

1. Identification

Product identifier

BEECHAMS POWDERS CAPSULES

Other means of identification

Synonyms

R&D CODE A32/12 * ITEM CODE 801J0 * PARACETAMOL 300 MG, CAFFEINE 25 MG AND PHENYLEPHRINE HYDROCHLORIDE 5 MG CAPSULES * PARACETAMOL, CAFFEINE AND PHENYLEPHRINE HYDROCHLORIDE, FORMULATED PRODUCT

Recommended use

Medicinal Product

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

Recommended restrictions

No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

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

2. Hazard(s) identification

Classified hazards

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

Label elements

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

Hazard(s) not otherwise classified (HNOC)

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

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
PARACETAMOL	ACETAMIDE, N-(4-HYDROXYPHENYL)- * ACETANILIDE, 4'-HYDROXY- * 4'-HYDROXYACETANILIDE * PANADOL * PARACETAMOL * TYLENOL * PARA-ACETAMIDOPHENOL * 4-ACETAMINOPHENOL * PARA-HYDROXYACETANILIDE	103-90-2	< 70
CAFFEINE	TRIMETHYLXANTHINE * METHYLTHEOBROMINE * CAFFEINE ANHYDROUS	58-08-2	< 6

Chemical name	Common name and synonyms	CAS number	%
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)MET HYL)-, HYDROCHLORIDE, (R)-	61-76-7	< 1.5
SILICON DIOXIDE	SILICA * SILICA GEL * AMORPHOUS SILICA * DIATOMACEOUS EARTH * INFUSORIAL EARTH * CAB-O-SIL M-5	7631-86-9	< 0.25
Other components below reportable levels			< 25

*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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
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Methods and materials for containment and cleaning up

Stop the flow of material, if this is without risk. Collect spillage. Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Collect dust using a vacuum cleaner equipped with HEPA filter. Prevent entry into waterways, sewer, basements or confined areas. Prevent product from entering drains. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage**Precautions for safe handling**

Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection**Occupational exposure limits****GSK****Components****Type****Value**

CAFFEINE (CAS 58-08-2)

8 HR TWA

200 mcg/m3

OHC

2

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

SILICON DIOXIDE (CAS 7631-86-9)

OHC

1

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

SILICON DIOXIDE (CAS 7631-86-9)

TWA

0.8 mg/m3

20 millions of
particle**US. NIOSH: Pocket Guide to Chemical Hazards****Components****Type****Value**

SILICON DIOXIDE (CAS 7631-86-9)

TWA

6 mg/m3

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.

Incompatible materials Alkaline metals. Peroxides.

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
CAFFEINE (CAS 58-08-2)		
Acute		
<i>Dermal</i>		
LD50	Rat	> 2000 mg/kg
<i>Oral</i>		
LD50	Rat	192 mg/kg
Subchronic		
<i>Oral</i>		
NOAEL	Mouse	167 - 179 mg/kg/day Dosed in drinking water - Continuous
	Rat	151 - 174 mg/kg/day Dosed in drinking water - Continuous
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
<i>Other</i>		
LOAEL	Mouse	130 ppm, 61 weeks dietary, continuous
NOAEL	Mouse	3200 ppm, 13 weeks dietary, continuous
		0.3 %, 41 weeks dietary, continuous
TD	Mouse	6100 ppm, 13 weeks dietary, continuous
		1.25 %, 41 weeks dietary, continuous
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)		
Acute		
<i>Oral</i>		
LD50	Rat	350 mg/kg
Subacute		
<i>Oral</i>		
NOAEL	Mouse	2000 ppm, 14 Day Dietary study, highest dose tested.
	Rat	2000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
<i>Oral</i>		
LD	Mouse	5000 - 20000 ppm, 12 weeks dietary study

Components	Species	Test Results
LOAEL	Rat	5000 - 20000 ppm, 12 weeks dietary study
	Mouse	1250 ppm, 12 weeks dietary study
	Rat	1250 ppm, 12 weeks dietary study
* 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		
CAFFEINE		Literature data Result: Non-irritant Species: Rabbit
PHENYLEPHRINE HYDROCHLORIDE		Supplier SDS Result: Non-irritant Species: Rabbit Notes: US Pharmacopeia
Irritation Corrosion - Skin: P.I.I. value		
PARACETAMOL		OECD 404, Literature data Result: Slight irritant Species: Rabbit
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use.	
Eye		
PHENYLEPHRINE HYDROCHLORIDE		Clinical use Result: Pharmacological, cardiovascular effects. Species: Human
CAFFEINE		Literature data Result: Not likely to be a severe irritant Species: Rabbit
PARACETAMOL		OECD 405 Result: Slight irritant Species: Rabbit
PHENYLEPHRINE HYDROCHLORIDE		Supplier SDS Result: Irritant
Eye / Initial pain reaction score		
PARACETAMOL		Literature data
Respiratory or skin sensitization		
Respiratory sensitization	Not available.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Sensitization		
PHENYLEPHRINE HYDROCHLORIDE		Clinical use - Ophthalmology Result: Low incidence of contact hypersensitivity. Species: Human
CAFFEINE		Literature data Result: Negative Species: Mouse
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
CAFFEINE		25 - 100 mg/kg Chromosomal Aberration Assay In Vivo Result: Positive Species: Mouse 25 - 100 mg/kg Micronucleus Assay Result: Negative Species: Mouse Ames Result: Negative
PHENYLEPHRINE HYDROCHLORIDE		Ames Result: Negative Notes: NTP Study report - Phenylephrine.
PARACETAMOL		Ames, Literature data Result: Negative
CAFFEINE		Chromosomal Aberration Assay In Vitro Result: Positive

Mutagenicity

PHENYLEPHRINE HYDROCHLORIDE

Chromosomal Aberration Assay In Vitro, CHO cells

Result: Negative

Notes: NTP Study report - Phenylephrine.

PARACETAMOL

Chromosomal Aberration Assay In Vitro, Literature data

Result: Positive

HPRT gene mutation in human lymphocytes, Literature data

Result: Negative

CAFFEINE

In vivo Micronucleus

Result: Positive

PARACETAMOL

In vivo Micronucleus, Literature data

Result: Negative

Species: Mouse

PHENYLEPHRINE HYDROCHLORIDE

L5178Y mouse lymphoma thymidine kinase locus assay

Result: Equivocal

Notes: NTP Study report - Phenylephrine.

CAFFEINE

L5178Y mouse lymphoma thymidine kinase locus assay

Result: Positive

PHENYLEPHRINE HYDROCHLORIDE

sister chromatid exchange

Result: Positive

Notes: NTP Study report - Phenylephrine.

Carcinogenicity

Health injuries are not known or expected under normal use.

CAFFEINE

0.1 - 0.2 %, Dosed in drinking water

Result: Negative

Species: Rat

Test Duration: 78 weeks

PHENYLEPHRINE HYDROCHLORIDE

133 - 270 mg/kg/day

Result: Negative

Species: Mouse

Test Duration: 103 weeks

Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride.

CAFFEINE

200 - 2000 mg/L, Dosed in drinking water

Result: Negative

Species: Rat

Test Duration: 2 years

PHENYLEPHRINE HYDROCHLORIDE

24 - 50 mg/kg/day

Result: Negative

Species: Rat

Test Duration: 103 weeks

Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride.

PARACETAMOL

Literature data

Result: Equivocal. Increase in adenomas at toxic dose.

Species: Mouse

Literature data

Result: Equivocal. Liver and bladder neoplasms at toxic doses.

Species: Rat

Literature data

Result: Negative

Species: Mouse

Literature data

Result: Negative

Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

CAFFEINE (CAS 58-08-2)

3 Not classifiable as to carcinogenicity to humans.

PARACETAMOL (CAS 103-90-2)

3 Not classifiable as to carcinogenicity to humans.

SILICON DIOXIDE (CAS 7631-86-9)

3 Not classifiable as to carcinogenicity 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

Reproductivity

CAFFEINE

25 mg/kg Embryofetal Development

Result: No effect

Species: Rat

PARACETAMOL

250 mg/kg/day Embryofetal Development, Literature data

Result: Foetal NOAEL

Species: Rat

CAFFEINE

300 mg/kg/day

Result: testicular toxicity

Species: Rat

PARACETAMOL

Test Duration: 75 Day

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

CAFFEINE

87.5 mg/kg/day Embryofetal Development

Result: Maternal toxicity; adverse foetal effects

Species: Mouse

PARACETAMOL

<= 1400 mg/kg/day Pre- and Post-natal development, Literature data

Result: reduced weight gain during nursing.

Species: Rat

CAFFEINE

>= 301 mg/day Epidemiology

Result: delayed conception

Species: Human

PHENYLEPHRINE HYDROCHLORIDE

Epidemiology

Result: Equivocal, evidence of malformations, or other adverse foetal effects from clinical use. Other studies show no such association.

Species: Human

PARACETAMOL

Epidemiology, Literature data

Result: No clear association with therapeutic use.

Species: Human

PHENYLEPHRINE HYDROCHLORIDE

Result: Foetal growth retardation and onset of early delivery at doses equivalent to clinical exposure.

Species: Rabbit

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

PHENYLEPHRINE HYDROCHLORIDE

Clinical use

Organ: Cardiovascular effects, some marked.

CAFFEINE

Literature data

Organ: Nervous system; Cardiovascular system

PARACETAMOL

Species: Human

Organ: Liver

Specific target organ toxicity - repeated exposure May cause damage to organs through prolonged or repeated exposure by ingestion.**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. Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
CAFFEINE (CAS 58-08-2)			
Aquatic			
<i>Acute</i>			
Activated Sludge Respiration	IC50	Residential sludge	> 1000 mg/l, 3 hours Nominal, OECD 209
	NOEC	Residential sludge	1000

Components		Species	Test Results
Algae	EC50	Green algae (Scenedesmus subspicatus)	> 100 mg/l, 72 hours Measured, OECD 201
	NOEC	Algae	100 mg/l
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 OECD 203
Microtox	EC50	Microtox	733 mg/l, 5 minutes
PARACETAMOL (CAS 103-90-2)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Scenedesmus subspicatus)	134 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	50 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	814 mg/l, 96 hours Flow-through test
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Selenastrum capricornutum)	> 124 mg/l, 72 hours Measured
	NOEC	Algae	31 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	0.86 mg/l, 48 hours Measured
	NOEC	Daphnia	0.21 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	> 100 mg/l, 96 hours Measured
	NOEC	Rainbow trout (Adult Oncorhynchus mykiss)	100 mg/l, 96 hours
SILICON DIOXIDE (CAS 7631-86-9)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes

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

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

CAFFEINE 2.5 Hours Estimated

UV/visible spectrum wavelength

CAFFEINE 227 nm

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)

CAFFEINE	-0.07
	-0.0907
PARACETAMOL	0.36
PHENYLEPHRINE HYDROCHLORIDE	0.49 (Measured).
Bioconcentration factor (BCF)	
CAFFEINE	0.52 - 2.25 Estimated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

CAFFEINE	1.25 - 1.34 Estimated
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Mobility in general

Volatility

Henry's law

CAFFEINE	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 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

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**

SILICON DIOXIDE (CAS 7631-86-9)

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

SILICON DIOXIDE (CAS 7631-86-9)

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

SILICON DIOXIDE (CAS 7631-86-9)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

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

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
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)	Yes
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 08-01-2014
Revision date 08-01-2014
Version # 12

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: Business Units Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Regulatory Information: United States GHS: Classification