SAFETY DATA SHEET

1. Identification

Product identifier **BEECHAMS ULTRA ALL IN ONE CAPSULES**

Other means of identification

Synonyms PROJECT POD 2 * MFC 885081 * PARACETAMOL, GUAIPHENESIN AND PHENYLEPHRINE HYDROCHLORIDE, FORMULATED PRODUCT

Recommended use Medicinal Product

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

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
PARACETAMOL	ACETAMIDE, N-(4-HYDROXYPHENYL)- * ACETANILIDE, 4'-HYDROXY- * 4'-HYDROXYACETANILIDE * PANADOL * PARACETAMOL * TYLENOL * PARA-ACETAMIDOPHENOL * 4-ACETAMINOPHENOL * PARA-HYDROXYACETANILIDE	103-90-2	65.0 - 66.0

Chemical name	Common name and synonyms	CAS number	%
GUAIPHENESIN	1,2-PROPANEDIOL, 3-(2-METHOXYPHENOXY)- * 3-(2-METHOXYPHENOXY)-1,2-PROPANEDIOL * GLYCEROL GUAIACOLATE * GLYCEROL ALPHA-GUAIACYL ETHER * ALPHA-GLYCERYL GUAIACOLATE ETHER * GLYCERYL GUAIACOL ETHER * O-METHOXYPHENYL GLYCERYL ETHER * ROBITUSSIN * 1,2-DIHYDROXY-3-(2-METHOXYPHENOXY)PROPANE	93-14-1	13.0 - 14.0
DODECYL SODIUM SULFATE	DODECYL SULFATE, SODIUM SALT * SODIUM LAURYL SULPHATE * LAURYL SULFATE SODIUM SALT	151-21-3	<1.0
PHENYLEPHRINE HYDROCHLORIDE	(-)-M-HYDROXY-ALPHA-((METHYLAMINO)METHYL)BENZYL ALCOHOL HYDROCHLORIDE * ISOPHRIN HYDROCHLORIDE * LEVOPHENYLEPHRINE HYDROCHLORIDE * METAOXEDRINE HYDROCHLORIDE * META-SYNEPHRINE HYDROCHLORIDE * NEOPHRYN * NEO-SYNEPHRINE HYDROCHLORIDE * L-PHENYLEPHRINE HYDROCHLORIDE * BENZENEMETHANOL, 3-HYDROXY-ALPHA-(METHYLAMINO)METHYL)-, HYDROCHLORIDE, (R)-	61-76-7	<1.0
TALC	TALCUM, NON-ASBESTOS FORM * TALC * HYDROUS MAGNESIUM SILICATE	14807-96-6	<1.0
D&C YELLOW #10	C.I. ACID YELLOW 3 * ACID YELLOW 3 * D & C YELLOW NO.10 * QUINOLINE YELLOW * QUINOLINE YELLOW EXTRA	8004-92-0	<0.1
TITANIUM DIOXIDE	TITANIUM OXIDE * TITANIUM(IV) OXIDE * TITANIUM PEROXIDE (TiO2) * PIGMENT WHITE 6	13463-67-7	<0.1
Other components below reportable levels			15.0 - 20.0

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

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

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

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

Most important symptoms/effects, acute and delayed None known.

Indication of immediate medical attention and special treatment needed No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

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

5. Fire-fighting measures

Suitable extinguishing media Water. Foam. Dry chemical powder. Carbon dioxide (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 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	Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.
Conditions for safe storage, including any incompatibilities	Store locked up. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value
DODECYL SODIUM SULFATE (CAS 151-21-3)	OHC	2
GUAIPHENESIN (CAS 93-14-1)	8 HR TWA	600 mcg/m3
	OHC	2
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m3
	OHC	1
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)	15 MIN STEL	200 mcg/m3
	8 HR TWA	30 mcg/m3
	OHC	3

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

Components	Type	Value	Form
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	

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

Components	Type	Value	Form
		2.4 mppcf	Respirable.

US. ACGIH Threshold Limit Values

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

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Skin protection

Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state Solid.

Form Capsule.

Color Not available.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

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

11. Toxicological information

Information on likely routes of exposure

Ingestion	Harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Symptoms related to the physical, chemical and toxicological characteristics	None known.

Information on toxicological effects

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

Components	Species	Test Results
D&C YELLOW #10 (CAS 8004-92-0)		
Acute		
Oral		
LD50	Rat	2000 mg/kg
DODECYL SODIUM SULFATE (CAS 151-21-3)		
Acute		
Oral		
LD50	Rat	1288 mg/kg
GUAIPHENESIN (CAS 93-14-1)		
Acute		
Oral		
LD50	Rat	1510 mg/kg
PARACETAMOL (CAS 103-90-2)		
Acute		
Oral		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg

Components	Species	Test Results
Subacute		
Oral		
NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
Subchronic		
Oral		
NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous
TD	Rat	>= 12500 ppm, 13 weeks dietary, continuous
Other		
LOAEL	Mouse	130 ppm, 61 weeks dietary, continuous
NOAEL	Mouse	3200 ppm, 13 weeks dietary, continuous
		0.3 %, 41 weeks dietary, continuous
TD	Mouse	6100 ppm, 13 weeks dietary, continuous
		1.25 %, 41 weeks dietary, continuous
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)		
Acute		
Oral		
LD50	Rat	350 mg/kg
Subacute		
Oral		
NOAEL	Mouse	2000 ppm, 14 Day Dietary study, highest dose tested.
	Rat	2000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
Oral		
LD	Mouse	5000 - 20000 ppm, 12 weeks dietary study
	Rat	5000 - 20000 ppm, 12 weeks dietary study
LOAEL	Mouse	1250 ppm, 12 weeks dietary study
	Rat	1250 ppm, 12 weeks dietary study
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.

Components	Species	Test Results
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	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
PHENYLEPHRINE HYDROCHLORIDE	Supplier SDS Result: Non-irritant Species: Rabbit Notes: US Pharmacopeia

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

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

Serious eye damage/eye irritation Health injuries are not known or expected under normal use.

Eye

PHENYLEPHRINE HYDROCHLORIDE	Clinical use Result: Pharmacological, cardiovascular effects. Species: Human
PARACETAMOL	OECD 405 Result: Slight irritant Species: Rabbit
TITANIUM DIOXIDE	OECD 405, Literature data Result: Mild irritant Species: Rabbit
PHENYLEPHRINE HYDROCHLORIDE	Supplier SDS Result: Irritant

Eye / Initial pain reaction score

PARACETAMOL	Literature data

Respiratory or skin sensitization

Respiratory sensitization Not available.

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

Sensitization

TITANIUM DIOXIDE	5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: Negative Species: Guinea pig Test Duration: 48 hour exposure
PHENYLEPHRINE HYDROCHLORIDE	Clinical use - Opthalmology Result: Low incidence of contact hypersensitivity. Species: Human
TITANIUM DIOXIDE	Patch test, Literature data Result: Negative Species: Human
GUAIPHENESIN	SAR / QSAR, DEREK, Lhasa, UK Result: Negative

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

Mutagenicity

PHENYLEPHRINE HYDROCHLORIDE	Ames Result: Negative Notes: NTP Study report - Phenylephrine.
PARACETAMOL	Ames, Literature data Result: Negative
TITANIUM DIOXIDE	Ames, Literature data Result: Negative
PHENYLEPHRINE HYDROCHLORIDE	Chromosomal Aberration Assay In Vitro, CHO cells Result: Negative Notes: NTP Study report - Phenylephrine.
PARACETAMOL	Chromosomal Aberration Assay In Vitro, Literature data Result: Positive HPRT gene mutation in human lymphocytes, Literature data Result: Negative In vivo Micronucleus, Literature data Result: Negative Species: Mouse
PHENYLEPHRINE HYDROCHLORIDE	L5178Y mouse lymphoma thymidine kinase locus assay Result: Equivocal Notes: NTP Study report - Phenylephrine.
TITANIUM DIOXIDE	Micronucleus Assay in vitro, CHO cells, Literature data Result: Negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: Positive
GUAIPHENESIN	SAR / QSAR, DEREK, Lhasa, UK Result: Negative
TITANIUM DIOXIDE	Syrian Hamster Embryo (SHE) cell transformation assay Result: Negative WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: Positive
PHENYLEPHRINE HYDROCHLORIDE	sister chromatid exchange Result: Positive Notes: NTP Study report - Phenylephrine.

Carcinogenicity Health injuries are not known or expected under normal use. Contains a material (titanium dioxide) classified as a carcinogen by external agencies. Titanium Dioxide produced carcinogenic effects in a lifetime study in mice. 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
PHENYLEPHRINE HYDROCHLORIDE	133 - 270 mg/kg/day Result: Negative Species: Mouse Test Duration: 103 weeks Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride. 24 - 50 mg/kg/day Result: Negative Species: Rat Test Duration: 103 weeks Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride.

Carcinogenicity

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
PARACETAMOL	Literature data Result: Equivocal. Increase in ademomas at toxic dose. Species: Mouse Literature data Result: Equivocal. Liver and bladder neoplasms at toxic doses. Species: Rat Literature data Result: Negative Species: Mouse Literature data Result: Negative Species: Rat
GUAIPHENESIN	SAR / QSAR, DEREK, Lhasa, UK Result: Negative

IARC Monographs. Overall Evaluation of Carcinogenicity

PARACETAMOL (CAS 103-90-2)	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 Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

Reproductivity

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 750 mg/kg/day Embryofetal Development, Literature data Result: decrease in foetal weght, minor skeletal abnormalities. Species: Rat <= 1400 mg/kg/day Pre- and Post-natal development, Literature data Result: reduced weight gain during nursing. Species: Rat
GUAIPHENESIN	Embryofetal Development, Epidemiology Result: No clear association with developmental effects. Species: Human
PHENYLEPHRINE HYDROCHLORIDE	Epidemiology Result: Equivocal, evidence of malformations, or other adverse foetal effectw from clinical use. Other studies show no such association. Species: Human
PARACETAMOL	Epidemiology, Literature data Result: No clear association with therapeutic use. Species: Human
PHENYLEPHRINE HYDROCHLORIDE	Result: Foetal growth retardation and onset of early delivery at doses equivalent to clinical exposure. Species: Rabbit

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

Specific target organ toxicity - single exposure

PHENYLEPHRINE HYDROCHLORIDE	Clinical use Organ: Cardiovascular effects, some marked.
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.

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
DODECYL SODIUM SULFATE (CAS 151-21-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	5.4 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	4.6 mg/l, 96 hours Flow-through test
Chronic			
Algae	NOEC	Green algae (Desmodesmus subspicatus)	30 mg/l, 72 hours
Crustacea	NOEC	Ceriodaphnia dubia	0.88 mg/l, 7 days Flow-though Test
Fish	NOEC	Fathead minnow (Pimephales promelas)	3.8 mg/l, 28 days Flow-through test
GUAIPHENESIN (CAS 93-14-1)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 100 mg/l, 24 hours
PARACETAMOL (CAS 103-90-2)			
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	134 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	50 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	814 mg/l, 96 hours Flow-through test
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	> 124 mg/l, 72 hours Measured
	NOEC	Algae	31 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	0.86 mg/l, 48 hours Measured
	NOEC	Daphnia	0.21 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	> 100 mg/l, 96 hours Measured
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	100 mg/l, 96 hours
TALC (CAS 14807-96-6)			
Aquatic			
Acute			
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 100 g/l, 24 hours Static renewal test

Components		Species	Test Results
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

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

PARACETAMOL	99 %, 5 days Modified Zahn-Wellens, Activated sludge
PHENYLEPHRINE HYDROCHLORIDE	81 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge 99 %, 7 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

DODECYL SODIUM SULFATE	1.6
GUAIPHENESIN	-0.98
PARACETAMOL	0.36
PHENYLEPHRINE HYDROCHLORIDE	0.49 (Measured).

Mobility in soil Not available.

Mobility in general Not available.

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).

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

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

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

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

TALC (CAS 14807-96-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

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

TALC (CAS 14807-96-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

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

TALC (CAS 14807-96-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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

Country(s) or region	Inventory name	On inventory (yes/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	08-27-2014
Revision date	08-27-2014
Version #	02
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: Product and Company Identification Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: