

1. Identification

Product identifier

BEECHAMS CAPLETS

Other means of identification

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

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	%
PARACETAMOL	ACETAMIDE, N-(4-HYDROXYPHENYL)- * ACETANILIDE, 4'-HYDROXY- * 4'-HYDROXYACETANILIDE * PANADOL * PARACETAMOL * TYLENOL * PARA-ACETAMIDOPHENOL * 4-ACETAMINOPHENOL * PARA-HYDROXYACETANILIDE	103-90-2	< 75
ALPHA-AMYLODEXTRIN	AMYLODEXTRIN * AMYLOGEN * SOLUBLE STARCH * THYODENE * STARCH SOLUBLE * OHS40192	9005-84-9	3 - < 5

Chemical name	Common name and synonyms	CAS number	%
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE * ABICEL * ALPHA-CELLULOSE * ARBOCEL * ARBOCELL B 600/30 * ARBOCELL BC 200 * AVICEL PH101 * AVICEL PH102 * AVICEL PH103 * AVICEL PH105 * AVICEL PH112 * AVICEL PH200 * BETA-AMYLOSE * CELLEX MX * CELLULOSE (8CI9CI) * CELLULOSE 248 * CELLULOSE CRYSTALLINE * CELLULOSE, FOOD GRADE * CELUFI * CRYSTALLINE CELLULOSE * EMOCEL * MCC * MICROCRYSTALLINE CELLULOSE * POWDERED CELLULOSE * RTECS FJ5691460 * SOLKA FLOC BW200 * CELLULOSA (FIBRA PAPEL) * CELLULOSE (PAPER FIBRES) * CELLULOSE-PAPER FIBER * CELULOSA (FIBRA PAPEL) * TSELLULOOS	9004-34-6	3 - < 5
PREGELATINIZED STARCH		9005-25-8	3 - < 5
L-ASCORBIC ACID	VITAMIN C	50-81-7	< 7.5
CAFFEINE	TRIMETHYLBENZYL XANTHINE * METHYLTHEOBROMINE * CAFFEINE ANHYDROUS	58-08-2	< 5
STARCH	ARROWROOT STARCH * CORN STARCH * POTATO STARCH * RICE STARCH	9005-25-8	< 5
TALC	TALCUM, NON-ASBESTOS FORM * TALC * HYDROUS MAGNESIUM SILICATE	14807-96-6	< 5
HYDROXYPROPYL METHYL CELLULOSE	METHOCEL K4M * GONIOSOL * ISOPRO ALKALINE * METHOCEL E,F,K * METHOCEL HG * METHYL CELLULOSE PROPYLENE GLYCOL ETHER * HYDROMELLOSE * CELLULOSE, 2-HYDROXYPROPYL METHYL ESTER * METHYLHYDROXYPROPYLCELLULOSE * PHARMACOAT 603	9004-65-3	1 - < 3
MAIZE STARCH	STARCH, EDIBLE * STARCH (CORN)	9005-25-8	1 - < 3
MASTERCOTE FA 1202			< 1
PHENYLEPHRINE HYDROCHLORIDE	(-)-M-HYDROXY-ALPHA-((METHYLAMINO) METHYL)BENZYL ALCOHOL HYDROCHLORIDE * ISOPHRIN HYDROCHLORIDE * LEVOPHENYLEPHRINE HYDROCHLORIDE * METAOXEDRINE HYDROCHLORIDE * META-SYNEPHRINE HYDROCHLORIDE * NEOPHRYN * NEO-SYNEPHRINE HYDROCHLORIDE * L-PHENYLEPHRINE HYDROCHLORIDE * BENZENEMETHANOL, 3-HYDROXY-ALPHA-(METHYLAMINO)METHYL-, HYDROCHLORIDE, (R)-	61-76-7	< = 1
POLYVINYLPIRROLIDONE	1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER * POLY(N-VINYLPYRROLIDONE) * PLASDONE	9003-39-8	< 1
STEARIC ACID	1-HEPTADECANECARBOXYLIC ACID * OCTADECANOIC ACID * STEAROPHANIC ACID * N-OCTADECANOIC ACID * C18H36O2 * OHS21873 * RTECS WI2800000	57-11-4	< 1
DODECYL SODIUM SULFATE	DODECYL SULFATE, SODIUM SALT * SODIUM LAURYL SULPHATE * LAURYL SULFATE SODIUM SALT	151-21-3	< 0.2

Chemical name	Common name and synonyms	CAS number	%
POLYETHYLENE GLYCOL	AZIRIDINE, HOMOPOLYMER, ETHOXYLATED * OHS19172	68130-99-4	< 0.2
PROPYLENE GLYCOL	1,2-PROPANEDIOL * 1,2-DIHYDROXYPROPANE * 2-HYDROXYPROPANOL * ISOPROPYLENE GLYCOL * METHYLETHYLENE GLYCOL * METHYLETHYL GLYCOL * MONOPROPYLENE GLYCOL * 2,3-PROPANEDIOL * ALPHA-PROPYLENE GLYCOL * 1,2-PROPYLENE GLYCOL * (RS)-1,2-PROPANEDIOL * 1,2-(RS)-PROPANEDIOL * 1,2-PROPANDIOL * DL-1,2-PROPANEDIOL * DL-PROPYLENE GLYCOL * PROPANE-1,2-DIOL (PROPYLENE GLYCOL) * PROPANE-1-2-DIOL * PROPANEDIOL,1,2-	57-55-6	< 0.2
FD & C YELLOW #6	2-NAPHTHALENESULFONIC ACID, 6-HYDROXY-5-((4-SULFOPHENYL)AZO)-, DISODIUM SALT * DISODIUM 6-HYDROXY-5-((4-SULPHONATOPHENYL) AZO)NAPHTHALENE-2-SU LPHONATE * DISODIUM 6-HYDROXY-5-((4-SULFONATOPHENYL)A ZO)NAPHTHALENE 2-SULFONATE * 6-HYDROXY-5-((4-SULFOPHENYL)AZO)-2- NAPHTHALENESULFONI C ACID DISODIUM SALT * 6-HYDROXY-5-((PARA-SULFOPHENYL)AZ O)-2-NAPHTHALENESULF ONIC ACID DISODIUM SALT * 6-HYDROXY-5-((P-SULFOPHENYL)AZO)-2- NAPHTHALENESULFONI C ACID DISODIUM SALT * 1-PARA-SULFOPHENYLAZO-2-HYDROXY NAPHTHALENE-6-SULFONAT E, DISODIUM SALT * 1-P-SULFOPHENYLAZO-2-HYDROXYNAP HTHALENE-6-SULFONATE, DISODIUM SALT * 1-PARA-SULFOPHENYLAZO-2-NAPHTHOL -6-SULFONIC ACID, DISODIUM SALT * 1-P-SULFOPHENYLAZO-2-NAPHTHOL-6-S ULFONIC ACID, DISODIUM SALT * 1-PARA-SULFOPHENYLAZO-2-NAPHTHOL -6-SULFONIC ACID DISODIUM SALT * 1-P-SULFOPHENYLAZO-2-NAPHTHOL-6-S ULFONIC ACID DISODIUM SALT * 1-PARA-SULPHOPHENYLAZO-2-NAPHTH OL-6-SULPHONIC ACID, DISODIUM SALT * 1-P-SULPHOPHENYLAZO-2-NAPHTHOL-6- SULPHONIC ACID, DISODIUM SALT * C.I. 15985 * C.I. FOOD YELLOW 3, DISODIUM SALT * C.I. FOOD YELLOW 3 * FD AND C YELLOW 6 * D AND C YELLOW NO. 6 * FD&C YELLOW 6 * FD AND C YELLOW NO. 6 * ACID FOOD YELLOW 3 * FOOD YELLOW 3 * FOOD YELLOW 5 * FOOD YELLOW 6 * 1351 YELLOW * 1899 YELLOW * NO. 8002 FD & C YELLOW #6 GRANULES * FOOD YELLOW NO. 5 * ACID YELLOW TRA * SUNSET YELLOW FCF * SUNSET YELLOW 3 * C16H10N2Na2O7S2 * OHS09671 * RTECS QK2450000	2783-94-0	0.06

Chemical name	Common name and synonyms	CAS number	%
ETHYLCELLULOSE	ETHYL ETHER CELLULOSE * CELLULOSE ETHYLATE * CELLULOSE ETHYL * ETHOCEL * CELLULOSE, ETHYL ETHER * ETHYL CELLULOSE ETHER * ETHYL CELLULOSE * OHS08875 * RTECS FJ5950500	9004-57-3	< 0.1
POTASSIUM SORBATE	SORBIC ACID, POTASSIUM SALT * SORBISTAT-K * SORBISTAT-POTASSIUM * 2,4-HEXADIENOIC ACID, POTASSIUM SALT, (E,E)- * (E,E)-2,4-HEXADIENOIC ACID, POTASSIUM SALT * POTASSIUM-2,4-HEXADIENOATE	24634-61-5	< 0.1 < 15

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

4. 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 center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	None known.
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 center.
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.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
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	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.
General fire hazards	No unusual fire or explosion hazards noted.

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 protective equipment and clothing during clean-up. Avoid inhalation of dust from the spilled material. 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. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
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Methods and materials 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. Minimize 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. For waste disposal, see section 13 of the SDS.

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.

7. Handling and storage**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.

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).

8. Exposure controls/personal protection**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

OHC

1

MICROCRYSTALLINE
CELLULOSE (CAS
9004-34-6)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

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**Components****Type****Value****Form**MAIZE STARCH (CAS
9005-25-8)

PEL

5 mg/m3

Respirable fraction.

15 mg/m3

Total dust.

MICROCRYSTALLINE
CELLULOSE (CAS
9004-34-6)

PEL

5 mg/m3

Respirable fraction.

15 mg/m3

Total dust.

PREGELATINIZED
STARCH (CAS 9005-25-8)

PEL

5 mg/m3

Respirable fraction.

15 mg/m3

Total dust.

STARCH (CAS 9005-25-8)

PEL

5 mg/m3

Respirable fraction.

15 mg/m3

Total dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)**Components****Type****Value****Form**

TALC (CAS 14807-96-6)

TWA

0.3 mg/m3

Total dust.

0.1 mg/m3

Respirable.

20 mppcf

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

Components	Type	Value	Form
		2.4 mppcf	Respirable.
US. ACGIH Threshold Limit Values			
Components	Type	Value	Form
MAIZE STARCH (CAS 9005-25-8)	TWA	10 mg/m3	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	
PREGELATINIZED STARCH (CAS 9005-25-8)	TWA	10 mg/m3	
STARCH (CAS 9005-25-8)	TWA	10 mg/m3	
STEARIC ACID (CAS 57-11-4)	TWA	10 mg/m3	
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.
US. NIOSH: Pocket Guide to Chemical Hazards			
Components	Type	Value	Form
MAIZE STARCH (CAS 9005-25-8)	TWA	5 mg/m3	Respirable.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	Total
		5 mg/m3	Respirable.
PREGELATINIZED STARCH (CAS 9005-25-8)	TWA	10 mg/m3	Total
		5 mg/m3	Respirable.
STARCH (CAS 9005-25-8)	TWA	10 mg/m3	Total
		5 mg/m3	Respirable.
TALC (CAS 14807-96-6)	TWA	10 mg/m3	Total
		2 mg/m3	Respirable.
US. AIHA Workplace Environmental Exposure Level (WEEL) Guides			
Components	Type	Value	Form
PROPYLENE GLYCOL (CAS 57-55-6)	TWA	10 mg/m3	Aerosol.

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

9. Physical and chemical properties

Appearance

Physical state	Solid.
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Form	Caplet.
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)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Incompatible materials	Alkaline metals.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

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 related to the physical, chemical and toxicological characteristics	None known.
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Information on toxicological effects

Acute toxicity	Harmful if swallowed. Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
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Components	Species	Test Results
CAFFEINE (CAS 58-08-2)		
Acute		
<i>Dermal</i>		
LD50	Rat	> 2000 mg/kg
<i>Oral</i>		
LD50	Rat	192 mg/kg
Subchronic		
<i>Oral</i>		
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		
<i>Oral</i>		
LD50	Rat	1288 mg/kg
ETHYLCELLULOSE (CAS 9004-57-3)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 5000 mg/kg
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
L-ASCORBIC ACID (CAS 50-81-7)		
Acute		
<i>Oral</i>		
LD50	Rat	11.9 g/kg
Subchronic		
<i>Oral</i>		
NOAEL	Rat	2000 mg/kg/day
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
PARACETAMOL (CAS 103-90-2)		
Acute		
<i>Oral</i>		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg
Subacute		
<i>Oral</i>		
NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
Subchronic		
<i>Oral</i>		
NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous

Components	Species	Test Results
TD	Rat	>= 12500 ppm, 13 weeks dietary, continuous
<i>Other</i>		
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		
<i>Oral</i>		
LD50	Rat	350 mg/kg
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
POLYVINYLPIRROLIDONE (CAS 9003-39-8)		
Acute		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
POTASSIUM SORBATE (CAS 24634-61-5)		
Acute		
<i>Oral</i>		
LD50	Rat	4340 mg/kg
STEARIC ACID (CAS 57-11-4)		
Acute		
<i>Oral</i>		
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 or skin sensitization**Respiratory sensitization**

Not available.

Skin sensitization

This product is not expected to cause skin sensitization.

Maximisation assay (Magnusson and Kligman)

HYDROXYPROPYL METHYL CELLULOSE

Result: Negative

Species: Guinea pig

Sensitization

PHENYLEPHRINE HYDROCHLORIDE

Clinical use - Ophthalmology

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

Mutagenicity

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.

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 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

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.

POLYVINYLPIRROLIDONE (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.

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. 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
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 weight, 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 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.
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
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Aspiration hazard	Not likely, due to the form of the product.
Further information	Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity 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			
<i>Acute</i>			
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
<i>Chronic</i>			
Algae	NOEC	Green algae (Desmodesmus subspicatus)	6.25 mg/l, 72 hours OECD 201
DODECYL SODIUM SULFATE (CAS 151-21-3)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	5.4 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	4.6 mg/l, 96 hours Flow-through test
<i>Chronic</i>			
Algae	NOEC	Green algae (Desmodesmus subspicatus)	30 mg/l, 72 hours
Crustacea	NOEC	Ceriodaphnia dubia	0.88 mg/l, 7 days Flow-through Test
Fish	NOEC	Fathead minnow (Pimephales promelas)	3.8 mg/l, 28 days Flow-through test
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Fish	> 100 mg/L, 96 hours
L-ASCORBIC ACID (CAS 50-81-7)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	1020 mg/l, 96 hours
PARACETAMOL (CAS 103-90-2)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Scenedesmus subspicatus)	134 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	50 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	814 mg/l, 96 hours Flow-through test

Components		Species	Test Results
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
POLYVINYLPIRROLIDONE (CAS 9003-39-8)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours Static test
Aquatic			
<i>Acute</i>			
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			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	750 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	> 500 mg/l, 96 hours Static test
		Zebra fish (Adult Brachydanio rerio)	1250 mg/l, 48 hours
			> 1000 mg/l, 96 hours
<i>Chronic</i>			
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)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
<i>Acute</i>			
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 Oncorhynchus mykiss)	51600 mg/l, 96 hours Static test
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhynchus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes

Components		Species	Test Results
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.

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

POLYVINYLPIRROLIDONE 0 %, 28 days Modified MITI test, Activated sludge

POTASSIUM SORBATE 95 %, 6 days Zahn-Wellens

PROPYLENE GLYCOL 62 %, 5 days BOD5, Activated sludge

79 %, 20 Days BOD20, Activated sludge

STEARIC ACID 77 %, 28 days BOD

Percent degradation (Aerobic biodegradation-soil)

STEARIC ACID 50 %, 13 days

Percent degradation (Anaerobic biodegradation)

PROPYLENE GLYCOL 100 %, 9 days

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

Mobility in soil

Adsorption

Soil/sediment sorption - log K_{oc}

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 m ³ /mol Estimated
PARACETAMOL	0 atm m ³ /mol Estimated
PROPYLENE GLYCOL	0 atm m ³ /mol Estimated
STEARIC ACID	0.000051 Estimated

Other adverse effects Not available.

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 Not applicable.

15. Regulatory information

US federal regulations One or more components are not listed on TSCA.

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 - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

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.**US state regulations****US. Massachusetts RTK - Substance List**

MAIZE STARCH (CAS 9005-25-8)

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

PREGELATINIZED STARCH (CAS 9005-25-8)

STARCH (CAS 9005-25-8)

TALC (CAS 14807-96-6)

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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

PROPYLENE GLYCOL (CAS 57-55-6)

TALC (CAS 14807-96-6)

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

MAIZE STARCH (CAS 9005-25-8)

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

PREGELATINIZED STARCH (CAS 9005-25-8)

PROPYLENE GLYCOL (CAS 57-55-6)

STARCH (CAS 9005-25-8)

TALC (CAS 14807-96-6)

US. Rhode Island RTK

Not regulated.

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
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	08-25-2014
Revision date	08-25-2014
Version #	10

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: 1 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 1 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.
Revision Information	Product and Company Identification: Synonyms Composition / Information on Ingredients: Ingredients Ecological information: Ecotoxicity