

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Trade name or designation of the mixture	PANADOL, (PARACETAMOL) AND CAFFEINE TABLETS
Registration number	-
Synonyms	PANADOL EXTRA CAPLETS * PANADOL EXTRA ADVANCE * PANADOL PERIOD PAIN * PANADOL EXTRA * PANADOL EXTRA SOLUBLE TABLETS * PANADOL EXTRA EFFERVESCENT TABLETS * DOLEX FORTE TABLETS * DOLEX EXTRA FUERTA * ALG 770 * MFC 30203 * MFC 50840 * PARACETAMOL 500 MG AND CAFFEINE 65 MG CAPLETS * PARACETAMOL AND CAFFEINE 500 MG/65 MG TABLETS * PARACETAMOL AND CAFFEINE, FORMULATED PRODUCT
Issue date	11-December-2014
Version number	05
Revision date	11-December-2014
Supersedes date	21-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](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://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.

**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



Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
D-SORBITOL	0 - <2	50-70-4 200-061-5	-	-	
<b>Classification:</b>	<b>DSD:</b> -				
	<b>CLP:</b> -				
Polyvinylpyrrolidone	0.3 - <1.5	9003-39-8	-	-	
<b>Classification:</b>	<b>DSD:</b> R52/53				
	<b>CLP:</b> Aquatic Chronic 3;H412				
NIPASEPT SODIUM	0 - <0.2	Unassigned	-	-	
<b>Classification:</b>	<b>DSD:</b> Xn;R22, Xi;R41				
	<b>CLP:</b> Acute Tox. 4;H302, Eye Dam. 1;H318				
Titanium dioxide	<0.1	13463-67-7 236-675-5	-	-	
<b>Classification:</b>	<b>DSD:</b> -				
	<b>CLP:</b> -				

Other components below reportable levels < 5

#### List of abbreviations and symbols that may be used above

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

<b>General information</b>	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.
<b>4.1. Description of first aid measures</b>	
<b>Inhalation</b>	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.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Get medical attention if irritation develops and persists. Take off contaminated clothing and wash before reuse.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting without advice from poison control center. Get medical advice/attention if you feel unwell.
<b>4.2. Most important symptoms and effects, both acute and delayed</b>	None known.
<b>4.3. Indication of any immediate medical attention and special treatment needed</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

## SECTION 5: Firefighting measures

<b>General fire hazards</b>	No unusual fire or explosion hazards noted.
<b>5.1. Extinguishing media</b>	
<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	None known.

<b>5.2. Special hazards arising from the substance or mixture</b>	During fire, gases hazardous to health may be formed.
<b>5.3. Advice for firefighters</b>	
<b>Special protective equipment for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Special fire fighting procedures</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	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

<b>For non-emergency personnel</b>	Keep unnecessary personnel away. Keep upwind. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Wear a dust mask if dust is generated above exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.
<b>For emergency responders</b>	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. For waste disposal, see section 13 of the SDS.

**6.4. Reference to other sections** For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

## SECTION 7: Handling and storage

<b>7.1. Precautions for safe handling</b>	Provide appropriate exhaust ventilation at places where dust is formed. Avoid breathing dust. Avoid contact with eyes. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. 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.
<b>7.2. Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
<b>7.3. Specific end use(s)</b>	Medicinal Product

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Occupational exposure limits

<b>GSK Components</b>	<b>Type</b>	<b>Value</b>
ALGINIC ACID (CAS 9005-32-7)	OHC	1
CAFFEINE (CAS 58-08-2)	8 HR TWA	200 mcg/m3
	OHC	2
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m3
	OHC	1
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m3
SODIUM BICARBONATE (CAS 144-55-8)	8 HR TWA	5000 mcg/m3
	OHC	1
Sodium carbonate (CAS 497-19-8)	8 HR TWA	5000 mcg/m3
	OHC	1

**Ireland. Occupational Exposure Limits**

Components	Type	Value	Form
Calcium carbonate (CAS 471-34-1)	TWA	4 mg/m <sup>3</sup>	Respirable dust.
MAIZE STARCH (CAS 9005-25-8)	TWA	10 mg/m <sup>3</sup>	Total inhalable dust.
		4 mg/m <sup>3</sup>	Respirable dust.
PARACETAMOL (CAS 103-90-2)	TWA	10 mg/m <sup>3</sup>	Total inhalable dust.
		10 mg/m <sup>3</sup>	Total inhalable dust.
Starch (CAS 9005-25-8)	TWA	4 mg/m <sup>3</sup>	Respirable dust.
		10 mg/m <sup>3</sup>	Total inhalable dust.
Talc (CAS 14807-96-6)	TWA	10 mg/m <sup>3</sup>	Total inhalable dust.
		0.8 mg/m <sup>3</sup>	Respirable dust.
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m <sup>3</sup>	Respirable dust.
		10 mg/m <sup>3</sup>	Total inhalable dust.

**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 material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits. 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** If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

**Skin protection**

**- Hand protection** 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** Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust)

**Respiratory protection** 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). When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**Hygiene measures** For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. 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. 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** Tablet.

**Colour** Not available.

**Odour** Not available.

**Odour threshold** Not available.

<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Solubility (other)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Explosive properties</b>	Not available.
<b>Oxidizing properties</b>	Not available.
<b>9.2. Other information</b>	
<b>VOC (Weight %)</b>	0.0168 % Switzerland estimated

## SECTION 10: Stability and reactivity

<b>10.1. Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>10.2. Chemical stability</b>	Material is stable under normal conditions.
<b>10.3. Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>10.4. Conditions to avoid</b>	Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
<b>10.5. Incompatible materials</b>	Alkali metals. Peroxides.
<b>10.6. Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## SECTION 11: Toxicological information

<b>General information</b>	Occupational exposure to the substance or mixture may cause adverse effects.
<b>Information on likely routes of exposure</b>	
<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
<b>Symptoms</b>	None known.
<b>11.1. Information on toxicological effects</b>	
<b>Acute toxicity</b>	Expected to be a low hazard for usual industrial or commercial handling by trained personnel. May be harmful if swallowed.

Components	Species	Test results
ALGINIC ACID (CAS 9005-32-7)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
CAFFEINE (CAS 58-08-2)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rat	> 2000 mg/kg
<i>Oral</i>		
LD50	Rat	192 mg/kg
<b>Subchronic</b>		
<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
Calcium carbonate (CAS 471-34-1)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	6450 mg/kg
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	3000 mg/kg
D-SORBITOL (CAS 50-70-4)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	15.9 g/kg
NIPASEPT SODIUM (CAS Unassigned)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	< 2000 mg/kg
PARACETAMOL (CAS 103-90-2)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg
<b>Subacute</b>		
<i>Oral</i>		
NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
<b>Subchronic</b>		
<i>Oral</i>		
NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous
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

Components	Species	Test results
Polyvinylpyrrolidone (CAS 9003-39-8)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
SODIUM BICARBONATE (CAS 144-55-8)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	4220 mg/kg
Titanium dioxide (CAS 13463-67-7)		
<b>Acute</b>		
<i>Inhalation</i>		
LC50	Rat	6820 mcg/m3
<i>Oral</i>		
LD50	Rat	> 24 g/kg
<b>Chronic</b>		
<i>Inhalation</i>		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose 5 mg/m3, 24 months
<b>Subacute</b>		
<i>Inhalation</i>		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks No evidence of significant inflammation in respiratory tract.
<i>Oral</i>		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
<b>Subchronic</b>		
<i>Inhalation</i>		
LOEC	Rat	3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

\* 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**

TITANIUM DIOXIDE

0, Literature data  
Result: Non-irritant  
Species: Guinea pig

CAFFEINE

0, Literature data  
Result: Non-irritant  
Species: Human

TITANIUM DIOXIDE

0, Literature data  
Result: Non-irritant  
Species: Rabbit  
Acute dermal irritation; OECD 404, Literature data  
Result: Non-irritant  
Species: Rabbit

**Irritation Corrosion - Skin: P.I.I. value**

CITRIC ACID ANHYDROUS

OECD 404  
Result: Mild to moderate irritant.  
Species: Rabbit

PARACETAMOL

OECD 404, Literature data  
Result: Slight irritant  
Species: Rabbit

<b>Serious eye damage/eye irritation</b>	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
<b>Eye</b>	
CAFFEINE	0, Literature data Result: Not likely to be a severe irritant Species: Rabbit
SODIUM CARBONATE	Acute ocular irritation; OECD 405 Result: Moderate Irritant Species: Rabbit
CITRIC ACID ANHYDROUS	Acute ocular irritation; OECD 405 Result: Severe Irritant Species: Rabbit
PARACETAMOL	OECD 405 Result: Slight irritant Species: Rabbit
TITANIUM DIOXIDE	OECD 405, Literature data Result: Mild irritant Species: Rabbit
<b>Eye / Initial pain reaction score</b>	
PARACETAMOL	0, Literature data
<b>Respiratory sensitisation</b>	Due to partial or complete lack of data the classification is not possible.
<b>Skin sensitisation</b>	This product is not expected to cause skin sensitisation.
<b>Sensitisation</b>	
CAFFEINE	0, Literature data Result: negative Species: Mouse
TITANIUM DIOXIDE	5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: negative Species: Guinea pig Test Duration: 48 hour exposure Patch test, Literature data Result: negative Species: Human
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
<b>Mutagenicity</b>	
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
PARACETAMOL	Ames, Literature data Result: negative
TITANIUM DIOXIDE	Ames, Literature data Result: negative
CAFFEINE	Chromosomal Aberration Assay In Vitro Result: positive
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
CAFFEINE	L5178Y mouse lymphoma thymidine kinase locus assay Result: positive
TITANIUM DIOXIDE	Micronucleus Assay in vitro, CHO cells, Literature data Result: negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: positive Syrian Hamster Embryo (SHE) cell transformation assay Result: negative WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: positive

**Carcinogenicity** Not classifiable as to carcinogenicity to humans. Contains a material (titanium dioxide, 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.

PARACETAMOL	0, Literature data Result: Equivocal. Increase in adenomas at toxic dose. Species: Mouse
	0, Literature data Result: Equivocal. Liver and bladder neoplasms at toxic doses. Species: Rat
	0, Literature data Result: negative Species: Mouse
	0, Literature data Result: negative Species: Rat
CAFFEINE	0.1 - 0.2 %, Dosed in drinking water Result: negative Species: Rat
	Test Duration: 78 weeks
TITANIUM DIOXIDE	0.5 mg/m3, Literature data Result: negative Species: Rat
	Test Duration: 24 months
	0.72 - 14.8 mg/m3, Literature data Result: negative Species: Mouse
	10 - 250 mg/m3, Dietary study - Literature data. Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration. Species: Rat
	Test Duration: 24 months
CAFFEINE	200 - 2000 mg/l, Dosed in drinking water Result: negative Species: Rat
	Test Duration: 2 years
TITANIUM DIOXIDE	25000 - 50000 ppm, Dietary study Result: negative Species: Mouse
	25000 - 50000 ppm, Dietary study - Literature data. Result: negative Species: Rat
	7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat
	Test Duration: 24 months

**IARC Monographs. Overall Evaluation of Carcinogenicity**

CAFFEINE (CAS 58-08-2)	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.
Titanium dioxide (CAS 13463-67-7)	2B Possibly carcinogenic to humans.

**Reproductive toxicity** Contains no ingredient listed as toxic to reproduction

**Reproductivity**

CAFFEINE	100 mg/kg/day Embryofetal Development Result: Maternal toxicity; adverse foetal effects Species: Rat
	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
	750 mg/kg/day Embryofetal Development, Literature data Result: decrease in foetal weight, minor skeletal abnormalities. Species: Rat

**Reproductivity**

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

&gt;= 301 mg/day Epidemiology

Result: delayed conception

Species: Human

PARACETAMOL

Epidemiology, Literature data

Result: No clear association with therapeutic use.

Species: Human

**Specific target organ toxicity - single exposure**

Causes damage to organs by ingestion.

CAFFEINE

0, 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.

**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

&gt; 1000 mg/l, 3 hours Nominal, OECD 209

NOEC

Residential sludge

1000

Algae

EC50

Green algae (Desmodesmus  
subspicatus)

&gt; 100 mg/l, 72 hours OECD 201

Green algae (Scenedesmus  
subspicatus)

&gt; 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

Calcium carbonate (CAS 471-34-1)

**Aquatic**

Fish

LC50

Western mosquitofish (Gambusia affinis)

&gt; 56000 mg/l, 24 hours

CITRIC ACID ANHYDROUS (CAS 77-92-9)

**Aquatic***Acute*

Algae

NOEC

Green algae (Scenedesmus  
quadricauda)

425 mg/l, 8 days Static Test

Crustacea

EC50

Water flea (Daphnia magna)

120 mg/l, 72 hours Static test

Fish

EC50

Bluegill sunfish (Adult Lepomis  
macrochirus)

1516 mg/l, 96 hours Static test

Components	Species	Test results
	Golden ide/orfe (Adult <i>Leuciscus idus</i> )	440 - 760 mg/l, 96 hours Static test
PARACETAMOL (CAS 103-90-2)		
<b>Aquatic</b>		
<i>Acute</i>		
Algae	EC50	Green algae ( <i>Scenedesmus subspicatus</i> ) 134 mg/l, 72 hours
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> ) 50 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile <i>Pimephales promelas</i> ) 814 mg/l, 96 hours Flow-through test
Polyvinylpyrrolidone (CAS 9003-39-8)		
<i>Acute</i>		
	IC50	Activated sludge > 1000 mg/l, 3 hours Static test
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> ) 84 mg/l, 48 hours Static test
	NOEC	Water flea ( <i>Daphnia magna</i> ) 32 mg/l, 48 hours Static test
SODIUM BICARBONATE (CAS 144-55-8)		
<b>Aquatic</b>		
<i>Acute</i>		
Algae	EC50	Algae ( <i>Nitscheria linearis</i> ) 650 mg/l, 5 days
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> ) 2350 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult <i>Lepomis macrochirus</i> ) 8250 - 9000 mg/l, 96 hours Static test
		Mosquito fish (Adult <i>Gambusia affinis</i> ) 7550 mg/l, 96 hours Static test
Sodium carbonate (CAS 497-19-8)		
<b>Aquatic</b>		
<i>Acute</i>		
Algae	EC50	Green algae ( <i>Selenastrum capricornutum</i> ) > 800 mg/l
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> ) 265 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult <i>Lepomis macrochirus</i> ) 300 mg/l, 96 hours Static test
		Fathead minnow (Juvenile <i>Pimephales promelas</i> ) < 850 mg/l, 96 hours Static test
		Mosquito fish (Adult <i>Gambusia affinis</i> ) 740 mg/l, 96 hours Static test
Talc (CAS 14807-96-6)		
<b>Aquatic</b>		
<i>Acute</i>		
Fish	EC50	Zebra fish (Adult <i>Brachydanio rerio</i> ) > 100 g/l, 24 hours Static renewal test
Titanium dioxide (CAS 13463-67-7)		
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> ) > 1000 mg/l, 48 hours Static test

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

## 12.2. Persistence and degradability

No data is available on the degradability of this product.

### Photolysis

#### Half-life (Photolysis-atmospheric)

CAFFEINE 2.5 Hours Estimated

#### UV/visible spectrum wavelength

CAFFEINE 227 nm

### Biodegradability

#### Percent degradation (Aerobic biodegradation-inherent)

CITRIC ACID ANHYDROUS 98 %, 2 days Modified Zahn-Wellens, Activated sludge

PARACETAMOL 99 %, 5 days Modified Zahn-Wellens, Activated sludge

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

### 12.3. Bioaccumulative potential

#### Partition coefficient

##### n-octanol/water (log Kow)

CAFFEINE	-0.07
	-0.0907
D-SORBITOL	-2.2
PARACETAMOL	0.36

#### Bioconcentration factor (BCF)

CAFFEINE	0.52 - 2.25 Estimated
D-SORBITOL	1 Estimated

### 12.4. Mobility in soil

#### Adsorption

##### Soil/sediment sorption - log Koc

CAFFEINE	1.25 - 1.34 Estimated
D-SORBITOL	0.3 Estimated

#### Mobility in general

#### Volatility

##### Henry's law

CAFFEINE	0 atm m <sup>3</sup> /mol Estimated
CITRIC ACID ANHYDROUS	< 0 atm m <sup>3</sup> /mol Calculated, 25 °C
D-SORBITOL	0 atm m <sup>3</sup> /mol Estimated
PARACETAMOL	0 atm m <sup>3</sup> /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

<b>Residual waste</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.
<b>Contaminated packaging</b>	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.
<b>EU waste code</b>	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Disposal methods/information</b>	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.
<b>Special precautions</b>	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(10) 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)  
Sodium carbonate (CAS 497-19-8)

**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**

R22 Harmful if swallowed.  
R36 Irritating to eyes.  
R41 Risk of serious damage to eyes.  
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
H302 Harmful if swallowed.  
H318 Causes serious eye damage.  
H319 Causes serious eye irritation.  
H412 Harmful to aquatic life with long lasting effects.

#### **Revision information**

Product and Company Identification: Synonyms  
Composition / Information on Ingredients: Ingredients  
SECTION 11: Toxicological information: Serious eye damage/eye irritation  
SECTION 11: Toxicological information: Other information

#### **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.