

Safety Data Sheet according to WHS Regulations

Printing date 16.08.2024

Version number 4

Revision: 16.08.2024


Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **Product identifier**
- **Trade name:** **UNIFAST LC Powder**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Auxillary for dental technology
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**

GC Australasia Dental Pty Ltd
1753 Botany Road
Banksmeadow, NSW 2019
Tel: +61 2 9301 8200
- **Further information obtainable from:** Regulatory affairs
- **Emergency telephone number:** 24 hours Emergency: 13 11 26.

2 Hazard(s) Identification

- **Classification of the substance or mixture**
Skin sensitisation – Category 1 H317 May cause an allergic skin reaction.
- **Label elements**
- **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Exemptions**
The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).
- **Hazard pictograms**

GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
Dibenzoyl peroxide (2.5-<5 %)
- **Hazard statements**
May cause an allergic skin reaction.
- **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapours/spray.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves.
If skin irritation or rash occurs: Get medical advice/attention.
Specific treatment (see on this label).

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Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:**

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

- **Dangerous components:**

94-36-0	Dibenzoyl peroxide Self-reactive substances and mixtures – Type B, H241; Organic peroxides – Type B, H241; Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317	2.5-<5%
9003-08-1	1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde Eye damage/irritation – Category 1, H318; Skin sensitisation – Category 1, H317; Specific target organ toxicity (single exposure) – Category 3, H335	0.5-<1%
13463-67-7	titanium dioxide Carcinogenicity – Category 2, H351	0.1-<0.2%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- **General information:**

Immediately remove any clothing soiled by the product.
If symptoms persist consult doctor.

- **After inhalation:**

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
Take affected persons into fresh air and keep quiet.

- **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.
Seek medical treatment.
If skin irritation continues, consult a doctor.

- **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- **After swallowing:**

Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.

- **Information for doctor:**

- **Most important symptoms and effects, both acute and delayed** Allergic reactions
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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5 Fire Fighting Measures

- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
No further relevant information available.
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.
Avoid formation of dust.
Avoid contact with the eyes and skin.
Wear protective clothing.
- **Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Do not allow to penetrate the ground/soil.
- **Methods and material for containment and cleaning up:**
Pick up mechanically.
Prevent formation of dust.
Dispose of the material collected according to regulations.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**
Prevent formation of dust.
Any unavoidable deposit of dust must be regularly removed.
Avoid contact with the eyes and skin.
- **Information about fire - and explosion protection:** Dust can combine with air to form an explosive mixture.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in unopened original receptacles.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.

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· **Ingredients with limit values that require monitoring at the workplace:**

94-36-0 Dibenzoyl peroxide

WES Long-term value: 5 mg/m³
Sen

13463-67-7 titanium dioxide

WES Long-term value: 10 mg/m³
inhalable dust

· **DNELs**

13463-67-7 titanium dioxide

Inhalative DNEL inhalation 10 mg/m³ (man)

· **Additional information:** The lists valid during the making were used as basis.

· **Personal protective equipment:**

· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

Do not inhale dust / smoke / mist.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing

· **Respiratory protection:** Suitable respiratory protective device recommended.

· **Protection of hands:**



Protective gloves

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product 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.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

9 Physical and Chemical Properties

· **General Information**

· **Appearance:**

· **Form:**

Powder

· **Colour:**

According to product specification

· **Odour:**

Odourless

· **Odour threshold:**

Not determined.

· **pH-value:**

Not applicable.

· **Change in condition**

· **Melting point/freezing point:**

Undetermined.

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- **Initial boiling point and boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.
- **Auto-ignition temperature:** Undetermined.
- **Decomposition temperature:** Not determined.
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Vapour pressure:** Not applicable.
- **Density at 20 °C (68 °F):** 1.2 g/cm³ (10.014 lbs/gal)
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with water:** Insoluble.
- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**
- **Dynamic:** Not applicable.
- **Kinematic:** Not applicable.
- **Other information** No further relevant information available.

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

13463-67-7 titanium dioxide

Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)
Inhalative	LC50/4 h	>6.82 mg/l (rat male)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.

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- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number · ADG, ADN, IMDG, IATA	not regulated
· UN proper shipping name · ADG, ADN, IMDG, IATA	not regulated
· Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class	not regulated
· Packing group · ADG, IMDG, IATA	not regulated
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.

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|---|-----------------|
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | not regulated |

15 Regulatory information

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

- **Australian Inventory of Industrial Chemicals**

All ingredients are listed.

- **Standard for the Uniform Scheduling of Medicines and Poisons**

94-36-0 Dibenzoyle peroxide

S2, S4, S5

- **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

- **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**



GHS07

- **Signal word** Warning

- **Hazard-determining components of labelling:**

Dibenzoyle peroxide (2.5-<5 %)

- **Hazard statements**

May cause an allergic skin reaction.

- **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.

Contaminated work clothing should not be allowed out of the workplace.

Wear protective gloves.

If skin irritation or rash occurs: Get medical advice/attention.

Specific treatment (see on this label).

Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

- **Relevant phrases**

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

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· **Department issuing SDS:** Regulatory affairs

· **Contact:** msds@gc.dental

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Self-reactive substances and mixtures – Type B: Self-reactive substances and mixtures – Type B

Organic peroxides – Type B: Organic peroxides – Type B

Eye damage/irritation – Category 1: Serious eye damage/eye irritation – Category 1

Eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

Skin sensitisation – Category 1: Skin sensitisation – Category 1

Carcinogenicity – Category 2: Carcinogenicity – Category 2

Specific target organ toxicity (single exposure) – Category 3: Specific target organ toxicity (single exposure) – Category 3

· **Sources**

• ECHA (<http://echa.europa.eu/>)

• EnviChem (www.echemportal.org)

· *** Data compared to the previous version altered.**

This version replaces all previous versions.

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