



SAFETY DATA SHEET

1. Identification

Product identifier

OS-CAL TABLETS

Other means of identification

Synonyms

OSCAL ULTRA TABLETS * OSCAL 500 + D * OS-CAL ULTRA 600 PLUS (US) * MFC 50066475 *
CALCIUM CARBONATE AND VITAMIN/MINERAL, FORMULATED PRODUCT

Recommended use

Food Supplement

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	%
CALCIUM CARBONATE	CARBONIC ACID, CALCIUM SALT * CALCIUM MONOCARBONATE * PRECIPITATED CALCIUM CARBONATE * CHALK	471-34-1	78.6 - 83.73
L-ASCORBIC ACID	VITAMIN C	50-81-7	3.8
SODIUM STARCH GLYCOLATE	STARCH, CARBOXYMETHYL ETHER, SODIUM SALT * CARBOXYMETHYL STARCH SODIUM SALT * EXPLOTAB * SODIUM CARBOXYMETHYL STARCH * SODIUM CM-STARCH * 738 (GW ACN) * CARBOXYMETHYLSTÄRKE, NATRIUMSALZ * SODIUM STARCH GLYCOLATE	9063-38-1	1 - < 3

Chemical name	Common name and synonyms	CAS number	%
MAGNESIUM OXIDE	GI197895X * MAGNESIA * MAGNESIUM MONOXIDE * CALCINED MAGNESIA * CALCINATED MAGNESIA * CAUSTIC MAGNESITE * MAGNESA PREPRATA * MAGNESIUM (II) OXIDE * SYNTHETIC PERICLASE * BURNT MAGNESIA * CI 77711 * LIGHT MAGNESIA * OXIDO DE MAGNESIO * ÓXIDO DE MAGNESIO,	1309-48-4	1.8
TOCOPHEROL ACETATE	BP-894 * VITAMIN E ACETATE * ALFACOL * COMBINAL E * CONTOPHERON * ECOFROL * E-FEROL * EPHYNAL ACETATE * E-TOPLEX * FERTILVIT * TOCOPHEREX * D-ALPHA-TOCOPHEROL ACETATE * (2R,4'R,8'R)-ALPHA-TOCOPHEROL ACETATE * (R,R,R)-ALPHA-TOCOPHEROL ACETATE * (+)-ALPHA-TOCOPHEROL ACETATE * TOCOPHRIN * TOFAXIN * TOKOFEROL ACETATE * D-ALPHA-TOCOPHERYL ACETATE * OHS60926 * RTECS GP8280000	58-95-7	1.02
ZINC OXIDE	ZINC MONOXIDE	1314-13-2	0.53
STARCH	ARROWROOT STARCH * CORN STARCH * POTATO STARCH * RICE STARCH	9005-25-8	< 1
TALC	TALCUM, NON-ASBESTOS FORM * TALC * HYDROUS MAGNESIUM SILICATE	14807-96-6	< 1
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	0.49
COPPER GLUCONATE	CUPRIC GLUCONATE	527-09-3	0.43
MANGANOUS SULFATE MONOHYDRATE	MANGAANI-(II)-SULFAATTI, MONOHYDRAATTI * MANGANESE (II) SULFATE MONOHYDRATE * MANGANESE SULFATE * MANGANESE(II) SULFATE MONOHYDRATE * GI151069B * MANGANESE SULFATE MONOHYDRATE	10034-96-5	0.19
POLYETHYLENE GLYCOL 3350	ALPHA-HYDRO-OMEGA-HYDROXY-POLY(OXY-1,2-ETHANEDIYL) * PEG * POLY G * CARBOWAX * POLYGLYCOL E * POLYOXYETHYLENE 3350 * CARBOWAX POLYETHYLENE GLYCOL 3350 * CARBOWAX PEG 3350 * OHS19124 * RTECS TQ4050000	25322-68-3	< 0.3
TITANIUM DIOXIDE	TITANIUM OXIDE * TITANIUM(IV) OXIDE * TITANIUM PEROXIDE (TiO2) * PIGMENT WHITE 6	13463-67-7	< 0.3
HYDROXYPROPYL METHYL CELLULOSE	METHOCEL K4M * GONIOSOL * ISOPRO ALKALINE * METHOCEL E,F,K * METHOCEL HG * METHYL CELLULOSE PROPYLENE GLYCOL ETHER * HYPROMELLOSE * CELLULOSE, 2-HYDROXYPROPYL METHYL ESTER * METHYLHYDROXYPROPYLCELLULOSE * PHARMACOAT 603	9004-65-3	0.12
CALCIUM STEARATE	CALCIUM DISTEARATE	1592-23-0	< 0.2
SUCROSE	SUGAR * CANE SUGAR * BEET SUGAR * CONFECTIONER'S SUGAR * ALPHA-D-GLUCOPYRANOSIDE, BETA-D-FRUCTOFURANOSYL * GRANULATED SUGAR * SUCRALOX	57-50-1	< 0.2
BORIC ACID	SB-258264 * ORTHOBORIC ACID * BORACIC ACID	10043-35-3	< 0.1

Chemical name	Common name and synonyms	CAS number	%
PROPYL PARABEN	PROPYL P-HYDROXYBENZOATE * PROTABEN * 4-HYDROXYBENZOIC ACID, PROPYL ESTER * P-HYDROXYBENZOIC ACID, PROPYL ESTER * PASEPTOL * PARASEPT * PROPYL ASEPTOFORM * PROPYL P-OXYBENZOATE	94-13-3	< 0.1
SILICON DIOXIDE	SILICA * SILICA GEL * AMORPHOUS SILICA * DIATOMACEOUS EARTH * INFUSORIAL EARTH * CAB-O-SIL M-5	7631-86-9	< 0.1
SORBIC ACID	2,4-HEXADIENOIC ACID * SORBISTAT * 2,4-HEXADIENOIC ACID, (E,E)- * E,E-2,4-HEXADIENOIC ACID * (E,E)-2,4-HEXADIENOIC ACID * TRANS, TRANS-2,4-HEXADIENOIC ACID * TRANS, TRANS-SORBIC ACID * (E,E)-SORBIC ACID * 2-PROPENYL-ACRYLIC ACID * HEXA-2,4-DIENSYRE * GI148909X	110-44-1	0.05
SOYBEAN OIL	DEGUMMED SOYBEAN OIL * SOYA BEAN OIL * CHINESE BEAN OIL * SOY OIL	8001-22-7	< 0.1
SODIUM BENZOATE	BENZOIC ACID, SODIUM SALT * BENZOATE OF SODA * SODIUM BENZOIC ACID	532-32-1	0.02
CHOLECALCIFEROL	CALCIOL * VITAMIN D3	67-97-0	<0.01
D-ALPHA-TOCOPHEROL	(+)-ALPHA-TOCOPHEROL * (2R-(2R*(4R*,8R*))) -3,4-DIHYDRO-2,5,7,8-T ETRAMETHYL-2 -(4,8,12- TRIMETHYLTRIDECYL)-2H-BENZOPYRAN -6-OL * (2R,4'R,8'R)-ALPHA-TOCOPHEROL * (R,R,R)-ALPHA-TOCOPHEROL * 2,5,7,8-TETRAMETHYL-2-(4',8',12'-TRIMET HYLTRIDECYL)-6 -CHROMANOL * 2H-1-BENZOPYRAN-6-OL, 3,4-DIHYDRO-2,5,7,8-TETRAMETHYL-2-(4, 8,12-TRIMETHYLTRIDECYL)-, (2R-(2R*(4R*,8R*))) - * 5,7,8-TRIMETHYLTOCOL * ALPHA TOCOPHEROL * ALPHA-TOCOPHEROL * AMLMEFROL * ANTISTERILITY VITAMIN * COVI-OX * COVITOL F 1000 * D-5,7,8-TRIMETHYLTOCOL * DENAMONE * D-PHYTOGERMINE * D-PROFECUNDIN * D-VITAMIN E * E 307 * EMIPHEROL * ENDO E * EPHYNAL * EPISILAN * EPROLIN * EPROLIN S * EPSILAN * ESORB * ETAMICAN * ETAVIT * EVION * EVITAMINUM * ILITIA * PHYTOGERMIN * PHYTOGERMINE * PROFECUNDIN * RHENOGRAN RONOTEC 50 * RRR-ALPHA-TOCOPHEROL * RTECS DJ2900000 * SPAVIT E * SYNTOPHEROL * TENOX GT 1 * TOKOPHARM * VASCUALS * VERRROL * VITAMIN E * VITAMIN E ALPHA * VITAPLEX E * VITAYONON * VITEOLIN	59-02-9	<0.01

Other components below reportable levels

10 - < 20

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.

Skin contact

Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Remove and isolate contaminated clothing and shoes. Get medical attention if symptoms occur.

Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Rinse with water.
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	Dusts may irritate the respiratory tract, skin and eyes.
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	Foam. Dry chemical powder. Carbon dioxide (CO ₂). Water.
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.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Collect spillage. Prevent entry into waterways, sewer, basements or confined areas. 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	Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment. Do not empty into drains. Observe good industrial hygiene practices.
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	Note
CHOLECALCIFEROL (CAS 67-97-0)	8 HR TWA	0.2 mcg/m ³	SKIN
D-ALPHA-TOCOPHEROL (CAS 59-02-9)	OHC	5	SKIN
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)	OHC	1	

GSK Components	Type	Value	Note
L-ASCORBIC ACID (CAS 50-81-7)	8 HR TWA	5000 mcg/m3	
	OHC	1	
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
PROPYL PARABEN (CAS 94-13-3)	8 HR TWA	5000 mcg/m3	
	OHC	1	
SILICON DIOXIDE (CAS 7631-86-9)	OHC	1	
SODIUM BENZOATE (CAS 532-32-1)	8 HR TWA	5000 mcg/m3	
	OHC	1	
SODIUM STARCH GLYCOLATE (CAS 9063-38-1)	OHC	1	
SORBIC ACID (CAS 110-44-1)	OHC	2	SKIN SENSITISER
ZINC OXIDE (CAS 1314-13-2)	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.
MAGNESIUM OXIDE (CAS 1309-48-4)	PEL	15 mg/m3	Total particulate.
MANGANOUS SULFATE MONOHYDRATE (CAS 10034-96-5)	Ceiling	5 mg/m3	
SOYBEAN OIL (CAS 8001-22-7)	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.
SUCROSE (CAS 57-50-1)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.
ZINC OXIDE (CAS 1314-13-2)	PEL	5 mg/m3	Respirable fraction.
		5 mg/m3	Fume.
		15 mg/m3	Total dust.

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

Components	Type	Value	Form
SILICON DIOXIDE (CAS 7631-86-9)	TWA	0.8 mg/m3	
		20 mppcf	
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
BORIC ACID (CAS 10043-35-3)	STEL	6 mg/m3	Inhalable fraction.
	TWA	2 mg/m3	Inhalable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
CALCIUM STEARATE (CAS 1592-23-0)	TWA	10 mg/m3	
MAGNESIUM OXIDE (CAS 1309-48-4)	TWA	10 mg/m3	Inhalable fraction.
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	
MANGANOUS SULFATE MONOHYDRATE (CAS 10034-96-5)	TWA	0.1 mg/m3	Inhalable fraction.
		0.02 mg/m3	Respirable fraction.
STARCH (CAS 9005-25-8)	TWA	10 mg/m3	
SUCROSE (CAS 57-50-1)	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	
ZINC OXIDE (CAS 1314-13-2)	STEL	10 mg/m3	Respirable fraction.
	TWA	2 mg/m3	Respirable fraction.

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
COPPER GLUCONATE (CAS 527-09-3)	TWA	1 mg/m3	Dust and mist.
MANGANOUS SULFATE MONOHYDRATE (CAS 10034-96-5)	STEL	3 mg/m3	Fume.
	TWA	1 mg/m3	Fume.
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m3	
SOYBEAN OIL (CAS 8001-22-7)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Mist.
STARCH (CAS 9005-25-8)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
SUCROSE (CAS 57-50-1)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable.
ZINC OXIDE (CAS 1314-13-2)	Ceiling	15 mg/m3	Dust.
	STEL	10 mg/m3	Fume.
	TWA	5 mg/m3	Fume.
		5 mg/m3	Dust.

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
POLYETHYLENE GLYCOL 3350 (CAS 25322-68-3)	TWA	10 mg/m3	Particulate.

Biological limit values

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

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. 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**

Chemical goggles are recommended. 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	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.

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	Fluorine.

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	Expected to be a low ingestion hazard. Health injuries are not known or expected under normal use.
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.

Symptoms related to the physical, chemical and toxicological characteristics

Dusts may irritate the respiratory tract, skin and eyes.

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

Components	Species	Test Results
BORIC ACID (CAS 10043-35-3)		
Acute		
<i>Oral</i>		
LD50	Rat	2500 mg/kg oral
CALCIUM CARBONATE (CAS 471-34-1)		
Acute		
<i>Oral</i>		
LD50	Rat	6450 mg/kg
CALCIUM STEARATE (CAS 1592-23-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
CHOLECALCIFEROL (CAS 67-97-0)		
Acute		
<i>Oral</i>		
LD50	Dog	80 mg/kg ; RTECS data
	Mouse	42.5 mg/kg ; RTECS data
	Rat	42 mg/kg ; RTECS data
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
L-ASCORBIC ACID (CAS 50-81-7)		
Acute		
<i>Oral</i>		
LD50	Rat	11.9 g/kg
Subchronic		
<i>Oral</i>		
NOAEL	Rat	2000 mg/kg/day
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg

Components	Species	Test Results
POLYETHYLENE GLYCOL 3350 (CAS 25322-68-3)		
Acute		
<i>Oral</i>		
LD50	Rat	> 20 g/kg
PROPYL PARABEN (CAS 94-13-3)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 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.
ZINC OXIDE (CAS 1314-13-2)		
Acute		
<i>Inhalation</i>		
LC50	Rat	> 200 mg/l
<i>Oral</i>		
LD50	Rat	> 8437 mg/kg

* 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
L-ASCORBIC ACID

Acute dermal irritation; OECD 404
Result: Non-irritant
Species: Rabbit

TITANIUM DIOXIDE

Notes: EU SCC Review 1986-1990
Acute dermal irritation; OECD 404, Literature data
Result: Non-irritant
Species: Rabbit

Irritation Corrosion - Skin		
TITANIUM DIOXIDE		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
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.	
Eye		
L-ASCORBIC ACID		Acute ocular irritation; OECD 405 Result: Slight irritant Species: Rabbit
		Notes: EU SCC Review 1986-1990
TITANIUM DIOXIDE		OECD 405, Literature data Result: Mild irritant Species: Rabbit
Eye / Kay and Calandra class - Intact		
MAGNESIUM STEARATE		4 Recovery Period: 2 days
Respiratory or skin sensitization		
Respiratory sensitization	Health injuries are not known or expected under normal use.	
Skin sensitization	Health injuries are not known or expected under normal use.	
Maximisation assay (Magnusson and Kligman)		
HYDROXYPROPYL METHYL CELLULOSE		Result: Negative Species: Guinea pig
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
CHOLECALCIFEROL		SAR / QSAR, DEREK, Lhasa, UK Result: No structural alerts identified.
Germ cell mutagenicity	Health injuries are not known or expected under normal use.	
Mutagenicity		
CHOLECALCIFEROL		Ames Assay, GLP assay; Literature data Result: Negative
TITANIUM DIOXIDE		Ames, Literature data Result: Negative 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	Risk of cancer cannot be excluded with prolonged exposure. Health injuries are not known or expected under normal use. Contains a material (talc) 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

Carcinogenicity

TITANIUM DIOXIDE

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

L-ASCORBIC ACID

1000 - 2000 mg/kg/day

Result: Negative

Species: Rat

Notes: UN SIDS Dossier

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

L-ASCORBIC ACID

< 6000 mg/kg/day

Result: Negative

Species: Mouse

Notes: UN SIDS Dossier

CHOLECALCIFEROL

SAR / QSAR, DEREK, Lhasa, UK

Result: No structural alerts identified.

IARC Monographs. Overall Evaluation of Carcinogenicity

SILICON DIOXIDE (CAS 7631-86-9)

3 Not classifiable as to carcinogenicity to humans.

TALC (CAS 14807-96-6)

2B Possibly carcinogenic to humans.

TITANIUM DIOXIDE (CAS 13463-67-7)

3 Not classifiable as to carcinogenicity to humans.

2B Possibly carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity

Health injuries are not known or expected under normal use.

Reproductivity

L-ASCORBIC ACID

1.5 - 100 mg/kg/day Embryo-foetal development

Result: No adverse foetal effects observed

Species: Guinea pig

Notes: EU SCC Review 1986-1990

200 - 2000 mg/kg/day Embryo-foetal development

Result: No adverse foetal effects observed

Species: Rat

Notes: EU SCC Review 1986-1990

5.2 - 520 mg/kg/day Embryo-foetal development

Result: No adverse foetal effects observed

Species: Mouse

Notes: EU SCC Review 1986-1990

CHOLECALCIFEROL

SAR / QSAR, DEREK, Lhasa, UK

Result: As a class vitamin D analogs are suspected of causing foetal malfomation at very high doses; physiological doses are not suspected of causing reproductive hazard

Specific target organ toxicity - single exposure

None known.

Specific target organ toxicity - repeated exposure

CHOLECALCIFEROL

Repeat dose non-clinical studies; clinical observation, Literature data

Organ: Kidney, bone

Species: Human

Organ: Red blood cells, kidneys.

Notes: EU SCC Review 1986-1990

L-ASCORBIC ACID

Aspiration hazard

Not an aspiration hazard.

Chronic effects

Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.

12. Ecological information**Ecotoxicity**

Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
BORIC ACID (CAS 10043-35-3)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)	133 mg/l, 48 hours Static test
Fish	EC50	Channel catfish (Adult <i>Ictalurus punctatus</i>)	22 mg/l, 96 hours
		Rainbow trout (Adult <i>Oncorhynchus mykiss</i>)	100 mg/l, 96 hours
CALCIUM CARBONATE (CAS 471-34-1)			
Aquatic			
Fish	LC50	Western mosquitofish (<i>Gambusia affinis</i>)	> 56000 mg/l, 24 hours
CALCIUM STEARATE (CAS 1592-23-0)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult <i>Oryzias latipes</i>)	266 mg/l, 96 hours
Microtox	EC50	Microtox	25.6 mg/l, 15 minutes
CHOLECALCIFEROL (CAS 67-97-0)			
Aquatic			
<i>Acute</i>			
Algae	NOEC	Green algae (<i>Selenastrum capricornutum</i>)	100 mg/l, 96 hours
Crustacea	NOEC	Water flea (<i>Daphnia magna</i>)	100 mg/l, 48 hours
Fish	NOEC	Golden ide/orfe (Adult <i>Leuciscus idus</i>)	> 10000 mg/l, 96 hours
D-ALPHA-TOCOPHEROL (CAS 59-02-9)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (<i>Selenastrum capricornutum</i>)	> 25.5 mg/l, 72 hours
	NOEC	Green algae (<i>Selenastrum capricornutum</i>)	25.5 mg/l, 72 hours
Fish	EC50	Rainbow trout (Adult <i>Oncorhynchus mykiss</i>)	> 91.1 mg/l, 96 hours
	NOEC	Rainbow trout (Adult <i>Oncorhynchus mykiss</i>)	91.1 mg/l, 96 hours
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Fish	> 100 mg/L, 96 hours
L-ASCORBIC ACID (CAS 50-81-7)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Rainbow trout (Adult <i>Oncorhynchus mykiss</i>)	1020 mg/l, 96 hours
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

Components	Species	Test Results
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
SODIUM BENZOATE (CAS 532-32-1)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) > 100 mg/L, 96 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas) 484 mg/L, 96 hours Flow-through 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
TOCOPHEROL ACETATE (CAS 58-95-7)		
Aquatic		
<i>Acute</i>		
Algae	EC50	Green algae (Selenastrum capricornutum) > 28 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum) 28 mg/l, 72 hours
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss) > 100 mg/l, 96 hours
	NOEC	Rainbow trout (Adult Oncorhynchus mykiss) 100 mg/l, 96 hours
ZINC OXIDE (CAS 1314-13-2)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Daphnia 1 mg/l, 48 hours OECD Guideline 202
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss) 1.1 mg/l, 96 hours Static test
	LC50	Striped bass (Morone saxatilis) 0.25 - 2.46 mg/l, 48 hours

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

CALCIUM STEARATE 17 Hours Estimated

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CALCIUM STEARATE 77 %, 28 days BOD

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

D-ALPHA-TOCOPHEROL	84 %, 28 days Modified MITI (II) Test.
L-ASCORBIC ACID	100 %, 15 days Zahn-Wellens
MAGNESIUM STEARATE	77 %, 28 days BOD
SUCROSE	69 % BOD5
TOCOPHEROL ACETATE	84 %, 28 days Modified MITI (II) Test.

Percent degradation (Aerobic biodegradation-soil)

CALCIUM STEARATE	> 50 %, 13 days
MAGNESIUM STEARATE	50 %, 13 days

Percent degradation (Anaerobic biodegradation)

SODIUM BENZOATE	93 %, 7 days Other degradation test system, Mixed Residential/Industrial
-----------------	--

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

BORIC ACID	0.175 (Calculated).
HYDROXYPROPYL METHYL CELLULOSE	-5
L-ASCORBIC ACID	-2.15
MANGANOUS SULFATE MONOHYDRATE	-2.174 (Calculated).
PROPYL PARABEN	3.04
SODIUM BENZOATE	1.89
SORBIC ACID	1.33
SUCROSE	-3

Bioconcentration factor (BCF)

CALCIUM STEARATE	> 1000 Estimated
HYDROXYPROPYL METHYL CELLULOSE	3.2 Estimated
MAGNESIUM STEARATE	> 9999 Estimated
ZINC OXIDE	> 1000

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

CALCIUM STEARATE	5.86 Estimated
MAGNESIUM STEARATE	5.86 Estimated
SODIUM BENZOATE	1.16 Calculated

Mobility in general

Volatility

Henry's law

HYDROXYPROPYL METHYL CELLULOSE	0 atm m ³ /mol Estimated
SUCROSE	< 0 atm m ³ /mol Estimated

Distribution

Octanol/water distribution coefficient log DOW

PROPYL PARABEN	3.04
----------------	------

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 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 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.

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

SORBIC ACID (CAS 110-44-1) 1.0 % One-Time Export Notification only.

CERCLA Hazardous Substance List (40 CFR 302.4)

COPPER GLUCONATE (CAS 527-09-3) Listed.

MANGANOUS SULFATE MONOHYDRATE (CAS 10034-96-5) Listed.

ZINC OXIDE (CAS 1314-13-2) 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 - No
Delayed Hazard - No
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**

MANGANOUS SULFATE MONOHYDRATE (CAS 10034-96-5)

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**

CALCIUM CARBONATE (CAS 471-34-1)

MAGNESIUM OXIDE (CAS 1309-48-4)

SILICON DIOXIDE (CAS 7631-86-9)

SOYBEAN OIL (CAS 8001-22-7)

STARCH (CAS 9005-25-8)

SUCROSE (CAS 57-50-1)

TALC (CAS 14807-96-6)

TITANIUM DIOXIDE (CAS 13463-67-7)

ZINC OXIDE (CAS 1314-13-2)

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

BORIC ACID (CAS 10043-35-3)

CALCIUM CARBONATE (CAS 471-34-1)

COPPER GLUCONATE (CAS 527-09-3)

MAGNESIUM OXIDE (CAS 1309-48-4)

MANGANOUS SULFATE MONOHYDRATE (CAS 10034-96-5)

SILICON DIOXIDE (CAS 7631-86-9)
TALC (CAS 14807-96-6)
TITANIUM DIOXIDE (CAS 13463-67-7)
ZINC OXIDE (CAS 1314-13-2)

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

CALCIUM CARBONATE (CAS 471-34-1)
MAGNESIUM OXIDE (CAS 1309-48-4)
SILICON DIOXIDE (CAS 7631-86-9)
SOYBEAN OIL (CAS 8001-22-7)
STARCH (CAS 9005-25-8)
SUCROSE (CAS 57-50-1)
TALC (CAS 14807-96-6)
TITANIUM DIOXIDE (CAS 13463-67-7)
ZINC OXIDE (CAS 1314-13-2)

US. Rhode Island RTK

COPPER GLUCONATE (CAS 527-09-3)
MANGANOUS SULFATE MONOHYDRATE (CAS 10034-96-5)
ZINC OXIDE (CAS 1314-13-2)

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	08-22-2014
Revision date	08-22-2014
Version #	06
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 0 Flammability: 1 Physical hazard: 0
NFPA ratings	Health: 0 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: Ingredients
Physical & Chemical Properties:
Toxicological Information:
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection
Regulatory Information: United States
GHS: Classification