1. Identification of the substance / Preparation and Company:

1.1 Product identifier:
Commercial product name: Zirkon BioStar L / Zirkon BioStar / Zirkon BioStar S

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Medical applications

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 (REGULATION (EC) No 1272/2008): No classification.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008): No labelling required

2.3 Other hazards
This mixture contains no substance considered to be persistent, bioaccumulating and toxic (PBT).

Zirconium dioxide:	This substance is not considered to be persistent, bioaccumulating and toxic (PBT).
Hafnium dioxide:	This substance is not considered to be persistent, bioaccumulating and toxic (PBT).
Yttrium oxide:	This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

3. Composition/information on ingredients

3.1 Mixtures
Chemical nature: Mixture
Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (REGULATION (EC) No 1272/2008)	Concentration [%]
zirconium dioxide	1314-23-4 215-227-2 01-2119486976-14		88 - 96
hafnium dioxide	12055-23-1 235-013-2 /		1 - 5
yttrium oxide	1314-36-9 215-233-5 /		4 - 6

4. First aid measures

4.1 Description of first aid measures

If inhaled:	Remove to fresh air. If symptoms persist, call a physician.
In case of skin contact:	Wash off with soap and water.
If swallowed:	Obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed
Symptoms: No information available.

	Risks:	No information available.
4.3	Indication of any immediate medical attention and special treatment needed	
	Treatment:	No information available.

5. Firefighting measures

5.1	Extinguishing media	
	Suitable extinguishing media:	The product itself does not burn, Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
	Unsuitable extinguishing media:	None known.
5.2	Special hazards arising from the substance or mixture	
	Specific hazards during firefighting:	None known.
	Hazardous combustion products:	None known.
5.3	Advice for firefighters	
	Special protective equipment for firefighters:	In the event of fire, wear self-contained breathing apparatus.
	Further information:	Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. Accidental release measures

6.1	Personal precautions, protective equipment and emergency procedures	
	Personal precautions:	Use personal protective equipment. Avoid dust formation. Avoid dust accumulation in enclosed space.
6.2	Environmental precautions:	Do not flush into surface water or sanitary sewer system.
6.3	Methods and materials for containment and cleaning up	
	Methods for cleaning up:	Use mechanical handling equipment. Pick up and transfer to properly labelled containers.
6.4	Reference to other sections:	For personal protection see section 8.

7. Handling and storage

7.1	Precautions for safe handling	
	Advice on safe handling:	Avoid dust formation. Provide sufficient air exchange and/or exhaust in work rooms. Avoid exceeding the given occupational exposure limits (see section 8).
	Advice on protection against fire and explosion:	No special precautions required.
	Hygiene measures:	Handle in accordance with good industrial hygiene and safety practice. Keep working clothes separately.
	Dust explosion class:	No data available.
7.2	Conditions for safe storage, including any incompatibilities	
	Requirements for storage areas and containers:	Store in accordance with the particular national regulations.
	Further information on storage conditions:	Store in tightly closed containers in a dry place.
7.3	Specific end use(s)	
	Specific use(s):	No data available.

8. Exposure controls/personal protection

8.1 Control parameters

Components	CAS-No.	Value type (Form of exposure	Control parameters	Update	Basis
zirconium dioxide	1314-23-4	TWA	5 mg/m3	2005-04-06	GB EH40
Further information	: Zirconium				
		STEL	10 mg/m3	2005-04-06	GB EH40

Further information	:	Zirconium

DNEL

Zirconium dioxide:	End Use: Workers Exposure routes: Skin contact Potential health effects: Long-term systemic effects Value: > 15.75 mg/kg No data available End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 5 mg/m3
Hafnium dioxide:	No data available.
Yttrium oxide:	No data available

PNEC

Zirconium dioxide:	No data available.
Hafnium dioxide:	No data available.
Yttrium oxide:	No data available.

8.2 Exposure controls

Engineering measures:	Dust must be extracted directly at the point of origin.
Personal protective equipment	
Eye protection	Safety glasses
Hand protection	
Material:	Chemical resistant gloves made of butyl rubber or nitrile rubber category III according to EN 374.
Remarks:	The data about break through time/strength of material is not valid for undissolved solids/dust.
Skin and body protection:	Protective suit
Respiratory protection:	Respiratory protective device with particle filter EN 143.
Environmental exposure controls	
General advice:	Do not flush into surface water or sanitary sewer system.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:	disc, block, cylinder, customer-specific form
Colour:	white
Odour:	odourless
Odour Threshold:	No data available.
pH:	No data available.
Melting point/range:	No data available.
Flash point:	Not applicable.
Flammability:	Negative.
Lower explosion limit:	No data available.
Upper explosion limit:	No data available.
Vapour pressure:	No data available.
Relative vapour density:	Remarks: Not applicable.
Density:	2.9 - 3.5 g/cm3
Water solubility:	No data available
Partition coefficient: noctanol/water:	Not applicable.
Auto-ignition temperature:	Not auto-flammable.
Thermal decomposition:	Not applicable.
Viscosity, dynamic:	Not applicable.
Viscosity, kinematic:	Not applicable.

	Explosive properties:	Not explosive.
	Oxidizing properties:	Not oxidizing.
9.2	Other information	
	Burning number:	1
	Flammability (contact with water):	Not highly flammable.

10. Stability and reactivity

10.1	Reactivity:	No hazards to be specially mentioned.
10.2	Chemical stability:	Stable under normal conditions.
10.3	Possibility of hazardous reactions:	
	Hazardous reactions:	None known.
10.4	Conditions to avoid:	None known.
10.5	Incompatible materials:	
	Materials to avoid:	None known.
10.6	Hazardous decomposition products:	
	Other information:	Not applicable.

11. Toxicological information

11.1	Information on toxicological effects	
	Product	
	Acute oral toxicity:	No data available.
	Acute inhalation toxicity:	No data available.
	Acute dermal toxicity:	No data available.
	Skin corrosion/irritation:	No data available.
	Serious eye damage/eye Irritation:	No data available.
	Respiratory or skin sensitisation:	No data available.
	Germ cell mutagenicity	
	Genotoxicity in vitro:	No data available.
	Genotoxicity in vivo:	No data available.
	Carcinogenicity:	No data available.
	Reproductive toxicity:	No data available.
	Teratogenicity:	No data available.
	STOT - single exposure:	Remarks: No data available.
	Repeated dose toxicity:	Remarks: No data available.
	STOT - repeated exposure:	Remarks: No data available.
	Further information:	For risk assessment data of relevant ingredients: None known.
	Components:	
	Zirconium dioxide :	
	Acute oral toxicity:	LD50 Rat, female: > 5,000 mg/kg Method: OECD Test Guideline 423 GLP: No data available
	Acute inhalation toxicity:	LC50 Rat, male and female: 4.3 mg/l Exposure time: 4 h Aerosol Method: OECD Test Guideline 436 GLP: No data available Remarks: An LC50/inhalation/4h/rat could not be determined because no mortality of rats was observed at the maximum achievable concentration.
	Acute dermal toxicity:	No data available.
	Skin corrosion/irritation:	Species: Rabbit Exposure time: 4 h Result: No skin irritation Method: OECD Test Guideline 404
	Serious eye damage/eye Irritation:	Species: Rabbit Exposure time: 1 h

	Result: No eye irritation Method: OECD Test Guideline 405
Respiratory or skin sensitisation:	Test Method: Maximisation Test (GPMT) Species: Guinea pig Result: Does not cause skin sensitisation. Method: OECD Test Guideline 406
Germ cell mutagenicity	
Genotoxicity in vitro:	Type: Ames test Test species: Salmonella typhimurium with and without metabolic activation Result: negative Method: OECD Test Guideline 471 GLP: No data available Type: Chromosome aberration test in vitro Test species: Human lymphocytes with and without metabolic activation Result: negative Method: OECD Test Guideline 473 GLP: No data available Type: In vitro gene mutation study in mammalian cells Test species: L5178Y cells (mouse lymphoma) with and without metabolic activation Result: negative Method: OECD Test Guideline 476 GLP: No data available
Genotoxicity in vivo:	No data available.
Carcinogenicity:	No data available.
Reproductive toxicity:	No data available.
Teratogenicity:	No data available.
STOT - single exposure:	Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.
Repeated dose toxicity:	Rat, male and female: NOAEL: 3,150 - 7,080 mg/kg Application Route: Oral Exposure time: 90-day Method: OECD Test Guideline 408 Test substance: CH2O7Zr2 (CAS-No. 5219-64-4) Remarks: Read-across (Analogy)
STOT - repeated exposure:	Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.
Further information:	None known.
Hafnium(IV) oxide :	
Acute oral toxicity:	No data available.
Acute inhalation toxicity:	No data available.
Acute dermal toxicity:	No data available.
Skin corrosion/irritation:	No data available.
Serious eye damage/eye Irritation:	No data available.
Respiratory or skin sensitisation:	No data available.
Germ cell mutagenicity	
Genotoxicity in vitro:	No data available.
Genotoxicity in vivo:	No data available.
Carcinogenicity:	No data available.
Reproductive toxicity:	No data available.
Teratogenicity:	No data available.
STOT - single exposure:	Remarks: No data available.
Repeated dose toxicity:	Remarks: No data available.
STOT - repeated exposure:	Remarks: No data available.
Further information:	None known.

Yttrium oxide :	
Acute oral toxicity:	LD50 Rat: > 5,000 mg/kg Method: No information available. GLP: No information available.
Acute inhalation toxicity:	No data available.
Acute dermal toxicity:	No data available Species: Rabbit
Skin corrosion/irritation:	Exposure time: 24 h Result: No skin irritation Method: No information available.
Serious eye damage/eye Irritation:	Result: Mild eye irritation Method: No information available.
Respiratory or skin sensitisation:	No data available.
Germ cell mutagenicity	
Genotoxicity in vitro:	No data available.
Genotoxicity in vivo:	No data available.
Carcinogenicity:	No data available.
Reproductive toxicity:	No data available.
Teratogenicity:	No data available.
STOT - single exposure:	Remarks: No data available.
Repeated dose toxicity:	Remarks: No data available.
STOT - repeated exposure:	Remarks: No data available.
Further information:	None known.

12. Ecological information

Toxicity	
Product:	
Toxicity to fish:	No data available.
Toxicity to daphnia and other aquatic invertebrates:	No data available.
Toxicity to algae:	No data available.
Toxicity to bacteria:	No data available.
Toxicity to fish (Chronic toxicity):	No data available.
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):	No data available.
Toxicity to soil dwelling organisms:	No data available.
Toxicity to terrestrial organisms:	No data available.
Components:	
Zirconium dioxide :	
Toxicity to fish:	LC50 (Danio rerio (zebra fish)): > 100 mg/l Exposure time: 96 h Test Method: static test Method: OECD Test Guideline 203 GLP: No data available Fresh water
Toxicity to daphnia and other aquatic invertebrates:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Test Method: static test Method: Directive 67/548/EEC, Annex V, C.2. GLP: No data available Fresh water
Toxicity to algae:	NOEC (Desmodesmus subspicatus): 0.004 mg/l Exposure time: 72 h Test Method: static test Test substance: Reaction mass of cerium dioxide and zirconium

		dioxide (909-709-8) Method: OECD Test Guideline 201 GLP: yes Fresh water Weight of Evidence Read-across (Analogy)
	Toxicity to fish (Chronic toxicity):	No data available.
	Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):	No data available.
	Toxicity to soil dwelling Organisms:	No data available.
	Plant toxicity:	NOEC: >= 264 mg/kg Species: Lycopersicon esculentum Test substance: Cl2OZr (CAS-No. 7699-43-6) Method: EPA OPPTS 850.4230 GLP: No data available Read-across (Analogy)
	Toxicity to terrestrial organisms:	No data available.
	Hafnium(IV) oxide :	
	Toxicity to fish:	No data available
	Toxicity to daphnia and other aquatic invertebrates:	No data available.
	Toxicity to algae:	No data available.
	Toxicity to bacteria:	No data available.
	Toxicity to fish (Chronic toxicity):	No data available.
	Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):	No data available.
	Toxicity to soil dwelling:	No data available.
	Yttrium oxide :	
	Toxicity to fish:	No data available.
	Toxicity to daphnia and other aquatic invertebrates:	No data available.
	Toxicity to algae:	No data available.
	Toxicity to bacteria:	No data available.
	Toxicity to fish (Chronic toxicity):	No data available.
	Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):	No data available.
	Toxicity to soil dwelling organisms:	No data available.
	Plant toxicity:	No data available.
	Toxicity to terrestrial organisms:	No data available.
12.1	Persistence and degradability	
	Product:	
	Biodegradability:	The methods for determining biodegradability are not applicable to inorganic substances.
	Stability in water:	No data available.
	Components:	
	Zirconium dioxide :	
	Biodegradability:	The methods for determining biodegradability are not applicable to inorganic substances.
	Stability in water:	No data available.
	Hafnium(IV) oxide :	
	Biodegradability:	The methods for determining biodegradability are not applicable to inorganic substances.
	Stability in water:	No data available

Yttrium oxide :
Biodegradability: The methods for determining biodegradability are not applicable to inorganic substances.

Stability in water: No data available

12.3 Bioaccumulative potential
Product:
Bioaccumulation: This mixture contains no substance considered to be persistent, bioaccumulating and toxic (PBT).

Partition coefficient: noctanol/water: Not applicable.
Components:
Zirconium dioxide :
Bioaccumulation: This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

Partition coefficient: noctanol/water: Not applicable.

Hafnium(IV) oxide :
Bioaccumulation: This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

Partition coefficient: noctanol/water: Not applicable.

Yttrium oxide :
Bioaccumulation: This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

Partition coefficient: noctanol/water: Not applicable

12.4 Mobility in soil
Product:
Mobility: No data available.
Components:
Zirconium dioxide :
Mobility No data available.
Hafnium(IV) oxide :
Mobility: No data available.
Yttrium oxide :
Mobility: No data available.

12.5 Results of PBT and vPvB assessment:

Product:
Assessment: This mixture contains no substance considered to be persistent, bioaccumulating and toxic (PBT).

Components:
Zirconium dioxide :
Assessment This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

Hafnium(IV) oxide:
Assessment: This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

Yttrium oxide :
Assessment: This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

12.6 Other adverse effects
Product:
Ozone-Depletion Potential: No data available.
Additional ecological information: No information on ecology is available.
None known.

Components:
Zirconium dioxide :
Ozone-Depletion Potential: No data available.

Additional ecological information:	None known.
Hafnium(IV) oxide	
Ozone-Depletion Potential:	No data available.
Additional ecological information:	None known.
Yttrium oxide :	
Ozone-Depletion Potential:	No data available
Additional ecological information:	None known.

13. Disposal considerations

13.1 Waste treatment methods

Product:	In accordance with local and national regulations. This product cannot be classified with disposal identification key acc. to the EU disposal directives as a classification results from the intended utilisation purpose of the consumer.

14. Transport information

14.1 UN number

ADR:	Not dangerous goods.
IMDG:	Not dangerous goods.
IATA:	Not dangerous goods.

14.2 UN proper shipping name

ADR:	Not dangerous goods.
IMDG:	Not dangerous goods.
IATA:	Not dangerous goods.

14.3 Transport hazard class(es)

ADR:	Not dangerous goods.
IMDG:	Not dangerous goods.
IATA:	Not dangerous goods.

14.4 Packing group

ADR:	Not dangerous goods.
IMDG:	Not dangerous goods.
IATA:	Not dangerous goods.

14.5 Environmental hazards

ADR:	Not dangerous goods.
IMDG:	Not dangerous goods.
IATA:	Not dangerous goods.

14.6 Special precautions for user

Remarks:	For personal protection see section 8.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Remarks:	No data available.

15. Regulatory information

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

Major Accident Hazard Legislation Seveso II - Directive 2003/105/EC amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances	Update: Not applicable

15.2 Chemical Safety Assessment no

16. Other information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.