confined areas. For waste disposal, see section 13 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.

7. Handling and storage

Precautions for safe handling	Minimize dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Avoid breathing dust. Avoid contact with skin and eyes. Avoid prolonged exposure. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Practice good housekeeping. Avoid release to the environment. Do not empty into drains.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store in a well-ventilated place. Guard against dust accumulation of this material. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

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
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

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.
SUCROSE (CAS 57-50-1)	PEL	5 mg/m3 15 mg/m3	Respirable fraction. Total dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	0.8 mg/m3 20 mppcf

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

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m3	
STARCH (CAS 9005-25-8)	TWA	5 mg/m3 10 mg/m3	Respirable. Total
SUCROSE (CAS 57-50-1)	TWA	5 mg/m3 10 mg/m3	Respirable. Total

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 Occupational Exposure Limit (OEL), suitable respiratory protection must be worn.

Individual protection measures, such as personal protective equipment

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

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

Skin protection

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. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
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. 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.
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)	Some components are soluble in water.
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Partition coefficient (n-octanol/water)	Not available.
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Auto-ignition temperature	Not available.
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Decomposition temperature	Not available.
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Viscosity	Not available.
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10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
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Chemical stability	Material is stable under normal conditions.
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Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
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Conditions to avoid	Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Contact with incompatible materials.
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Incompatible materials	Alkaline metals.
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Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.
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11. Toxicological information

Information on likely 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 the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort.

Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use.
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Product	Species	Test Results
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
TD	Human	>= 150 mg/kg

Subacute

Oral

NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
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Subchronic

Oral

NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous
TD	Rat	>= 12500 ppm, 13 weeks dietary, continuous

Other

LOAEL	Mouse	130 ppm, 61 weeks dietary, continuous
NOAEL	Mouse	3200 ppm, 13 weeks dietary, continuous
		0.3 %, 41 weeks dietary, continuous
TD	Mouse	6100 ppm, 13 weeks dietary, continuous
		1.25 %, 41 weeks dietary, continuous

PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)

Acute

Oral

LD50	Rat	350 mg/kg
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Components	Species	Test Results
Subacute		
<i>Oral</i>		
NOAEL	Mouse	2000 ppm, 14 Day Dietary study, highest dose tested.
	Rat	2000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
<i>Oral</i>		
LD	Mouse	5000 - 20000 ppm, 12 weeks dietary study
	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/eye 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 sensitization		
Respiratory sensitization	Due to partial or complete lack of data the classification is not possible.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Sensitization		
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

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

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

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.

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.

Reproductivity

L-ASCORBIC ACID

1.5 - 100 mg/kg/day Embryo-foetal development

Result: No adverse foetal effects observed

Species: Guinea pig

Notes: EU SCC Review 1986-1990

200 - 2000 mg/kg/day Embryo-foetal development

Result: No adverse foetal effects observed

Species: Rat

Notes: EU SCC Review 1986-1990

PARACETAMOL

250 mg/kg/day Embryofetal Development, Literature data

Result: Foetal NOAEL

Species: Rat

387 mg/kg/day Embryofetal Development, Literature data

Result: Negative

Species: Mouse

L-ASCORBIC ACID

5.2 - 520 mg/kg/day Embryo-foetal development

Result: No adverse foetal effects observed

Species: Mouse

Notes: EU SCC Review 1986-1990

PARACETAMOL

750 mg/kg/day Embryofetal Development, Literature data

Result: decrease in foetal weight, minor skeletal abnormalities.

Species: Rat

<= 1400 mg/kg/day Pre- and Post-natal development, Literature data

Result: reduced weight gain during nursing.

Species: Rat

PHENYLEPHRINE HYDROCHLORIDE

Epidemiology

Result: Equivocal, evidence of malformations, or other adverse foetal effects from clinical use. Other studies show no such association.

Species: Human

PARACETAMOL

Epidemiology, Literature data

Result: No clear association with therapeutic use.

Species: Human

PHENYLEPHRINE HYDROCHLORIDE

Result: Foetal growth retardation and onset of early delivery at doses equivalent to clinical exposure.

Species: Rabbit

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.

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.

Further information

Caution - Pharmaceutical agent.

12. Ecological information**Ecotoxicity**

No information is available about the potential of this product to produce adverse environmental effects. 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	1020 mg/l, 96 hours
	Rainbow trout (Adult Oncorhynchus mykiss)	

Components		Species	Test Results
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
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
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Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

SACCHARIN SODIUM SALT	1.88 Estimated
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Mobility in general

Volatility

Henry's law

PARACETAMOL	0 atm m ³ /mol Estimated
SUCROSE	< 0 atm m ³ /mol Estimated

Other adverse effects	Not available.
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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).
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.
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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 - Yes
	Pressure Hazard - No
	Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	No
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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.
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US state regulations**US. Massachusetts RTK - Substance List**

SACCHARIN SODIUM SALT (CAS 128-44-9)
SILICON DIOXIDE (CAS 7631-86-9)
STARCH (CAS 9005-25-8)
SUCROSE (CAS 57-50-1)

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

SILICON DIOXIDE (CAS 7631-86-9)

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

SACCHARIN SODIUM SALT (CAS 128-44-9)
SILICON DIOXIDE (CAS 7631-86-9)
STARCH (CAS 9005-25-8)
SUCROSE (CAS 57-50-1)

US. Rhode Island RTK

SACCHARIN SODIUM SALT (CAS 128-44-9)

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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

Country(s) or region	Inventory name	On inventory (yes/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, including date of preparation or last revision

Issue date	08-14-2014
Version #	09
Further information	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 2* Flammability: 2 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 2 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.