



Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: AFFINIS regular body / fast regular body

Manufacturer: Dent4You AG

SDS Expiry: 9 September 2029

Supplier Details: Henry Schein New Zealand

243-249 Bush Road, Rosedale, Auckland, 0632 PO Box 101 140, North Shore, Auckland 0745

Ph. 0800 808 855

www.henryschein.co.nz

Emergency Contacts: Poisons/Hazardous Chemical Info Centre –

0800POISON/0800764766 (24 Hours) Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: Non-Hazardous

HSNO Group Standard: Non-Hazardous

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared – October 2024

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.





AFFINIS regular body / fast regular body

Dent4You AG

Version No: 1.1

Safety Data Sheet according to the Health and Safety at Work (Hazardous Substances) Regulations 2017

Issue Date: **09/09/2024**Print Date: **09/09/2024**S.GHS.NZL.EN

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

Product Identifier

Product name	AFFINIS regular body / fast regular body
Synonyms	Not Available
Other means of identification	Not Available

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Medical device, for dental use only Use according to manufacturer's directions.
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Details of the manufacturer or supplier of the safety data sheet

Registered company name	Dent4You AG
Address	Bahnhofstrasse 2 Heerbrugg 9435 Switzerland
Telephone	+41 (0) 71 222 7171
Fax	Not Available
Website	Not Available
Email	info@dent4you.ch

Emergency telephone number

Association / Organisation	CHEMWATCH EMERGENCY RESPONSE (24/7)
Emergency telephone numbers	+64 800 700 112
Other emergency telephone numbers	+61 3 9573 3188

SECTION 2 Hazards identification

Classification of the substance or mixture

Classification ^[1]	Not Applicable
Determined by Chemwatch using GHS/HSNO criteria	Not Available

Label elements

Hazard pictogram(s)	Not Applicable
Signal word	Not Applicable

Hazard statement(s)

Not Applicable

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Not Applicable

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
68855-54-9*	2.5-7.5	Celite
68909-20-6*	1-5	silica amorphous
14464-46-1*	25-40	cristobalite
Legend: 1. Classified by Chemwatch; 2. Classification drawn from CCID EPA NZ; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L * EU IOELVs available		

SECTION 4 First aid measures

Description of first aid measures

Eye Contact	If this product comes in contact with eyes: • Wash out immediately with water. • If irritation continues, seek medical attention. • Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin or hair contact occurs: ► Flush skin and hair with running water (and soap if available). ► Seek medical attention in event of irritation.
Inhalation	 If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually unnecessary.
Ingestion	 Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures

Extinguishing media

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

Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.
-	

Advice for firefighters

Fire Fighting	
Fire/Explosion Hazard	 Non combustible. Not considered a significant fire risk, however containers may burn.

SECTION 6 Accidental release measures

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See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	 Clean up all spills immediately. Avoid contact with skin and eyes. Wear impervious gloves and safety goggles. Trowel up/scrape up. Place spilled material in clean, dry, sealed container. Flush spill area with water.
Major Spills	 Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. Control personal contact with the substance, by using protective equipment. Prevent spillage from entering drains, sewers or water courses. Recover product wherever possible. Put residues in labelled containers for disposal. If contamination of drains or waterways occurs, advise emergency services.

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

SECTION 7 Handling and storage

Precautions for safe handling		
Safe handling	 Limit all unnecessary personal contact. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers. Always wash hands with soap and water after handling. Work clothes should be laundered separately. Use good occupational work practice. Observe manufacturer's storage and handling recommendations contained within this SDS. Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained. 	
Other information	 Store in original containers. Keep containers securely sealed. Store in a cool, dry, well-ventilated area. Store away from incompatible materials and foodstuff containers. Protect containers against physical damage and check regularly for leaks. Observe manufacturer's storage and handling recommendations contained within this SDS. 	

Conditions for safe storage, including any incompatibilities

Suitable container	Recommended storage temperature: 15 - 23 °C Polyethylene or polypropylene container. Packing as recommended by manufacturer. Check all containers are clearly labelled and free from leaks.
Storage incompatibility	Avoid contamination of water, foodstuffs, feed or seed. None known

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
New Zealand Workplace Exposure Standards (WES)	Celite	Inhalable dust (not otherwise classified)	10 mg/m3	Not Available	Not Available	Not Available

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Source	Ingredient	Material name	TWA	STEL	Peak	Notes
New Zealand Workplace Exposure Standards (WES)	Celite	Respirable dust (not otherwise classified)	3 mg/m3	Not Available	Not Available	Not Available
New Zealand Workplace Exposure Standards (WES)	silica amorphous	Inhalable dust (not otherwise classified)	10 mg/m3	Not Available	Not Available	Not Available
New Zealand Workplace Exposure Standards (WES)	silica amorphous	Respirable dust (not otherwise classified)	3 mg/m3	Not Available	Not Available	Not Available
New Zealand Workplace Exposure Standards (WES)	cristobalite	Respirable dust (not otherwise classified)	3 mg/m3	Not Available	Not Available	Not Available
New Zealand Workplace Exposure Standards (WES)	cristobalite	Inhalable dust (not otherwise classified)	10 mg/m3	Not Available	Not Available	Not Available
New Zealand Workplace Exposure Standards (WES)	cristobalite	Silica- Crystalline (all forms) respirable dust	0.025 mg/m3	Not Available	Not Available	carcinogen category 1 - Known or presumed human carcinogen; α-quartz and cristobalite are confirmed carcinogens. Significant risk to workers will remain at WES-TWA exposures of 0.025mg/m3. The US Occupational Safety and Health Administration (OSHA) has estimated the lifetime silicosis mortality risk for workers exposed at this level for 8 hours per day at between 4 and 22 deaths per 1,000 workers and the lifetime lung cancer mortality risk for workers exposed at this level for 8 hours per day at between 3 and 23 deaths per 1,000 workers.

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
cristobalite	0.075 mg/m3	33 mg/m3	200 mg/m3

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

Exposure controls

Appropriate engineering controls

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.

The basic types of engineering controls are:

Process controls which involve changing the way a job activity or process is done to reduce the risk.

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.

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.

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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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 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.

Individual protection measures, such as personal protective equipment









Eye and face protection

Safety glasses with side shields

- Chemical goggles.
- 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

▶ Wear general protective gloves, eg. light weight rubber gloves.

Body protection

See Other protection below

Other protection

No special equipment needed when handling small quantities. **OTHERWISE:**

on

- Overalls.
- Barrier cream.
- Eyewash unit.

Respiratory protection

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

SECTION 9 Physical and chemical properties

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

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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/m3)	Not Available	Enclosed Space Ignition Deflagration Density (g/m3)	Not Available

SECTION 10 Stability and reactivity

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

SECTION 11 Toxicological information

Information on toxicological effects

Respiratory or Skin

sensitisation Mutagenicity

AFFINIS regular body / fast	TOXICITY		IRRITATION			
regular body	Not Available	Not Available				
	TOXICITY	IRRITAT	TON			
Celite	Inhalation (Rat) LC50: >2.6 mg/l4h ^[1]	Eye: no	adverse effect o	observed (not irritating) ^[1]		
	Oral (Rat) LD50: >2000 mg/kg ^[1]	Skin: no	adverse effect	observed (not irritating) ^[1]		
	TOXICITY		IRRITATIO	ON		
	Dermal (rabbit) LD50: >5000 mg/kg * ^[2]			Eye (rabbit): non-irritating ** [Grace]		
silica amorphous	Inhalation (Rat) LC50: >0.139 mg/l/14h *[2]			Skin (rabbit): non-irritating *		
	Oral (Rat) LD50: 3160 mg/kg ^[2]					
	TOXICITY		IRRITATION			
cristobalite	Not Available		Not Available	nt Available		
Legend:	Value obtained from Europe ECHA Registere Unless otherwise specified data extracted from		•			
Acute Toxicity	×	Ca	rcinogenicity	×		
Skin Irritation/Corrosion	×	R	eproductivity	×		
Serious Eye Damage/Irritation	×	STOT - Sin	gle Exposure	×		

STOT - Repeated Exposure

Aspiration Hazard

×

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🗶 – Data either not available or does not fill the criteria for classification

– Data available to make classification

Legend:

SECTION 12 Ecological information

Toxicity

FFINIS regular body / fast	Endpoint	Test Duration (hr)	Species	Value	Source
regular body	Not Available	Not Available	Not Available	Not Available	Not Available
	Endneint	Toot Duration (hr)	Species	Value	Source
Celite	Not Available	Test Duration (hr) Not Available	Species Not Available	Not Available	Not Available
	Endpoint	Test Duration (hr)	Species	Value	Source
silica amorphous	Not Available	Not Available	Not Available	Not Available	Not Available
	Endpoint	Test Duration (hr)	Species	Value	Source
cristobalite	Not Available	Not Available	Not Available	Not Available	Not Available
Legend:	4. US EPA, Ecotox	ICLID Toxicity Data 2. Europe E database - Aquatic Toxicity Data ata 7. METI (Japan) - Bioconcei	a 5. ECETOC Aquatic Haz	zard Assessment Data 6	•

Persistence and degradability

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

Bioaccumulative potential

Ingredient	Bioaccumulation
	No Data available for all ingredients

Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal

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.)

Ensure that the hazardous substance is disposed in accordance with the Hazardous Substances (Disposal) Notice 2017

Disposal Requirements

Not applicable as substance/ material is non hazardous.

SECTION 14 Transport information

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Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

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

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

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

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
cristobalite	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

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

SECTION 15 Regulatory information

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

This substance is to be managed using the conditions specified in an applicable Group Standard

HSR Number	Group Standard
Not Applicable	Not Applicable

Please refer to Section 8 of the SDS for any applicable tolerable exposure limit or Section 12 for environmental exposure limit.

Celite is found on the following regulatory lists

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

New Zealand Inventory of Chemicals (NZIoC)

New Zealand Workplace Exposure Standards (WES)

silica amorphous is found on the following regulatory lists

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

New Zealand Inventory of Chemicals (NZIoC)

New Zealand Workplace Exposure Standards (WES)

cristobalite 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)

New Zealand Approved Hazardous Substances with controls

New Zealand Hazardous Substances and New Organisms (HSNO) Act - Classification of Chemicals

New Zealand Hazardous Substances and New Organisms (HSNO) Act - Classification of Chemicals - Classification Data

New Zealand Inventory of Chemicals (NZIoC)

New Zealand Workplace Exposure Standards (WES)

Additional Regulatory Information

Not Applicable

Hazardous Substance Location

Subject to the Health and Safety at Work (Hazardous Substances) Regulations 2017.

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Hazard Class	Quantities
Not Applicable	Not Applicable

Certified Handler

Subject to Part 4 of the Health and Safety at Work (Hazardous Substances) Regulations 2017.

Class of substance	Quantities
Not Applicable	Not Applicable

Refer Group Standards for further information

Maximum quantities of certain hazardous substances permitted on passenger service vehicles

Subject to Regulation 13.14 of the Health and Safety at Work (Hazardous Substances) Regulations 2017.

Hazard Class	Gas (aggregate water capacity in mL)	Liquid (L)	Solid (kg)	Maximum quantity per package for each classification
Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable

Tracking Requirements

Not Applicable

National Inventory Status

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

SECTION 16 Other information

Revision Date	09/09/2024
Initial Date	17/12/2021

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.

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