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 LEMON + D CHEWABLE (NORWAY MFR)
Registration number	-
Synonyms	OS-CAL CHEWABLE PLUS VITAMIN D TABLETS * CALCIUM CARBONATE AND VITAMIN D, FORMULATED PRODUCT
Issue date	22-August-2014
Version number	03
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	71.51	471-34-1 207-439-9	-	-	
Classification: **DSD:** - **CLP:** -					
Starch	5 - < 10	9005-25-8 232-679-6	-	-	
Classification: **DSD:** - **CLP:** -					
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					

Other components below reportable levels 20 - < 30

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. Get medical advice/attention if you feel unwell. 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). Do not induce vomiting without medical advice. If ingestion of a large amount does occur, call a poison control centre immediately.

4.2. Most important symptoms and effects, both acute and delayed Dust may irritate the eyes and the respiratory system.

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 (CO2). 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. Avoid inhalation of dust. 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 discharge into drains, water courses or onto the ground.
6.3. Methods and material for containment and cleaning up	Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Stop the flow of material, if this is without risk. Large Spills: Wet down with water and dike for later disposal. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Never return spills to original containers for re-use.
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. Do not get in eyes, on skin, or on clothing. Avoid breathing dust. Avoid prolonged exposure. 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. Wash contaminated clothing before reuse. Avoid release to the environment.
7.2. Conditions for safe storage, including any incompatibilities	Store locked up. Store in original tightly closed container. Store in a well-ventilated place. 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-SORBITOL (CAS 50-70-4)	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.
Starch (CAS 9005-25-8)	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	General ventilation normally adequate.

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	Chewable 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 None known.

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

* 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.

Serious eye damage/eye irritation Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.

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

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

Sensitisation

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

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

CHOLECALCIFEROL — SAR / QSAR, DEREK, Lhasa, UK
Result: No structual alerts identified.

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 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

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

12.2. Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

CHOLECALCIFEROL	< 7 %, 28 days MITI test

12.3. Bioaccumulative potential No data available.

Partition coefficient n-octanol/water (log Kow) Not available.

12.4. Mobility in soil No data available.

Mobility in general Not available.

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. 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

Young people under 18 years old are not allowed to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. 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: Ingredients Regulatory Information: United States
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.