

VDW GmbH

Chemwatch: **5618-87** Version No: **2.1** Safety Data Sheet according to OSHA HazCom Standard (2012) requirements

SECTION 1 Identification

Product Identifier

Product name	VDW Gutta Percha Points
Chemical Name	Not Applicable
Synonyms	Not Available
Proper shipping name	Environmentally hazardous substance, solid, n.o.s. (contains zinc oxide)
Chemical formula	Not Applicable
Other means of identification	Not Available

Recommended use of the chemical and restrictions on use

Relevant identified uses	Device intended for filling of the shaped, cleaned and irrigated root canal space.
	Use according to manufacturer's directions.

Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party

Registered company name	VDW GmbH
Address	Bayerwaldstrasse 15 Munich 81737 Germany
Telephone	+49 (0)89 627340
Fax	+49 (0)89 62734-190
Website	www.vdw-dental.com
Email	info@vdw-dental.com

Emergency phone number

Association / Organisation	Berliner Betrieb für Zentrale gesundheitliche Aufgaben, Institute for Toxicology, Clinical toxicology and Poison information Centre Berlin	CHEMWATCH EMERGENCY RESPONSE (24/7)
Emergency telephone numbers	+49-(0)30-19240	+1 855-237-5573
Other emergency telephone numbers	Not Available	+61 3 9573 3188

Once connected and if the message is not in your preferred language then please dial 01

Una vez conectado y si el mensaje no está en su idioma preferido, por favor marque 02

SECTION 2 Hazard(s) identification

Classification of the substance or mixture

Issue Date: 07/09/2023

Print Date: 08/09/2023

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Issue Date: 07/09/2023 Print Date: 08/09/2023

VDW Gutta Percha Points

NFPA 704 diamond



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Classification

Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2A, Carcinogenicity Category 2, Hazardous to the Aquatic Environment Acute Hazard Category 3, Hazardous to the Aquatic Environment Long-Term Hazard Category 1

Label elements



Hazard statement(s)

H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H351	Suspected of causing cancer.
H402	Harmful to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Hazard(s) not otherwise classified

Not Applicable

Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
P261	Avoid breathing dust/fumes.
P273	Avoid release to the environment.
P202	Do not handle until all safety precautions have been read and understood.
P264	Wash all exposed external body areas thoroughly after handling.
P272	Contaminated work clothing must not be allowed out of the workplace.

Precautionary statement(s) Response

P308+P313	IF exposed or concerned: Get medical advice/ attention.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P391	Collect spillage.

Precautionary statement(s) Storage

P405 Store locked up.

Precautionary statement(s) Disposal

P501

Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
1314-13-2	>60	zinc oxide
57-11-4	1-5	stearic acid
14807-96-6	1-5	talc
Not Available	balance	Ingredients determined not to be hazardous

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4 First-aid measures

Description of first aid measures

Eye Contact	 If this product comes in contact with the eyes: Immediately hold eyelids apart and flush the eye continuously with running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. Transport to hospital or doctor without delay. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	 If skin or hair contact occurs: Immediately flush body and clothes with large amounts of water, using safety shower if available. Quickly remove all contaminated clothing, including footwear. Wash skin and hair with running water. Continue flushing with water until advised to stop by the Poisons Information Centre. Transport to hospital, or doctor.
Inhalation	 If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. Transport to hospital, or doctor, without delay.
Ingestion	 Give a slurry of activated charcoal in water to drink. NEVER GIVE AN UNCONSCIOUS PATIENT WATER TO DRINK. At least 3 tablespoons in a glass of water should be given. Although induction of vomiting may be recommended (IN CONSCIOUS PERSONS ONLY), such a first aid measure is dissuaded due to the risk of aspiration of stomach contents. (i) It is better to take the patient to a doctor who can decide on the necessity and method of emptying the stomach. (ii) Special circumstances may however exist; these include non-availability of charcoal and the ready availability of the doctor. NOTE: If vomiting is induced, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. NOTE: Wear protective gloves when inducing vomiting. REFER FOR MEDICAL ATTENTION WITHOUT DELAY. In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition. If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action will be the responsibility of the medical specialist. If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS. (ICSC20305/20307)

Most important symptoms and effects, both acute and delayed

See Section 11

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

- Absorption of zinc compounds occurs in the small intestine.
- The metal is heavily protein bound.
- Elimination results primarily from faecal excretion.
- The usual measures for decontamination (Ipecac Syrup, lavage, charcoal or cathartics) may be administered, although patients usually have sufficient vomiting not to require them.
- CaNa2EDTA has been used successfully to normalise zinc levels and is the agent of choice.

Continued...

SECTION 5 Fire-fighting measures

Extinguishing media

- Water spray or fog.
- ▶ Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

Special hazards arising from the substrate or mixture

Fire Incompatibility	Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

Special protective equipment and precautions for fire-fighters

Fire Fighting	 Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. Use fire fighting procedures suitable for surrounding area. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	 Solid which exhibits difficult combustion or is difficult to ignite. Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited; once initiated larger particles up to 1400 microns diameter will contribute to the propagation of an explosion. A dust explosion may release large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people. Usually the initial or primary explosion takes place in a confined space such as plant or machinery, and can be of sufficient force to damage or rupture the plant. If the shock wave from the primary explosion enters the surrounding area, it will disturb any settled dust layers, forming a second dust cloud, and often initiate a much larger secondary explosion. All large scale explosions have resulted from chain reactions of this type. Dry dust can also be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport. Build-up of electrostatic charge may be prevented by bonding and grounding. Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting. All movable parts coming in contact with this material should have a speed of less than 1-metre/sec. Combustion products include: carbon monxide (CO) carbon dioxide (CO) sulfur oxides (SOX) metal oxides other pyrolysis products typical of burning organic material.

SECTION 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	 Remove all ignition sources. Clean up all spills immediately. Avoid contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Use dry clean up procedures and avoid generating dust. Place in a suitable, labelled container for waste disposal. Environmental hazard - contain spillage.
Major Spills	Environmental hazard - contain spillage. Moderate hazard. CAUTION: Advise personnel in area.

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	 Alert Emergency Services and tell them location and nature of hazard.
	Control personal contact by wearing protective clothing.
	Prevent, by any means available, spillage from entering drains or water courses.
	Recover product wherever possible.
	▶ IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other
	containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal.
	ALWAYS: Wash area down with large amounts of water and prevent runoff into drains.
	If contamination of drains or waterways occurs, advise Emergency Services.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

Precautions for safe handling

Safe handling	 Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Prevent concentration in hollows and sumps. DO NOT enter confined spaces until atmosphere has been checked. DO NOT allow material to contact humans, exposed food or food utensits. Avoid contact with incompatible materials. When handing, DO NOT eat, drink or sonke. Keep containers securely sealed when not in use. Avoid physical damage to containers. Avoid physical damage to containers. Avoid physical damage to containers. Work clothes should be laundered separately. Launder contaminated clothing before re-use. Use good occupational work practice. Observe manufacturer's storage and handling recommendations contained within this SDS. Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained. Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions) Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame. Establish good housekeeping practices. Wes continuous suction at points of dust generation to capture and minimise the accumulation of dust. Particular attention should be given to overhead and hidden horizontal surfaces to minimise the probability of a "secondary" explosion. According to NFPA Standard 654, dust layers 172 in (10.8 mm) hick can be sufficient to warrant immediate cleaning of the area. Do not use air hoses for cleaning. Minimise aystems must be designed in accordance with applicable standards (e.g. NFPA including 654 and 77) and other national
Other information	 Store in original containers. Keep containers securely sealed. Store in a cool, dry area protected from environmental extremes. Store away from incompatible materials and foodstuff containers. Protect containers against physical damage and check regularly for leaks. Observe manufacturer's storage and handling recommendations contained within this SDS. For major quantities: Consider storage in bunded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams). Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities.

Conditions for safe storage, including any incompatibilities

Suitable container	Polyethylene or polypropylene container.

	Check all containers are clearly labelled and free from leaks.
Storage incompatibility	 Avoid strong acids, bases. Avoid reaction with oxidising agents

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
US OSHA Permissible Exposure Limits (PELs) Table Z-1	zinc oxide	Zinc oxide fume	5 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1	zinc oxide	Zinc oxide- Respirable fraction	5 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1	zinc oxide	Zinc oxide- Total dust	15 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3	zinc oxide	Inert or Nuisance Dust: Respirable fraction	5 mg/m3 / 15 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3	zinc oxide	Inert or Nuisance Dust: Total Dust	15 mg/m3 / 50 mppcf	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)	zinc oxide	Zinc oxide - Dust	5 mg/m3	Not Available	15 mg/m3	Not Available
US NIOSH Recommended Exposure Limits (RELs)	zinc oxide	Zinc oxide - Fume	5 mg/m3	10 mg/m3	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1	talc	Particulates Not Otherwise Regulated (PNOR)- Total dust	15 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1	talc	Particulates Not Otherwise Regulated (PNOR)- Respirable fraction	5 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3	talc	Silicates (less than 1% crystalline silica): Talc (not containing asbestos)	20 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3	talc	Silicates (less than 1% crystalline silica): Soapstone	20 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3	talc	Silicates (less than 1% crystalline silica): Talc (containing asbestos)	Not Available	Not Available	Not Available	Use asbestos limit
US NIOSH Recommended Exposure Limits (RELs)	talc	Talc (containing no asbestos and less than 1% quartz) - respirable	2 mg/m3	Not Available	Not Available	Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2		TEEL-3
zinc oxide	10 mg/m3	15 mg/m3		2,500 mg/m3
stearic acid	14 mg/m3	150 mg/m3		910 mg/m3
Ingredient	Original IDLH		Revised IDLH	
zinc oxide	500 mg/m3		Not Available	
stearic acid	Not Available		Not Available	
talc	1,000 mg/m3		Not Available	

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
stearic acid	E	≤ 0.01 mg/m³

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limi	it		
Notes:	Occupational exposure banding is a process of assigning ch potency and the adverse health outcomes associated with ex band (OEB), which corresponds to a range of exposure cond	xposure. The output of this process is an oc	cupational exposure		
xposure controls					
	Engineering controls are used to remove a hazard or place a engineering controls can be highly effective in protecting wor provide this high level of protection. The basic types of engineering controls are: Process controls which involve changing the way a job activi Enclosure and/or isolation of emission source which keeps a that strategically "adds" and "removes" air in the work enviro designed properly. The design of a ventilation system must m Employers may need to use multiple types of controls to prev Local exhaust ventilation usually required. If risk of overexpo obtain adequate protection. Supplied-air type respirator may ensure adequate protection. An approved self contained breathing apparatus (SCBA) ma Provide adequate ventilation in warehouse or closed storage "escape" velocities which, in turn, determine the "capture vel contaminant. Type of Contaminant:	kers and will typically be independent of work ty or process is done to reduce the risk. The selected hazard "physically" away from the nment. Ventilation can remove or dilute an a natch the particular process and chemical or vent employee overexposure. Sure exists, wear approved respirator. Correct be required in special circumstances. Correct y be required in some situations.	rker interactions to worker and ventilation ir contaminant if contaminant in use. In this essential to ct fit is essential to rkplace possess varyin		
	solvent, vapours, degreasing etc., evaporating from tank (i	n still air)	0.25-0.5 m/s		
		-	(50-100 f/min.)		
Appropriate engineering controls	aerosols, fumes from pouring operations, intermittent conta welding, spray drift, plating acid fumes, pickling (released a generation)	0.5-1 m/s (100-200 f/min.)			
	direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)		1-2.5 m/s (200-500 f/min.)		
	grinding, abrasive blasting, tumbling, high speed wheel gen velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)			
	Within each range the appropriate value depends on:				
	Lower end of the range	Upper end of the range			
	1: Room air currents minimal or favourable to capture	1: Disturbing room air currents			
	2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity			
	3: Intermittent, low production.	3: High production, heavy use			
	4: Large hood or large air mass in motion Simple theory shows that air velocity falls rapidly with distance generally decreases with the square of distance from the ext extraction point should be adjusted, accordingly, after referent extraction fan, for example, should be a minimum of 1-2 m/s meters distant from the extraction point. Other mechanical co- apparatus, make it essential that theoretical air velocities are installed or used.	raction point (in simple cases). Therefore the nee to distance from the contaminating source (200-400 f/min) for extraction of solvents ge onsiderations, producing performance deficit	e air speed at the ce. The air velocity at th nerated in a tank 2 s within the extraction		
Individual protection measures, such as personal protective equipment		3			
Eye and face protection	 Safety glasses with unperforated side shields may be use spectacles are not sufficient where complete eye protect a danger of splashing, or if the material may be under protecting a goggles. Whenever there is a danger of the material goggles. Whenever there is a danger of the material equivalent] Full face shield (20 cm, 8 in minimum) may be required for afford face protection. Alternatively a gas mask may replace splash goggles and Contact lenses may pose a special hazard; soft contact I document, describing the wearing of lenses or restriction include a review of lens absorption and adsorption for the Medical and first-aid personnel should be trained in their event of chemical exposure, begin eye irrigation immedia be removed at the first signs of eye redness or irritation - 	ion is needed such as when handling bulk-quessure. aterial coming in contact with the eyes; gogg or supplementary but never for primary prote d face shields. enses may absorb and concentrate irritants. s on use, should be created for each workpl e class of chemicals in use and an account of removal and suitable equipment should be r ately and remove contact lens as soon as pro-	uantities, where there is les must be properly ection of eyes; these A written policy ace or task. This should of injury experience. eadily available. In the acticable. Lens should		

	have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].
Skin protection	See Hand protection below
Hands/feet protection	 Is blow length PVC gloves NOTE: The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. Contaminated learther items, such as shoes, belts and vatch-bands should be removed and destroyed. The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer to manufacturer to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be obtained from the manufacturer of the protective gloves and has to be obtained from the manufacturer of the protective gloves, hands should be washed and dride through. Application of a non-profined motisturies is recommended. Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: inequency and duration of contact. chemical resistance of glove material. glove thickness and dexterity Select gloves tested to a nelevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent). When prohoged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.1.0 or national equivalent) is recommended. Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for tong-term use. Contaminated gloves should be replaced. As defined in ASTM F-733-96 in any application, gloves are rated as: Excellent when breakthrough time < 20 min Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for tong-term stating digroves that i
Body protection	See Other protection below
Other protection	 Overalls. P.V.C apron. Barrier cream. Skin cleansing cream. Eye wash unit.

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the *computer-generated* selection:

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Material

Respiratory protection

Type AX-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Required Minimum	Half-Face	Full-Face	Powered Air
Protection Factor	Respirator	Respirator	Respirator
up to 10 x ES	AX P1 Air-line*	-	AX PAPR-P1 -

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BUTYL	С
BUTYL/NEOPRENE	С
CPE	С
HYPALON	С
NATURAL RUBBER	С
NATURAL+NEOPRENE	С
NEOPRENE	С
NEOPRENE/NATURAL	С
NITRILE	С
NITRILE+PVC	С
PE/EVAL/PE	С
PVA	С
PVC	С
PVDC/PE/PVDC	С
SARANEX-23	С
SARANEX-23 2-PLY	С
TEFLON	С
VITON	С
VITON/NEOPRENE	C

* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

 $\ensuremath{\textbf{NOTE}}$: As a series of factors will influence the actual performance of the glove,

a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

Ansell Glove Selection

Glove — In order of recommendation
AlphaTec 02-100
AlphaTec® 15-554
AlphaTec® Solvex® 37-185
AlphaTec® 38-612
AlphaTec® 58-008
AlphaTec® 58-530B
AlphaTec® 58-530W
AlphaTec® 58-735
AlphaTec® 79-700
AlphaTec® Solvex® 37-675

up to 50 x ES	Air-line**	AX P2	AX PAPR-P2
up to 100 x ES	-	AX P3	-
		Air-line*	-
100+ x ES	-	Air-line**	AX PAPR-P3

* - Negative pressure demand ** - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.

 The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).

• Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.

 Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.

 Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)

· Use approved positive flow mask if significant quantities of dust becomes airborne.

· Try to avoid creating dust conditions.

Where significant concentrations of the material are likely to enter the breathing zone, a Class P3 respirator may be required.

Class P3 particulate filters are used for protection against highly toxic or highly irritant particulates.

Filtration rate: Filters at least 99.95% of airborne particles Suitable for:

Relatively small particles generated by mechanical processes eg. grinding, cutting, sanding, drilling, sawing.

Sub-micron thermally generated particles e.g. welding fumes, fertilizer and bushfire smoke.

Biologically active airborne particles under specified infection control applications e.g. viruses, bacteria, COVID-19, SARS

 \cdot Highly toxic particles e.g. Organophosphate Insecticides, Radionuclides, Asbestos

Note: P3 Rating can only be achieved when used with a Full Face Respirator or Powered Air-Purifying Respirator (PAPR). If used with any other respirator, it will only provide filtration protection up to a P2 rating.

SECTION 9 Physical and chemical properties

Information on basic phy	formation on basic physical and chemical properties		
Appearance	Pink cylindrical shape solid; insoluble in water.		
Physical state	Solid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Applicable

pH (as supplied)	Not Applicable	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Applicable
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Applicable	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Applicable	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Applicable	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Applicable	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Applicable	Gas group	Not Available
Solubility in water	Immiscible	pH as a solution (1%)	Not Applicable
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	 Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

Inhaled	There is some evidence to suggest that the material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. Inhalation of vapours or aerosols (mists, fumes), generated by the material during the course of normal handling, may be damaging to the health of the individual. Effects on lungs are significantly enhanced in the presence of respirable particles.
Ingestion	Soluble zinc salts produce irritation and corrosion of the alimentary tract with pain, and vomiting. Death can occur due to insufficiency of food intake due to severe narrowing of the oesophagus and pylorus.
Skin Contact	There is some evidence to suggest that the material may cause mild but significant inflammation of the skin either following direct contact or after a delay of some time. Repeated exposure can cause contact dermatitis which is characterised by redness, swelling and blistering. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. Repeated or excessive handling, coupled with poor personal hygiene, may result in acne-like eruptions known as "zinc oxide pox".
Eye	There is some evidence to suggest that this material can cause eye irritation and damage in some persons.
Chronic	Welding or flame cutting of metals with zinc or zinc dust coatings may result in inhalation of zinc oxide fume; high concentrations of zinc oxide fume may result in "metal fume fever"; also known as "brass chills", an industrial disease of short duration. [I.L.O] Symptoms include malaise, fever, weakness, nausea and may appear quickly if operations occur in enclosed or poorly ventilated areas. There has been some concern that this material can cause cancer or mutations but there is not enough data to make an assessment. Overexposure to the breathable dust may cause coughing, wheezing, difficulty in breathing and impaired lung function. Chronic symptoms may include decreased vital lung capacity and chest infections. Repeated exposures in the workplace to high levels of fine-divided dusts may produce a condition known as pneumoconiosis, which is the lodgement of any inhaled dusts in the lung, irrespective of the effect. This is particularly true when a significant number of particles less than 0.5 microns (1/50000 inch) are present. Lung shadows are seen in the X-ray. Symptoms of pneumoconiosis may include a progressive dry cough, shortness of breath on exertion, increased chest expansion, weakness and weight loss. As the disease progresses, the cough produces stringy phlegm, vital capacity decreases further, and shortness of breath becomes more severe. Other signs or symptoms include changed breath sounds, reduced oxygen uptake during exercise, emphysema and rarely, pneumothorax (air in the lung cavity).

Removing workers from the possibility of further exposure to dust generally stops the progress of lung abnormalities. When there is high potential for worker exposure, examinations at regular period with emphasis on lung function should be performed. Inhaling dust over an extended number of years may cause pneumoconiosis, which is the accumulation of dusts in the lungs and the subsequent tissue reaction. This may or may not be reversible.

Not Available	Not Available	
ΤΟΧΙΟΙΤΥ	IRRITATION	
dermal (rat) LD50: >2000 mg/kg ^[1]	Eye (rabbit) : 500 mg/24 h - mild	
Inhalation(Rat) LC50: >1.79 mg/l4h ^[1]	Eye: no adverse effect observed (not irritating) ^[1]	
Oral (Rat) LD50: >5000 mg/kg ^[1]	Skin (rabbit) : 500 mg/24 h- mild	
	Skin: no adverse effect observed (not irritating) ^[1]	
ΤΟΧΙΟΙΤΥ	IRRITATION	
Dermal (rabbit) LD50: >5000 mg/kg ^[2]	Eye: no adverse effect observed (not irritating) ^[1]	
Inhalation(Rat) LC50: >0.162 mg/l4h ^[1]	Skin (human): 75 mg/3d-I-mild	
Oral (Rat) LD50: >2000 mg/kg ^[1]	Skin (rabbit):500 mg/24h-moderate	
	Skin: no adverse effect observed (not irritating) ^[1]	
ΤΟΧΙΟΙΤΥ	IRRITATION	
dermal (rat) LD50: >2000 mg/kg ^[1]	Eye: no adverse effect observed (not irritating) ^[1]	
Inhalation(Rat) LC50: >2.1 mg/l4h ^[1]	Skin (human): 0.3 mg/3d-I mild	
Oral (Rat) LD50: >5000 mg/kg ^[1]	Skin: no adverse effect observed (not irritating) ^[1]	
	dermal (rat) LD50: >2000 mg/kg ^[1] Inhalation(Rat) LC50: >1.79 mg/l4h ^[1] Oral (Rat) LD50: >5000 mg/kg ^[1] TOXICITY Dermal (rabbit) LD50: >5000 mg/kg ^[2] Inhalation(Rat) LC50: >0.162 mg/l4h ^[1] Oral (Rat) LD50: >2000 mg/kg ^[1] TOXICITY dermal (rat) LD50: >2000 mg/kg ^[1] Inhalation(Rat) LC50: >2.1 mg/l4h ^[1]	

STEARIC ACID	Equivocal tumorigen by RTEC criteria
TALC	No significant acute toxicological data identified in literature search. The overuse of talc in nursing infants has resulted in respiratory damage causing fluid in the lungs and lung inflammation which may lead to death within hours of inhalation. Long-term exposure can also cause a variety of respiratory symptoms. The substance is classified by IARC as Group 3: NOT classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing.
ZINC OXIDE & STEARIC ACID	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
STEARIC ACID & TALC	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.

Acute Toxicity	×	Carcinogenicity	×
Skin Irritation/Corrosion	×	Reproductivity	×
Serious Eye Damage/Irritation	×	STOT - Single Exposure	×
Respiratory or Skin sensitisation	×	STOT - Repeated Exposure	×
Mutagenicity	×	Aspiration Hazard	×

Legend: X – Data either not available or does not fill the criteria for classification

Data available to make classification

SECTION 12 Ecological information

	Endpoint	Test Duration (hr)	Species	Value	Source
/DW Gutta Percha Points	Not Available	Not Available	Not Available	Not Available	Not Available
	Endpoint	Test Duration (hr)	Species	Value	Source
	BCF	1344h	Fish	19-110	7
	EC50	72h	Algae or other aquatic plants	0.022mg/L	2
ato a cast da	EC50	48h	Crustacea	0.105mg/L	2
zinc oxide	EC50	96h	Algae or other aquatic plants	0.042mg/L	2
	ErC50	72h	Algae or other aquatic plants	0.62mg/l	2
	LC50	96h	Fish	0.102mg/L	2
	EC10(ECx)	168h	Algae or other aquatic plants	0.003mg/L	2
	Endpoint	Test Duration (hr)	Species	Value	Sourc
eteenie eeid	EC50	72h	Algae or other aquatic plants	>0.9mg/l	2
stearic acid	EC50	48h	Crustacea	>4.8mg/l	2
	NOEC(ECx)	504h	Crustacea	>0.22mg/	2
	Endpoint	Test Duration (hr)	Species	Value	Sourc
6.1-	EC50	96h	Algae or other aquatic plants	7202.7mg/l	2
talc	LC50	96h	Fish	89581.016mg/	2
	NOEC(ECx)	720h	Algae or other aquatic plants	918.089mg/l	2
Legend:	Extracted from	1. IUCLID Toxicity Data 2. Europ	e ECHA Registered Substances - Ecotoxic	cological Information - Ag	uatic Toxici

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. **DO NOT** discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
stearic acid	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
zinc oxide	LOW (BCF = 217)
stearic acid	LOW (LogKOW = 8.23)

Mobility in soil

Ingredient	Mobility
stearic acid	LOW (KOC = 11670)

SECTION 13 Disposal considerations

aste treatment methods		
Product / Packaging disposal	 DO NOT allow wash water from cleaning or process equipment to enter drains. It may be necessary to collect all wash water for treatment before disposal. In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. Where in doubt contact the responsible authority. 	

SECTION 14 Transport information

Labels Required

Marine Pollutant	₹ <u>¥</u>	

Shipping container and transport vehicle placarding and labeling may vary from the below information. Products that are regulated for transport will be packaged and marked as Dangerous Goods in Limited Quantities according to US DOT, IATA and IMDG regulations. In case of reshipment, it is the responsibility of the shipper to determine the appropriate labels and markings in accordance with applicable transport regulations.

Land transport (DOT)

14.1. UN number or ID number	3077			
14.2. UN proper shipping name	Environmentally haz	Environmentally hazardous substance, solid, n.o.s. (contains zinc oxide)		
14.3. Transport hazard	Class	9		
class(es)	Subsidiary risk	Not Applicable		
14.4. Packing group	III			
14.5. Environmental hazard	Environmentally hazardous			
14.6. Special precautions for user	Hazard Label	9		
	Special provisions	8, 146, 335, 384, 441, A112, B54, B120, IB8, IP3, N20, N91, T1, TP33		

For Individual Packages of Environmentally Hazardous Substances meeting the descriptions of UN 3077 or UN 3082 that contain LESS THAN the reportable quantity (5 kg or 5 L) - Not Regulated

For Individual Packages of Environmentally Hazardous Substances meeting the descriptions of UN 3077 or UN 3082 that contain MORE THAN the reportable quantity (5 kg or 5 L) - Regulated and classified as below:

Air transport (ICAO-IATA / DGR)

14.1. UN number	3077			
14.2. UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (contains zinc oxide)			
	ICAO/IATA Class	9		
14.3. Transport hazard class(es)	ICAO / IATA Subsidiary Hazard	Not Applicable		
Class(65)	ERG Code	9L		
14.4. Packing group	Ш	III		
14.5. Environmental hazard	Environmentally hazardous			
	Special provisions		A97 A158 A179 A197 A215	
	Cargo Only Packing Instructions		956	
14.6. Special precautions for user	Cargo Only Maximum Qty / Pack		400 kg	
	Passenger and Cargo Packing Instructions		956	
	Passenger and Cargo Maximum Qty / Pack		400 kg	
	Passenger and Cargo Limited Quantity Packing Instructions		Y956	
	Passenger and Cargo Limited Maximum Qty / Pack		30 kg G	

Sea transport (IMDG-Code / GGVSee)

14.1. UN number	3077
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains zinc oxide)

14.3. Transport hazard class(es)	IMDG Class 9 IMDG Subrisk N	lot Applicable	
14.4. Packing group	III		
14.5 Environmental hazard	Marine Pollutant		
14.6. Special precautions for user	EMS Number Special provisions Limited Quantities	F-A, S-F 274 335 966 967 969 5 kg	

14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
zinc oxide	Not Available
stearic acid	Not Available
talc	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
zinc oxide	Not Available
stearic acid	Not Available
talc	Not Available

SECTION 15 Regulatory information

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

zinc oxide is found on the following regulatory lists

International WHO List of Proposed Occupational Exposure Limit (OEL)	US EPA Integrated Risk Information System (IRIS)	
Values for Manufactured Nanomaterials (MNMS)	US EPCRA Section 313 Chemical List	
US - Alaska Air Quality Control - Concentrations Triggering an Air Quality	US NIOSH Recommended Exposure Limits (RELs)	
Episode for Air Pollutants Other Than PM-2.5	US OSHA Permissible Exposure Limits (PELs) Table Z-1	
US - Massachusetts - Right To Know Listed Chemicals	US OSHA Permissible Exposure Limits (PELs) Table Z-3	
US CWA (Clean Water Act) - Priority Pollutants	US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory	
US CWA (Clean Water Act) - Toxic Pollutants		
US DOE Temporary Emergency Exposure Limits (TEELs)		
et and and the formula of the following maintenant later.		
stearic acid is found on the following regulatory lists		
US DOE Temporary Emergency Exposure Limits (TEELs)	US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory	
talc is found on the following regulatory lists		
Chemical Footprint Project - Chemicals of High Concern List	US - Massachusetts - Right To Know Listed Chemicals	
International Agency for Research on Cancer (IARC) - Agents Classified by	US NIOSH Carcinogen List	
the IARC Monographs	US NIOSH Recommended Exposure Limits (RELs)	
International Agency for Research on Cancer (IARC) - Agents Classified by	US OSHA Permissible Exposure Limits (PELs) Table Z-1	
the IARC Monographs - Group 2B: Possibly carcinogenic to humans	US OSHA Permissible Exposure Limits (PELs) Table Z-3	
International Agency for Research on Cancer (IARC) - Agents Classified by	US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory	
the IARC Monographs - Not Classified as Carcinogenic		
International WHO List of Proposed Occupational Exposure Limit (OEL)		
Values for Manufactured Nanomaterials (MNMS)		
US - Alaska Air Quality Control - Concentrations Triggering an Air Quality		
Episode for Air Pollutants Other Than PM-2.5		

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Flammable (Gases, Aerosols, Liquids, or Solids)	
Gas under pressure	No
Explosive	No
Self-heating	No
Pyrophoric (Liquid or Solid)	No
Pyrophoric Gas	No
Corrosive to metal	No
Oxidizer (Liquid, Solid or Gas)	No
Organic Peroxide	No
Self-reactive	No
In contact with water emits flammable gas	No
Combustible Dust	No
Carcinogenicity	Yes
Acute toxicity (any route of exposure)	No
Reproductive toxicity	No
Skin Corrosion or Irritation	No
Respiratory or Skin Sensitization	Yes
Serious eye damage or eye irritation	
Specific target organ toxicity (single or repeated exposure)	No
Aspiration Hazard	No
Germ cell mutagenicity	No
Simple Asphyxiant	No
Hazards Not Otherwise Classified	No

US. EPA CERCLA Hazardous Substances and Reportable Quantities (40 CFR 302.4)

None Reported

State Regulations

US. California Proposition 65

None Reported

National Inventory Status

National Inventory	Status	
Australia - AIIC / Australia Non-Industrial Use	Yes	
Canada - DSL	Yes	
Canada - NDSL	No (talc)	
China - IECSC	Yes	
Europe - EINEC / ELINCS / NLP	Yes	
Japan - ENCS	Yes	
Korea - KECI	Yes	
New Zealand - NZIoC	Yes	
Philippines - PICCS	Yes	
USA - TSCA	Yes	
Taiwan - TCSI	Yes	
Mexico - INSQ	Yes	
Vietnam - NCI	Yes	
Russia - FBEPH	Yes	
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.	

Revision Date	07/09/2023
Initial Date	21/08/2023

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC - TWA: Permissible Concentration-Time Weighted Average PC - STEL: Permissible Concentration-Short Term Exposure Limit IARC: International Agency for Research on Cancer ACGIH: American Conference of Governmental Industrial Hygienists STEL: Short Term Exposure Limit TEEL: Temporary Emergency Exposure Limit. IDLH: Immediately Dangerous to Life or Health Concentrations ES: Exposure Standard OSF: Odour Safety Factor NOAEL :No Observed Adverse Effect Level LOAEL: Lowest Observed Adverse Effect Level TLV: Threshold Limit Value LOD: Limit Of Detection OTV: Odour Threshold Value BCF: BioConcentration Factors BEI: Biological Exposure Index AIIC: Australian Inventory of Industrial Chemicals DSL: Domestic Substances List NDSL: Non-Domestic Substances List IECSC: Inventory of Existing Chemical Substance in China EINECS: European INventory of Existing Commercial chemical Substances ELINCS: European List of Notified Chemical Substances NLP: No-Longer Polymers ENCS: Existing and New Chemical Substances Inventory KECI: Korea Existing Chemicals Inventory NZIoC: New Zealand Inventory of Chemicals PICCS: Philippine Inventory of Chemicals and Chemical Substances TSCA: Toxic Substances Control Act TCSI: Taiwan Chemical Substance Inventory INSQ: Inventario Nacional de Sustancias Químicas NCI: National Chemical Inventory FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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TEL (+61 3) 9572 4700.