



# Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)

Maillefer Instruments Holding S.à.r.l

Chemwatch Hazard Alert Code: 3

Chemwatch: 5588-13

Issue Date: 08/02/2023

Version No: 2.1

Print Date: 14/03/2023

Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878)

S.REACH.CHE.EN.E

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

### 1.1. Product Identifier

Product name	Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)
Chemical Name	Not Applicable
Synonyms	A0166*, A0348*, A0167*, A0168*, A0348*, A1411*
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains zinc oxide and 4,4'-thiobis(6-tert-butyl-m-cresol))
Chemical formula	Not Applicable
Other means of identification	Not Available

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

Relevant identified uses	Carrier-based obturator intended for filling of the shaped, cleaned and irrigated root canal space. Use according to manufacturer's directions.  Notes: Hazard statement relates to device ingredients. Potential for exposure should not exist unless the device leaks, is exposed to high temperatures or is mechanically, physically or electrically abused.
Uses advised against	No specific uses advised against are identified.

### 1.3. Details of the manufacturer or supplier of the safety data sheet

Registered company name	Maillefer Instruments Holding S.à.r.l	Dentsply Sirona Venlo Distribution Center
Address	Chemin du Verger 3 Ballaigues 1338 Switzerland	Piri Reisweg 23 Sevenum 5975 PV Netherlands
Telephone	Not Available	+31 77 389 9916
Fax	Not Available	Not Available
Website	Not Available	Not Available
Email	Not Available	Not Available

### 1.4. Emergency telephone number

Association / Organisation	Tox Info Suisse	CHEMWATCH EMERGENCY RESPONSE (24/7)
Emergency telephone numbers	+41 145	+41 44 551 43 62
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

Une fois connecté et si le message n'est pas dans votre langue préférée alors s'il vous plaît cadran 07

Una volta collegato, se il messaggio non è nella lingua di preferenza, si prega di digitare 08

Sobald die Verbindung hergestellt und wenn die Nachricht nicht in der gewünschten Sprache dann wählen Sie bitte 10

## SECTION 2 Hazards identification

### 2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments [1]	H351 - Carcinogenicity Category 2, H400 - Hazardous to the Aquatic Environment Acute Hazard Category 1, H410 - Hazardous to the Aquatic Environment Long-Term Hazard Category 1
Legend:	1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)

2.2. Label elements

Hazard pictogram(s)	
Signal word	Warning

Hazard statement(s)

H351	Suspected of causing cancer.
H410	Very toxic to aquatic life with long lasting effects.

Supplementary Phrases

EUH208	Contains 4,4'-thiobis(6-tert-butyl-m-cresol). May produce an allergic reaction.
--------	---

Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P280	Wear protective gloves and protective clothing.
P273	Avoid release to the environment.

Precautionary statement(s) Response

P308+P313	IF exposed or concerned: Get medical advice/ attention.
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.
------	--

2.3. Other hazards

Inhalation and/or ingestion may produce health damage\*.

Cumulative effects may result following exposure\*.

May produce discomfort of the eyes, respiratory tract and skin\*.

Possible respiratory and skin sensitizer\*.

May possibly affect fertility\*.

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3 Composition / information on ingredients

3.1. Substances

See 'Composition on ingredients' in Section 3.2

3.2. Mixtures

1.CAS No 2.EC No 3.Index No 4.REACH No	%[weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
1.1314-13-2 2.215-222-5 3.030-013-00-7 4.Not Available	<50	<u>zinc oxide</u>	Hazardous to the Aquatic Environment Acute Hazard Category 1, Hazardous to the Aquatic Environment Long-Term Hazard Category 1; H400, H410, Not Applicable [2]	Not Available	Not Available
1.13463-67-7 2.236-675-5 3.022-006-00-2 4.Not Available	<10	<u>titanium dioxide</u>	Carcinogenicity Category 2; H351, Not Applicable [2]	Not Available	Not Available
1.14807-96-6 2.238-877-9 3.Not Available 4.Not Available	<7	<u>talc</u>	Acute Toxicity (Inhalation) Category 4, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H332, H335, Not Applicable [1]	Not Available	Not Available
1.14808-60-7 2.238-878-4 3.Not Available 4.Not Available	<5	<u>silica crystalline - quartz</u>	Specific Target Organ Toxicity - Repeated Exposure Category 2; H373, Not Applicable [1]	Not Available	Not Available
1.2379-74-0 2.219-163-6 3.Not Available	<2	<u>C.I. Pigment Red 181</u>	Hazardous to the Aquatic Environment Long-Term Hazard Category 1; H410, Not Applicable [1]	Not Available	Not Available

Continued...

**Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)**

1.CAS No 2.EC No 3.Index No 4.REACH No	[%[weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
4.Not Available					
1.67701-03-5 2.266-928-5 3.Not Available 4.Not Available	<2	<u>stearine, fatty acids C16-18</u>	Serious Eye Damage/Eye Irritation Category 2; H319, Not Applicable [1]	Not Available	Not Available
1.96-69-5 2.202-525-2 3.Not Available 4.Not Available	<1	<u>4,4'-thiobis(6-tert-butyl-m-cresol)</u>	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2, Sensitisation (Skin) Category 1, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, Hazardous to the Aquatic Environment Long-Term Hazard Category 1; H315, H319, H317, H335, H410, Not Applicable [1]	Not Available	Not Available
1.292-64-8 2.206-031-8 3.Not Available 4.Not Available	<1	<u>cyclooctane</u>	Flammable Liquids Category 3, Specific Target Organ Toxicity - Single Exposure (Narcotic Effects) Category 3, Aspiration Hazard Category 1; H226, H336, H304, Not Applicable [1]	Not Available	Not Available
Not Available	balance	Ingredients determined not to be hazardous	Not Applicable	Not Applicable	Not Available
<b>Legend:</b> 1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties					

## SECTION 4 First aid measures

### 4.1. Description of first aid measures

<b>Eye Contact</b>	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> <li>▶ Immediately hold eyelids apart and flush the eye continuously with running water.</li> <li>▶ 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.</li> <li>▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.</li> <li>▶ Transport to hospital or doctor without delay.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul> <p>For THERMAL burns:</p> <ul style="list-style-type: none"> <li>▶ <b>Do NOT remove contact lens</b></li> <li>▶ Lay victim down, on stretcher if available and pad <b>BOTH</b> eyes, make sure dressing does not press on the injured eye by placing thick pads under dressing, above and below the eye.</li> <li>▶ Seek urgent medical assistance, or transport to hospital.</li> <li>▶ <b>DO NOT attempt to remove particles attached to or embedded in eye .</b></li> <li>▶ Lay victim down, on stretcher if available and pad <b>BOTH</b> eyes, make sure dressing does not press on the injured eye by placing thick pads under dressing, above and below the eye.</li> <li>▶ Seek urgent medical assistance, or transport to hospital.</li> </ul>
<b>Skin Contact</b>	<p>In case of burns:</p> <ul style="list-style-type: none"> <li>▶ Immediately apply cold water to burn either by immersion or wrapping with saturated clean cloth.</li> <li>▶ <b>DO NOT remove or cut away clothing over burnt areas. DO NOT pull away clothing which has adhered to the skin as this can cause further injury.</b></li> <li>▶ <b>DO NOT break blister or remove solidified material.</b></li> <li>▶ Quickly cover wound with dressing or clean cloth to help prevent infection and to ease pain.</li> <li>▶ For large burns, sheets, towels or pillow slips are ideal; leave holes for eyes, nose and mouth.</li> <li>▶ <b>DO NOT apply ointments, oils, butter, etc. to a burn under any circumstances.</b></li> <li>▶ Water may be given in small quantities if the person is conscious.</li> <li>▶ Alcohol is not to be given under any circumstances.</li> <li>▶ Reassure.</li> <li>▶ Treat for shock by keeping the person warm and in a lying position.</li> <li>▶ Seek medical aid and advise medical personnel in advance of the cause and extent of the injury and the estimated time of arrival of the patient.</li> </ul>
<b>Inhalation</b>	<p>Finished product is unlikely to generate dust when used according to the intended purpose.</p> <ul style="list-style-type: none"> <li>▶ If fumes or combustion products are inhaled remove from contaminated area.</li> <li>▶ Lay patient down. Keep warm and rested.</li> <li>▶ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.</li> <li>▶ 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.</li> <li>▶ Transport to hospital, or doctor, without delay.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▶ Give a slurry of activated charcoal in water to drink. <b>NEVER GIVE AN UNCONSCIOUS PATIENT WATER TO DRINK.</b></li> <li>▶ At least 3 tablespoons in a glass of water should be given.</li> <li>▶ Although induction of vomiting may be recommended (<b>IN CONSCIOUS PERSONS ONLY</b>), 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.</li> </ul> <p><b>NOTE:</b> If vomiting is induced, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</p> <p><b>NOTE:</b> Wear protective gloves when inducing vomiting.</p> <ul style="list-style-type: none"> <li>▶ REFER FOR MEDICAL ATTENTION WITHOUT DELAY.</li> <li>▶ 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.</li> <li>▶ 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.</li> <li>▶ 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)</li> </ul>

## Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)

### 4.2 Most important symptoms and effects, both acute and delayed

See Section 11

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

Both dimercaptol and calcium disodium edetate are said to be effective in acute experimental tungsten poisonings.

- ▶ 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.

[Ellenhorn and Barceloux: Medical Toxicology]

- ▶ After ingestion of barium acid salts, severe gastro-intestinal irritation followed by muscle twitching, progressive flaccid paralysis and severe hypokalaemia and hypertension, occurs.
- ▶ Respiratory failure, renal failure and occasional cardiac dysrhythmias may result from an acute ingestion.
- ▶ Use sodium sulfate as a cathartic. Add 5-10 gm of sodium sulfate to lavage solution or as fluid supplement to Ipecac syrup (the sulfate salt is not absorbed)
- ▶ Monitor cardiac rhythm and serum potassium closely to establish the trend over the first 24 hours. Large doses of potassium may be needed to correct the hypokalaemia.
- ▶ Administer generous amounts of fluid replacement but monitor the urine and serum for evidence of renal failure. [Ellenhorn and Barceloux: Medical Toxicology]

Copper, magnesium, aluminium, antimony, iron, manganese, nickel, zinc (and their compounds) in welding, brazing, galvanising or smelting operations all give rise to thermally produced particulates of smaller dimension than may be produced if the metals are divided mechanically. Where insufficient ventilation or respiratory protection is available these particulates may produce "metal fume fever" in workers from an acute or long term exposure.

- ▶ Onset occurs in 4-6 hours generally on the evening following exposure. Tolerance develops in workers but may be lost over the weekend. (Monday Morning Fever)
- ▶ Pulmonary function tests may indicate reduced lung volumes, small airway obstruction and decreased carbon monoxide diffusing capacity but these abnormalities resolve after several months.
- ▶ Although mildly elevated urinary levels of heavy metal may occur they do not correlate with clinical effects.
- ▶ The general approach to treatment is recognition of the disease, supportive care and prevention of exposure.
- ▶ Seriously symptomatic patients should receive chest x-rays, have arterial blood gases determined and be observed for the development of tracheobronchitis and pulmonary edema.

[Ellenhorn and Barceloux: Medical Toxicology]

## SECTION 5 Firefighting measures

### 5.1. Extinguishing media

- ▶ **Do NOT direct a solid stream of water or foam into burning molten material; this may cause spattering and spread the fire.**
- ▶ **DO NOT** use halogenated fire extinguishing agents.

### 5.2. Special hazards arising from the substrate or mixture

<b>Fire Incompatibility</b>	<p>always follow finished product IFU</p> <ul style="list-style-type: none"> <li>▶ Reacts with acids producing flammable / explosive hydrogen (H2) gas</li> </ul>
-----------------------------	---

### 5.3. Advice for firefighters

<b>Fire Fighting</b>	<p>Finished product is unlikely to generate fire when used according to the intended purpose.</p> <ul style="list-style-type: none"> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves in the event of a fire.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Use fire fighting procedures suitable for surrounding area.</li> <li>▶ <b>DO NOT</b> approach containers suspected to be hot.</li> <li>▶ Cool fire exposed containers with water spray from a protected location.</li> <li>▶ If safe to do so, remove containers from path of fire.</li> <li>▶ Equipment should be thoroughly decontaminated after use.</li> </ul>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ Solid which exhibits difficult combustion or is difficult to ignite.</li> <li>▶ 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.</li> <li>▶ 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.</li> <li>▶ 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.</li> <li>▶ 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.</li> <li>▶ Dry dust can also be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.</li> <li>▶ Build-up of electrostatic charge may be prevented by bonding and grounding.</li> <li>▶ Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.</li> <li>▶ All movable parts coming in contact with this material should have a speed of less than 1-metre/sec.</li> </ul> <p>Combustion products include:</p> <ul style="list-style-type: none"> <li>carbon monoxide (CO)</li> <li>carbon dioxide (CO2)</li> <li>nitrogen oxides (NOx)</li> <li>sulfur oxides (SOx)</li> <li>sulfur dioxide (SO2)</li> <li>silicon dioxide (SiO2)</li> <li>metal oxides</li> <li>tungsten</li> <li>other pyrolysis products typical of burning organic material.</li> </ul> <p>Decomposes at high temperatures to produce barium oxide. Barium oxide is strongly alkaline and, upon contact with water, is exothermic. When barium oxide reacts with oxygen to give a peroxide, there is a fire and explosion risk.</p>

## Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)

### SECTION 6 Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

See section 8

#### 6.2. Environmental precautions

See section 12

#### 6.3. Methods and material for containment and cleaning up

<b>Minor Spills</b>	<ul style="list-style-type: none"> <li>▶ Remove all ignition sources.</li> <li>▶ Clean up all spills immediately.</li> <li>▶ Avoid contact with skin and eyes.</li> <li>▶ Control personal contact with the substance, by using protective equipment.</li> <li>▶ Use dry clean up procedures and avoid generating dust.</li> <li>▶ Place in a suitable, labelled container for waste disposal.</li> </ul> <p>Environmental hazard - contain spillage.</p>
<b>Major Spills</b>	<p>Environmental hazard - contain spillage. Moderate hazard.</p> <ul style="list-style-type: none"> <li>▶ <b>CAUTION:</b> Advise personnel in area.</li> <li>▶ Alert Emergency Services and tell them location and nature of hazard.</li> <li>▶ Control personal contact by wearing protective clothing.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Recover product wherever possible.</li> <li>▶ <b>IF DRY:</b> Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. <b>IF WET:</b> Vacuum/shovel up and place in labelled containers for disposal.</li> <li>▶ <b>ALWAYS:</b> Wash area down with large amounts of water and prevent runoff into drains.</li> <li>▶ If contamination of drains or waterways occurs, advise Emergency Services.</li> </ul>

#### 6.4. Reference to other sections

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

### SECTION 7 Handling and storage

#### 7.1. Precautions for safe handling

<b>Safe handling</b>	<ul style="list-style-type: none"> <li>▶ The greatest potential for injury caused by molten materials occurs during purging of machinery (moulders, extruders etc.)</li> <li>▶ It is essential that workers in the immediate area of the machinery wear eye and skin protection (such as full face, safety glasses, heat resistant gloves, overalls and safety boots) as protection from thermal burns.</li> <li>▶ Fumes or vapours emitted from hot melted materials, during converting operations, may condense on overhead metal surfaces or exhaust ducts. The condensate may contain substances which are irritating or toxic. Avoid contact of that material with the skin. Wear rubber or other impermeable gloves when cleaning contaminated areas.</li> <li>▶ Avoid process temperatures above decomposition temperatures. Overheating may occur at excessively high cylinder heats, overworking of the melt by wrong screw configuration, or by long dwell time in the machine. Under such conditions, thermal emissions and heat-degradation products might, without proper ventilation, reach hazardous concentrations in the converting area. Hot purgings should be collected only as thin flat strands to allow for rapid cooling. Hot purgings should be cooled by quenching in water in a well-ventilated area.</li> </ul> <p>For molten metals:</p> <ul style="list-style-type: none"> <li>· Molten metal and water can be an explosive combination. The risk is greatest when there is sufficient molten metal to entrap or seal off water. Water and other forms of contamination on or contained in scrap or remelt ingot are known to have caused explosions in melting operations. While the products may have minimal surface roughness and internal voids, there remains the possibility of moisture contamination or entrapment. If confined, even a few drops can lead to violent explosions.</li> <li>· All tooling, containers, molds and ladles, which come in contact with molten metal must be preheated or specially coated, rust free and approved for such use.</li> <li>· Any surfaces that may contact molten metal (e.g. concrete) should be specially coated</li> <li>· Drops of molten metal in water (e.g. from plasma arc cutting), while not normally an explosion hazard, can generate enough flammable hydrogen gas to present an explosion hazard. Vigorous circulation of the water and removal of the particles minimise the hazard.</li> </ul> <p>During melting operations, the following minimum guidelines should be observed:</p> <ul style="list-style-type: none"> <li>· Inspect all materials prior to furnace charging and completely remove surface contamination such as water, ice, snow, deposits of grease and oil or other surface contamination resulting from weather exposure, shipment, or storage.</li> <li>· Store materials in dry, heated areas with any cracks or cavities pointed downwards.</li> <li>· Preheat and dry large objects adequately before charging in to a furnace containing molten metal. This is typically done by the use of a drying oven or homogenising furnace. The dry cycle should bring the metal temperature of the coldest item of the batch to 200 degree C (400 deg F) and then hold at that temperature for 6 hours.</li> <li>▶ Avoid all personal contact, including inhalation.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Prevent concentration in hollows and sumps.</li> <li>▶ <b>DO NOT enter confined spaces until atmosphere has been checked.</b></li> <li>▶ <b>DO NOT allow material to contact humans, exposed food or food utensils.</b></li> <li>▶ Avoid contact with incompatible materials.</li> <li>▶ <b>When handling, DO NOT eat, drink or smoke.</b></li> <li>▶ Keep containers securely sealed when not in use.</li> <li>▶ Avoid physical damage to containers.</li> <li>▶ Always wash hands with soap and water after handling.</li> <li>▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use.</li> <li>▶ Use good occupational work practice.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</li> <li>▶ 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)</li> <li>▶ Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.</li> <li>▶ Establish good housekeeping practices.</li> <li>▶ Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.</li> <li>▶ Use continuous suction at points of dust generation to capture and minimise the accumulation of dusts. Particular attention should be given</li> </ul>
----------------------	---

## Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)

	<p>to overhead and hidden horizontal surfaces to minimise the probability of a "secondary" explosion. According to NFPA Standard 654, dust layers 1/32 in.(0.8 mm) thick can be sufficient to warrant immediate cleaning of the area.</p> <ul style="list-style-type: none"> <li>▶ Do not use air hoses for cleaning.</li> <li>▶ Minimise dry sweeping to avoid generation of dust clouds. Vacuum dust-accumulating surfaces and remove to a chemical disposal area. Vacuums with explosion-proof motors should be used.</li> <li>▶ Control sources of static electricity. Dusts or their packages may accumulate static charges, and static discharge can be a source of ignition.</li> <li>▶ Solids handling systems must be designed in accordance with applicable standards (e.g. NFPA including 654 and 77) and other national guidance.</li> <li>▶ Do not empty directly into flammable solvents or in the presence of flammable vapors.</li> <li>▶ The operator, the packaging container and all equipment must be grounded with electrical bonding and grounding systems. Plastic bags and plastics cannot be grounded, and antistatic bags do not completely protect against development of static charges.</li> </ul> <p>Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.</p> <ul style="list-style-type: none"> <li>▶ <b>Do NOT cut, drill, grind or weld such containers.</b></li> <li>▶ In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.</li> </ul>
<b>Fire and explosion protection</b>	See section 5
<b>Other information</b>	<ul style="list-style-type: none"> <li>▶ Store in original containers.</li> <li>▶ Keep containers securely sealed.</li> <li>▶ Store in a cool, dry area protected from environmental extremes.</li> <li>▶ Store away from incompatible materials and foodstuff containers.</li> <li>▶ Protect containers against physical damage and check regularly for leaks.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul> <p>For major quantities:</p> <ul style="list-style-type: none"> <li>▶ Consider storage in bunded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams).</li> <li>▶ Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities.</li> </ul>

### 7.2. Conditions for safe storage, including any incompatibilities

<b>Suitable container</b>	<ul style="list-style-type: none"> <li>▶ Polyethylene or polypropylene container.</li> <li>▶ Check all containers are clearly labelled and free from leaks.</li> </ul>
<b>Storage incompatibility</b>	<ul style="list-style-type: none"> <li>▶ Avoid strong acids, bases.</li> <li>▶ Avoid reaction with oxidising agents</li> <li>▶ Shall be stored away from sunlight in dry conditions and at a temperature of up to 30°C.</li> </ul>
<b>Hazard categories in accordance with Regulation (EC) No 1272/2008</b>	E1: Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1
<b>Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of</b>	E1 Lower- / Upper-tier requirements: 100 / 200

### 7.3. Specific end use(s)

See section 1.2

## SECTION 8 Exposure controls / personal protection

### 8.1. Control parameters

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
zinc oxide	Dermal 83 mg/kg bw/day (Systemic, Chronic) Inhalation 2 mg/m <sup>3</sup> (Systemic, Chronic) Inhalation 0.5 mg/m <sup>3</sup> (Local, Chronic) Inhalation 2 mg/m <sup>3</sup> (Systemic, Acute) <i>Dermal 83 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 1 mg/m<sup>3</sup> (Systemic, Chronic) *</i> <i>Oral 0.83 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 1 mg/m<sup>3</sup> (Systemic, Acute) *</i>	0.19 µg/L (Water (Fresh)) 1.14 µg/L (Water - Intermittent release) 1.2 µg/L (Water (Marine)) 18 mg/kg sediment dw (Sediment (Fresh Water)) 6.4 mg/kg sediment dw (Sediment (Marine)) 0.7 mg/kg soil dw (Soil) 20 µg/L (STP) 0.16 mg/kg food (Oral)
titanium dioxide	<i>Oral 700 mg/kg bw/day (Systemic, Chronic) *</i>	0.127 mg/L (Water (Fresh)) 1 mg/L (Water - Intermittent release) 0.61 mg/L (Water (Marine)) 1000 mg/kg sediment dw (Sediment (Fresh Water)) 100 mg/kg sediment dw (Sediment (Marine)) 100 mg/kg soil dw (Soil) 100 mg/L (STP)
talc	Dermal 43.2 mg/kg bw/day (Systemic, Chronic) Inhalation 2.16 mg/m <sup>3</sup> (Systemic, Chronic) Dermal 4.54 mg/cm <sup>2</sup> (Local, Chronic) Inhalation 3.6 mg/m <sup>3</sup> (Local, Chronic) Inhalation 2.16 mg/m <sup>3</sup> (Systemic, Acute) Inhalation 3.6 mg/m <sup>3</sup> (Local, Acute) <i>Dermal 21.6 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 1.08 mg/m<sup>3</sup> (Systemic, Chronic) *</i> <i>Oral 160 mg/kg bw/day (Systemic, Chronic) *</i> <i>Dermal 2.27 mg/cm<sup>2</sup> (Local, Chronic) *</i> <i>Inhalation 1.8 mg/m<sup>3</sup> (Local, Chronic) *</i> <i>Inhalation 1.08 mg/m<sup>3</sup> (Systemic, Acute) *</i> <i>Oral 160 mg/kg bw/day (Systemic, Acute) *</i> <i>Inhalation 1.8 mg/m<sup>3</sup> (Local, Acute) *</i>	597.97 mg/L (Water (Fresh)) 141.26 mg/L (Water - Intermittent release) 597.97 mg/L (Water (Marine)) 31.33 mg/kg sediment dw (Sediment (Fresh Water)) 3.13 mg/kg sediment dw (Sediment (Marine))

## Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
4,4'-thiobis(6-tert-butyl-m-cresol)	Dermal 1 mg/kg bw/day (Systemic, Chronic) Inhalation 2.8 mg/m <sup>3</sup> (Systemic, Chronic) <i>Dermal 0.5 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 0.7 mg/m<sup>3</sup> (Systemic, Chronic) *</i> <i>Oral 0.2 mg/kg bw/day (Systemic, Chronic) *</i>	0 mg/L (Water (Fresh)) 0 mg/L (Water - Intermittent release) 0.002 mg/L (Water (Marine)) 5.77 mg/kg sediment dw (Sediment (Fresh Water)) 0.577 mg/kg sediment dw (Sediment (Marine)) 1.15 mg/kg soil dw (Soil) 2 mg/kg food (Oral)
cyclooctane	Dermal 773 mg/kg bw/day (Systemic, Chronic) Inhalation 2 035 mg/m <sup>3</sup> (Systemic, Chronic) <i>Dermal 699 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 608 mg/m<sup>3</sup> (Systemic, Chronic) *</i> <i>Oral 699 mg/kg bw/day (Systemic, Chronic) *</i>	Not Available

\* Values for General Population

### Occupational Exposure Limits (OEL)

#### INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Switzerland Occupational Exposure Limits (German)	zinc oxide	Zinkoxid (Rauch) - alveolengängiger Staub (Feinstaub)	3 mg/m <sup>3</sup>	3 mg/m <sup>3</sup>	Not Available	NIOSH OSHA
Switzerland Occupational Exposure Limits (German)	titanium dioxide	Titandioxid - alveolengängiger Staub (Feinstaub)	3 mg/m <sup>3</sup>	Not Available	Not Available	NIOSH
Switzerland Occupational Exposure Limits (German)	talc	Talk (asbestfaserfrei) - alveolengängiger Staub (Feinstaub)	3 mg/m <sup>3</sup>	Not Available	Not Available	OSHA
European Union Directive (EU) 2017/2398 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work	silica crystalline - quartz	Not Available	0,1 mg/m <sup>3</sup>	Not Available	Not Available	(TWA (8) Respirable fraction.)
Switzerland Occupational Exposure Limits (German)	silica crystalline - quartz	Siliciumdioxid, kristallin - alveolengängiger Staub (Feinstaub)	0.15 mg/m <sup>3</sup>	Not Available	Not Available	NIOSH OSHA HSE
Switzerland Occupational Exposure Limits (German)	C.I. Pigment Red 181	Staub, einatembar - einatembarer Staub (Gesamtstaub)	10 mg/m <sup>3</sup>	Not Available	Not Available	Not Available
Switzerland Occupational Exposure Limits (German)	stearine, fatty acids C16-18	Staub, einatembar - einatembarer Staub (Gesamtstaub)	10 mg/m <sup>3</sup>	Not Available	Not Available	Not Available
Switzerland Occupational Exposure Limits (German)	4,4'-thiobis(6-tert-butyl-m-cresol)	4,4'-Thiobis-(6-tert-butyl-m-cresol) - einatembarer Staub (Gesamtstaub)	10 mg/m <sup>3</sup>	Not Available	Not Available	Not Available

### Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
zinc oxide	10 mg/m <sup>3</sup>	15 mg/m <sup>3</sup>	2,500 mg/m <sup>3</sup>
titanium dioxide	30 mg/m <sup>3</sup>	330 mg/m <sup>3</sup>	2,000 mg/m <sup>3</sup>
silica crystalline - quartz	0.075 mg/m <sup>3</sup>	33 mg/m <sup>3</sup>	200 mg/m <sup>3</sup>
4,4'-thiobis(6-tert-butyl-m-cresol)	3 mg/m <sup>3</sup>	82 mg/m <sup>3</sup>	460 mg/m <sup>3</sup>
cyclooctane	26 ppm	290 ppm	1,700 ppm

Ingredient	Original IDLH	Revised IDLH
zinc oxide	500 mg/m <sup>3</sup>	Not Available
titanium dioxide	5,000 mg/m <sup>3</sup>	Not Available
talc	1,000 mg/m <sup>3</sup>	Not Available
silica crystalline - quartz	25 mg/m <sup>3</sup> / 50 mg/m <sup>3</sup>	Not Available
C.I. Pigment Red 181	Not Available	Not Available
stearine, fatty acids C16-18	Not Available	Not Available
4,4'-thiobis(6-tert-butyl-m-cresol)	Not Available	Not Available
cyclooctane	Not Available	Not Available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

For molten materials:  
Provide mechanical ventilation; in general such ventilation should be provided at compounding/ converting areas and at fabricating/ filling work stations where the material is heated. Local exhaust ventilation should be used over and in the vicinity of machinery involved in handling the molten material.  
Keep dry!!  
Processing temperatures may be well above boiling point of water, so wet or damp material may cause a serious steam explosion if used in unvented equipment.

Metal dusts must be collected at the source of generation as they are potentially explosive.

- ▶ Avoid ignition sources.
- ▶ Good housekeeping practices must be maintained.
- ▶ Dust accumulation on the floor, ledges and beams can present a risk of ignition, flame propagation and secondary explosions.
- ▶ Do not use compressed air to remove settled materials from floors, beams or equipment
- ▶ Vacuum cleaners, of flame-proof design, should be used to minimise dust accumulation.

## Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)

- ▶ Use non-sparking handling equipment, tools and natural bristle brushes. Cover and reseal partially empty containers. Provide grounding and bonding where necessary to prevent accumulation of static charges during metal dust handling and transfer operations.
- ▶ Do not allow chips, fines or dusts to contact water, particularly in enclosed areas.
- ▶ Metal spraying and blasting should, where possible, be conducted in separate rooms. This minimises the risk of supplying oxygen, in the form of metal oxides, to potentially reactive finely divided metals such as aluminium, zinc, magnesium or titanium.
- ▶ Work-shops designed for metal spraying should possess smooth walls and a minimum of obstructions, such as ledges, on which dust accumulation is possible.
- ▶ Wet scrubbers are preferable to dry dust collectors.
- ▶ Bag or filter-type collectors should be sited outside the workrooms and be fitted with explosion relief doors.
- ▶ Cyclones should be protected against entry of moisture as reactive metal dusts are capable of spontaneous combustion in humid or partially wetted states.
- ▶ Local exhaust systems must be designed to provide a minimum capture velocity at the fume source, away from the worker, of 0.5 metre/sec.
- ▶ Local ventilation and vacuum systems must be designed to handle explosive dusts. Dry vacuum and electrostatic precipitators must not be used, unless specifically approved for use with flammable/ explosive dusts.

Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
welding, brazing fumes (released at relatively low velocity into moderately still air)	0.5-1.0 m/s (100-200 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	4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

### 8.2.2. Individual protection measures, such as personal protective equipment



### Eye and face protection

- ▶ Safety glasses with unperforated side shields may be used where continuous eye protection is desirable, as in laboratories; spectacles are not sufficient where complete eye protection is needed such as when handling bulk-quantities, where there is a danger of splashing, or if the material may be under pressure.
- ▶ Chemical goggles whenever there is a danger of the material coming in contact with the eyes; goggles must be properly fitted.
- ▶ Full face shield (20 cm, 8 in minimum) may be required for supplementary but never for primary protection of eyes; these afford face protection.
- ▶ Alternatively a gas mask may replace splash goggles and face shields.
- ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]

### Skin protection

See Hand protection below

### Hands/feet protection

- ▶ Elbow 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 leather items, such as shoes, belts and watch-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. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore 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 observed when making a final choice.

Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- When prolonged 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 2161.10.1 or national equivalent) is recommended.
  - When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 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 long-term use.
  - Contaminated gloves should be replaced.
- As defined in ASTM F-739-96 in any application, gloves are rated as:
- Excellent when breakthrough time > 480 min
  - Good when breakthrough time > 20 min
  - Fair when breakthrough time < 20 min
  - Poor when glove material degrades

## Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)

	<p>For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended. It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.</p> <p>Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task.</p> <p>Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:</p> <ul style="list-style-type: none"> <li>· Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.</li> <li>· Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential</li> </ul> <p>Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.</p> <ul style="list-style-type: none"> <li>▶ Protective gloves eg. Leather gloves or gloves with Leather facing</li> <li>▶ When handling hot materials wear heat resistant, elbow length gloves.</li> <li>▶ Rubber gloves are not recommended when handling hot objects, materials</li> </ul> <p>Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.</p> <ul style="list-style-type: none"> <li>▶ polychloroprene.</li> <li>▶ nitrile rubber.</li> <li>▶ butyl rubber.</li> <li>▶ fluorocautchouc.</li> <li>▶ polyvinyl chloride.</li> </ul> <p>Gloves should be examined for wear and/ or degradation constantly.</p>
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	<ul style="list-style-type: none"> <li>▶ When handling hot or molten liquids, wear trousers or overalls outside of boots, to avoid spills entering boots.</li> <li>▶ Usually handled as molten liquid which requires worker thermal protection and increases hazard of vapour exposure.</li> <li>▶ <b>CAUTION: Vapours may be irritating.</b></li> </ul> <p>· During repair or maintenance activities the potential exists for exposures to toxic metal particulate in excess of the occupational standards. Under these circumstances, protecting workers can require the use of specific work practices or procedures involving the combined use of ventilation, wet and vacuum cleaning methods, respiratory protection, decontamination, special protective clothing, and when necessary, restricted work zones.</p> <p>· Protective over-garments or work clothing must be worn by persons who may become contaminated with particulate during activities such as machining, furnace rebuilding, air cleaning equipment filter changes, maintenance, furnace tending, etc. Contaminated work clothing and over-garments must be managed in a controlled manner to prevent secondary exposure to workers of third parties, to prevent the spread of particulate to other areas, and to prevent particulate from being taken home by workers.</p> <p>· Personnel who handle and work with <u>molten metal</u> should utilise primary protective clothing like polycarbonate face shields, fire resistant tapper's jackets, neck shades (snoods), leggings, spats and similar equipment to prevent burn injuries. In addition to primary protection, secondary or day-to-day work clothing that is fire resistant and sheds metal splash is recommended for use with molten metal. Synthetic materials should never be worn even as secondary clothing (undergarments).</p>

### Respiratory protection

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

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required. Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	A-AUS P2	-	A-PAPR-AUS / Class 1 P2
up to 50 x ES	-	A-AUS / Class 1 P2	-
up to 100 x ES	-	A-2 P2	A-PAPR-2 P2 ^

^ - Full-face

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(SO<sub>2</sub>), G = Agricultural chemicals, K = Ammonia(NH<sub>3</sub>), 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
- 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.

If inhalation risk above the TLV exists, wear approved dust respirator.

Use respirators with protection factors appropriate for the exposure level.

- ▶ Up to 5 X TLV, use valveless mask type; up to 10 X TLV, use 1/2 mask dust respirator
- ▶ Up to 50 X TLV, use full face dust respirator or demand type C air supplied respirator
- ▶ Up to 500 X TLV, use powered air-purifying dust respirator or a Type C pressure demand supplied-air respirator
- ▶ Over 500 X TLV wear full-face self-contained breathing apparatus with positive pressure mode or a combination respirator with a Type C positive pressure supplied-air full-face respirator and an auxiliary self-contained breathing apparatus operated in pressure demand or other positive pressure mode

For molten materials:

**Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)**

76a-p()

**8.2.3. Environmental exposure controls**

See section 12

**SECTION 9 Physical and chemical properties****9.1. Information on basic physical and chemical properties**

<b>Appearance</b>	Coloured cylindrical shape solid; insoluble in water.		
<b>Physical state</b>	Manufactured	<b>Relative density (Water = 1)</b>	Not Available
<b>Odour</b>	Not Available	<b>Partition coefficient n-octanol / water</b>	Not Available
<b>Odour threshold</b>	Not Available	<b>Auto-ignition temperature (°C)</b>	Not Applicable
<b>pH (as supplied)</b>	Not Applicable	<b>Decomposition temperature (°C)</b>	Not Available
<b>Melting point / freezing point (°C)</b>	Not Available	<b>Viscosity (cSt)</b>	Not Applicable
<b>Initial boiling point and boiling range (°C)</b>	Not Available	<b>Molecular weight (g/mol)</b>	Not Applicable
<b>Flash point (°C)</b>	Not Applicable	<b>Taste</b>	Not Available
<b>Evaporation rate</b>	Not Available	<b>Explosive properties</b>	Not Available
<b>Flammability</b>	Not Applicable	<b>Oxidising properties</b>	Not Available
<b>Upper Explosive Limit (%)</b>	Not Applicable	<b>Surface Tension (dyn/cm or mN/m)</b>	Not Applicable
<b>Lower Explosive Limit (%)</b>	Not Applicable	<b>Volatile Component (%vol)</b>	Not Available
<b>Vapour pressure (kPa)</b>	Not Applicable	<b>Gas group</b>	Not Available
<b>Solubility in water</b>	Immiscible	<b>pH as a solution (1%)</b>	Not Applicable
<b>Vapour density (Air = 1)</b>	Not Available	<b>VOC g/L</b>	Not Available
<b>Nanoform Solubility</b>	Not Available	<b>Nanoform Particle Characteristics</b>	Not Available
<b>Particle Size</b>	Not Available		

**9.2. Other information**

Not Available

**SECTION 10 Stability and reactivity**

<b>10.1. Reactivity</b>	See section 7.2
<b>10.2. Chemical stability</b>	<ul style="list-style-type: none"> <li>▶ Unstable in the presence of incompatible materials.</li> <li>▶ Product is considered stable.</li> <li>▶ Hazardous polymerisation will not occur.</li> </ul>
<b>10.3. Possibility of hazardous reactions</b>	See section 7.2
<b>10.4. Conditions to avoid</b>	See section 7.2
<b>10.5. Incompatible materials</b>	See section 7.2
<b>10.6. Hazardous decomposition products</b>	See section 5.3

**SECTION 11 Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

<b>Inhaled</b>	<p>Processing for an overly long time or processing at overly high temperatures may cause generation and release of highly irritating vapours, which irritate eyes, nose, throat, causing red itching eyes, coughing, sore throat.</p> <p>Inhalation hazard is increased at higher temperatures.</p> <p>Tungsten is relatively inert and produces few respiratory effects.</p> <p>The inhalation of small particles of metal oxide results in sudden thirst, a sweet, metallic foul taste, throat irritation, cough, dry mucous membranes, tiredness and general unwellness. Headache, nausea and vomiting, fever or chills, restlessness, sweating, diarrhoea, excessive urination and prostration may also occur.</p>
<b>Ingestion</b>	<p>Not normally a hazard due to the physical form of product. The material is a physical irritant to the gastro-intestinal tract</p> <p>High molecular weight material; on single acute exposure would be expected to pass through gastrointestinal tract with little change / absorption. Occasionally accumulation of the solid material within the alimentary tract may result in formation of a bezoar (concretion), producing discomfort.</p> <p>If given orally, tungsten can accumulate in the spleen, kidney and liver. Symptoms of poisoning include diarrhoea, stoppage of breathing and circulatory collapse leading to death.</p> <p>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.</p>
<b>Skin Contact</b>	<p>Molten material is capable of causing burns.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>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.</p>

Continued...

**Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)**

	Repeated or excessive handling, coupled with poor personal hygiene, may result in acne-like eruptions known as "zinc oxide pox".
<b>Eye</b>	The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.
<b>Chronic</b>	<p>This material contains a substantial amount of polymer considered to be of low concern. These are classified under having MWs of between 1000 to 10000 with less than 25% of molecules with MWs under 1000 and less than 10% under 500; or having a molecular weight average of over 10000.</p> <p>Amorphous silicas generally are less hazardous than crystalline silicas, but the former can be converted to the latter on heating and subsequent cooling. Inhalation of dusts containing crystalline silicas may lead to silicosis, a disabling lung disease that may take years to develop. Animal testing shows long term exposure to aluminium oxides may cause lung disease and cancer, depending on the size of the particle. The smaller the size, the greater the tendencies of causing harm.</p> <p>Bisphenol A may have effects similar to female sex hormones and when administered to pregnant women, may damage the foetus. It may also damage male reproductive organs and sperm.</p> <p>Crystalline silicas activate the inflammatory response of white blood cells after they injure the lung epithelium. Chronic exposure to crystalline silicas reduces lung capacity and predisposes to chest infections.</p> <p>Soluble silicates do not exhibit sensitizing potential. Testing in bacterial and animal experiments have not shown any evidence of them causing mutations or birth defects.</p> <p>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.</p> <p>Barium compounds may cause high blood pressure, airway irritation and damage the liver, spleen and bone marrow. Prolonged exposure may cause a lung inflammation and scarring.</p> <p>There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment.</p> <p>Metallic dusts generated by the industrial process give rise to a number of potential health problems. The larger particles, above 5 micron, are nose and throat irritants.</p> <p>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).</p> <p>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.</p> <p>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.</p>

<b>Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Not Available	Not Available
<b>zinc oxide</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	dermal (rat) LD50: >2000 mg/kg <sup>[1]</sup>	Eye (rabbit) : 500 mg/24 h - mild
	Inhalation(Rat) LC50: >1.79 mg/4h <sup>[1]</sup>	Eye: no adverse effect observed (not irritating) <sup>[1]</sup>
	Oral (Rat) LD50: >5000 mg/kg <sup>[1]</sup>	Skin (rabbit) : 500 mg/24 h- mild
		Skin: no adverse effect observed (not irritating) <sup>[1]</sup>
<b>titanium dioxide</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	dermal (hamster) LD50: >=10000 mg/kg <sup>[2]</sup>	Eye: no adverse effect observed (not irritating) <sup>[1]</sup>
	Inhalation(Rat) LC50: >2.28 mg/4h <sup>[1]</sup>	Skin (human): 0.3 mg /3D (int)-mild *
	Oral (Rat) LD50: >=2000 mg/kg <sup>[1]</sup>	Skin: no adverse effect observed (not irritating) <sup>[1]</sup>
<b>talc</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	dermal (rat) LD50: >2000 mg/kg <sup>[1]</sup>	Eye: no adverse effect observed (not irritating) <sup>[1]</sup>
	Inhalation(Rat) LC50: >2.1 mg/4h <sup>[1]</sup>	Skin (human): 0.3 mg/3d-I mild
	Oral (Rat) LD50: >5000 mg/kg <sup>[1]</sup>	Skin: no adverse effect observed (not irritating) <sup>[1]</sup>
<b>silica crystalline - quartz</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Oral (Rat) LD50: 500 mg/kg <sup>[2]</sup>	Not Available
<b>C.I. Pigment Red 181</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Oral (Rat) LD50: >10000 mg/kg <sup>[1]</sup>	Not Available
<b>stearine, fatty acids C16-18</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Dermal (rabbit) LD50: >2000 mg/kg <sup>[1]</sup>	Not Available
	Inhalation(Rat) LC50: >0.162 mg/4h <sup>[1]</sup>	
	Oral (Rat) LD50: >5000 mg/kg <sup>[1]</sup>	
<b>4,4'-thiobis(6-tert-butyl-m-cresol)</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Dermal (rabbit) LD50: >5010 mg/kg <sup>[2]</sup>	Eye (rabbit): non irritant * * [Monsanto]
	Oral (Rat) LD50: 2345 mg/kg <sup>[2]</sup>	Skin (rabbit): slight irritant *

**Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)**

	TOXICITY	IRRITATION
cyclooctane	Oral (Rat) LD50: >2000 mg/kg <sup>[1]</sup>	Eye: no adverse effect observed (not irritating) <sup>[1]</sup> Skin: no adverse effect observed (not irritating) <sup>[1]</sup>
<b>Legend:</b>	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

<b>TITANIUM DIOXIDE</b>	<p>* IUCLID Laboratory (in vitro) and animal studies show, exposure to the material may result in a possible risk of irreversible effects, with the possibility of producing mutation. Exposure to titanium dioxide is via inhalation, swallowing or skin contact. When inhaled, it may deposit in lung tissue and lymph nodes causing dysfunction of the lungs and immune system. Absorption by the stomach and intestines depends on the size of the particle. It penetrated only the outermost layer of the skin, suggesting that healthy skin may be an effective barrier. There is no substantive data on genetic damage, though cases have been reported in experimental animals. Studies have differing conclusions on its cancer-causing potential. The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.</p> <p><b>WARNING:</b> This substance has been classified by the IARC as Group 2B: Possibly Carcinogenic to Humans.</p>
<b>TALC</b>	<p>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: <b>NOT</b> classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing.</p>
<b>SILICA CRYSTALLINE - QUARTZ</b>	<p><b>WARNING:</b> For inhalation exposure <b>ONLY:</b> This substance has been classified by the IARC as Group 1: <b>CARCINOGENIC TO HUMANS</b></p> <p>The International Agency for Research on Cancer (IARC) has classified occupational exposures to <b>respirable</b> (&lt;5 µm) crystalline silica as being carcinogenic to humans. This classification is based on what IARC considered sufficient evidence from epidemiological studies of humans for the carcinogenicity of inhaled silica in the forms of quartz and cristobalite. Crystalline silica is also known to cause silicosis, a non-cancerous lung disease. Intermittent exposure produces; focal fibrosis, (pneumoconiosis), cough, dyspnoea, liver tumours.</p> <p>* Millions of particles per cubic foot (based on impinger samples counted by light field techniques). NOTE : the physical nature of quartz in the product determines whether it is likely to present a chronic health problem. To be a hazard the material must enter the breathing zone as respirable particles.</p>
<b>C.I. PIGMENT RED 181</b>	No data of toxicological significance identified in literature search.
<b>STEARINE, FATTY ACIDS C16-18</b>	<p>For group E aliphatic esters (polyol esters): The polyol esters, including trimethylolpropane (TMP), pentaerythritol (PE) and dipentaerythritol (diPE) are unique in their chemical characteristics since they lack beta-tertiary hydrogen atoms, thus leading to stability against oxidation and elimination. Therefore their esters with C5-C10 fatty acids have applications as artificial lubricants. Because of their stability at high temperatures, they are also used in high temperature applications such as industrial oven chain oils, high temperature greases, fire resistant transformer coolants and turbine engines. Polyol esters that are extensively esterified also have greater polarity, less volatility and enhanced lubricating properties. Acute toxicity: Animal studies show relatively low toxicity by swallowing. These esters are hydrolysed in the gastrointestinal tract, and studies have not shown evidence of these accumulating in body tissues. Acute toxicity by skin contact was also found to be low. Repeat dose toxicity: According to animal testing, polyol esters show a low level of toxicity following repeated application, either by swallowing or by skin contact. Reproductive and developmental toxicity: This group should not produce profound reproductive effects in animals. Genetic toxicity: Tests have shown this group to be inactive. It is unlikely that these substances cause mutations. Cancer-causing potential: No association between this group of substances and cancer. For aliphatic fatty acids (and salts) Acute oral (gavage) toxicity: The acute oral LD50 values in rats for both were greater than &gt;2000 mg/kg bw Clinical signs were generally associated with poor condition following administration of high doses (salivation, diarrhoea, staining, piloerection and lethargy). There were no adverse effects on body weight in any study. In some studies, excess test substance and/or irritation in the gastrointestinal tract was observed at necropsy. Skin and eye irritation potential, with a few stated exceptions, is chain length dependent and decreases with increasing chain length According to several OECD test regimes the animal skin irritation studies indicate that the C6-10 aliphatic acids are severely irritating or corrosive, while the C12 aliphatic acid is irritating, and the C14-22 aliphatic acids generally are not irritating or mildly irritating. Human skin irritation studies using more realistic exposures (30-minute, 1-hour or 24-hours) indicate that the aliphatic acids have sufficient, good or very good skin compatibility. Animal eye irritation studies indicate that among the aliphatic acids, the C8-12 aliphatic acids are irritating to the eye while the C14-22 aliphatic acids are not irritating. Eye irritation potential of the ammonium salts does not follow chain length dependence; the C18 ammonium salts are corrosive to the eyes. Dermal absorption: The in vitro penetration of C10, C12, C14, C16 and C18 fatty acids (as sodium salt solutions) through rat skin decreases with increasing chain length. At 86.73 µg C16/cm<sup>2</sup> and 91.84 µg C18/cm<sup>2</sup>, about 0.23% and less than 0.1% of the C16 and C18 soap solutions is absorbed after 24 h exposure, respectively. Sensitisation: No sensitisation data were located. Repeat dose toxicity: Repeated dose oral (gavage or diet) exposure to aliphatic acids did not result in systemic toxicity with NOAELs greater than the limit dose of 1000 mg/kg bw. . Mutagenicity Aliphatic acids do not appear to be mutagenic or clastogenic in vitro or in vivo Carcinogenicity No data were located for carcinogenicity of aliphatic fatty acids. Reproductive toxicity No effects on fertility or on reproductive organs, or developmental effects were observed in studies on aliphatic acids and the NOAELs correspond to the maximum dose tested. The weight of evidence supports the lack of reproductive and developmental toxicity potential of the aliphatic acids category.</p> <p>Given the large number of substances in this category, their closely related chemical structure, expected trends in physical chemical properties, and similarity of toxicokinetic properties, both mammalian and aquatic endpoints were filled using read-across to the closest structural analogue,</p>

**Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)**

and selecting the most conservative supporting substance effect level.

Structure-activity relationships are not evident for the mammalian toxicity endpoints. That is, the low mammalian toxicity of this category of substances limits the ability to discern structural effects on biological activity. Regardless, the closest structural analogue with the most conservative effect value was selected for read across. Irritation is observed for chain lengths up to a cut-off at or near 12 carbons).

Metabolism:

The aliphatic acids share a common degradation pathway in which they are metabolized to acetyl-CoA or other key metabolites in all living systems. Common biological pathways result in structurally similar breakdown products, and are, together with the physico-chemical properties, responsible for similar environmental behavior and essentially identical hazard profiles with regard to human health.

Differences in metabolism or biodegradability of even and odd numbered carbon chain compounds or saturated/ unsaturated compounds are not expected; even- and odd-numbered carbon chain compounds, and the saturated and unsaturated compounds are naturally occurring and are expected to be metabolized and biodegraded in the same manner.

The acid and alkali salt forms of the homologous aliphatic acid are expected to have many similar physicochemical and toxicological properties when they become bioavailable; therefore, data read across is used for those instances where data are available for the acid form but not the salt, and vice versa. In the gastrointestinal tract, acids and bases are absorbed in the undissociated (non-ionised) form by simple diffusion or by facilitated diffusion. It is expected that both the acids and the salts will be present in (or converted to) the acid form in the stomach. This means that for both aliphatic acid or aliphatic acid salt, the same compounds eventually enter the small intestine, where equilibrium, as a result of increased pH, will shift towards dissociation (ionised form).

Hence, the situation will be similar for compounds originating from acids and therefore no differences in uptake are anticipated

Note that the saturation or unsaturation level is not a factor in the toxicity of these substances and is not a critical component of the read across process..

Toxicokinetics:

The turnover of the [<sup>14</sup>C] surfactants in the rat showed that there was no significant difference in the rate or route of excretion of <sup>14</sup>C given by intraperitoneal or subcutaneous administration. The main route of excretion was as <sup>14</sup>CO<sub>2</sub> in the expired air at 6 h after administration. The remaining material was incorporated in the body. Longer fatty acid chains are more readily incorporated than shorter chains. At ca. 1.55 and 1.64 mg/kg bw, 71% of the C16:0 and 56% of the C18:0 was incorporated and 21% and 38% was excreted as <sup>14</sup>CO<sub>2</sub>, respectively.

Glycidyl fatty acid esters (GEs), one of the main contaminants in processed oils, are mainly formed during the deodorisation step in the refining process of edible oils and therefore occur in almost all refined edible oils. GEs are potential carcinogens, due to the fact that they readily hydrolyze into the free form glycidol in the gastrointestinal tract, which has been found to induce tumours in various rat tissues. Therefore, significant effort has been devoted to inhibit and eliminate the formation of GEs

GEs contain a common terminal epoxide group but exhibit different fatty acid compositions. This class of compounds has been reported in edible oils after overestimation of 3-monochloropropane-1,2-diol (3-MCPD) fatty acid esters analysed by an indirect method, 3-MCPD esters have been studied as food processing contaminants and are found in various food types and food ingredients, particularly in refined edible oils.

3-Monochloropropane-1,2-diol (3-MCPD) and 2-monochloropropane-1,3-diol (2-MCPD) are chlorinated derivatives of glycerol (1,2,3-propanetriol). 3- and 2-MCPD and their fatty acid esters are among non-volatile chloropropanols, Glycidol is associated with the formation and decomposition of 3- and 2-MCPD. It forms monoesters with fatty acids (GE) during the refining of vegetable oils. Chloropropanols are formed in HVP during the hydrochloric acid-mediated hydrolysis step of the manufacturing process. In food production, chloropropanols form from the reaction of endogenous or added chloride with glycerol or acylglycerol.

Although harmful effects on humans and animals have not been demonstrated, the corresponding hydrolysates, 3-MCPD and glycidol, have been identified as rodent genotoxic carcinogens, ultimately resulting in the formation of kidney tumours (3-MCPD) and tumours at other tissue sites (glycidol). Therefore, 3-MCPD and glycidol have been categorised as "possible human carcinogens (group 2B) and "probably carcinogenic to humans (group 2A), respectively, by the International Agency for Research on Cancer (IARC).

Diacylglyceride (DAG) based oils produced by one company were banned from the global market due to "high levels" of GEs.

Several reports have also suggested that a bidirectional transformation process may occur not only between glycidol and 3-MCPD but also their esterified forms in the presence of chloride ions. The transformation rate of glycidol to 3-MCPD was higher than that of 3-MCPD to glycidol under acidic conditions in the presence of chloride ion.

Precursors of GEs in refined oils have been identified as partial acylglycerols, that is, DAGs and monoacylglycerides (MAGs); however, whether they also originate from triacylglycerides (TAGs) is still a topic of controversial debates. Several authors noted that pure TAGs were stable during heat treatment (such as 235 deg C) for 3 h and were therefore not involved in the formation of GEs. However, experimental results have shown that small amounts of GEs are present in a heat-treated oil model consisting of almost 100% TAGs. The formation of GEs from TAGs can be attributed to the pyrolysis of TAGs to DAGs and MAGs. In contrast, 3-MCPD esters in refined oils can be obtained from TAG. Presently, the mechanism for the formation of GE intermediates and the relationship between GEs and 3-MCPD esters are still unknown.

For triglycerides:

Carboxylic acid esters will undergo enzymatic hydrolysis by ubiquitously expressed GI esterases. The rate of hydrolysis is dependant on the structure of the ester, and may therefore be rapid or rather slow. Thus, due to hydrolysis, predictions on oral absorption based on the physico-chemical characteristics of the intact parent substance alone may no longer apply.

When considering the hydrolysis product glycerol, absorption is favoured based on passive and active absorption of glycerol.

The Cosmetic Ingredient Review (CIR) Expert Panel has issued three final reports on the safety of 25 triglycerides, i.e., fatty acid triesters of glycerin

High purity is needed for the triglycerides. Previously the Panel published a final report on a diglycerides, and concluded that the ingredients in the diglyceride family are safe in the present practices of use and concentration provided the content of 1,2-diester is not high enough to induce epidermal hyperplasia. The Panel discussed that there was an increased level of concern because of data regarding the induction of protein kinase C (PKC) and the tumor promotion potential of 1,2-diacylglycerols. The Panel noted that, nominally, glyceryl-1,3-diester contain 1,2-diester, raising the concern that 1,2-diester could potentially induce hyperplasia. The Panel did note that these compounds are more likely to cause these effects when the fatty acid chain length is <=14 carbons, when one fatty acid is saturated and one is not, and when given at high doses, repeatedly. Although minimal percutaneous absorption of triolein has been demonstrated in vivo using guinea pigs (but not hairless mice) and in vitro using full-thickness skin from hairless mice, the Expert Panel recognizes that, reportedly, triolein and tricaprylin can enhance the skin penetration of other chemicals, and recommends that care should be exercised in using these and other glyceryl triesters in cosmetic products.

The Panel acknowledged that some of the triglycerides may be formed from plant-derived or animal-derived constituents. The Panel thus expressed concern regarding pesticide residues and heavy metals that may be present in botanical ingredients. They stressed that the cosmetics industry should continue to use the necessary procedures to sufficiently limit amounts of such impurities in an ingredient before blending them into cosmetic formulations. Additionally, the Panel considered the risks inherent in using animal-derived ingredients, namely the transmission of infectious agents. Although tallow may be used in the manufacture of glyceryl tallowate and is clearly animal-derived, the Panel notes that tallow is highly processed, and tallow derivatives even more so. The Panel agrees with determinations by the U.S. FDA that tallow derivatives are not risk materials for transmission of infectious agents.

Finally, the Panel discussed the issue of incidental inhalation exposure, as some of the triglycerides are used in cosmetic sprays and could possibly be inhaled. For example, triethylhexanoin and triisostearin are reported to be used at maximum concentrations of 36% and 30%, respectively, in perfumes, and 14.7% and 10.4%, respectively, in face powders. The Panel noted that in aerosol products, 95% – 99% of droplets/particles would not be respirable to any appreciable amount. Furthermore, droplets/particles deposited in the nasopharyngeal or bronchial regions of the respiratory tract present no toxicological concerns based on the chemical and biological properties of these ingredients. Coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects

Cosmetic Ingredient Review (CIR) : Amended Safety Assessment of Triglycerides as Used in Cosmetics August 2017

Glyceryl triesters are also known as triglycerides; ingested triglycerides are metabolized to monoglycerides, free fatty acids, and glycerol, all of which are absorbed in the intestinal mucosa and undergo further metabolism. Dermal absorption of Triolein in mice was nil; the oil remained at the application site. Only slight absorption was seen in guinea pig skin. Tricaprylin and other glyceryl triesters have been shown to increase the skin penetration of drugs. Little or no acute, subchronic, or chronic oral toxicity was seen in animal studies unless levels approached a significant percentage of caloric intake. Subcutaneous injections of Tricaprylin in rats over a period of 5 weeks caused a granulomatous reaction

**Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)**

characterized by oil deposits surrounded by macrophages. Dermal application was not associated with significant irritation in rabbit skin. Ocular exposures were, at most, mildly irritating to rabbit eyes. No evidence of sensitization or photosensitization was seen in a guinea pig maximization test. Most of the genotoxicity test systems were negative. Tricaprylin, Trioctanoin, and Triolein have historically been used as vehicles in carcinogenicity testing of other chemicals. In one study, subcutaneous injection of Tricaprylin in newborn mice produced more tumors in lymphoid tissue than were seen in untreated animals, whereas neither subcutaneous or intraperitoneal injection in 4- to 6-week-old female mice produced any tumors in another study. Trioctanoin injected subcutaneously in hamsters produced no tumors. Trioctanoin injected intraperitoneally in pregnant rats was associated with an increase in mammary tumors in the offspring compared to that seen in offspring of untreated animals, but similar studies in pregnant hamsters and rabbits showed no tumors in the offspring. One study of Triolein injected subcutaneously in rats showed no tumors at the injection site. As part of an effort to evaluate vehicles used in carcinogenicity studies, the National Toxicology Program conducted a 2-year carcinogenicity study in rats given Tricaprylin by gavage. This treatment was associated with a statistically significant dose-related increase in pancreatic acinar cell hyperplasia and adenoma, but there were no acinar carcinomas, the incidence of mononuclear leukemia was less, and nephropathy findings were reduced, all compared to corn oil controls. Overall, the study concluded that Tricaprylin did not offer significant advantages over corn oil as vehicles in carcinogenicity studies. Trilaurin was found to inhibit the formation of neoplasms initiated by dimethylbenzanthracene (DMBA) and promoted by croton oil. Tricaprylin was not teratogenic in mice or rats, but some reproductive effects were seen in rabbits. A low level of fetal eye abnormalities and a small percentage of abnormal sperm were reported in mice injected with Trioctanoin as a vehicle control. Clinical tests of Trilaurin at 36.3% in a commercial product applied to the skin produced no irritation reactions. Trilaurin, Tristearin, and Tribehenin at 40%, 1.68%, and 0.38%, respectively, in commercial products were also negative in repeated-insult patch tests. Tristearin at 0.32% in a commercial product induced transient, mild to moderate, ocular irritation after instillation into the eyes of human subjects. Based on the enhancement of penetration of other chemicals by skin treatment with glyceryl triesters, it is recommended that care be exercised in using them in cosmetic products.

Cosmetic Ingredient Review (CIR) Expert Panel: Final Report on the Safety Assessment of Trilaurin etc: Int J Toxicol, 20 Suppl 4, 61-94 2001

The following information refers to contact allergens as a group and may not be specific to this product.

Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.

Data show that acute toxicity following oral and topical use of hindered phenols is low. They are not proven to cause mutations. However, long term use may affect the liver, thyroid, kidney and lymph nodes. Liver tumours have been reported.

for thioalkyl substituted hindered phenols:

As represented by 2-methyl-4,6-[(octylthio)methyl]phenol (CAS RN:110553-27-0, syn: Irganox 1520) and 4,6-bis(dodecylthiomethyl-o-cresol (CAS RN 110675-26-8; syn: Irganox 1726)

**Acute toxicity:** Irganox 1520 showed low acute toxicity in rats by the oral and dermal routes (LD50 > 5000 and 2000 mg/kg bw, respectively). It was a slight irritant to rabbit skin and eyes. Sensitisation testing resulted in up to 7 of 20 guinea pigs showing responses on challenge, which, for an adjuvant test, would indicate that classification should occur. However, a rechallenge at the same concentration resulted in dermal responses in only 1 of 20 animals, which indicates that the original result was not indicative of true sensitisation; the study authors suggested that it may have been due to hypersensitivity resulting from use of the adjuvant.

No test for inhalation toxicity was conducted but the properties of the chemical (low melting solid with low volatility) indicate that aerosol formation and vapour inhalation are very improbable.

**Repeat dose toxicity:** In a 28-day repeat dose study in rats, a NOEL of 50 mg/kg bw/day was established for Irganox 1520, with small changes in alkaline phosphatase levels and liver weights above this dose. The substance was not clastogenic to CHO cells in vitro.

**Reproductive and developmental toxicity:** Irganox 1520 was tested for reproductive and developmental toxicity in two studies. In a teratogenicity study, where the dams were treated only during gestation, a NOEL of 150 mg/kg bw/day was established, with embryotoxicity but no teratogenicity seen at 300 mg/kg bw/day. In a one generation reproductive study (originally designed for a longer study but terminated at one generation), no significant effects were seen and a NOAEL of 200 mg/kg bw/day was established. Several other studies on Irganox 1520 were summarised in a European notification. In a 90-day oral repeat dose study in rats, a NOEL of 10 mg/kg bw/day was established; the only reported observations at higher doses (100 and 1000 mg/kg bw/day) were changes in liver weight. In a similar study in beagle dogs, histopathological studies showed biliary cell proliferation which did not reverse after 28 days; also reversible changes in neutrophils and aminotransferase and/or alkaline phosphatase activities were seen at 100 and 1000 mg/kg bw/day; a NOEL of 10 mg/kg bw/day was established.

**Genotoxicity:** Irganox 1520 was not mutagenic when tested in the bacterial reverse mutation test.

A bone marrow micronucleus test in Chinese hamsters showed no evidence of mutagenicity at 5000 mg/kg bw.

NICNAS Full Public Report Irganox 1726

for bridged alkyl phenols:

**Acute toxicity:** Acute oral and dermal toxicity data are available for all but two of the substances in the group. The data show that acute toxicity of these substances is low. The testing for acute toxicity spans five decades

**Repeat dose toxicity:** Repeat dose studies on the members of this category include both subchronic and chronic exposures. The liver is identified as the target organ in rats for all of the substances tested. NOAEL s or NOEL s in rats for 13- week studies ranged from 100 ppm (approximately 5 mg/kg/day) to 500 ppm (approximately 25 mg/kg/day) while NOAEL s or NOEL s in rats for chronic studies were the same, 25 mg/kg/day (500 ppm).

**Reproductive toxicity:** Evaluation of effects on reproduction for the bridged alkyl phenols is supplemented by histopathological data on male and female reproductive organs in repeated dose studies. The data on the effects of bridged alkyl phenols on reproduction and reproductive organs span the range of structures and molecular weights. While not all of the data for reproductive effects are from reproduction studies, microscopic evaluations of reproductive organs along with other short-term tests for reproductive effects provide adequate data to evaluate the effects of these bridged alkyl phenols on reproduction. It can be concluded that reproductive toxicity is low.

Typically a two-year chronic feeding study provides data for 4,4'-thiobis-6-(t-butyl-m-cresol) (96-69-5). No adverse effects were noted on reproductive organs

**Genotoxicity:** Data from bacterial reverse mutation assays and in vitro and in vivo chromosome aberration studies were reviewed. Adequate bacterial gene mutation assays have been conducted with all of the category chemicals except two. Chromosome aberration studies, in vitro and/or in vivo, are available for all but two substances. The mutagenicity data span the range of structures and molecular weights and data can be bridged from other members of the group to meet any outstanding requirements. The weight of evidence for mutagenic potential for this category indicates these substances are not mutagenic.

**Carcinogenicity:** The mutagenicity data combined with the animal data plus the long historical use of BHT (128-37-0) indicate that the chemicals in this class are not expected to exhibit any significant potential to cause cancer. The weight of the evidence indicates that these chemicals are not genotoxic.

The Bridged Alkyl Phenols Category consists of a group of chemicals in which two molecules of mono or di-substituted alkyl (C1, C4, and/or C9) phenols are "bridged" or linked by a single atom (carbon or sulfur). The carbon atom linking the alkyl phenol groups contains hydrogen, propyl, or methyl substitutions. CAS No. 128-37-0 (BHT) is included in this category for data purposes because it is an alkyl phenol with a single carbon group such as the ones that link the phenol groups

4,4'-thiobis(6-tert-butyl-m-cresol) in animal testing has caused changes to the urinary system, blood counts, cholesterol levels and sugar balance at sufficient doses, with changes to liver cells and the small bowel microscopically. It has not been shown to cause either mutations or genetic damage.

**4,4'-THIOBIS(6-TERT-BUTYL-M-CRESOL)**

**ZINC OXIDE & TITANIUM DIOXIDE**

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.

**Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)**

<b>TITANIUM DIOXIDE &amp; TALC &amp; 4,4'-THIOBIS(6-TERT-BUTYL-M-CRESOL)</b>	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.
<b>TITANIUM DIOXIDE &amp; TALC &amp; STEARINE, FATTY ACIDS C16-18 &amp; CYCLOOCTANE</b>	No significant acute toxicological data identified in literature search.

<b>Acute Toxicity</b>	✗	<b>Carcinogenicity</b>	✓
<b>Skin Irritation/Corrosion</b>	✗	<b>Reproductivity</b>	✗
<b>Serious Eye Damage/Irritation</b>	✗	<b>STOT - Single Exposure</b>	✗
<b>Respiratory or Skin sensitisation</b>	✗	<b>STOT - Repeated Exposure</b>	✗
<b>Mutagenicity</b>	✗	<b>Aspiration Hazard</b>	✗

**Legend:** ✗ – Data either not available or does not fill the criteria for classification  
 ✓ – Data available to make classification

## 11.2 Information on other hazards

### 11.2.1. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

### 11.2.2. Other information

See Section 11.1

## SECTION 12 Ecological information

### 12.1. Toxicity

Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
zinc oxide	Endpoint	Test Duration (hr)	Species	Value	Source
	BCF	1344h	Fish	19-110	7
	LC50	96h	Fish	0.112mg/l	2
	EC50	72h	Algae or other aquatic plants	0.036-0.049mg/l	4
	EC50	48h	Crustacea	0.105mg/l	2
	EC10(ECx)	168h	Algae or other aquatic plants	0.0025mg/l	2
EC50	96h	Algae or other aquatic plants	0.3mg/l	2	
titanium dioxide	Endpoint	Test Duration (hr)	Species	Value	Source
	BCF	1008h	Fish	<1.1-9.6	7
	LC50	96h	Fish	1.85-3.06mg/l	4
	EC50	72h	Algae or other aquatic plants	3.75-7.58mg/l	4
	EC50	48h	Crustacea	1.9mg/l	2
	EC50	96h	Algae or other aquatic plants	179.05mg/l	2
NOEC(ECx)	504h	Crustacea	0.02mg/l	4	
talc	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96h	Fish	89581.016mg/l	2
	EC50	96h	Algae or other aquatic plants	7202.7mg/l	2
NOEC(ECx)	720h	Algae or other aquatic plants	918.089mg/l	2	
silica crystalline - quartz	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
C.I. Pigment Red 181	Endpoint	Test Duration (hr)	Species	Value	Source
	NOEC(ECx)	72h	Algae or other aquatic plants	1mg/l	2
stearine, fatty acids C16-18	Endpoint	Test Duration (hr)	Species	Value	Source
	NOEC(ECx)	504h	Crustacea	>0.22mg/l	2
LC50	96h	Fish	>1000mg/l	2	

Continued...

**Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)**

	EC50	72h	Algae or other aquatic plants	>0.9mg/l	2
	EC50	48h	Crustacea	>4.8mg/l	2
<b>4,4'-thiobis(6-tert-butyl-m-cresol)</b>	<b>Endpoint</b>	<b>Test Duration (hr)</b>	<b>Species</b>	<b>Value</b>	<b>Source</b>
	BCF	1008h	Fish	<0.12-4.2	7
	NOEC(ECx)	504h	Crustacea	0.0071mg/l	2
	EC50	96h	Algae or other aquatic plants	0.696mg/l	2
	EC50	48h	Crustacea	0.16mg/l	2
	LC50	96h	Fish	0.13mg/l	2
<b>cyclooctane</b>	<b>Endpoint</b>	<b>Test Duration (hr)</b>	<b>Species</b>	<b>Value</b>	<b>Source</b>
	NOEC(ECx)	72h	Algae or other aquatic plants	<0.00576mg/l	2
	EC50	72h	Algae or other aquatic plants	0.227mg/l	2
	EC50	48h	Crustacea	0.092mg/l	2
<b>Legend:</b>	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data				

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**DO NOT** discharge into sewer or waterways.

### 12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
titanium dioxide	HIGH	HIGH
4,4'-thiobis(6-tert-butyl-m-cresol)	LOW (Half-life = 49 days)	LOW (Half-life = 0.67 days)
cyclooctane	LOW	LOW

### 12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
zinc oxide	LOW (BCF = 217)
titanium dioxide	LOW (BCF = 10)
4,4'-thiobis(6-tert-butyl-m-cresol)	LOW (BCF = 11)
cyclooctane	MEDIUM (LogKOW = 4.45)

### 12.4. Mobility in soil

Ingredient	Mobility
titanium dioxide	LOW (KOC = 23.74)
4,4'-thiobis(6-tert-butyl-m-cresol)	LOW (KOC = 4297000)
cyclooctane	LOW (KOC = 562.9)

### 12.5. Results of PBT and vPvB assessment

	P	B	T
Relevant available data	Not Available	Not Available	Not Available
PBT	✘	✘	✘
vPvB	✘	✘	✘
PBT Criteria fulfilled?	No		
vPvB	No		

### 12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

### 12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.

## SECTION 13 Disposal considerations

### 13.1. Waste treatment methods

<b>Product / Packaging disposal</b>	<ul style="list-style-type: none"> <li>▶ <b>DO NOT</b> allow wash water from cleaning or process equipment to enter drains.</li> <li>▶ It may be necessary to collect all wash water for treatment before disposal.</li> <li>▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.</li> <li>▶ Where in doubt contact the responsible authority.</li> </ul>
<b>Waste treatment options</b>	Not Available
<b>Sewage disposal options</b>	Not Available

**Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)**

## SECTION 14 Transport information

### Labels Required

	
Marine Pollutant	

### Land transport (ADR-RID)

14.1. UN number or ID number	3077	
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains zinc oxide and 4,4'-thiobis(6-tert-butyl-m-cresol))	
14.3. Transport hazard class(es)	Class	9
	Subsidiary risk	Not Applicable
14.4. Packing group	III	
14.5. Environmental hazard	Environmentally hazardous	
14.6. Special precautions for user	Hazard identification (Kemler)	90
	Classification code	M7
	Hazard Label	9
	Special provisions	274 335 375 601
	Limited quantity	5 kg
	Tunnel Restriction Code	3 (-)

### 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 and 4,4'-thiobis(6-tert-butyl-m-cresol))	
14.3. Transport hazard class(es)	ICAO/IATA Class	9
	ICAO / IATA Subrisk	Not Applicable
	ERG Code	9L
14.4. Packing group	III	
14.5. Environmental hazard	Environmentally hazardous	
14.6. Special precautions for user	Special provisions	A97 A158 A179 A197 A215
	Cargo Only Packing Instructions	956
	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 and 4,4'-thiobis(6-tert-butyl-m-cresol))	
14.3. Transport hazard class(es)	IMDG Class	9
	IMDG Subrisk	Not Applicable
14.4. Packing group	III	
14.5. Environmental hazard	Marine Pollutant	
14.6. Special precautions for user	EMS Number	F-A, S-F
	Special provisions	274 335 966 967 969
	Limited Quantities	5 kg

**Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)**

**Inland waterways transport (ADN)**

14.1. UN number	3077	
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains zinc oxide and 4,4'-thiobis(6-tert-butyl-m-cresol))	
14.3. Transport hazard class(es)	9	Not Applicable
14.4. Packing group	III	
14.5. Environmental hazard	Environmentally hazardous	
14.6. Special precautions for user	Classification code	M7
	Special provisions	274; 335; 375; 601
	Limited quantity	5 kg
	Equipment required	PP, A***
	Fire cones number	0

**14.7. Maritime transport in bulk according to IMO instruments****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
titanium dioxide	Not Available
talc	Not Available
silica crystalline - quartz	Not Available
C.I. Pigment Red 181	Not Available
stearine, fatty acids C16-18	Not Available
4,4'-thiobis(6-tert-butyl-m-cresol)	Not Available
cyclooctane	Not Available

**14.7.3. Transport in bulk in accordance with the IGC Code**

Product name	Ship Type
zinc oxide	Not Available
titanium dioxide	Not Available
talc	Not Available
silica crystalline - quartz	Not Available
C.I. Pigment Red 181	Not Available
stearine, fatty acids C16-18	Not Available
4,4'-thiobis(6-tert-butyl-m-cresol)	Not Available
cyclooctane	Not Available

**SECTION 15 Regulatory information****15.1. Safety, health and environmental regulations / legislation specific for the substance or mixture****zinc oxide is found on the following regulatory lists**

EU European Chemicals Agency (ECHA) Community Rolling Action Plan (CoRAP) List of Substances

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

Switzerland Occupational Exposure Limits (German)

**titanium dioxide is found on the following regulatory lists**

Chemical Footprint Project - Chemicals of High Concern List

EU European Chemicals Agency (ECHA) Community Rolling Action Plan (CoRAP) List of Substances

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 2B: Possibly carcinogenic to humans

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

Switzerland Occupational Exposure Limits (German)

**talc is found on the following regulatory lists**

## Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)

### Chemical Footprint Project - Chemicals of High Concern List

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 2B: Possibly carcinogenic to humans

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Not Classified as Carcinogenic

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

Switzerland Occupational Exposure Limits (German)

### silica crystalline - quartz is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

European Union Directive (EU) 2017/2398 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 1: Carcinogenic to humans

Switzerland Occupational Exposure Limits - Carcinogens (German)

Switzerland Occupational Exposure Limits (German)

### C.I. Pigment Red 181 is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

Switzerland Occupational Exposure Limits (German)

### stearine, fatty acids C16-18 is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

Switzerland Occupational Exposure Limits (German)

### 4,4'-thiobis(6-tert-butyl-m-cresol) is found on the following regulatory lists

EU European Chemicals Agency (ECHA) Community Rolling Action Plan (CoRAP) List of Substances

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

Switzerland Occupational Exposure Limits (German)

### cyclooctane is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

### Information according to 2012/18/EU (Seveso III):

Seveso Category	E1

### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

### ECHA SUMMARY

Ingredient	CAS number	Index No	ECHA Dossier
zinc oxide	1314-13-2	030-013-00-7	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Aquatic Acute 1; Aquatic Chronic 1	GHS09; Wng	H410
2	Aquatic Acute 1; Aquatic Chronic 1; Repr. 1A; STOT SE 3; STOT SE 1; STOT RE 1; Acute Tox. 2; Acute Tox. 2; Skin Sens. 1; Eye Dam. 1; Muta. 2; Carc. 1A; Skin Corr. 1B	GHS09; GHS08; Dgr; GHS06; GHS05	H410; H360; H400; H335; H370; H372; H300; H330; H317; H318; H341; H350; H314
1	Acute Tox. 4; Eye Dam. 1; Acute Tox. 4; Carc. 1A; Repr. 1A; Lact.; STOT RE 1; Aquatic Acute 1; Aquatic Chronic 1	GHS08; GHS09; GHS05; Dgr	H302; H332; H315; H318; H350; H360; H373; H410
2	Acute Tox. 4; Eye Dam. 1; Acute Tox. 4; Carc. 1A; Repr. 1A; Lact.; STOT RE 1; Aquatic Acute 1; Aquatic Chronic 1	GHS08; GHS09; GHS05; Dgr	H302; H332; H315; H318; H350; H360; H373; H410
1	Not Classified	Not Available	Not Available
2	Not Classified	Not Available	Not Available

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
titanium dioxide	13463-67-7	022-006-00-2	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	Not Available	Not Available
2	Carc. 2; Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2; Acute Tox. 4; STOT SE 3	GHS08; Dgr	H351; H302; H315; H319; H332; H335
1	Not Classified	Not Available	Not Available

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

**Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)**

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
2	Carc. 2; Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2; Acute Tox. 4; STOT SE 3; STOT RE 1; Aquatic Chronic 4	GHS08; Dgr	H351; H302; H315; H319; H332; H335; H372; H413
1	Not Classified	Not Available	Not Available
2	Acute Tox. 4; Eye Irrit. 2; STOT SE 3; STOT RE 1; Carc. 1B; STOT SE 2; Aquatic Chronic 4; Acute Tox. 4; Skin Irrit. 2; Acute Tox. 4; Resp. Sens. 1B; Muta. 2; STOT SE 3	GHS08; Dgr; GHS02	H332; H335; H372; H350; H412; H318; H315; H302; H312; H334; H341; H226; H336; H371
1	Not Classified	Not Available	Not Available
2	Not Classified	Not Available	Not Available

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
talc	14807-96-6	Not Available	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	Not Available	Not Available
2	Carc. 1A; Eye Irrit. 2; STOT RE 1; Acute Tox. 4; STOT SE 3; Aquatic Chronic 4; Acute Tox. 3	GHS08; Dgr; GHS06	H350; H319; H372; H302; H335; H413; H331

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
silica crystalline - quartz	14808-60-7	Not Available	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	Not Available	Not Available
2	Carc. 1A; STOT RE 1; Acute Tox. 4; STOT SE 3; Muta. 2; STOT SE 1; Eye Irrit. 2; Acute Tox. 4; Skin Irrit. 2	GHS08; Dgr	H350; H372; H332; H335; H341; H302; H370; H319; H315; H413

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
C.I. Pigment Red 181	2379-74-0	Not Available	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	Not Available	Not Available
2	Aquatic Acute 1; Aquatic Chronic 1; Skin Sens. 1; Eye Irrit. 2; STOT SE 3	GHS09; Wng; GHS07	H410; H317; H319; H335

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
stearine, fatty acids C16-18	67701-03-5	Not Available	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Asp. Tox. 1	GHS08; Dgr	H304
2	Asp. Tox. 1	GHS08; Dgr	H304

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
4,4'-thiobis(6-tert-butyl-m-cresol)	96-69-5	Not Available	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Skin Sens. 1; Eye Irrit. 2	GHS07; Wng	H317; H319
2	Skin Sens. 1A; Aquatic Acute 1; Eye Irrit. 2; Aquatic Chronic 1; Repr. 2; Skin Irrit. 2; STOT SE 3	GHS09; Wng; GHS08	H317; H400; H410; H319; H315; H335

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
cyclooctane	292-64-8	Not Available	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Flam. Liq. 3	GHS02; Wng	H226
2	Flam. Liq. 3; Asp. Tox. 1; Skin Irrit. 2; Skin Sens. 1B; Aquatic Acute 1; Aquatic Chronic 1	GHS08; GHS02; GHS09; Dgr	H226; H304; H315; H317; H400; H410

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

**Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)**

**National Inventory Status**

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	No (cyclooctane)
Canada - DSL	No (cyclooctane)
Canada - NDSL	No (talc; silica crystalline - quartz; C.I. Pigment Red 181; stearine, fatty acids C16-18; 4,4'-thiobis(6-tert-butyl-m-cresol); cyclooctane)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (cyclooctane)
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	No (cyclooctane)
Taiwan - TCSI	Yes
Mexico - INSQ	No (C.I. Pigment Red 181; stearine, fatty acids C16-18; cyclooctane)
Vietnam - NCI	Yes
Russia - FBEPH	No (C.I. Pigment Red 181; cyclooctane)
<b>Legend:</b>	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.

**SECTION 16 Other information**

<b>Revision Date</b>	08/02/2023
<b>Initial Date</b>	17/01/2023

**Full text Risk and Hazard codes**

<b>H226</b>	Flammable liquid and vapour.
<b>H300</b>	Fatal if swallowed.
<b>H302</b>	Harmful if swallowed.
<b>H304</b>	May be fatal if swallowed and enters airways.
<b>H312</b>	Harmful in contact with skin.
<b>H314</b>	Causes severe skin burns and eye damage.
<b>H315</b>	Causes skin irritation.
<b>H317</b>	May cause an allergic skin reaction.
<b>H318</b>	Causes serious eye damage.
<b>H319</b>	Causes serious eye irritation.
<b>H330</b>	Fatal if inhaled.
<b>H331</b>	Toxic if inhaled.
<b>H332</b>	Harmful if inhaled.
<b>H334</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
<b>H335</b>	May cause respiratory irritation.
<b>H336</b>	May cause drowsiness or dizziness.
<b>H341</b>	Suspected of causing genetic defects.
<b>H350</b>	May cause cancer.
<b>H360</b>	May damage fertility or the unborn child.
<b>H370</b>	Causes damage to organs.
<b>H371</b>	May cause damage to organs.
<b>H372</b>	Causes damage to organs through prolonged or repeated exposure.
<b>H373</b>	May cause damage to organs through prolonged or repeated exposure.
<b>H400</b>	Very toxic to aquatic life.
<b>H412</b>	Harmful to aquatic life with long lasting effects.
<b>H413</b>	May cause long lasting harmful effects to aquatic life.

**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.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

Continued...

**Thermafil® Obturators, ProTaper® Universal Obturators, Domino Otturatori Endodontici per Mtwo (ISO 020-040)**

EN 13832 Footwear protecting against chemicals  
EN 133 Respiratory protective devices

**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  
AII: 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

This document is copyright.

Apart from any fair dealing for the purposes of private study, research, review or criticism, as permitted under the Copyright Act, no part may be reproduced by any process without written permission from CHEMWATCH.

TEL (+61 3) 9572 4700.