

according to Regulation (EC) No. 1907/2006 (REACH)

Issue date: 28.08.2020

Version 1.0

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Zirkon BioStar HT Colour, Zirkon BioStar HT Multilayer**1. Identification of the substance / Preparation and Company:**

- 1.1 Product identifier:
Commercial product name: Zirkon BioStar Colour HT, Zirkon BioStar HT Multilayer
- 1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Medical technology
- 1.3 Details of the supplier of the safety data sheet
Manufacturer/Supplier: SILADENT Dr. Böhme & Schöps GmbH
Street / mailbox: Im Klei 26
Country code. / postal code / city: D - 38644 Goslar
Phone: 0 53 21 / 37 79 – 0
Fax: 0 53 21 / 38 96 32
E-mail / Website: info@siladent.de / www.siladent.de
Further information obtainable from: SILADENT Dr. Böhme & Schöps GmbH
- 1.4 Emergency telephone number
SILADENT Dr. Böhme & Schöps GmbH: +49 (0) 53 21 / 37 79 - 0 (Mon-Fri. 8 a.m. - 4 p.m.)

2. Hazards identification

- 2.1 Classification of the substance or mixture
Classification according to Regulation (EC) No. 1272/2008 [CLP]: Not classified
Adverse physicochemical, human health and environmental effects: To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.
- 2.2 Label elements
Labelling according to Regulation (EC) No. 1272/2008 [CLP]: No labelling applicable.
- 2.3 Other hazards
No additional information available

3. Composition/information on ingredients

3.1 Mixtures

Chemical nature: Mixture

Hazardous components

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Zirconium dioxide	(CAS-No.) 1314-23-4 (EC-No.) 215-227-2 (REACH-no) 01-2119486976-14	≥ 85	Not classified
Yttrium oxide	(CAS-No.) 1314-36-9 (EC-No.) 215-233-5 (REACH-no) 01-2119971254-36	≥ 5 – < 10	Not classified
Hafnium oxide (HfO ₂)	(CAS-No.) 12055-23-1 (EC-No.) 235-013-2	≥ 1 – < 10	Not classified
Aluminium oxide	(CAS-No.) 1344-28-1 (EC-No.) 215-691-6 (REACH-no) 01-2119529248-35	< 3	Not classified

4. First aid measures

- 4.1 Description of first aid measures
First-aid measures after inhalation: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact: Wash skin with plenty of water.
First-aid measures after eye contact: Rinse eyes with water as a precaution.
First-aid measures after ingestion: Call a poison centre or a doctor if you feel unwell.
- 4.2 Most important symptoms and effects, both acute and delayed: No additional information available

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- 4.3 Indication of any immediate medical attention and special treatment needed: Treat symptomatically.

5. Firefighting measures

- 5.1 Extinguishing media
Suitable extinguishing media: Product itself does not burn. Fire-extinguishing activities according to surrounding.
- 5.2 Special hazards arising from the substance or mixture
Hazardous decomposition products in case of fire: Toxic fumes may be released.
- 5.3 Advice for firefighters
Protection during firefighting: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
- Other information: Do not allow run-off from firefighting to enter drains or water courses.

6. Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures
General measures: Avoid dust formation.
- 6.1.1. For non-emergency personnel
Emergency procedures: Ventilate spillage area.
- 6.1.2. For emergency responders
Protective equipment: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
- 6.2 Environmental precautions: Avoid release to the environment.
- 6.3 Methods and materials for containment and cleaning up
Methods for cleaning up: Mechanically recover the product.
- Other information: Dispose of materials or solid residues at an authorised site.
- 6.4 Reference to other sections: For further information, refer to section 13.

7. Handling and storage

- 7.1 Precautions for safe handling
Precautions for safe handling: Ensure good ventilation of the work station. Wear personal protective equipment.
- Hygiene measures: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.
- 7.2 Conditions for safe storage, including any incompatibilities
Storage conditions: Keep container tightly closed. Store in a dry place.
- 7.3 Specific end use(s): No additional information available

8. Exposure controls/personal protection

- 8.1 Control parameters No additional information available.

iron(III) oxide (1309-37-1)	
United Kingdom - Occupational Exposure Limits	
Local name	Aluminium oxides
WEL TWA (mg/m ³)	10 mg/m ³ inhalable dust 4 mg/m ³ respirable dust
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

- 8.2 Exposure controls
Appropriate engineering controls: Ensure good ventilation of the work station.
- Hand protection:

Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Chemically resistant protective gloves	Butyl rubber, Nitrile rubber				EN ISO 374

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Eye protection
Skin and body protection:
Respiratory protection:
Personal protective equipment symbol(s):

Safety glasses.
Protective clothing.
Respiratory protective device with a particle filter.



Environmental exposure controls

Avoid release to the environment.

9. Physical and chemical properties

9.1	Information on basic physical and chemical properties	
	Physical state:	Solid.
	Appearance:	Disc
	Colour:	White.
	Odour:	Odourless.
	Odour Threshold:	No data available
	pH:	No data available
	Relative evaporation rate (butylacetate=1):	No data available
	Melting point:	No data available
	Freezing point:	Not applicable
	Boiling point:	No data available
	Flash point:	No data available
	Auto-ignition temperature:	No data available
	Decomposition temperature:	No data available
	Flammability (solid, gas):	Non flammable.
	Vapour pressure:	No data available
	Relative vapour density at 20 °C:	No data available
	Relative density:	No data available
	Density:	> 6 g/cm ³
	Solubility:	No data available
	Log Pow:	No data available
	Viscosity, kinematic:	No data available
	Viscosity, dynamic:	No data available
	Explosive properties:	Product is not explosive.
	Oxidising properties:	Non oxidizing.
	Explosive limits	Not applicable
9.2	Other information	
	Combustion class:	1

10. Stability and reactivity

10.1	Reactivity:	The product is non-reactive under normal conditions of use, storage and transport.
10.2	Chemical stability:	Stable under normal conditions.
10.3	Possibility of hazardous reactions:	No dangerous reactions known under normal conditions of use.
10.4	Conditions to avoid:	None under recommended storage and handling conditions (see section 7).
10.5	Incompatible materials:	No additional information available.
10.6	Hazardous decomposition products:	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. Toxicological information

11.1	Information on toxicological effects	
	Acute toxicity (oral):	Not classified
	Acute toxicity (dermal):	Not classified
	Acute toxicity (inhalation):	Not classified
	Skin corrosion/irritation:	Not classified

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Serious eye damage/irritation:	Not classified
Respiratory or skin sensitisation:	Not classified
Germ cell mutagenicity:	Not classified
Carcinogenicity:	Not classified
Reproductive toxicity:	Not classified
STOT - single exposure:	Not classified
STOT- repeated exposure:	Not classified
Aspiration hazard:	Not classified

12. Ecological information

12.1	Toxicity	
	Ecology – general:	The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
	Hazardous to the aquatic environment, short-term (acute):	Not classified
	Hazardous to the aquatic environment, long-term (chronic):	Not classified
12.2	Persistence and degradability	No additional information available
12.3	Bioaccumulative potential	No additional information available
12.4	Mobility in soil	No additional information available
12.5	Results of PBT and vPvB assessment:	No additional information available
12.6	Other adverse effects	No additional information available

13. Disposal considerations

13.1	Waste treatment methods	Dispose of contents/container in accordance with licensed collector's sorting instructions.
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14. Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

	ADR	IMDG	IATA	ADN	RID
14.1	UN number				
	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2	UN proper shipping name				
	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3	Transport hazard class(es)				
	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4	Packing group				
	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5	Environmental hazards				
	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
	No supplementary information available				
14.6	Special precautions for user				
	Overland transport:				Not applicable
	Transport by sea:				Not applicable
	Air transport:				Not applicable
	Inland waterway transport:				Not applicable
	Rail transport:				Not applicable
14.7	Transport in bulk according to Annex II of Marpol and the IBC Code:				Not applicable

15. Regulatory information

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture.
15.1.1.	EU-Regulations
	Contains no REACH substances with Annex XVII restrictions
	Contains no substance on the REACH candidate list

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Contains no REACH Annex XIV substances
Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.
Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

- 15.1.2. National regulations: No additional information available.
15.2 Chemical Safety Assessment No chemical safety assessment has been carried out.

16. Other information

Abbreviations and acronyms:

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
DOT	Department of Transport
TDG	Transportation of Dangerous Goods
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
IARC	International Agency for Research on Cancer
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
CAS	CAS (Chemical Abstracts Service) number
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
ATE	Acute Toxicity Estimate
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
BCF	Bioconcentration factor
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships
ADG	Transport of Australian Dangerous Goods
BLV	Biological limit value
CAS-No.	Chemical Abstract Service number
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EC-No.	European Community number
EN	European Standard
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OEL	Occupational Exposure Limit
SDS	Safety Data Sheet
WGK	Water Hazard Class

Other information: Data of sections 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities. The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the



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characteristics of the product(s) as defined by the legal warranty regulations.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.