

## 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 500 + D TABLETS
Registration number	-
Synonyms	OS-CAL 500 + D [200 IU] CAPLETS * OS-CAL 500 MG + D TABLETS (US) * MFC 50357B * CALCIUM CARBONATE AND VITAMIN D, FORMULATED PRODUCT
Issue date	25-August-2014
Version number	08
Revision date	25-August-2014

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

Identified uses	Food Supplement
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 of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device. This preparation does not meet the criteria for classification according to Directive 1999/45/EC as amended.

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

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device. This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

#### Hazard summary

Physical hazards	Not classified for physical hazards.
Health hazards	Not classified for health hazards. However, occupational exposure to the mixture or substance(s) may cause adverse health effects.
Environmental hazards	Not classified for hazards to the environment.
Specific hazards	None known.
Main symptoms	Dusts may irritate the respiratory tract, skin and eyes.

### 2.2. Label elements

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

Contains:	CHOLECALCIFEROL, Calcium carbonate, D-ALPHA-TOCOPHEROL, Starch, Talc
Hazard pictograms	None.
Signal word	None.
Hazard statements	The mixture does not meet the criteria for classification.

#### Precautionary statements

Prevention	Not available.
Response	Not available.
Storage	Not available.
Disposal	Not available.

**Supplemental label information** None.

**2.3. Other hazards** Expected to be non-combustible.  
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	80 - < 90	471-34-1 207-439-9	-	-	
<b>Classification:</b>					
<b>DSD:</b>	-				
<b>CLP:</b>	-				
Talc	3 - < 5	14807-96-6 238-877-9	-	-	
<b>Classification:</b>					
<b>DSD:</b>	-				
<b>CLP:</b>	-				
Starch	1 - < 3	9005-25-8 232-679-6	-	-	
<b>Classification:</b>					
<b>DSD:</b>	-				
<b>CLP:</b>	-				
CHOLECALCIFEROL	0,0005	67-97-0 200-673-2	-	603-180-00-4	
<b>Classification:</b>					
<b>DSD:</b>	T+;R26, T;R24/25-48/25				
<b>CLP:</b>	Acute Tox. 3;H301, Acute Tox. 3;H311, Acute Tox. 2;H330, STOT RE 1;H372				
D-ALPHA-TOCOPHEROL	0,0004	59-02-9 200-412-2	-	-	
<b>Classification:</b>					
<b>DSD:</b>	-				
<b>CLP:</b>	-				

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<sub>2</sub>). 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** No special control measures required for the normal handling of this product. Avoid prolonged exposure. Normal room ventilation is expected to be adequate for routine handling of this product.

**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). No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

**7.3. Specific end use(s)** Food Supplement

## 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/m <sup>3</sup>	Skin
	OHC	5	Skin
D-ALPHA-TOCOPHEROL (CAS 59-02-9)	OHC	1	

**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

White.

#### 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.

<b>Solubility (other)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Explosive properties</b>	Not available.
<b>Oxidizing properties</b>	Not available.
<b>9.2. Other information</b>	No relevant additional information available.

## SECTION 10: Stability and reactivity

<b>10.1. Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>10.2. Chemical stability</b>	This product is expected to be stable.
<b>10.3. Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>10.4. Conditions to avoid</b>	None for normal handling of this product. Contact with incompatible materials.
<b>10.5. Incompatible materials</b>	Fluorine.
<b>10.6. Hazardous decomposition products</b>	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

<b>Ingestion</b>	Expected to be a low ingestion hazard.
<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	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.

<b>Components</b>	<b>Species</b>	<b>Test results</b>
Calcium carbonate (CAS 471-34-1)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	6450 mg/kg
CHOLECALCIFEROL (CAS 67-97-0)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Dog	80 mg/kg ; RTECS data
	Mouse	42,5 mg/kg ; RTECS data
	Rat	42 mg/kg ; RTECS data

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

<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.
<b>Serious eye damage/eye irritation</b>	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.
<b>Respiratory sensitisation</b>	Health injuries are not known or expected under normal use.
<b>Skin sensitisation</b>	Health injuries are not known or expected under normal use.
<b>Sensitisation</b>	
CHOLECALCIFEROL	SAR / QSAR, DEREK, Lhasa, UK Result: No structural alerts identified.
<b>Germ cell mutagenicity</b>	Health injuries are not known or expected under normal use.
<b>Mutagenicity</b>	
CHOLECALCIFEROL	Ames Assay, GLP assay; Literature data Result: negative
<b>Carcinogenicity</b>	Health injuries are not known or expected under normal use.

**Carcinogenicity**

CHOLECALCIFEROL

SAR / QSAR, DEREK, Lhasa, UK  
Result: No structural alerts identified.**IARC Monographs. Overall Evaluation of Carcinogenicity**

TALC (CAS 14807-96-6)

2B Possibly carcinogenic to humans.  
3 Not classifiable as to carcinogenicity to humans.**Reproductive toxicity**

Health injuries are not known or expected under normal use.

**Reproductivity**

CHOLECALCIFEROL

SAR / QSAR, DEREK, Lhasa, UK  
Result: As a class vitamin D analogs are suspected of causing foetal malformation 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**

Due to partial or complete lack of data the classification is not possible.

CHOLECALCIFEROL

Repeat dose non-clinical studies; clinical observation, Literature data  
Organ: Kidney, bone**Aspiration hazard**

Not likely, due to the form of the product.

**Mixture versus substance information**

No information available.

**Other information**

Not available.

**SECTION 12: Ecological information****12.1. Toxicity**

Not expected to be harmful to aquatic organisms.

**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 Oncorhynchus mykiss*) > 91,1 mg/l, 96 hours

NOEC

Rainbow trout (*Adult Oncorhynchus mykiss*) 91,1 mg/l, 96 hours

Talc (CAS 14807-96-6)

**Aquatic***Acute*

Fish

EC50

Zebra fish (*Adult Brachydanio rerio*) > 100 g/l, 24 hours Static renewal test**12.2. Persistence and degradability**

No data is available on the degradability of this product.

**Biodegradability****Percent degradation (Aerobic biodegradation-inherent)**

D-ALPHA-TOCOPHEROL

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

**Percent degradation (Aerobic biodegradation-ready)**

CHOLECALCIFEROL

&lt; 7 %, 28 days MITI test

D-ALPHA-TOCOPHEROL

17 %, 28 days Manometric Respirometry Test

<b>12.3. Bioaccumulative potential</b>	No data available.
<b>Partition coefficient n-octanol/water (log Kow)</b>	Not available.
<b>12.4. Mobility in soil</b>	No data available.
<b>Mobility in general</b>	Not available.
<b>12.5. Results of PBT and vPvB assessment</b>	Not available.
<b>12.6. Other adverse effects</b>	Not available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

<b>Residual waste</b>	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).
<b>Contaminated packaging</b>	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.
<b>EU waste code</b>	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Disposal methods/information</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Observe all local and national regulations when disposing of this product. Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
<b>Special precautions</b>	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.  
R48/25 Toxic: danger of serious damage to health by prolonged exposure if swallowed.  
H301 Toxic if swallowed.  
H311 Toxic in contact with skin.  
H330 Fatal if inhaled.  
H372 Causes damage to organs through prolonged or repeated exposure.

### Revision information

Product and Company Identification: Product and Company Identification  
Composition / Information on Ingredients: Undisclosed Ingredient Statement  
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.