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 BEECHAMS HOT FLAVORS (WITH PARACETAMOL AND PHENYLEPHRINE HCL)

Registration number -

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

Issue date 14-August-2014

Version number 09

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

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 Assume that this material is capable of sustaining combustion.
Caution - Pharmaceutical agent.
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
Sucrose	55 - < 65	57-50-1 200-334-9	-	-	
Classification: **DSD:** -					
CLP: -					
PARACETAMOL	10 - < 16	103-90-2 203-157-5	-	-	
Classification: **DSD:** Xn;R22, R52/53					
CLP: Acute Tox. 4;H302, Aquatic Chronic 3;H412					
CITRIC ACID ANHYDROUS 60/120	6 - < 12	77-92-9 201-069-1	-	-	
Classification: **DSD:** Xi;R36					
CLP: Eye Irrit. 2;H319					
SODIUM CITRATE, ANHYDROUS	6 - < 12	68-04-2 200-675-3	-	-	
Classification: **DSD:** -					
CLP: -					
SODIUM CITRATE DIHYDRATE	0 - < 12	6132-04-3 200-675-3	-	-	
Classification: **DSD:** -					
CLP: -					
LEMON FLAVOUR PFW 610399E	0 - < 3.5	Unassigned -	-	-	
Classification: **DSD:** R43, N;R51-53					
CLP: Skin Sens. 1;H317, Aquatic Chronic 2;H411					
Starch	0 - < 3.5	9005-25-8 232-679-6	-	-	
Classification: **DSD:** -					
CLP: -					
SODIUM CYCLAMATE	1 - 2	139-05-9 205-348-9	-	-	
Classification: **DSD:** Xn;R22					
CLP: Acute Tox. 4;H302					
SACCHARIN SODIUM SALT	0.5 - < 1	128-44-9 204-886-1	-	-	
Classification: **DSD:** -					
CLP: -					
L-ASCORBIC ACID	0.5 - < 0.75	50-81-7 200-066-2	-	-	
Classification: **DSD:** -					
CLP: -					

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
PHENYLEPHRINE HYDROCHLORIDE	0.15 - 0.2	61-76-7 200-517-3	-	-	
Classification: **DSD:** Repr. Cat. 3;R62-63, T;R24, Xn;R22, Xi;R37, N;R50/53					
CLP: Acute Tox. 4;H302, Acute Tox. 3;H311, Acute Tox. 4;H312, STOT SE 3;H335, Repr. 2;H361, Aquatic Acute 1;H400, Aquatic Chronic 1;H410					
Silicon dioxide	0 - < 0.05	7631-86-9 231-545-4	-	-	
Classification: **DSD:** -					
CLP: -					

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.
#: 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 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.

4.1. Description of 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.

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

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 Assume that this product is capable of sustaining combustion.

5.1. Extinguishing media

Suitable extinguishing media Alcohol resistant foam. Water spray. Water fog. Dry chemical powder.

Unsuitable extinguishing media Carbon dioxide (CO_2).

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 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.

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. Wear appropriate personal protective equipment. Wear a dust mask if dust is generated above exposure limits. 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.

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

6.2. 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.

6.3. Methods and material for containment and cleaning up Minimise 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 product from entering drains.

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 Minimise 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.

7.2. 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).

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
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

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).
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	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, 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	No personal respiratory protective equipment normally required. 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. 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.

Environmental exposure controls

Hazard guidance and control recommendations	Contain spills and prevent releases and observe national regulations on emissions. 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	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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.

Solubility(ies)

Solubility (water)	Some components are soluble in water.
Solubility (other)	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 dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Contact with incompatible materials.
10.5. Incompatible materials	Alkali metals.
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	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	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort.

11.1. Information on toxicological effects

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

Product	Species	Test results
BEECHAMS HOT FLAVORS (WITH PARACETAMOL AND PHENYLEPHRINE HCL)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg

Components	Species	Test results
L-ASCORBIC ACID (CAS 50-81-7)		
Acute		
Oral		
LD50	Rat	11.9 g/kg
Subchronic		
Oral		
NOAEL	Rat	2000 mg/kg/day
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

Components	Species	Test results
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
Subacute		
Oral		
NOAEL	Mouse	2000 ppm, 14 Day Dietary study, highest dose tested.
	Rat	2000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
Oral		
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		
Oral		
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

Eye

PHENYLEPHRINE HYDROCHLORIDE	Supplier SDS Result: Irritant

Eye / Initial pain reaction score

PARACETAMOL	Literature data

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 - Opthalmology 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 ademomas 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.

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 weght, 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 effectw 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.

Mixture versus substance information No information available.

Other information Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity 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			
Acute			
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	1020 mg/l, 96 hours
PARACETAMOL (CAS 103-90-2)			
Aquatic			
Acute			
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			
Acute			
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 Oncorhyncus mykiss)	> 100 mg/l, 96 hours Measured
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	100 mg/l, 96 hours
SACCHARIN SODIUM SALT (CAS 128-44-9)			
Aquatic			
Acute			
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	16700 mg/l, 96 hours
Silicon dioxide (CAS 7631-86-9)			
Aquatic			
Acute			
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			
Acute			
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.

12.2. 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

12.3. 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

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

SACCHARIN SODIUM SALT	1.88 Estimated

Mobility in general

Volatility

Henry's law

PARACETAMOL	0 atm m^3/mol Estimated
Sucrose	< 0 atm m^3/mol Estimated

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. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

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 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

Not listed.

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

Not listed.

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	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. 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	R22 Harmful if swallowed. R24 Toxic in contact with skin. R36 Irritating to eyes. R37 Irritating to respiratory system. R43 May cause sensitization by skin contact. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R51 Toxic to aquatic organisms.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R53 May cause long term adverse effects in the aquatic environment.
R62 Possible risk of impaired fertility.
R63 Possible risk of harm to the unborn child.
H302 Harmful if swallowed.
H311 Toxic in contact with skin.
H312 Harmful in contact with skin.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H361 Suspected of damaging fertility or the unborn child.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

Revision information None.

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.