SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	OS-CAL TABLETS
Registration number	-
Synonyms	OSCAL ULTRA TABLETS * OSCAL 500 + D * OS-CAL ULTRA 600 PLUS (US) * MFC 50066475 * CALCIUM CARBONATE AND VITAMIN/MINERAL, FORMULATED PRODUCT
Issue date	22-August-2014
Version number	06
Revision date	22-August-2014

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	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.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

Supplemental label information None.

2.3. Other hazards See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Calcium carbonate	78.6 - 83.73	471-34-1 207-439-9	-	-	
Classification: **DSD:** -					
CLP: -					
L-ASCORBIC ACID	3.8	50-81-7 200-066-2	-	-	
Classification: **DSD:** -					
CLP: -					
TOCOPHEROL ACETATE	1 - < 3	58-95-7 200-405-4	-	-	
Classification: **DSD:** R52/53					
CLP: Aquatic Chronic 3;H412					
MAGNESIUM STEARATE	< 1	557-04-0 209-150-3	-	-	
Classification: **DSD:** -					
CLP: -					
Starch	< 1	9005-25-8 232-679-6	-	-	
Classification: **DSD:** -					
CLP: -					
Talc	< 1	14807-96-6 238-877-9	-	-	
Classification: **DSD:** -					
CLP: -					
Zinc oxide	< 1	1314-13-2 215-222-5	-	030-013-00-7	
Classification: **DSD:** Xi;R37, N;R50/53					
CLP: Aquatic Acute 1;H400, Aquatic Chronic 1;H410					
Titanium dioxide	< 0.3	13463-67-7 236-675-5	-	-	
Classification: **DSD:** -					
CLP: -					
HYDROXYPROPYL METHYL CELLULOSE	< 0.2	9004-65-3 -	-	-	
Classification: **DSD:** -					
CLP: -					
Silicon dioxide	< 0.1	7631-86-9 231-545-4	-	-	
Classification: **DSD:** -					
CLP: -					

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
CHOLECALCIFEROL	<0.01	67-97-0 200-673-2	-	603-180-00-4	
Classification: **DSD:** T+;R26, T;R24/25-48/25					
CLP: Acute Tox. 3;H301, Acute Tox. 3;H311, Acute Tox. 2;H330, STOT RE 1;H372					
D-ALPHA-TOCOPHEROL	<0.01	59-02-9 200-412-2	-	-	
Classification: **DSD:** -					
CLP: -					
Other components below reportable levels	10 - < 20				

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

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.

4.1. Description of 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 centre immediately. Do not induce vomiting without medical advice.

4.2. Most important symptoms and effects, both acute and delayed Dusts may irritate the respiratory tract, skin and eyes.

4.3. Indication of any 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.

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media Foam. Dry chemical powder. Carbon dioxide (CO_2). Water.

Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures 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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	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.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
6.2. 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.
6.3. Methods and material 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.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Minimise 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.
7.2. Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
7.3. Specific end use(s)	Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value	Note
CHOLECALCIFEROL (CAS 67-97-0)	8 HR TWA	0.2 mcg/m3	Skin
	OHC	5	Skin
D-ALPHA-TOCOPHEROL (CAS 59-02-9)	OHC	1	
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)	OHC	1	
L-ASCORBIC ACID (CAS 50-81-7)	8 HR TWA	5000 mcg/m3	
	OHC	1	
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
Silicon dioxide (CAS 7631-86-9)	OHC	1	
SODIUM STARCH GLYCOLATE (CAS 9063-38-1)	OHC	1	
Zinc oxide (CAS 1314-13-2)	OHC	1	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Calcium carbonate (CAS 471-34-1)	TWA	4 mg/m3	Respirable.
		4 mg/m3	Respirable dust.
		10 mg/m3	Inhalable
		10 mg/m3	Inhalable dust.
Magnesium oxide (CAS 1309-48-4)	TWA	4 mg/m3	Respirable dust and/or fume.
		10 mg/m3	Inhalable dust.
Silicon dioxide (CAS 7631-86-9)	TWA	6 mg/m3	Inhalable dust.
		2.4 mg/m3	Respirable dust.
Starch (CAS 9005-25-8)	TWA	4 mg/m3	Respirable.

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
		10 mg/m3	Inhalable
Talc (CAS 14807-96-6)	TWA	1 mg/m3	Respirable dust.
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m3	Respirable.
		10 mg/m3	Inhalable

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

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no-effect level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

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

General information Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

Skin protection

- Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust)

Respiratory protection No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures 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.

Environmental exposure controls

Hazard guidance and control recommendations Contain spills and prevent releases and observe national regulations on emissions. Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state Solid.

Form Tablet.

Colour Not available.

Odour Not available.

Odour 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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Fluorine.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
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	Dusts may irritate the respiratory tract, skin and eyes.

11.1. Information on toxicological effects

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

Components	**Species**	**Test results**
Calcium carbonate (CAS 471-34-1)		
Acute		
Oral		
LD50	Rat	6450 mg/kg
CHOLECALCIFEROL (CAS 67-97-0)		
Acute		
Oral		
LD50	Dog	80 mg/kg ; RTECS data
	Mouse	42.5 mg/kg ; RTECS data
	Rat	42 mg/kg ; RTECS data

Components	Species	Test results
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
L-ASCORBIC ACID (CAS 50-81-7)		
Acute		
Oral		
LD50	Rat	11.9 g/kg
Subchronic		
Oral		
NOAEL	Rat	2000 mg/kg/day
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
Titanium dioxide (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
Chronic		
Inhalation		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophrages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose 5 mg/m3, 24 months
Subacute		
Inhalation		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks No evidence of significant inflammation in respiratory tract.
Oral		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
Inhalation		
LOEC	Rat	3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.
Zinc oxide (CAS 1314-13-2)		
Acute		
Inhalation		
LC50	Rat	> 200 mg/l
Oral		
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 Notes: EU SCC Review 1986-1990

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

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 sensitisation Health injuries are not known or expected under normal use.

Skin sensitisation Health injuries are not known or expected under normal use.

Maximisation assay (Magnusson and Kligman)

HYDROXYPROPYL METHYL CELLULOSE	Result: negative Species: Guinea pig

Sensitisation

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 0.72 - 14.8 mg/m3, Literature data Result: negative Species: Mouse

Carcinogenicity

TITANIUM DIOXIDE	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 structual 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. 3 Not classifiable as to carcinogenicity to humans.
TITANIUM DIOXIDE (CAS 13463-67-7)	2B Possibly carcinogenic to humans.

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
L-ASCORBIC ACID	Species: Human Organ: Red blood cells, kidneys. Notes: EU SCC Review 1986-1990

Aspiration hazard Not an aspiration hazard.

Mixture versus substance information No information available.

Other information Not available.

SECTION 12: Ecological information

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

Components		Species	Test results
Calcium carbonate (CAS 471-34-1)			
Aquatic			
Fish	LC50	Western mosquitofish (Gambusia affinis)	> 56000 mg/l, 24 hours
CHOLECALCIFEROL (CAS 67-97-0)			
Aquatic			
Acute			
Algae	NOEC	Green algae (Selenastrum capricornutum)	100 mg/l, 96 hours
Crustacea	NOEC	Water flea (Daphnia magna)	100 mg/l, 48 hours
Fish	NOEC	Golden ide/orfe (Adult Leuciscus idus)	> 10000 mg/l, 96 hours
D-ALPHA-TOCOPHEROL (CAS 59-02-9)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	> 25.5 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	25.5 mg/l, 72 hours
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	> 91.1 mg/l, 96 hours
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	91.1 mg/l, 96 hours
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)			
Aquatic			
Acute			
Fish	EC50	Fish	> 100 mg/l, 96 hours
L-ASCORBIC ACID (CAS 50-81-7)			
Aquatic			
Acute			
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	1020 mg/l, 96 hours
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
Silicon dioxide (CAS 7631-86-9)			
Aquatic			
Acute			
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
Talc (CAS 14807-96-6)			
Aquatic			
Acute			
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 100 g/l, 24 hours Static renewal test
Titanium dioxide (CAS 13463-67-7)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours Static test

Components		Species	Test results
TOCOPHEROL ACETATE (CAS 58-95-7)			
Aquatic			
Acute			
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 Oncorhyncus mykiss)	> 100 mg/l, 96 hours
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	100 mg/l, 96 hours
Zinc oxide (CAS 1314-13-2)			
Aquatic			
Acute			
Crustacea	EC50	Daphnia	1 mg/l, 48 hours OECD Guideline 202
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	1.1 mg/l, 96 hours Static test
	LC50	Striped bass (Morone saxatilis)	0.25 - 2.46 mg/l, 48 hours

12.2. Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE	17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE	210 nm

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
TOCOPHEROL ACETATE	84 %, 28 days Modified MITI (II) Test.

Percent degradation (Aerobic biodegradation-ready)

CHOLECALCIFEROL	< 7 %, 28 days MITI test
D-ALPHA-TOCOPHEROL	17 %, 28 days Manometric Respirometry Test
MAGNESIUM STEARATE	95 %, 22 days Sturm test
TOCOPHEROL ACETATE	17 %, 28 days Manometric Respirometry Test

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

HYDROXYPROPYL METHYL CELLULOSE	-5
L-ASCORBIC ACID	-2.15

Bioconcentration factor (BCF)

HYDROXYPROPYL METHYL CELLULOSE	3.2 Estimated
MAGNESIUM STEARATE	> 9999 Estimated
Zinc oxide	> 1000

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE	5.86 Estimated

Mobility in general

Volatility

Henry's law

HYDROXYPROPYL METHYL CELLULOSE	0 atm m3/mol Estimated

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	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.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

CHOLECALCIFEROL (CAS 67-97-0)

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

CHOLECALCIFEROL (CAS 67-97-0)

Directive 94/33/EC on the protection of young people at work

CHOLECALCIFEROL (CAS 67-97-0)

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.
National regulations	Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R24/25 Toxic in contact with skin and if swallowed. R26 Very toxic by inhalation. R37 Irritating to respiratory system. R48/25 Toxic: danger of serious damage to health by prolonged exposure if swallowed. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. H301 Toxic if swallowed. H311 Toxic in contact with skin. H330 Fatal if inhaled. H372 Causes damage to organs through prolonged or repeated exposure. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects.
Revision information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: TOXICOLOGICAL INFORMATION: Transport Information: Agency Name and Packaging Type/Transport Mode Selection Regulatory Information: United States GHS: Classification
Training information	Follow training instructions when handling this material.
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.