

Printing date 19.07.2024 Version number 5 Revision: 19.07.2024

1 Identification of the substance or mixture and of the supplier

- · Product identifier
- · Trade name: KOOLINER 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 Henry Schein Dental

243-249 Bush Road, Rosedale Auckland 0632, NEW ZEALAND

Free Phone: 0800 808 855

· Further information obtainable from: Regulatory affairs

· Emergency telephone number: 0800 764 766 (National Poisons Centre)

2 Hazards identification

· Classification of the substance or mixture

Skin sensitisation Category 1

Specific target organ toxicity - repeated exposure

Category 2

H317 May cause an allergic skin reaction.

H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

- · Label elements
- · GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).

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





GHS08

- · Signal word Warning
- · Hazard-determining components of labelling:

Quartz

Dibenzoyl peroxide

· Hazard statements

May cause an allergic skin reaction.

May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· Precautionary statements

Do not breathe dust/fume/gas/mist/vapours/spray.

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

Wear protective gloves.

(Contd. on page 2)

Printing date 19.07.2024 Version number 5 Revision: 19.07.2024

Trade name: KOOLINER Powder

(Contd. of page 1)

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.

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

3 Composition/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.

| ſ | Dangerous components: | | |
|---|-----------------------|---|---------|
| Γ | | Quartz | 5-<10% |
| | EINECS: 238-878-4 | Specific target organ toxicity - repeated exposure Category 1, H372 | |
| Γ | CAS: 94-36-0 | Dibenzoyl peroxide | 1-<2.5% |
| | EINECS: 202-327-6 | Organic peroxide Type B, H241; Eye irritation Category 2, H319; Skin sensitisation Category 1, H317 | |

[·] 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

 $No\ further\ relevant\ information\ available.$

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.

(Contd. on page 3)

Printing date 19.07.2024 Version number 5 Revision: 19.07.2024

Trade name: KOOLINER_Powder

(Contd. of page 2)

- · 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/personal protection

- Additional information about design of technical facilities: No further data; see section 7.
- · Ingredients with limit values that require monitoring at the workplace:

14808-60-7 Quartz

TWA (New Zealand) Long-term value: 0.2 mg/m³ confirmed carcinogen; respirable dust

(Contd. on page 4)

Printing date 19.07.2024 Version number 5 Revision: 19.07.2024

Trade name: KOOLINER Powder

WES (New Zealand)

Long-term value: 0.2 mg/m³

confirmed carcinogen; respirable dust

BOELV (European Union)

Long-term value: 0.1* mg/m³

*respirable fraction

94-36-0 Dibenzoyl peroxide

WES (New Zealand)

Long-term value: 5 mg/m³

dsen

(Contd. of page 3)

(Contd. of page 3)

- 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: Characteristic
 Odour threshold: Not determined.
 pH-value: Not applicable.

· Change in condition

Melting point/freezing point: 136 °C
 Initial boiling point and boiling range: Undetermined.
 Flash point: Not applicable.
 Flammability (solid, gas): Not determined.
 Auto-ignition temperature: Undetermined.

(Contd. on page 5)

Printing date 19.07.2024 Version number 5 Revision: 19.07.2024

Trade name: KOOLINER Powder

(Contd. of page 4)

• **Decomposition temperature:** Not determined.

• Ignition temperature: Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Lower:
Not determined.
Vapour pressure:
Density at 20 °C:
Relative density
Vapour density
Vapour density
Vapour density
Not applicable.
Not applicable.
Not applicable.
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: No further relevant information available.
- · 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

May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

- · Aspiration hazard Based on available data, the classification criteria are not met.
- Additional toxicological information:
- · Repeated dose toxicity May cause damage to organs through prolonged or repeated exposure.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

No further relevant information available.

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Printing date 19.07.2024 Version number 5 Revision: 19.07.2024

Trade name: KOOLINER Powder

(Contd. of page 5)

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.

| Transport information | | |
|--|---------------------------------------|--|
| UN-Number NZS, ADN, IMDG, IATA | not regulated | |
| UN proper shipping name NZS, ADN, IMDG, IATA | not regulated | |
| Transport hazard class(es) | | |
| NZS, ADN, IMDG, IATA Class | not regulated | |
| Packing group NZS, IMDG, IATA | not regulated | |
| Environmental hazards: Marine pollutant: | No | |
| Special precautions for user | Not applicable. | |
| Transport in bulk according to Annex L and the IBC Code | I of Marpol Not applicable. | |
| UN "Model Regulation": | not regulated | |

- NZ

Printing date 19.07.2024 Version number 5 Revision: 19.07.2024

Trade name: KOOLINER Powder

(Contd. of page 6)

15 Regulatory information

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

| | · New Zealand Inventory of Chemicals | | |
|------------|---|--|--|
| | Polyethylethacrylate | | |
| 14808-60-7 | | | |
| | Dibenzoyl peroxide | | |
| 13463-67-7 | titanium dioxide | | |
| 51274-00-1 | iron hydroxide oxide yellow | | |
| 3049-71-6 | 2,9-bis[4-(phenylazo)phenyl]anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone | | |

· HSNO Approval numbers

14808-60-7 Quartz

HSR003125

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





GHS07

GHS08

- · Signal word Warning
- · Hazard-determining components of labelling:

Quartz

Dibenzoyl peroxide

· Hazard statements

May cause an allergic skin reaction.

May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· Precautionary statements

Do not breathe 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.

H319 Causes serious eye irritation.

H372 Causes damage to organs through prolonged or repeated exposure.

- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental

(Contd. on page 8)

Printing date 19.07.2024 Version number 5 Revision: 19.07.2024

Trade name: KOOLINER Powder

(Contd. of page 7)

· 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Organic peroxide Type B: Organic peroxides – Type B

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

Skin sensitisation Category 1: Skin sensitisation – Category 1

Specific target organ toxicity - repeated exposure Category 1: Specific target organ toxicity (repeated exposure) - Category 1

Specific target organ toxicity - repeated exposure Category 2: Specific target organ toxicity (repeated exposure) - Category 2

·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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N7