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 CAPLETS
Registration number	-
Synonyms	BEECHAMS FLU PLUS CAPLETS * BEECHAMS ACTIVE COLD RELIEF CAPLETS * PARACETAMOL 500 MG, CAFFEINE 25 MG AND PHENYLEPHRINE HYDROCHLORIDE 5 MG CAPLETS * PARACETAMOL, CAFFEINE AND PHENYLEPHRINE HYDROCHLORIDE, FORMULATED PRODUCT
Issue date	25-August-2014
Version number	10
Revision date	25-August-2014
Supersedes date	13-August-2014

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

Identified uses Medicinal Product

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

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

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

1.4. Emergency telephone number

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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 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
PARACETAMOL	< 75	103-90-2 203-157-5	-	-	
Classification: **DSD:** Xn;R22, R52/53 **CLP:** Acute Tox. 4;H302, Aquatic Chronic 3;H412					
ALPHA-AMYLODEXTRIN	3 - < 5	9005-84-9 232-686-4	-	-	
Classification: **DSD:** - **CLP:** -					
MICROCRYSTALLINE CELLULOSE	3 - < 5	9004-34-6 232-674-9	-	-	
Classification: **DSD:** - **CLP:** -					
PREGELATINIZED STARCH	3 - < 5	9005-25-8 232-679-6	-	-	
Classification: **DSD:** - **CLP:** -					
L-ASCORBIC ACID	< 7,5	50-81-7 200-066-2	-	-	
Classification: **DSD:** - **CLP:** -					
CAFFEINE	< 5	58-08-2 200-362-1	-	613-086-00-5	
Classification: **DSD:** Xn;R22 **CLP:** Acute Tox. 4;H302					
Starch	< 5	9005-25-8 232-679-6	-	-	
Classification: **DSD:** - **CLP:** -					
Talc	< 5	14807-96-6 238-877-9	-	-	
Classification: **DSD:** - **CLP:** -					
HYDROXYPROPYL METHYL CELLULOSE	1 - < 3	9004-65-3 -	-	-	
Classification: **DSD:** - **CLP:** -					
MAIZE STARCH	1 - < 3	9005-25-8 232-679-6	-	-	
Classification: **DSD:** - **CLP:** -					

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
MASTERCOTE FA 1202	< 1		-	-	
Classification:	**DSD:** -				
	CLP: -				
PHENYLEPHRINE HYDROCHLORIDE	< = 1	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				
Polyvinylpyrrolidone	< 1	9003-39-8 -	-	-	
Classification:	**DSD:** R52/53				
	CLP: Aquatic Chronic 3;H412				
Stearic acid	< 1	57-11-4 200-313-4	-	-	
Classification:	**DSD:** -				
	CLP: -				
DODECYL SODIUM SULFATE	< 0,2	151-21-3 205-788-1	-	-	
Classification:	**DSD:** F;R11, Xn;R22, Xi;R36/38				
	CLP: Flam. Sol. 1;H228, Acute Tox. 4;H302, Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335				
Polyethylene glycol	< 0,2	68130-99-4 -	-	-	
Classification:	**DSD:** -				
	CLP: -				
Propylene glycol	< 0,2	57-55-6 200-338-0	-	-	
Classification:	**DSD:** -				
	CLP: -				
ETHYLCELLULOSE	< 0,1	9004-57-3 -	-	-	
Classification:	**DSD:** -				
	CLP: -				
FD & C YELLOW #6	< 0,1	2783-94-0 220-491-7	-	-	
Classification:	**DSD:** -				
	CLP: -				
POTASSIUM SORBATE	< 0,1	24634-61-5 246-376-1	-	-	
Classification:	**DSD:** Xi;R36/38				
	CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319				

< 15

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.

4.1. Description of first aid measures

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

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

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

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without medical advice.

4.2. Most important symptoms and effects, both acute and delayed None known.

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 No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

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

Special fire fighting procedures 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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust from the spilled material. Wear a dust mask if dust is generated above exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up Stop the flow of material, if this is without risk. Collect spillage. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Collect dust using a vacuum cleaner equipped with HEPA filter. Minimise dust generation and accumulation. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Sweep up or vacuum up spillage and collect in suitable container for disposal.

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

Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

7.2. Conditions for safe storage, including any incompatibilities

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

7.3. Specific end use(s)

Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value
CAFFEINE (CAS 58-08-2)	8 HR TWA	200 mcg/m3
	OHC	2
DODECYL SODIUM SULFATE (CAS 151-21-3)	OHC	2
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)	OHC	1
L-ASCORBIC ACID (CAS 50-81-7)	8 HR TWA	5000 mcg/m3
	OHC	1
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	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

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. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

Individual protection measures, such as personal protective equipment

General information

Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection

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.
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	Caplet.
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)	Not available.
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	Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
10.5. Incompatible materials	Alkali metals.
10.6. Hazardous decomposition products	None known. 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	Harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Symptoms	None known.

11.1. Information on toxicological effects

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

Components	Species	Test results
CAFFEINE (CAS 58-08-2)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg
Oral		
LD50	Rat	192 mg/kg
Subchronic		
Oral		
NOAEL	Mouse	167 - 179 mg/kg/day Dosed in drinking water - Continuous
	Rat	151 - 174 mg/kg/day Dosed in drinking water - Continuous
DODECYL SODIUM SULFATE (CAS 151-21-3)		
Acute		
Oral		
LD50	Rat	1288 mg/kg
ETHYLCELLULOSE (CAS 9004-57-3)		
Acute		
Dermal		
LD50	Rabbit	> 5000 mg/kg
Oral		
LD50	Rat	> 5000 mg/kg
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
L-ASCORBIC ACID (CAS 50-81-7)		
Acute		
Oral		
LD50	Rat	11,9 g/kg
Subchronic		
Oral		
NOAEL	Rat	2000 mg/kg/day
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg
PARACETAMOL (CAS 103-90-2)		
Acute		
Oral		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg

Components	Species	Test results
Subacute		
Oral		
NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
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
Polyvinylpyrrolidone (CAS 9003-39-8)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
POTASSIUM SORBATE (CAS 24634-61-5)		
Acute		
Oral		
LD50	Rat	4340 mg/kg
Stearic acid (CAS 57-11-4)		
Acute		
Oral		
LD50	Rat	> 5000 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
CAFFEINE	Literature data Result: Non-irritant Species: Rabbit
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 Health injuries are not known or expected under normal use.

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
CAFFEINE	Literature data Result: Not likely to be a severe irritant Species: Rabbit
PARACETAMOL	OECD 405 Result: Slight irritant Species: Rabbit
PHENYLEPHRINE HYDROCHLORIDE	Supplier SDS Result: Irritant

Eye / Initial pain reaction score

PARACETAMOL	Literature data

Respiratory sensitisation Not available.

Skin sensitisation This product is not expected to cause skin sensitisation.

Maximisation assay (Magnusson and Kligman)

HYDROXYPROPYL METHYL CELLULOSE	Result: negative Species: Guinea pig

Sensitisation

PHENYLEPHRINE HYDROCHLORIDE	Clinical use - Opthalmology Result: Low incidence of contact hypersensitivity. Species: Human
CAFFEINE	Literature data Result: negative Species: Mouse

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

Mutagenicity

CAFFEINE	25 - 100 mg/kg Chromosomal Aberration Assay In Vivo Result: positive Species: Mouse 25 - 100 mg/kg Micronucleus Assay Result: negative Species: Mouse Ames Result: negative
PHENYLEPHRINE HYDROCHLORIDE	Ames Result: negative Notes: NTP Study report - Phenylephrine.
PARACETAMOL	Ames, Literature data Result: negative
CAFFEINE	Chromosomal Aberration Assay In Vitro Result: positive
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
CAFFEINE	In vivo Micronucleus Result: positive
PARACETAMOL	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.

Mutagenicity

CAFFEINE	L5178Y mouse lymphoma thymidine kinase locus assay Result: positive
PHENYLEPHRINE HYDROCHLORIDE	sister chromatid exchange Result: positive Notes: NTP Study report - Phenylephrine.

Carcinogenicity Health injuries are not known or expected under normal use. Contains a material (talc) classified as a carcinogen by external agencies. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

CAFFEINE	0.1 - 0.2 %, Dosed in drinking water Result: negative Species: Rat Test Duration: 78 weeks
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.
CAFFEINE	200 - 2000 mg/l, Dosed in drinking water Result: negative Species: Rat Test Duration: 2 years
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

CAFFEINE (CAS 58-08-2)	3 Not classifiable as to carcinogenicity to humans.
FD & C YELLOW #6 (CAS 2783-94-0)	3 Not classifiable as to carcinogenicity to humans.
PARACETAMOL (CAS 103-90-2)	3 Not classifiable as to carcinogenicity to humans.
POLYVINYLPYRROLIDONE (CAS 9003-39-8)	3 Not classifiable as to carcinogenicity to humans.
TALC (CAS 14807-96-6)	2B Possibly carcinogenic to humans. 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. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

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
CAFFEINE	100 mg/kg/day Embryofetal Development Result: Maternal toxicity; adverse foetal effects Species: Rat
L-ASCORBIC ACID	200 - 2000 mg/kg/day Embryo-foetal development Result: No adverse foetal effects observed Species: Rat Notes: EU SCC Review 1986-1990

Reproductivity

CAFFEINE	25 mg/kg Embryofetal Development Result: No effect Species: Rat
PARACETAMOL	250 mg/kg/day Embryofetal Development, Literature data Result: Foetal NOAEL Species: Rat
CAFFEINE	300 mg/kg/day Result: testicular toxicity Species: Rat Test Duration: 75 Day
PARACETAMOL	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
CAFFEINE	87.5 mg/kg/day Embryofetal Development Result: Maternal toxicity; adverse foetal effects Species: Mouse
PARACETAMOL	<= 1400 mg/kg/day Pre- and Post-natal development, Literature data Result: reduced weight gain during nursing. Species: Rat
CAFFEINE	>= 301 mg/day Epidemiology Result: delayed conception Species: Human
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.
CAFFEINE	Literature data Organ: Nervous system; Cardiovascular system
PARACETAMOL	Species: Human Organ: Liver

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

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 The product contains a substance which may cause long-term adverse effects in the environment.

Components		Species	Test results
CAFFEINE (CAS 58-08-2)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 1000 mg/l, 3 hours Nominal, OECD 209
	NOEC	Residential sludge	1000
Algae	EC50	Green algae (Desmodesmus subspicatus)	> 100 mg/l, 72 hours OECD 201
		Green algae (Scenedesmus subspicatus)	> 100 mg/l, 72 hours Measured, OECD 201
	NOEC	Algae	100 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	182 mg/l, 48 hours German std DIN 38412
Fish	LC50	Fathead minnow (Adult Pimephales promelas)	151 mg/l, 96 hours OECD 203
		Golden ide/orfe (Adult Leuciscus idus)	87 mg/l, 96 hours German std DIN 38412 Part 15
Chronic			
Algae	NOEC	Green algae (Desmodesmus subspicatus)	6,25 mg/l, 72 hours OECD 201
DODECYL SODIUM SULFATE (CAS 151-21-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	5,4 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	4,6 mg/l, 96 hours Flow-through test
Chronic			
Algae	NOEC	Green algae (Desmodesmus subspicatus)	30 mg/l, 72 hours
Crustacea	NOEC	Ceriodaphnia dubia	0,88 mg/l, 7 days Flow-though Test
Fish	NOEC	Fathead minnow (Pimephales promelas)	3,8 mg/l, 28 days Flow-through test
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)			
Aquatic			
Acute			
Fish	EC50	Fish	> 100 mg/l, 96 hours
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

Components		Species	Test results
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	> 100 mg/l, 96 hours Measured
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	100 mg/l, 96 hours
Polyvinylpyrrolidone (CAS 9003-39-8)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours Static test
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	84 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours Static test
POTASSIUM SORBATE (CAS 24634-61-5)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	750 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	> 500 mg/l, 96 hours Static test
		Zebra fish (Adult Brachydanio rerio)	1250 mg/l, 48 hours
			> 1000 mg/l, 96 hours
Chronic			
Crustacea	EC50	Water flea (Daphnia magna)	901 mg/l, 24 hours
Other	EC50	Bacteria	5000 mg/l, 21 hours
Propylene glycol (CAS 57-55-6)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days
	NOEC	Green algae (Selenastrum capricornutum)	15000 mg/l, 14 days
Crustacea	EC50	Daphnia	43500 mg/l, 48 hours
	NOEC	Daphnia	28500 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	51400 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	51600 mg/l, 96 hours Static test
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes
Stearic acid (CAS 57-11-4)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 32 mg/l, 47 hours EU Method C.2
Fish	LC0	Carp (Cyprinus carpio)	1000 mg/l, 48 hours OECD 203
Talc (CAS 14807-96-6)			
Aquatic			
Acute			
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 100 g/l, 24 hours Static renewal test

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

12.2. Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

Propylene glycol	1,3 - 2,3 years Estimated

Half-life (Photolysis-atmospheric)

CAFFEINE	2,5 Hours Estimated
Propylene glycol	32 Hours Estimated
Stearic acid	17 Hours Estimated

UV/visible spectrum wavelength

CAFFEINE	227 nm
Stearic acid	210 nm

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
POTASSIUM SORBATE	95 %, 6 days Zahn-Wellens
Polyvinylpyrrolidone	0 %, 28 days Modified MITI test, Activated sludge
Propylene glycol	62 %, 5 days BOD5, Activated sludge
	79 %, 20 Days BOD20, Activated sludge
Stearic acid	77 %, 28 days BOD

Percent degradation (Aerobic biodegradation-ready)

DODECYL SODIUM SULFATE	95 % OECD 301 B
Stearic acid	95 %, 22 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

Stearic acid	50 %, 13 days

Percent degradation (Anaerobic biodegradation)

Propylene glycol	100 %, 9 days

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

CAFFEINE	-0,07
	-0,0907
DODECYL SODIUM SULFATE	1,6
HYDROXYPROPYL METHYL CELLULOSE	-5
L-ASCORBIC ACID	-2,15
PARACETAMOL	0,36
PHENYLEPHRINE HYDROCHLORIDE	0,49 (Measured).
Propylene glycol	-0,92
	-1,35
Stearic acid	8,23
	8,42

Bioconcentration factor (BCF)

CAFFEINE	0,52 - 2,25 Estimated
HYDROXYPROPYL METHYL CELLULOSE	3,2 Estimated
Propylene glycol	< 1 Estimated
Stearic acid	> 9999 Estimated

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

CAFFEINE	1,25 - 1,34 Estimated
Stearic acid	5,86 Estimated

Mobility in general

Volatility

Henry's law

CAFFEINE	0 atm m^3/mol Estimated
HYDROXYPROPYL METHYL CELLULOSE	0 atm m3/mol Estimated
PARACETAMOL	0 atm m^3/mol Estimated
Propylene glycol	0 atm m^3/mol Estimated
Stearic acid	0,000051 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	Not applicable.

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

CAFFEINE (CAS 58-08-2)

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

Not listed.

Other regulations The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations Not available.

References GSK Hazard Determination

Information on evaluation method leading to the classification of mixture The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R11 Highly flammable.
R22 Harmful if swallowed.
R24 Toxic in contact with skin.
R36/38 Irritating to eyes and skin.
R37 Irritating to respiratory system.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R52/53 Harmful to aquatic organisms, 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.
H228 Flammable solid.
H302 Harmful if swallowed.
H311 Toxic in contact with skin.
H312 Harmful in contact with skin.
H315 Causes skin irritation.
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.
H412 Harmful to aquatic life with long lasting effects.

Revision information Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients

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.