

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: Coltene Whaledent

SDS Expiry: 11 April 2027

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](http://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 – November 2023

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

### Coltène/Whaledent AG

Version No: 1.1

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

Issue Date: 11/04/2022

Print Date: 17/10/2023

L.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
Chemical Name	Not Applicable
Synonyms	Not Available
Chemical formula	Not Applicable
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	Coltène/Whaledent AG
Address	Feldwiesenstrasse 20 Altstätten CH-9450 Switzerland
Telephone	+41 (71) 75 75 300
Fax	+41 (71) 75 75 301
Website	<a href="http://www.coltene.com">www.coltene.com</a>
Email	msds@coltene.com

##### 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

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

#### 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	<b>Not Applicable</b>

##### Hazard statement(s)

Not Applicable

##### Precautionary statement(s) Prevention

Not Applicable

## AFFINIS regular body / fast regular body

**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
540-97-6	<0.2	<u>dodecamethylcyclohexasiloxane</u>
<b>Legend:</b> 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**

<b>Eye Contact</b>	<p>If this product comes in contact with eyes:</p> <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>	<p>If skin or hair contact occurs:</p> <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> <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>

**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**

<b>Fire Incompatibility</b>	None known.
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**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****Personal precautions, protective equipment and emergency procedures**

See section 8

**Environmental precautions**

See section 12

**Methods and material for containment and cleaning up**

Continued...

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	<ul style="list-style-type: none"> <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>

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

## SECTION 7 Handling and storage

### 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> <li>▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</li> </ul>
<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>

### Conditions for safe storage, including any incompatibilities

<b>Suitable container</b>	<p>Recommended storage temperature: 15 - 23 °C</p> <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>	<p>Avoid contamination of water, foodstuffs, feed or seed. None known</p>

## SECTION 8 Exposure controls / personal protection

### Control parameters

#### Occupational Exposure Limits (OEL)

#### INGREDIENT DATA

Not Available

#### Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
dodecamethylcyclohexasiloxane	150 mg/m3	1,700 mg/m3	9,900 mg/m3

Ingredient	Original IDLH	Revised IDLH
dodecamethylcyclohexasiloxane	Not Available	Not Available

#### MATERIAL DATA

### Exposure controls

<b>Appropriate engineering controls</b>	<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>	<b>Continued...</b>
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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.)

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. [AS/NZS 1337.1, EN166 or national equivalent]
- ▶ 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].

**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:**

- ▶ Overalls.
- ▶ Barrier cream.
- ▶ Eyewash unit.

## Respiratory protection

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

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	- -	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3 Air-line*	- -

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\* - Negative pressure demand \*\* - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(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)

## 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
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

## 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

Inhaled	
Ingestion	
Skin Contact	
Eye	
Chronic	

AFFINIS regular body / fast regular body	TOXICITY	IRRITATION
	Not Available	Not Available
dodecamethylcyclohexasiloxane	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg <sup>[1]</sup>	Eye: no adverse effect observed (not irritating) <sup>[1]</sup>
	Oral (Rat) LD50: >2000 mg/kg <sup>[1]</sup>	Skin: adverse effect observed (irritating) <sup>[1]</sup>
		Skin: no adverse effect observed (not irritating) <sup>[1]</sup>

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Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

<b>DODECAMETHYLCYCLOHEXASILOXANE</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

## SECTION 12 Ecological information

## Toxicity

AFFINIS regular body / fast regular body	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available

  

dodecamethylcyclohexasiloxane	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	>0.002mg/L	2
	NOEC(ECx)	72h	Algae or other aquatic plants	>=0.002mg/L	2

**Legend:** 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

## Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
dodecamethylcyclohexasiloxane	HIGH	HIGH

## Bioaccumulative potential

Ingredient	Bioaccumulation
dodecamethylcyclohexasiloxane	HIGH (LogKOW = 6.3286)

## Mobility in soil

Ingredient	Mobility
dodecamethylcyclohexasiloxane	LOW (KOC = 1174000)

## SECTION 13 Disposal considerations

## Waste treatment methods

<b>Product / Packaging disposal</b>	<p>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.)</p> <ul style="list-style-type: none"> <li>▶ Recycle wherever possible or consult manufacturer for recycling options.</li> <li>▶ Consult State Land Waste Management Authority for disposal.</li> <li>▶ Bury residue in an authorised landfill.</li> <li>▶ Recycle containers if possible, or dispose of in an authorised landfill.</li> </ul>
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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.

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## SECTION 14 Transport information

## AFFINIS regular body / fast regular body

## 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
dodecamethylcyclohexasiloxane	Not Available

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

Product name	Ship Type
dodecamethylcyclohexasiloxane	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.

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

Chemical Footprint Project - Chemicals of High Concern List

New Zealand Inventory of Chemicals (NZIoC)

**Hazardous Substance Location**

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

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 - AIIIC / Australia Non-Industrial Use	Yes

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## AFFINIS regular body / fast regular body

National Inventory	Status
Canada - NDSL	No (dodecamethylcyclohexasiloxane)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	Yes
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	Yes
Taiwan - TCSI	Yes
Mexico - INSQ	No (dodecamethylcyclohexasiloxane)
Vietnam - NCI	Yes
Russia - FBEPH	Yes
<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

Revision Date	11/04/2022
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.

## 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  
 AIIC: Australian Inventory of Industrial Chemicals  
 DSL: Domestic Substances List  
 NDSL: Non-Domestic Substances List  
 IECSC: Inventory of Existing Chemical Substance in China  
 EINECS: European INventory of Existing Commercial chemical Substances  
 ELINCS: European List of Notified Chemical Substances  
 NLP: No-Longer Polymers  
 ENCS: Existing and New Chemical Substances Inventory  
 KECI: Korea Existing Chemicals Inventory  
 NZIoC: New Zealand Inventory of Chemicals  
 PICCS: Philippine Inventory of Chemicals and Chemical Substances  
 TSCA: Toxic Substances Control Act  
 TCSI: Taiwan Chemical Substance Inventory  
 INSQ: Inventario Nacional de Sustancias Químicas  
 NCI: National Chemical Inventory

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