SAFETY DATA SHEET

1. Identification

Product identifier **PANADOL, (PARACETAMOL) AND CAFFEINE TABLETS**

Other means of identification

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

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	16.5 - <75

Chemical name	Common name and synonyms	CAS number	%
SODIUM BICARBONATE	BAKING SODA * BICARBONATE OF SODA * CARBONIC ACID MONOSODIUM SALT * CARBONIC ACID SODIUM SALT (1:1) * MONOSODIUM CARBONATE * MONOSODIUM HYDROGEN CARBONATE * RTECS VZ0950000 * SODIUM ACID CARBONATE * SODIUM HYDROGEN CARBONATE	144-55-8	0 - <45
CITRIC ACID ANHYDROUS	BETA-HYDROXYTRICARBALLYLIC ACID * ANHYDROUS CITRIC ACID * 2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID * CITIRIC ACID	77-92-9	0 - <35
STARCH	ARROWROOT STARCH * CORN STARCH * POTATO STARCH * RICE STARCH	9005-25-8	10 - <15
CAFFEINE	TRIMETHYLXANTHINE * METHYLTHEOBROMINE * CAFFEINE ANHYDROUS	58-08-2	2.15 - <10
CALCIUM CARBONATE	CARBONIC ACID, CALCIUM SALT * CALCIUM MONOCARBONATE * PRECIPITATED CALCIUM CARBONATE * CHALK	471-34-1	0 - <10
MAIZE STARCH	STARCH, EDIBLE * STARCH (CORN)	9005-25-8	0 - <7
SODIUM CARBONATE	CARBONIC ACID, DISODIUM SALT * BISODIUM CARBONATE * DISODIUM CARBONATE * SODA ASH	497-19-8	0 - <5
TALC	TALCUM, NON-ASBESTOS FORM * TALC * HYDROUS MAGNESIUM SILICATE	14807-96-6	0 - <2.5
ALGINIC ACID	KELACID * NORGINE * POLYMANNURONIC ACID	9005-32-7	0 - <2
D-SORBITOL	SORBITOL * L-GULITOL * 1,2,3,4,5,6-HEXANEHEXOL * D-SORBOL	50-70-4	0 - <2
POLYVINYLPYRROLIDONE	1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER * POLY(N-VINYLPYRROLIDONE) * POVIDONE * PLASDONE * PLASDONE K29/32	9003-39-8	0.3 - <1.5
NIPASEPT SODIUM	BUTYL PARABEN SODIUM	Unassigned	0 - <0.2
TITANIUM DIOXIDE	TITANIUM OXIDE * TITANIUM(IV) OXIDE * TITANIUM PEROXIDE (TiO2) * PIGMENT WHITE 6	13463-67-7	<0.1
Other components below reportable levels			< 5

*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. Get medical attention if irritation develops and persists. Take off contaminated clothing and wash before reuse.

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). Do not induce vomiting without advice from poison control center. Get medical advice/attention if you feel unwell.

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 local poison control information centre.

General information In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

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

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 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. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up 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 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.

Conditions for safe storage, including any incompatibilities 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
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

GSK

Components	Type	Value
	OHC	1

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
CALCIUM CARBONATE (CAS 471-34-1)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
MAIZE 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.
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	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	
		2.4 mppcf	Respirable.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
MAIZE STARCH (CAS 9005-25-8)	TWA	10 mg/m3	
STARCH (CAS 9005-25-8)	TWA	10 mg/m3	
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m3	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
CALCIUM CARBONATE (CAS 471-34-1)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
MAIZE STARCH (CAS 9005-25-8)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
STARCH (CAS 9005-25-8)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable.

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

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

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection For prolonged or repeated skin contact use suitable protective gloves.

Other Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection 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	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.

9. Physical and chemical properties

Appearance	
Physical state	Solid.
Form	Tablet.
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.
Other information	
VOC (Weight %)	0.0168 % Switzerland estimated

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. Peroxides.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of 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.
Ingestion	May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms related to the physical, chemical and toxicological characteristics	None known.

Information on toxicological effects

Acute toxicity 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)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
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
CALCIUM CARBONATE (CAS 471-34-1)		
Acute		
Oral		
LD50	Rat	6450 mg/kg
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	3000 mg/kg
D-SORBITOL (CAS 50-70-4)		
Acute		
Oral		
LD50	Rat	15.9 g/kg
NIPASEPT SODIUM (CAS Unassigned)		
Acute		
Oral		
LD50	Rat	< 2000 mg/kg
PARACETAMOL (CAS 103-90-2)		
Acute		
Oral		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg
Subacute		
Oral		
NOAEL	Rat	12500 ppm, 14 Day dietary, continuous

Components	Species	Test Results
Subchronic		
Oral		
NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous
TD	Rat	>= 12500 ppm, 13 weeks dietary, continuous
Other		
LOAEL	Mouse	130 ppm, 61 weeks dietary, continuous
NOAEL	Mouse	3200 ppm, 13 weeks dietary, continuous
		0.3 %, 41 weeks dietary, continuous
TD	Mouse	6100 ppm, 13 weeks dietary, continuous
		1.25 %, 41 weeks dietary, continuous
POLYVINYLPYRROLIDONE (CAS 9003-39-8)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
SODIUM BICARBONATE (CAS 144-55-8)		
Acute		
Oral		
LD50	Rat	4220 mg/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
Chronic		
Inhalation		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophrages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose
		5 mg/m3, 24 months
Subacute		
Inhalation		
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.
Oral		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
Inhalation		
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 0, Literature data Result: Non-irritant Species: Human
CAFFEINE	0, Literature data Result: Non-irritant Species: Rabbit
TITANIUM DIOXIDE	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

Serious eye damage/eye irritation Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Eye

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

Eye / Initial pain reaction score

PARACETAMOL	0, Literature data

Respiratory or skin sensitization

Respiratory sensitization Not available.

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

Sensitization

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

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

Mutagenicity

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 ademomas 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

Carcinogenicity

TITANIUM DIOXIDE	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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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 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
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.

Chronic effects Prolonged exposure may cause chronic effects.

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			
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
CALCIUM CARBONATE (CAS 471-34-1)			
Aquatic			
Fish	LC50	Western mosquitofish (Gambusia affinis)	> 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
		Golden ide/orfe (Adult Leuciscus idus)	440 - 760 mg/l, 96 hours Static test
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
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
SODIUM BICARBONATE (CAS 144-55-8)			
Aquatic			
Acute			
Algae	EC50	Algae (Nitscheria linearis)	650 mg/l, 5 days
Crustacea	EC50	Water flea (Daphnia magna)	2350 mg/l, 48 hours Static test

Components		Species	Test Results
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	8250 - 9000 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	7550 mg/l, 96 hours Static test
SODIUM CARBONATE (CAS 497-19-8)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	> 800 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	265 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	300 mg/l, 96 hours Static test
		Fathead minnow (Juvenile Pimephales promelas)	< 850 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	740 mg/l, 96 hours Static test
TALC (CAS 14807-96-6)			
Aquatic			
Acute			
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 100 g/l, 24 hours Static renewal test
TITANIUM DIOXIDE (CAS 13463-67-7)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours Static test

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

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

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

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^3/mol Estimated
CITRIC ACID ANHYDROUS	< 0 atm m^3/mol Calculated, 25 °C
D-SORBITOL	0 atm m^3/mol Estimated

Volatility

Henry's law

PARACETAMOL	0 atm m^3/mol 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). Avoid discharge into water courses or onto the ground.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - 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. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

CALCIUM CARBONATE (CAS 471-34-1)
MAIZE STARCH (CAS 9005-25-8)
STARCH (CAS 9005-25-8)
TALC (CAS 14807-96-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

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

CALCIUM CARBONATE (CAS 471-34-1)
TALC (CAS 14807-96-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

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

CALCIUM CARBONATE (CAS 471-34-1)
MAIZE STARCH (CAS 9005-25-8)
STARCH (CAS 9005-25-8)
TALC (CAS 14807-96-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7) Listed: September 2, 2011

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 12-11-2014

Revision date 12-11-2014

Version # 05

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 Toxicological information: Further information Regulatory information: US federal regulations