

## AFFINIS regular body / fast regular body

### Coltène/Whaledent AG

Version No: 3.3

Safety data sheet according to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

Issue Date: **10/09/2024**

Print Date: **25/11/2024**

L.REACH.GB.EN

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

### 1.1. Product Identifier

<b>Product name</b>	AFFINIS regular body / fast regular body
<b>Chemical Name</b>	Not Applicable
<b>Synonyms</b>	Not Available
<b>Chemical formula</b>	Not Applicable
<b>Other means of identification</b>	Not Available

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

<b>Relevant identified uses</b>	Medical device, for dental use only Use according to manufacturer's directions.
<b>Uses advised against</b>	No specific uses advised against are identified.

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

<b>Registered company name</b>	Coltène/Whaledent AG
<b>Address</b>	Feldwiesenstrasse 20 Altstätten 9450 Switzerland
<b>Telephone</b>	+41 (71) 75 75 300
<b>Fax</b>	+41 (71) 75 75 301
<b>Website</b>	<a href="http://www.coltene.com">www.coltene.com</a>
<b>Email</b>	msds@coltene.com

### 1.4. Emergency telephone number

<b>Association / Organisation</b>	CHEMWATCH EMERGENCY RESPONSE (24/7)
<b>Emergency telephone number(s)</b>	+44 20 3901 3542
<b>Other emergency telephone number(s)</b>	+44 808 164 9592

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

## SECTION 2 Hazards identification

### 2.1. Classification of the substance or mixture

<b>Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567 <sup>[1]</sup></b>	Non hazardous
<b>Legend:</b>	1. Classified by Chemwatch; 2. Classification drawn from GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567

### 2.2. Label elements

<b>Hazard pictogram(s)</b>	Not Applicable
<b>Signal word</b>	<b>Not Applicable</b>

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**Hazard statement(s)**

Not Applicable

**Supplementary statement(s)**

EUH210	Safety data sheet available on request.
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**Precautionary statement(s) Prevention**

Not Applicable

**Precautionary statement(s) Response**

Not Applicable

**Precautionary statement(s) Storage**

Not Applicable

**Precautionary statement(s) Disposal**

Not Applicable

Material contains cristobalite, Celite, silica amorphous.

**2.3. Other hazards**

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	Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567	SCL / M-Factor	Nanoform Particle Characteristics
1. 68855-54-9 2. 272-489-0 3. Not Available 4. Not Available	2.5-7.5	<u>Celite</u>	Specific Target Organ Toxicity - Repeated Exposure Category 2; H373 <sup>[1]</sup>	SCL: Not Available Acute M factor: Not Applicable Chronic M factor: Not Applicable	Not Available
1. 68909-20-6 2. 231-545-4 3. Not Available 4. Not Available	1-5	<u>silica</u> <u>amorphous</u>	Specific Target Organ Toxicity - Repeated Exposure Category 2; H373, EUH210 <sup>[1]</sup>	SCL: Not Available Acute M factor: Not Applicable Chronic M factor: Not Applicable	Not Available
1. 14464-46-1 2. 238-455-4 3. Not Available 4. Not Available	25-40	<u>cristobalite</u>	Specific Target Organ Toxicity - Repeated Exposure Category 2; H373 <sup>[1]</sup>	SCL: Not Available Acute M factor: Not Applicable Chronic M factor: Not Applicable	Not Available

**Legend:**

1. Classified by Chemwatch; 2. Classification drawn from GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567; 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>	If this product comes in contact with eyes: <ul style="list-style-type: none"> <li>▶ Wash out immediately with water.</li> <li>▶ If irritation continues, seek medical attention.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
<b>Skin Contact</b>	If skin or hair contact occurs: <ul style="list-style-type: none"> <li>▶ Flush skin and hair with running water (and soap if available).</li> <li>▶ Seek medical attention in event of irritation.</li> </ul>
<b>Inhalation</b>	<ul style="list-style-type: none"> <li>▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> </ul>

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	<ul style="list-style-type: none"> <li>▶ Other measures are usually unnecessary.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▶ Immediately give a glass of water.</li> <li>▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.</li> </ul>

**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.

**SECTION 5 Firefighting measures****5.1. Extinguishing media**

- ▶ There is no restriction on the type of extinguisher which may be used.
- ▶ Use extinguishing media suitable for surrounding area.

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

<b>Fire Incompatibility</b>	None known.
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**5.3. Advice for firefighters**

<b>Fire Fighting</b>	
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ Non combustible.</li> <li>▶ Not considered a significant fire risk, however containers may burn.</li> </ul>

**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>▶ Clean up all spills immediately.</li> <li>▶ Avoid contact with skin and eyes.</li> <li>▶ Wear impervious gloves and safety goggles.</li> <li>▶ Trowel up/scrape up.</li> <li>▶ Place spilled material in clean, dry, sealed container.</li> <li>▶ Flush spill area with water.</li> </ul>
<b>Major Spills</b>	<ul style="list-style-type: none"> <li>▶ Clear area of personnel and move upwind.</li> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Control personal contact with the substance, by using protective equipment.</li> <li>▶ Prevent spillage from entering drains, sewers or water courses.</li> <li>▶ Recover product wherever possible.</li> <li>▶ Put residues in labelled containers for disposal.</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>▶ Limit all unnecessary personal contact.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Avoid contact with incompatible materials.</li> <li>▶ When handling, <b>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.</li> <li>▶ Use good occupational work practice.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul>
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	<ul style="list-style-type: none"> <li>▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</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, well-ventilated area.</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>

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

<b>Suitable container</b>	Recommended storage temperature: 15 - 23 °C <ul style="list-style-type: none"> <li>▶ Polyethylene or polypropylene container.</li> <li>▶ Packing as recommended by manufacturer.</li> <li>▶ Check all containers are clearly labelled and free from leaks.</li> </ul>
<b>Storage incompatibility</b>	None known
<b>Hazard categories in accordance with Regulation (EC) No 2012/18/EU (Seveso III)</b>	Not Available
<b>Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of</b>	Not Available

## 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
Celite	Inhalation 0.05 mg/m <sup>3</sup> (Systemic, Chronic) Inhalation 0.00005 mg/m <sup>3</sup> (Systemic, Chronic) * Oral 18.7 mg/kg bw/day (Systemic, Chronic) *	100 mg/L (STP)

\* Values for General Population

## Occupational Exposure Limits (OEL)

## INGREDIENT DATA


Source	Ingredient	Material name	TWA	STEL	Peak	Notes
UK Workplace Exposure Limits (WELs).	Celite	Silica, amorphous: respirable dust	2.4 mg/m <sup>3</sup>	Not Available	Not Available	Not Available
UK Workplace Exposure Limits (WELs).	Celite	Silica, amorphous: inhalable dust	6 mg/m <sup>3</sup>	Not Available	Not Available	Not Available
UK Workplace Exposure Limits (WELs).	silica amorphous	Silica, amorphous: inhalable dust	6 mg/m <sup>3</sup>	Not Available	Not Available	Not Available
UK Workplace Exposure Limits (WELs).	silica amorphous	Silica, amorphous: respirable dust	2.4 mg/m <sup>3</sup>	Not Available	Not Available	Not Available
UK Workplace Exposure Limits (WELs).	crystalite	Silica, respirable crystalline (respirable fraction)	0.1 mg/m <sup>3</sup>	Not Available	Not Available	Carc (where generated as a result of a work process)

Ingredient	Original IDLH	Revised IDLH
Celite	Not Available	Not Available
silica amorphous	Not Available	Not Available
crystalite	Not Available	Not Available

## MATERIAL DATA

## 8.2. Exposure controls

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8.2.1. Appropriate engineering controls	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas. 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.</p>										
	<table border="1"> <thead> <tr> <th>Type of Contaminant:</th> <th>Air Speed:</th> </tr> </thead> <tbody> <tr> <td>solvent, vapours, degreasing etc., evaporating from tank (in still air)</td> <td>0.25-0.5 m/s (50-100 f/min)</td> </tr> <tr> <td>aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)</td> <td>0.5-1 m/s (100-200 f/min.)</td> </tr> <tr> <td>direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)</td> <td>1-2.5 m/s (200-500 f/min)</td> </tr> <tr> <td>grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).</td> <td>2.5-10 m/s (500-2000 f/min.)</td> </tr> </tbody> </table>	Type of Contaminant:	Air Speed:	solvent, vapours, degreasing etc., evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min)	aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)	direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min)	grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)
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<p>Within each range the appropriate value depends on:</p> <table border="1"> <thead> <tr> <th>Lower end of the range</th> <th>Upper end of the range</th> </tr> </thead> <tbody> <tr> <td>1: Room air currents minimal or favourable to capture</td> <td>1: Disturbing room air currents</td> </tr> <tr> <td>2: Contaminants of low toxicity or of nuisance value only</td> <td>2: Contaminants of high toxicity</td> </tr> <tr> <td>3: Intermittent, low production.</td> <td>3: High production, heavy use</td> </tr> <tr> <td>4: Large hood or large air mass in motion</td> <td>4: Small hood - local control only</td> </tr> </tbody> </table>	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	
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<p>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 m/s (200-400 f/min.) for extraction of solvents generated in a tank 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.</p>											
8.2.2. Individual protection measures, such as personal protective equipment											
Eye and face protection	<ul style="list-style-type: none"> <li>▶ Safety glasses with side shields</li> <li>▶ Chemical goggles.</li> <li>▶ 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]</li> </ul>										
Skin protection	See Hand protection below										
Hands/feet protection	<ul style="list-style-type: none"> <li>▶ Wear general protective gloves, eg. light weight rubber gloves.</li> </ul>										
Body protection	See Other protection below										
Other protection	<p>No special equipment needed when handling small quantities.</p> <p><b>OTHERWISE:</b></p> <ul style="list-style-type: none"> <li>▶ Overalls.</li> <li>▶ Barrier cream.</li> <li>▶ Eyewash unit.</li> </ul>										

## 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

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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)

## 8.2.3. Environmental exposure controls

See section 12

## SECTION 9 Physical and chemical properties

## 9.1. Information on basic physical and chemical properties

Appearance	Blue		
Physical state	Free-flowing Paste	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Available
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Immiscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
Heat of Combustion (kJ/g)	Not Available	Ignition Distance (cm)	Not Available
Flame Height (cm)	Not Available	Flame Duration (s)	Not Available
Enclosed Space Ignition Time Equivalent (s/m <sup>3</sup> )	Not Available	Enclosed Space Ignition Deflagration Density (g/m <sup>3</sup> )	Not Available
Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available
Particle Size	Not Available		

## 9.2. Other information

Not Available

## SECTION 10 Stability and reactivity

10.1.Reactivity	See section 7.2
10.2. Chemical stability	Product is considered stable and hazardous polymerisation will not occur.
10.3. Possibility of hazardous reactions	See section 7.2
10.4. Conditions to avoid	See section 7.2
10.5. Incompatible materials	See section 7.2
10.6. Hazardous decomposition products	See section 5.3

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## SECTION 11 Toxicological information

## 11.1. Information on toxicological effects

Inhaled		
Ingestion		
Skin Contact		
Eye		
Chronic		
AFFINIS regular body / fast regular body	<b>TOXICITY</b> Not Available	<b>IRRITATION</b> Not Available
	<b>TOXICITY</b> Inhalation (Rat) LC50: >2.6 mg/l4h <sup>[1]</sup> Oral (Rat) LD50: >2000 mg/kg <sup>[1]</sup>	<b>IRRITATION</b> Eye: no adverse effect observed (not irritating) <sup>[1]</sup> Skin: no adverse effect observed (not irritating) <sup>[1]</sup>
silica amorphous	<b>TOXICITY</b> Dermal (rabbit) LD50: >5000 mg/kg * <sup>[2]</sup> Inhalation (Rat) LC50: >0.139 mg/l/14h * <sup>[2]</sup> Oral (Rat) LD50: 3160 mg/kg <sup>[2]</sup>	<b>IRRITATION</b> Not Available
	<b>TOXICITY</b> Not Available	<b>IRRITATION</b> Not Available
	<b>TOXICITY</b> Not Available	<b>IRRITATION</b> Not Available
<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	

silica amorphous	<p>Reports indicate high/prolonged exposures to amorphous silicas induced lung fibrosis in experimental animals; in some experiments these effects were reversible. [PATTYS]</p> <p>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>
crystalite	<p>Inhalation (human) TCLo: 16 mppcf*/8H/17.9y-I * Millions of particles per cubic foot <b>WARNING:</b> For inhalation exposure <u>ONLY</u>: 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 um) 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>
Celite & silica amorphous	<p>For silica amorphous: Derived No Adverse Effects Level (NOAEL) in the range of 1000 mg/kg/d.</p> <p>In humans, synthetic amorphous silica (SAS) is essentially non-toxic by mouth, skin or eyes, and by inhalation. Epidemiology studies show little evidence of adverse health effects due to SAS. Repeated exposure (without personal protection) may cause mechanical irritation of the eye and drying/cracking of the skin.</p> <p>When experimental animals inhale synthetic amorphous silica (SAS) dust, it dissolves in the lung fluid and is rapidly eliminated. If swallowed, the vast majority of SAS is excreted in the faeces and there is little accumulation in the body. Following absorption across the gut, SAS is eliminated via urine without modification in animals and humans. SAS is not expected to be broken down (metabolised) in mammals.</p> <p>After ingestion, there is limited accumulation of SAS in body tissues and rapid elimination occurs. Intestinal absorption has not been calculated, but appears to be insignificant in animals and humans. SASs injected subcutaneously are subjected to rapid dissolution and removal. There is no indication of metabolism of SAS in animals or humans based on chemical structure and available data. In contrast to crystalline silica, SAS is soluble in physiological media and the soluble chemical species that are formed are eliminated via the urinary tract without modification.</p> <p>Both the mammalian and environmental toxicology of SASs are significantly influenced by the physical and chemical properties, particularly those of solubility and particle size. SAS has no acute intrinsic toxicity by inhalation. Adverse effects, including suffocation, that have been reported were caused by the presence of high numbers of respirable particles generated to meet the required test atmosphere. These results are not representative of exposure to commercial SASs and should not be used for human risk assessment. Though repeated exposure of the skin may cause dryness and cracking, SAS is not a skin or eye irritant, and it is not a sensitiser.</p>

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Repeated-dose and chronic toxicity studies confirm the absence of toxicity when SAS is swallowed or upon skin contact. Long-term inhalation of SAS caused some adverse effects in animals (increases in lung inflammation, cell injury and lung collagen content), all of which subsided after exposure.

Numerous repeated-dose, subchronic and chronic inhalation toxicity studies have been conducted with SAS in a number of species, at airborne concentrations ranging from 0.5 mg/m<sup>3</sup> to 150 mg/m<sup>3</sup>. Lowest-observed adverse effect levels (LOAELs) were typically in the range of 1 to 50 mg/m<sup>3</sup>. When available, the no-observed adverse effect levels (NOAELs) were between 0.5 and 10 mg/m<sup>3</sup>. The difference in values may be explained by different particle size, and therefore the number of particles administered per unit dose. In general, as particle size decreases so does the NOAEL/LOAEL.

Neither inhalation nor oral administration caused neoplasms (tumours). SAS is not mutagenic in vitro. No genotoxicity was detected in in vivo assays. SAS does not impair development of the foetus. Fertility was not specifically studied, but the reproductive organs in long-term studies were not affected.

For Synthetic Amorphous Silica (SAS)

Repeated dose toxicity

Oral (rat), 2 weeks to 6 months, no significant treatment-related adverse effects at doses of up to 8% silica in the diet.

Inhalation (rat), 13 weeks, Lowest Observed Effect Level (LOEL) = 1.3 mg/m<sup>3</sup> based on mild reversible effects in the lungs.

Inhalation (rat), 90 days, LOEL = 1 mg/m<sup>3</sup> based on reversible effects in the lungs and effects in the nasal cavity.

For silane treated synthetic amorphous silica:

Repeated dose toxicity: oral (rat), 28-d, diet, no significant treatment-related adverse effects at the doses tested.

There is no evidence of cancer or other long-term respiratory health effects (for example, silicosis) in workers employed in the manufacture of SAS. Respiratory symptoms in SAS workers have been shown to correlate with smoking but not with SAS exposure, while serial pulmonary function values and chest radiographs are not adversely affected by long-term exposure to SAS.

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

**Legend:** ✗ – 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

AFFINIS regular body / fast regular body	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
Celite	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
silica amorphous	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
crystalite	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
<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				

## 12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients



## AFFINIS regular body / fast regular body

**12.3. Bioaccumulative potential**

Ingredient	Bioaccumulation
	No Data available for all ingredients

**12.4. Mobility in soil**

Ingredient	Mobility
	No Data available for all ingredients

**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>	Dispose of waste according to applicable legislation. Special country-specific regulations may apply. Can be disposed together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge. (Only dispose of completely emptied packages.)
<b>Waste treatment options</b>	Not Available
<b>Sewage disposal options</b>	Not Available

**SECTION 14 Transport information****Labels Required**

<b>Marine Pollutant</b>	NO
<b>HAZCHEM</b>	Not Applicable

**Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

<b>14.1. UN number or ID number</b>	Not Applicable												
<b>14.2. UN proper shipping name</b>	Not Applicable												
<b>14.3. Transport hazard class(es)</b>	<table border="1"> <tbody> <tr> <td>Class</td> <td>Not Applicable</td> </tr> <tr> <td>Subsidiary Hazard</td> <td>Not Applicable</td> </tr> </tbody> </table>	Class	Not Applicable	Subsidiary Hazard	Not Applicable								
Class	Not Applicable												
Subsidiary Hazard	Not Applicable												
<b>14.4. Packing group</b>	Not Applicable												
<b>14.5. Environmental hazard</b>	Not Applicable												
<b>14.6. Special precautions for user</b>	<table border="1"> <tbody> <tr> <td>Hazard identification (Kemler)</td> <td>Not Applicable</td> </tr> <tr> <td>Classification code</td> <td>Not Applicable</td> </tr> <tr> <td>Hazard Label</td> <td>Not Applicable</td> </tr> <tr> <td>Special provisions</td> <td>Not Applicable</td> </tr> <tr> <td>Limited quantity</td> <td>Not Applicable</td> </tr> <tr> <td>Tunnel Restriction Code</td> <td>Not Applicable</td> </tr> </tbody> </table>	Hazard identification (Kemler)	Not Applicable	Classification code	Not Applicable	Hazard Label	Not Applicable	Special provisions	Not Applicable	Limited quantity	Not Applicable	Tunnel Restriction Code	Not Applicable
Hazard identification (Kemler)	Not Applicable												
Classification code	Not Applicable												
Hazard Label	Not Applicable												
Special provisions	Not Applicable												
Limited quantity	Not Applicable												
Tunnel Restriction Code	Not Applicable												

## AFFINIS regular body / fast regular body

**Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

14.1. UN number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	ICAO/IATA Class	Not Applicable
	ICAO / IATA Subsidiary Hazard	Not Applicable
	ERG Code	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	Special provisions	Not Applicable
	Cargo Only Packing Instructions	Not Applicable
	Cargo Only Maximum Qty / Pack	Not Applicable
	Passenger and Cargo Packing Instructions	Not Applicable
	Passenger and Cargo Maximum Qty / Pack	Not Applicable
	Passenger and Cargo Limited Quantity Packing Instructions	Not Applicable
	Passenger and Cargo Limited Maximum Qty / Pack	Not Applicable

**Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

14.1. UN number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	IMDG Class	Not Applicable
	IMDG Subsidiary Hazard	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	EMS Number	Not Applicable
	Special provisions	Not Applicable
	Limited Quantities	Not Applicable

**Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

14.1. UN number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	Not Applicable	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	Classification code	Not Applicable
	Special provisions	Not Applicable
	Limited quantity	Not Applicable
	Equipment required	Not Applicable
	Fire cones number	Not Applicable

**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
Celite	Not Available
silica amorphous	Not Available
crystalite	Not Available

## AFFINIS regular body / fast regular body

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

Product name	Ship Type
Celite	Not Available
silica amorphous	Not Available
crystalite	Not Available

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

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)  
UK Workplace Exposure Limits (WELs).

**silica amorphous is found on the following regulatory lists**

Great Britain GB Biocidal Active Substances  
Great Britain GB mandatory classification and labelling (GB MCL) technical reports  
Great Britain GB mandatory classification and labelling list (GB MCL)  
International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)  
UK Workplace Exposure Limits (WELs).

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

Chemical Footprint Project - Chemicals of High Concern List  
International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)  
UK Workplace Exposure Limits (WELs).

**Additional Regulatory Information**

Not Applicable

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	Not Available

**15.2. Chemical safety assessment**

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

**National Inventory Status**

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (Celite; silica amorphous; crystalite)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (Celite; silica amorphous)
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	All chemical substances in this product have been designated as TSCA Inventory 'Active'
Taiwan - TCSI	Yes
Mexico - INSQ	No (silica amorphous)
Vietnam - NCI	Yes
Russia - FBEPH	No (silica amorphous)
<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.

## AFFINIS regular body / fast regular body

## SECTION 16 Other information

<b>Revision Date</b>	10/09/2024
<b>Initial Date</b>	17/12/2021

## Full text Risk and Hazard codes

<b>H373</b>	May cause damage to organs through prolonged or repeated exposure.
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## SDS Version Summary

Version	Date of Update	Sections Updated
2.3	10/09/2024	Toxicological information - Acute Health (inhaled), Toxicological information - Acute Health (skin), Toxicological information - Chronic Health, Hazards identification - Classification, Disposal considerations - Disposal, Exposure controls / personal protection - Engineering Control, Ecological Information - Environmental, Exposure controls / personal protection - Exposure Standard, Firefighting measures - Fire Fighter (fire fighting), Composition / information on ingredients - Ingredients, Exposure controls / personal protection - Personal Protection (other), Exposure controls / personal protection - Personal Protection (Respirator), Accidental release measures - Spills (major), Handling and storage - Storage (storage incompatibility)

## 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
- 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
- DNEL: Derived No-Effect Level
- PNEC: Predicted no-effect concentration
- MARPOL: International Convention for the Prevention of Pollution from Ships
- IMSBC: International Maritime Solid Bulk Cargoes Code
- IGC: International Gas Carrier Code
- IBC: International Bulk Chemical Code
  
- AIIC: Australian Inventory of Industrial Chemicals
- DSL: Domestic Substances List
- NDSL: Non-Domestic Substances List
- IECSC: Inventory of Existing Chemical Substance in China
- EINECS: European INventory of Existing Commercial chemical Substances
- ELINCS: European List of Notified Chemical Substances
- NLP: No-Longer Polymers
- ENCS: Existing and New Chemical Substances Inventory
- KECI: Korea Existing Chemicals Inventory
- NZIoC: New Zealand Inventory of Chemicals
- PICCS: Philippine Inventory of Chemicals and Chemical Substances

## AFFINIS regular body / fast regular body

- 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

**Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]**

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	Classification Procedure
, EUH210	Calculation method

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