



SAFETY DATA SHEET

1. Identification

Product identifier	CENTRUM ADULT ULTRAMEN
Other means of identification	
Product code	WH-2024-0001, H000020681, H000020680
Synonyms	CENTRUM ADULT ULTRAMEN (ULTRAMEN - GELATIN BHT FREE FORMULA) * CENTRUM MEN ULTRAMEN * WH-2024-0001 * H000020680 * H000020681
Recommended use	Not available.
Recommended restrictions	Not available.
Manufacturer/Importer/Supplier/Distributor information	
COMPANY NAME	GlaxoSmithKline US
Address:	5 Moore Drive Research Triangle Park, NC 27709 USA
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EMERGENCY CONTACTS

Telephone:	VERISK 3E GLOBAL INCIDENT RESPONSE +(1) 760 476 3971 (In country) +(1) 760 476 3962 or +(1) 866 519 4752 (International) 24/7; multi-language response
Contract Number:	334878

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, dermal	Category 4
	Specific target organ toxicity, repeated exposure	Category 1
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3
	Hazardous to the aquatic environment, long-term hazard	Category 3
OSHA defined hazards	Not classified.	

Label elements



Signal word	Danger
Hazard statement	Harmful in contact with skin. Causes damage to organs through prolonged or repeated exposure. Harmful to aquatic life. Harmful to aquatic life with long lasting effects.
Precautionary statement	
Prevention	Do not breathe dust/fume. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment. Wear protective gloves/protective clothing.
Response	If on skin: Wash with plenty of water/. If exposed or concerned: Get medical advice/attention. Specific measures (see on this label).
Storage	Not available.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

Occupational Exposure Limits for constituents are listed in Section 8. 21.3% of the mixture consists of component(s) of unknown acute oral toxicity. 72.8% of the mixture consists of component(s) of unknown acute dermal toxicity. 67.1% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 67.1% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

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	36
MAGNESIUM OXIDE	G1197895X MAGNESIA MAGNESIUM MONOXIDE CALCINED MAGNESIA CALCINATED MAGNESIA CAUSTIC MAGNESITE MAGNESA PREPRATA MAGNESIUM (II) OXIDE SYNTHETIC PERICLASE BURNT MAGNESIA LIGHT MAGNESIA OXIDO DE MAGNESIO ÓXIDO DE MAGNESIO,	1309-48-4	12.3
POTASSIUM CHLORIDE	POTASSIUM CHLORIDE (KCL) POTASSIUM MONOCHLORIDE SUPER K (SALT) POTASSIUM MURIATE	7447-40-7	11
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE ALPHA-CELLULOSE AVICEL PH101 AVICEL PH102 AVICEL PH103 AVICEL PH105 AVICEL PH112 AVICEL PH200 CELLULOSE (8CI9CI) CELLULOSE CRYSTALLINE CELLULOSE, FOOD GRADE CRYSTALLINE CELLULOSE	9004-34-6	9
L-ASCORBIC ACID	VITAMIN C L-XYLOASCORBIC ACID ASCORBUTINA ANTISCORBUTIC VITAMIN CEVITAMIC ACID ASCORIN (+)-ASCORBIC ACID L-(+)-ASCORBIC ACID L-LYXOASCORBIC ACID 3-KETO-L-GULOFURANOLACTONE L-THREO-HEX-2-ENONIC ACID, GAMA-LACTONE L-3-KETOTHREOHEXURONIC ACID LACTONE 3-OXO-L-GULOFURANOLACTONE	50-81-7	7

Chemical name	Common name and synonyms	CAS number	%
CALCIUM PHOSPHATE, DIBASIC	CALCIUM ACID PHOSPHATE CALCIUM HYDROGEN ORTHOPHOSPHATE CALCIUM HYDROGEN PHOSPHATE CALCIUM MONOHYDROGEN PHOSPHATE CALCIUM ORTHOPHOSPHATE (CAHPO4) DIBASIC CALCIUM PHOSPHATE DICALCIUM ORTHOPHOSPHATE DICALCIUM PHOSPHATE MONOCALCIUM ACID PHOSPHATE CALCIUM PHOSPHATE	7757-93-9	6
FERROUS FUMARATE	IRON FUMARATE IRON FUMARATE (FE(C4H2O4))	141-01-5	1.8
POVIDONE 30	Poly(1-ethenylpyrrolid-2-one) CROSPVIDONE POLY(1-VINYL-2-PYRROLIDINONE) 2-PYRROLIDINONE, 1-VINYL-, POLYMERS	9003-39-8	1.7
NICOTINAMIDE	AMINICOTIN 3-CARBOAMOYLPYRIDINE NIACINAMIDE NICOTONIC AMIDE VITAMIN B3	98-92-0	1.2
CHOLECALCIFEROL (VITAMIN D3)	CALCIOL VITAMIN D3	67-97-0	1
ZINC OXIDE	ZINC MONOXIDE	1314-13-2	1
COPPER SULFATE MONOHYDRATE		10257-54-2	0.5
MANGANESE SULFATE	MANGANESE(2+) SULFATE MANGANESE SULPHATE MANGANOUS SULFATE MAN-GRO SORBRA-SPRAY MN SULFURIC ACID, MANGANESE(II) SALT SULFURIC ACID, MANGANESE(2+) SALT (1:1) MANGANESE MONOSULFATE MANGANESE(II) SULFATE MANGANESE(II) SULPHATE MANGANESE SULFATE (1:1) MANGANESE SULFATE (MnSO4) MANGANESE(2+) SULFATE (1:1) MANGANESE(2+) SULFATE (MnSO4) SULFURIC ACID, MANGANESE(2+) SAL T OHS13650 RTECS OP1050000	7785-87-7	0.5
SILICON DIOXIDE	SILICA SILICA GEL AMORPHOUS SILICA DIATOMACEOUS EARTH INFUSORIAL EARTH CAB-O-SIL M-5	7631-86-9	0.4
BIOTIN	VITAMIN B7 VITAMIN H	58-85-5	0.3
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	0.2

Chemical name	Common name and synonyms	CAS number	%
PYRIDOXINE HYDROCHLORIDE	5-HYDROXY-6-METHYL-3,4-PYRIDINED IMETHANOL, HYDROCHLORIDE PYRIDOXOL, HYDROCHLORIDE PYRIDOXINE HYDROGEN CHLORIDE PYRIDOXINE MONOHYDROCHLORIDE VITAMIN B6 HYDROCHLORIDE	58-56-0	0.2
RIBOFLAVIN	RIBOFLAVINE VITAMIN B2 VITAMIN G FOOD YELLOW 15	83-88-5	0.11
THIAMINE MONONITRATE	THIAMINE NITRATE (SALT) VITAMIN B1 MONONITRATE VITAMIN B1 NITRATE	532-43-4	0.1
CYANOCOBALAMIN	VITAMIN B12 B-12	68-19-9	0.05
POTASSIUM IODIDE	POTASSIUM MONIODIDE IODIC ACID, POTASSIUM SALT	7681-11-0	0.02
SODIUM SELENATE	SELENIC ACID, SODIUM SALT SELENIC ACID, DISODIUM SALT DISODIUM SELENATE P-40 SEL-TOX SSO2 OHS21580 RTECS VS6650000	13410-01-0	0.02
POLYETHYLENE GLYCOL	GLYCOLS, POLYETHYLENE ETHYLENE GLYCOL HOMOPOLYMER ETHYLENE GLYCOL POLYMER ETHYLENE OXIDE POLYMER ETHYLENE POLYOXIDE ALPHA, OMEGA-HYDROXYPOLY(ETHYLENE OXIDE) POLY(ETHYLENE OXIDES) POLY(ETHYLENE ETHER) GLYCOL ALPH-HYDRO-OMEGA-HYDROXY POLY(OXY-1,2-ETHANEDIYL) POLYETHYLENE GLYCOL POLY(VINYL OXIDE) 1,2-ETHANEDIOL, MONOPOLYMER POLYETHYLENE OXIDE OXIRANE POLYMER CARBOWAX PEG PEG-100 PEG-4 PEG-40 MACROGOL	25322-68-3	0.001
TALC	TALCUM, NON-ASBESTOS FORM TALC HYDROUS MAGNESIUM SILICATE	14807-96-6	0.001
TITANIUM DIOXIDE	TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO2) PIGMENT WHITE 6	13463-67-7	0.001
Other components below reportable levels			9.597

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical advice/attention if you feel unwell. Wash contaminated clothing before reuse.
Eye contact	Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical advice/attention if you feel unwell.

Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed.
General information	If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
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	Wear appropriate protective equipment and clothing during clean-up. 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	Avoid the generation of dusts during clean-up. Prevent product from entering drains. Large Spills: Following product recovery, flush area with water. Small Spills: Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	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. Wash hands thoroughly after handling. Avoid release to the environment. Wash contaminated clothing before reuse. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK Components	Type	Value	Note
BIOTIN (CAS 58-85-5)	OHC	1	
CALCIUM PHOSPHATE, DIBASIC (CAS 7757-93-9)	OHC	1	
CHOLECALCIFEROL (VITAMIN D3) (CAS 67-97-0)	OHC	5	SKIN
		0.2 mcg/m ³	SKIN

GSK Components	Type	Value	Note
CYANOCOBALAMIN (CAS 68-19-9)	8 HR TWA	5 mg/m3	
	OHC	1	
FERROUS FUMARATE (CAS 141-01-5)	8 HR TWA	1000 mcg/m3	
	OHC	1	
L-ASCORBIC ACID (CAS 50-81-7)	8 HR TWA	5000 mcg/m3	
NICOTINAMIDE (CAS 98-92-0)	8 HR TWA	1000 mcg/m3	
	OHC	1	
POTASSIUM CHLORIDE (CAS 7447-40-7)	8 HR TWA	5000 mcg/m3	
	OHC	1	
POTASSIUM IODIDE (CAS 7681-11-0)	OHC	3	REPRODUCTIVE HAZARD
		3	PROVISIONAL
PYRIDOXINE HYDROCHLORIDE (CAS 58-56-0)	8 HR TWA	400 mcg/m3	
	OHC	2	
RIBOFLAVIN (CAS 83-88-5)	OHC	1	>1000 - <=5000 mcg/m3
THIAMINE MONONITRATE (CAS 532-43-4)	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.
MANGANESE SULFATE (CAS 7785-87-7)	Ceiling	5 mg/m3	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
SODIUM SELENATE (CAS 13410-01-0)	PEL	0.2 mg/m3	
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.
ZINC OXIDE (CAS 1314-13-2)	PEL	5 mg/m3	Fume.
		5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

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

Components	Type	Value	Form
MAGNESIUM OXIDE (CAS 1309-48-4)	TWA	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

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.
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
COPPER SULFATE MONOHYDRATE (CAS 10257-54-2)	TWA	1 mg/m3	Dust and mist.
		0.2 mg/m3	Fume.
FERROUS FUMARATE (CAS 141-01-5)	TWA	1 mg/m3	
MAGNESIUM OXIDE (CAS 1309-48-4)	TWA	10 mg/m3	Inhalable fraction.
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	
MANGANESE SULFATE (CAS 7785-87-7)	TWA	0.1 mg/m3	Inhalable fraction.
		0.02 mg/m3	Respirable fraction.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	
POTASSIUM IODIDE (CAS 7681-11-0)	TWA	0.01 ppm	Inhalable fraction and vapor.
SODIUM SELENATE (CAS 13410-01-0)	TWA	0.2 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 SULFATE MONOHYDRATE (CAS 10257-54-2)	TWA	1 mg/m3	Dust and mist.
		0.1 mg/m3	Fume.
FERROUS FUMARATE (CAS 141-01-5)	TWA	1 mg/m3	
MANGANESE SULFATE (CAS 7785-87-7)	STEL	3 mg/m3	Fume.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
	TWA	1 mg/m3	Fume.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m3	
SODIUM SELENATE (CAS 13410-01-0)	TWA	0.2 mg/m3	
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. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
POLYETHYLENE GLYCOL (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 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.

Individual protection measures, such as personal protective equipment**Eye/face protection**

Wear safety glasses with side shields (or goggles).

Skin protection**Hand protection**

Wear appropriate chemical resistant gloves.

Other

Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.

Respiratory protection

In case of insufficient ventilation, wear suitable respiratory equipment.

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.

9. Physical and chemical properties**Appearance****Physical state**

Solid.

Form

Solid. Tablet.

Color

Orange.

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.

Other information

Explosive properties Not explosive.

Oxidizing properties Not oxidizing.

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 Strong oxidizing agents. Chlorine. Fluorine. Phosphorus.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation Prolonged inhalation may be harmful.

Skin contact Harmful in contact with skin.

Eye contact Knowledge about health hazard is incomplete.

Ingestion Knowledge about health hazard is incomplete.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation.

Information on toxicological effects

Acute toxicity Harmful in contact with skin.

Components	Species	Test Results
CALCIUM CARBONATE (CAS 471-34-1)		
Acute		
Oral		
LD50	Rat	6450 mg/kg
CALCIUM PHOSPHATE, DIBASIC (CAS 7757-93-9)		
Acute		
Dermal		
LD50	Rabbit	> 7940 mg/kg
Oral		
LD50	Rat	> 10 g/kg

Components	Species	Test Results
CHOLECALCIFEROL (VITAMIN D3) (CAS 67-97-0)		
<u>Acute</u>		
Dermal		
LD50	Rat	61 mg/kg
Inhalation		
LC50	Rat	2.04 mg/l
Oral		
LD50	Dog	80 mg/kg ; RTECS data
	Mouse	42.5 mg/kg ; RTECS data
	Rat	42 mg/kg ; RTECS data
CYANOCOBALAMIN (CAS 68-19-9)		
<u>Acute</u>		
Oral		
LD	Mouse	> 5 g/kg
FERROUS FUMARATE (CAS 141-01-5)		
<u>Acute</u>		
Oral		
LD50	Rat	3850 mg/kg
L-ASCORBIC ACID (CAS 50-81-7)		
<u>Acute</u>		
Oral		
LD50	Rat	11.9 g/kg
<u>Subchronic</u>		
Oral		
NOAEL	Rat	2000 mg/kg/day
MAGNESIUM STEARATE (CAS 557-04-0)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg
NICOTINAMIDE (CAS 98-92-0)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2000 mg/kg
POLYETHYLENE GLYCOL (CAS 25322-68-3)		
<u>Acute</u>		
Oral		
LD50	Rat	10000 mg/kg
POTASSIUM CHLORIDE (CAS 7447-40-7)		
<u>Acute</u>		
Oral		
LD50	Rat	2600 mg/kg

Components	Species	Test Results
POVIDONE 30 (CAS 9003-39-8)		
<u>Acute</u>		
Oral		
LD50	Rat	> 5000 mg/kg
RIBOFLAVIN (CAS 83-88-5)		
<u>Acute</u>		
Oral		
LD50	Rat	> 10 g/kg
THIAMINE MONONITRATE (CAS 532-43-4)		
<u>Acute</u>		
Oral		
LD50	Rat	3710 mg/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
<u>Acute</u>		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
<u>Chronic</u>		
Inhalation		
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
<u>Subacute</u>		
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.
<u>Subchronic</u>		
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)		
<u>Acute</u>		
Inhalation		
LC50	Rat	> 200 mg/l
Oral		
LD50	Rat	> 8437 mg/kg
Skin corrosion/irritation	Due to partial or complete lack of data the classification is not possible.	
Irritation Corrosion - Skin		
TITANIUM DIOXIDE		
0, Literature data Result: Non-irritant Species: Guinea pig		

Irritation Corrosion - Skin

TITANIUM DIOXIDE

0, Literature data
Result: Non-irritant
Species: Human

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: P.I.I. value**

MAGNESIUM STEARATE

0

Serious eye damage/eye irritation

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

Eye

L-ASCORBIC ACID

Acute ocular irritation; OECD 405
Result: Slight irritant
Species: Rabbit

TITANIUM DIOXIDE

Notes: EU SCC Review 1986-1990
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**

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

Skin sensitization

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

Sensitization

TITANIUM DIOXIDE

5 % Optimisation Test, Literature data - Vehicle: petrolatum
Result: Negative
Species: Guinea pig
Test Duration: 48 hour exposure

CYANOCOBALAMIN

Epidemiology
Result: Hypersensitivity reactions can occur rarely.

TITANIUM DIOXIDE

Patch test, Literature data
Result: Negative
Species: Human

CHOLECALCIFEROL (VITAMIN D3)

SAR / QSAR, DEREK, Lhasa, UK
Result: No structural alerts identified.**Germ cell mutagenicity**

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

Mutagenicity

CHOLECALCIFEROL (VITAMIN D3)

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. Carcinogenic effects are not expected as a result of occupational exposure. Due to partial or complete lack of data the classification is not possible. Contains a material (Titanium Dioxide, Talc) classified as a carcinogen by external agencies.

L-ASCORBIC ACID

< 6000 mg/kg/day
Result: Negative
Species: Mouse
Notes: UN SIDS Dossier

Carcinogenicity

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

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 - Literature data.

Result: Negative

Species: Rat

25000 - 50000 ppm, Dietary study

Result: Negative

Species: Mouse

7.2 - 14.8 mg/m³, Literature data

Result: Lung tumour

Species: Rat

Test Duration: 24 months

CHOLECALCIFEROL (VITAMIN D3)

SAR / QSAR, DEREK, Lhasa, UK

Result: No structural alerts identified.

IARC Monographs. Overall Evaluation of Carcinogenicity

POVIDONE 30 (CAS 9003-39-8)

3 Not classifiable as to carcinogenicity to humans.

SILICON DIOXIDE (CAS 7631-86-9)

3 Not classifiable as to carcinogenicity to humans.

SODIUM SELENATE (CAS 13410-01-0)

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

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

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 (VITAMIN D3)

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

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

Specific target organ toxicity - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

CHOLECALCIFEROL (VITAMIN D3)

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

Organ: Kidney, bone

Specific target organ toxicity - repeated exposure

L-ASCORBIC ACID

Species: Human
Organ: Red blood cells, kidneys.
Notes: EU SCC Review 1986-1990**Aspiration hazard** Due to partial or complete lack of data the classification is not possible.**Chronic effects** Prolonged inhalation may be harmful. Causes damage to organs through prolonged or repeated exposure.**12. Ecological information****Ecotoxicity** Harmful to aquatic life with long lasting effects.

Components		Species	Test Results
CALCIUM CARBONATE (CAS 471-34-1)			
Aquatic			
Fish	LC50	Western mosquitofish (<i>Gambusia affinis</i>)	> 56000 mg/l, 24 hours
CHOLECALCIFEROL (VITAMIN D3) (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 (<i>Adult Leuciscus idus</i>)	> 10000 mg/l, 96 hours
CYANOCOBALAMIN (CAS 68-19-9)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)	> 100 mg/l, 48 hours
L-ASCORBIC ACID (CAS 50-81-7)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Rainbow trout (<i>Adult Oncorhynchus mykiss</i>)	1020 mg/l, 96 hours
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (<i>Adult Oryzias latipes</i>)	130 mg/l, 96 hours
NICOTINAMIDE (CAS 98-92-0)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Algae	> 1000 mg/l, 72 hours
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)	> 1000 mg/l, 48 hours
Fish	EC50	Guppy (<i>Juvenile Poecilia reticulata</i>)	> 1000 mg/l, 96 hours
POTASSIUM CHLORIDE (CAS 7447-40-7)			
Aquatic			
<i>Acute</i>			
Algae	NOEC	Green algae (<i>Chlorella vulgaris</i>)	600 mg/l, 4 months
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)	83 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (<i>Adult Lepomis macrochirus</i>)	951 mg/l, 96 hours Static test
		Channel catfish (<i>Adult Ictalurus punctatus</i>)	720 mg/l, 48 hours Static test
		Fathead minnow (<i>Adult Pimephales promelas</i>)	880 mg/l, 96 hours Static test
		Mosquito fish (<i>Adult Gambusia affinis</i>)	435 mg/l, 96 hours Static test

Components	Species	Test Results
POVIDONE 30 (CAS 9003-39-8)		
<i>Acute</i>		
	IC50	Activated sludge > 1000 mg/l, 3 hours Static test
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) 84 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna) 32 mg/l, 48 hours Static test
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
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		
Fish	LC50	Mummichog (Fundulus heteroclitus) > 1000 mg/l, 96 hours
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) > 1000 mg/l, 48 hours Static test
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)

MAGNESIUM STEARATE	17 Hours Estimated
NICOTINAMIDE	7 Days Estimated

UV/visible spectrum wavelength

CYANOCOBALAMIN	278 nm
MAGNESIUM STEARATE	210 nm

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

L-ASCORBIC ACID	100 %, 15 days Zahn-Wellens
MAGNESIUM STEARATE	77 %, 28 days BOD
POVIDONE 30	0 %, 28 days Modified MITI test, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

CHOLECALCIFEROL (VITAMIN D3)	< 7 %, 28 days MITI test
CYANOCOBALAMIN	< 5 %
MAGNESIUM STEARATE	95 %, 22 days Sturm test
NICOTINAMIDE	96 %, 28 days Modified OECD Screening Test (OECD 301E)

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days
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Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

L-ASCORBIC ACID	-2.15
NICOTINAMIDE	-0.37
RIBOFLAVIN	-1.46
	-1.46 (Measured).

Bioconcentration factor (BCF)

MAGNESIUM STEARATE	> 9999 Estimated
NICOTINAMIDE	< 1 Estimated
POTASSIUM IODIDE	> 1000 Measured
ZINC OXIDE	> 1000

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE	5.86 Estimated
NICOTINAMIDE	1.18 Estimated

Mobility in general

Volatility

Henry's law

NICOTINAMIDE	0 atm m ³ /mol Estimated
RIBOFLAVIN	< 0 atm m ³ /mol, 25 C Estimated

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Incinerate the material under controlled conditions in an approved incinerator. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code D010: Waste Selenium
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 Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as a dangerous good.
Read safety instructions, SDS and emergency procedures before handling.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

MANGANESE SULFATE (CAS 7785-87-7) Listed.
 ZINC OXIDE (CAS 1314-13-2) Listed.

SARA 304 Emergency release notification

SODIUM SELENATE (CAS 13410-01-0) 100 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
SODIUM SELENATE	13410-01-0	100	100		

SARA 311/312 Hazardous chemical

Yes
 Classified hazard categories Acute toxicity (any route of exposure)
 Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
ZINC OXIDE	1314-13-2	1

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

MANGANESE SULFATE (CAS 7785-87-7)
 SODIUM SELENATE (CAS 13410-01-0)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Contains component(s) regulated under the Safe Drinking Water Act.

US state regulations**California Proposition 65**

WARNING: This product can expose you to TITANIUM DIOXIDE, which is known to the State of California to cause cancer, and VITAMIN A ACETATE, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7) Listed: September 2, 2011

California Proposition 65 - CRT: Listed date/Developmental toxin

VITAMIN A ACETATE (CAS 127-47-9) Listed: July 1, 1989

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

MAGNESIUM OXIDE (CAS 1309-48-4)
 SODIUM SELENATE (CAS 13410-01-0)
 TALC (CAS 14807-96-6)
 TITANIUM DIOXIDE (CAS 13463-67-7)

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	Yes

Country(s) or region	Inventory name	On inventory (yes/no)*
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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	05-13-2020
Version #	01
HMIS® ratings	Health: 3* Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 0 Instability: 0
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