



SAFETY DATA SHEET

1. Identification

Product identifier

PANADOL (PARACETAMOL) TABLETS / CAPLETS

Other means of identification

Synonyms

PANADOL TABLETS (UK AND CANADA) * PANADOL EXTRA STRENGTH CAPLETS (US AND CANADA) * PANADOL EXTRA-FORT CAPLETS * PANADOL ADVANCE * PANADOL BPI TABLETS * PANADOL BPI CAPLETS * BPI 500 MG TABLETS * PANADOL EXTEND CAPLETS * PANADOL EXTEND CAPLETS (AUSTRALIA) * FORMULA NUMBER 9464/112 * PANADOL SOLUBLE TABLETS * PANADOL CLEAR * HEDEX SOLUBLE * DOLEX EFFERVESCENTE * PANADOL EFFERVESCENT * ANAFLOIN B EFFERVESCENT * PANADOL OSTEO CAPLETS * PANADOL OSTEO TABLETS 665MG (AUSTRALIA) * PANADOL 500 MG CAPLETS * PANADOL 500 TABLETS * PANADOL ADULTOS TAB * PANADOL ADULT TABLETS * PANADOL COMPRIMADOS * DOLEX TABLETS * DOLEX TABLETS 500 MG * DOLEX ADULT TABLETS 500 MG * DOLEX TABLETS 500 MG * MFC 50577, 50578, 50699 * ALG490 * ALG 722 * PARACETAMOL, 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	16.9 - 93.0

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 - < 47
CITRIC ACID ANHYDROUS	BETA-HYDROXYTRICARBALLYLIC ACID * ANHYDROUS CITRIC ACID * 2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID * CITRIC ACID	77-92-9	0 - < 35
STARCH	ARROWROOT STARCH * CORN STARCH * POTATO STARCH * RICE STARCH	9005-25-8	0.3 - 12.0
CALCIUM CARBONATE	CARBONIC ACID, CALCIUM SALT * CALCIUM MONOCARBONATE * PRECIPITATED CALCIUM CARBONATE * CHALK	471-34-1	0 - 10.0
SODIUM CARBONATE	CARBONIC ACID, DISODIUM SALT * BISODIUM CARBONATE * DISODIUM CARBONATE * SODA ASH	497-19-8	0 - < 5
POLYVINYLPIRROLIDONE	1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER * POLY(N-VINYLPYRROLIDONE) * PLASDONE	9003-39-8	0 - 3.0
ALGINIC ACID	KELACID * NORGINE * POLYMANNURONIC ACID	9005-32-7	0 - 2.5
TALC	TALCUM, NON-ASBESTOS FORM * TALC * HYDROUS MAGNESIUM SILICATE	14807-96-6	0 - 2.5
D-SORBITOL	SORBITOL * L-GULITOL * 1,2,3,4,5,6-HEXANEHEXOL * D-SORBOL	50-70-4	0 - < 2
POLYVINYLPOLYPYRROLIDONE	CROSPVIDONE * CROSPVIDONE (KOLLIDON CL-SF) * PVPP * POLY[1-(2-OXO-1-PYRROLIDINYL)-1,2-ETHANEDIYL]	25249-54-1	0 - 1.0
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	0 - 0.5
NIPASEPT SODIUM	BUTYL PARABEN SODIUM	Unassigned	0 - 0.2
POVIDONE 30	Poly(1-ethenylpyrrolid-2-one) * CROSPVIDONE * POLY(1-VINYL-2-PYRROLIDINONE) * 2-PYRROLIDINONE, 1-VINYL-, POLYMERS	9003-39-8	0 - < 0.05
TITANIUM DIOXIDE	TITANIUM OXIDE * TITANIUM(IV) OXIDE * TITANIUM PEROXIDE (TiO ₂) * PIGMENT WHITE 6	13463-67-7	0 - 0.03
Other components below reportable levels			0 - 40.0

*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. Under normal conditions of intended use, this material is not expected to be an inhalation hazard. Call a physician if symptoms develop or persist.

Skin contact

Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact

Rinse with water. Get medical attention if irritation develops and persists.

Ingestion

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

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	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. 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.
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. Minimize dust generation and accumulation. 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 in a well-ventilated place. 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
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m ³
	OHC	1

GSK

Components	Type	Value
D-SORBITOL (CAS 50-70-4)	OHC	1
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m3
SODIUM BICARBONATE (CAS 144-55-8)	OHC	1
	8 HR TWA	5000 mcg/m3
SODIUM CARBONATE (CAS 497-19-8)	OHC	1
	8 HR TWA	5000 mcg/m3
	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.
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
MAGNESIUM STEARATE (CAS 557-04-0)	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
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

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.

Hand protection

For prolonged or repeated skin contact use suitable protective gloves.

Skin protection	
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.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Tablet. 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	Acids. Alkaline metals.
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

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.

Information on toxicological effects

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

Components	Species	Test Results
ALGINIC ACID (CAS 9005-32-7)		
Acute		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
CALCIUM CARBONATE (CAS 471-34-1)		
Acute		
<i>Oral</i>		
LD50	Rat	6450 mg/kg
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
<i>Oral</i>		
LD50	Rat	3000 mg/kg
D-SORBITOL (CAS 50-70-4)		
Acute		
<i>Oral</i>		
LD50	Rat	15.9 g/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
NIPASEPT SODIUM (CAS Unassigned)		
Acute		
<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
TD	Rat	>= 12500 ppm, 13 weeks dietary, continuous

Components	Species	Test Results
<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
POLYVINYLPIRROLIDONE (CAS 9003-39-8)		
Acute		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
POVIDONE 30 (CAS 9003-39-8)		
Acute		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
SODIUM BICARBONATE (CAS 144-55-8)		
Acute		
<i>Oral</i>		
LD50	Rat	4220 mg/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
Acute		
<i>Inhalation</i>		
LC50	Rat	6820 mcg/m3
<i>Oral</i>		
LD50	Rat	> 24 g/kg
Chronic		
<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
Subacute		
<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.
Subchronic		
<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

Acute dermal irritation; OECD 404, Literature data

Result: Non-irritant

Species: Rabbit

Literature data

Result: Non-irritant

Species: Guinea pig

Literature data

Result: Non-irritant

Species: Human

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

MAGNESIUM STEARATE

0

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

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

Literature data

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE

4

Recovery Period: 2 days

Respiratory or skin sensitization**Respiratory sensitization**

Not available.

Skin sensitization

This product is not expected to cause skin sensitization.

Sensitization

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

PARACETAMOL

Ames, Literature data

Result: Negative

TITANIUM DIOXIDE

Ames, Literature data

Result: Negative

PARACETAMOL

Chromosomal Aberration Assay In Vitro, Literature data

Result: Positive

HPRT gene mutation in human lymphocytes, Literature data

Result: Negative

In vivo Micronucleus, Literature data

Result: Negative

Species: Mouse

TITANIUM DIOXIDE

Micronucleus Assay in vitro, CHO cells, Literature data

Result: Negative

Mutagenicity
TITANIUM DIOXIDE

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

Health injuries are not known or expected under normal use. Contains a material (titanium dioxide) classified as a carcinogen by external agencies. 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.

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
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
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

PARACETAMOL

IARC Monographs. Overall Evaluation of Carcinogenicity

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.
POVIDONE 30 (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.
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

PARACETAMOL

250 mg/kg/day Embryofetal Development, Literature data
Result: Foetal NOAEL
Species: Rat
387 mg/kg/day Embryofetal Development, Literature data
Result: Negative
Species: Mouse

Reproductivity
PARACETAMOL

750 mg/kg/day Embryofetal Development, Literature data
Result: decrease in foetal weight, minor skeletal abnormalities.
Species: Rat
<= 1400 mg/kg/day Pre- and Post-natal development, Literature data
Result: reduced weight gain during nursing.
Species: Rat
Epidemiology, Literature data
Result: No clear association with therapeutic use.
Species: Human

Specific target organ toxicity - single exposure Causes damage to organs by ingestion.

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. Symptoms may be delayed.

12. Ecological information

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

Components	Species	Test Results
CALCIUM CARBONATE (CAS 471-34-1)		
Aquatic		
Fish	LC50	Western mosquitofish (<i>Gambusia affinis</i>) > 56000 mg/l, 24 hours
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Aquatic		
<i>Acute</i>		
Algae	NOEC	Green algae (<i>Scenedesmus quadricauda</i>) 425 mg/l, 8 days Static Test
Crustacea	EC50	Water flea (<i>Daphnia magna</i>) 120 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult <i>Lepomis macrochirus</i>) 1516 mg/l, 96 hours Static test
		Golden ide/orfe (Adult <i>Leuciscus idus</i>) 440 - 760 mg/l, 96 hours Static test
MAGNESIUM STEARATE (CAS 557-04-0)		
Aquatic		
<i>Acute</i>		
Fish	EC50	Orange-red killfish (Adult <i>Oryzias latipes</i>) 130 mg/l, 96 hours
PARACETAMOL (CAS 103-90-2)		
Aquatic		
<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
POLYVINYLPIRROLIDONE (CAS 25249-54-1)		
<i>Acute</i>		
	IC50	Activated sludge > 1000 mg/l, 3 hours Static test
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (<i>Daphnia magna</i>) 84 mg/l, 48 hours Static test

Components		Species	Test Results
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours Static test
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
POVIDONE 30 (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
SODIUM BICARBONATE (CAS 144-55-8)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Algae (Nitscheria linearis)	650 mg/l, 5 days
Crustacea	EC50	Water flea (Daphnia magna)	2350 mg/l, 48 hours Static test
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			
<i>Acute</i>			
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			
<i>Acute</i>			
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 100 g/l, 24 hours Static renewal test
TITANIUM DIOXIDE (CAS 13463-67-7)			
Aquatic			
<i>Acute</i>			
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)

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CITRIC ACID ANHYDROUS	98 %, 2 days Modified Zahn-Wellens, Activated sludge
MAGNESIUM STEARATE	77 %, 28 days BOD
PARACETAMOL	99 %, 5 days Modified Zahn-Wellens, Activated sludge
POLYVINYLPIRROLIDONE	0 %, 28 days Modified MITI test, Activated sludge
POLYVINYLPIRROLIDONE	0 %, 28 days Modified MITI test, Activated sludge
POVIDONE 30	0 %, 28 days Modified MITI test, Activated sludge

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days
--------------------	---------------

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

D-SORBITOL	-2.2
PARACETAMOL	0.36

Bioconcentration factor (BCF)

D-SORBITOL	1 Estimated
MAGNESIUM STEARATE	> 9999 Estimated

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

D-SORBITOL	0.3 Estimated
MAGNESIUM STEARATE	5.86 Estimated

Mobility in general

Volatility

Henry's law

CITRIC ACID ANHYDROUS	< 0 atm m ³ /mol Calculated, 25 °C
D-SORBITOL	0 atm m ³ /mol Estimated
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 allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international 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

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

One or more components are not listed on TSCA.

Country(s) or region	Inventory name	On inventory (yes/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	08-21-2014
Revision date	08-21-2014
Version #	14
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: Undisclosed Ingredient Statement Fire-fighting measures: General fire hazards Exposure controls/personal protection: Appropriate engineering controls Toxicological information: Further information Ecological information: Ecotoxicity Ecological information: Bioaccumulative potential Ecological information: Other adverse effects