

OSHA HazCom Standard 29 CFR 1910.1200(g) revised in 2012 and GHS Rev 03.

#### Issue date 12/06/2022

Reviewed on 12/06/2022

# 1 Identification

- · Product Identifier
- · Trade Name: KTR Pediatric Zirconia Crown
- · Relevant identified uses of the substance or mixture and uses advised against:
- · Product Description: Pediatric Crowns
- · Details of the Supplier of the Safety Data Sheet:
- *Manufacturer/Supplier:* KTR, LTD 8500 Menaul Blvd. NE, Ste. A-400 Albuquerque, NM 78521 1-800-506-5108
- *Emergency telephone number:* 1-800-506-5108

#### 2 Hazard(s) Identification

· Classification of the substance or mixture:



Sensitization - Respiratory 1

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



Sensitization - Skin 1 H317 May cause an allergic skin reaction. Specific Target Organ Toxicity - Single Exposure 3 H335 May cause respiratory irritation.

· Label elements:

· Hazard pictograms:



#### · Signal word: Danger

#### · Hazard statements:

- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H317 May cause an allergic skin reaction.
- H335 May cause respiratory irritation.

#### Precautionary statements:

- P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
- P271 Use only outdoors or in a well-ventilated area.
- P272 Contaminated work clothing must not be allowed out of the workplace.
- P280 Wear protective gloves.
- P284 [In case of inadequate ventilation] wear respiratory protection.
- P302+P352 If on skin: Wash with plenty of water.
- P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P304+P341 If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
- P312 Call a poison center/doctor if you feel unwell.
- P321 Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P342+P311 If experiencing respiratory symptoms: Call a poison center/doctor.



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- P363 Wash contaminated clothing before reuse.
- P403+P233 Store in a well-ventilated place. Keep container tightly closed.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- Unknown acute toxicity:

This value refers to knowledge of known, established toxicological or ecotoxicological values.

- 95 % of the mixture consists of component(s) of unknown toxicity.
- · Classification system: NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme
- NFPA ratings (scale 0 4)



# · HMIS-ratings (scale 0 - 4)

HEALTHImage: Constraint of the sectorHealth = 0FIREImage: Constraint of the sectorFire = 0REACTIVITYPhysical Hazard = 0

## · Hazard(s) not otherwise classified (HNOC): None known

# 3 Composition/Information on Ingredients

· Chemical characterization: Substance

• **Description:** Mixture of substances listed below with non-hazardous additions.

· Dangerous Components:		
CAS: 1314-23-4 RTECS: ZH8800000	Zirconium oxide	88-96%
CAS: 1314-36-9 RTECS: ZG 3850000	Yttrium Oxide	4-6%
CAS: 12055-23-1	hafnium dioxide	4-6%

#### Additional information:

The exact percentages of the ingredients of this mixture are considered to be proprietary and are withheld in accordance with the provisions of paragraph (i) of §1910.1200 of 29 CFR 1910.1200 Trade Secrets.

## 4 First-Aid Measures

- · Description of first aid measures
- · General information: If symptoms persist, call a physician.
- After inhalation:

Supply fresh air. If required, provide artificial respiration. Consult doctor if symptoms persist.

In case of unconsciousness place patient stably in the side position for transportation.

• After skin contact:

Generally, the product does not irritate the skin.

- If skin irritation occurs, consult a doctor.
- After eye contact:

If eye irritation occurs, consult a doctor.

Rinse opened eye for several minutes under running water.

• After swallowing: If swallowed and symptoms occur, consult a doctor.

· Information for doctor

• Most important symptoms and effects, both acute and delayed: No further relevant information available.

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

# 5 Fire-Fighting Measures

- Extinguishing media
- Suitable extinguishing agents: Use fire fighting measures that suit the environment.
- For safety reasons unsuitable extinguishing agents: No further relevant information.
- · Special hazards arising from the substance or mixture: No further relevant information available.
- Advice for firefighters
- Special protective equipment for firefighters:

As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

# 6 Accidental Release Measures

- · Personal precautions, protective equipment and emergency procedures: Not required.
- · Environmental precautions: No special measures required.
- Methods and material for containment and cleaning up:
- Dispose of contaminated material as waste according to section 13.
- Ensure adequate ventilation.

Dispose of the collected material 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.

# · PAC-1:

1314-23-4	Zirconium oxide	14 mg/m³
1314-36-9	Yttrium Oxide	3.8 mg/m³
12055-23-1	hafnium dioxide	1.8 mg/m³
PAC-2		

1 40 2.		
1314-23-4	Zirconium oxide	110 mg/m³
1314-36-9	Yttrium Oxide	43 mg/m <sup>3</sup>
12055-23-1	hafnium dioxide	19 mg/m³
• PAC-3:		
1314-23-4	Zirconium oxide	680 mg/m³
1314-36-9	Yttrium Oxide	260 mg/m <sup>3</sup>
12055-23-1	hafnium dioxide	120 mg/m³

#### 7 Handling and Storage

#### · Handling

• Precautions for safe handling:

Avoid creating and breathing dust/fume/gas/mist/vapors/spray.

Ensure good ventilation/exhaustion at the workplace.

- · Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage
- · Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Keep receptacle tightly sealed.



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· Specific end use(s): No further relevant information available.

# 8 Exposure Controls/Personal Protection

· Additional information about design of technical systems: No further data; see section 7.

· Control parameters:
Components with accuration

Components with occupational exposure limits:	
1314-23-4 Zirconium oxide	
PEL Long-term value: 5 mg/m³ as Zr	
REL Short-term value: 10 mg/m³ Long-term value: 5 mg/m³ as Zr	
TLV Short-term value: 10 mg/m³ Long-term value: 5 mg/m³ as Zr; A4	
1314-36-9 Yttrium Oxide	
PEL Long-term value: 1 mg/m³ as Y	
REL Long-term value: 1 mg/m³ as Y	
TLV Long-term value: 1 mg/m³ as Y	
12055-23-1 hafnium dioxide	
PEL Long-term value: 0.5 mg/m³ as Hf	
REL Long-term value: 0.5 mg/m³ as Hf	
TLV Long-term value: 0.5 mg/m³ as Hf	
Additional information: The lists that were valid during the creation of this SDS	S were used as basis.

Additional information: The lists that were valid during the creation of this SDS were used as basis.

- Exposure controls:
- Personal protective equipment
- General protective and hygienic measures: Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work.
- · Breathing equipment: Not required. · Protection of hands: Not required.
- Material of gloves: Not applicable.
- · Penetration time of glove material: Not applicable.
- Eye protection: Not required.
- · Limitation and supervision of exposure into the environment: None

9 Physical and Chemical Properties

- · Information on basic physical and chemical properties
- · General Information
- Appearance: Form:

Granulate



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Color: · Odor: · Odor threshold:	Brown Odorless Not determined.	
· pH-value:	Not determined.	
<ul> <li>Change in condition Melting point/Melting range: Boiling point/Boiling range:</li> </ul>	Not determined. ≥4,300 °C (≥39.700 °F)	
· Flash point:	None	
· Flammability (solid, gaseous):	Not determined.	
· Ignition temperature:	Not applicable	
· Decomposition temperature:	Not determined.	
· Auto igniting:	Product is not self-igniting.	
· Danger of explosion:	Product does not present an explosion hazard.	
<ul> <li>Explosion limits: Lower: Upper:</li> </ul>	Not determined. Not determined.	
· Vapor pressure:	Not applicable.	
· Density @ 20 °C (68 °F):	6 g/cm³ (50.07 lbs/gal)	
<ul> <li>Bulk density:</li> <li>Relative density:</li> <li>Vapor density:</li> <li>Evaporation rate:</li> </ul>	5,999.5 kg/m³ Not determined. Not applicable. Not applicable.	
<ul> <li>Solubility in / Miscibility with: Water:</li> </ul>	Insoluble.	
· Partition coefficient (n-octanol/water)	· Partition coefficient (n-octanol/water): Not determined.	
<ul> <li>Viscosity: Dynamic: Kinematic:</li> </ul>	Not applicable. Not applicable.	
<ul> <li>Solvent content: VOC content:</li> </ul>	0.00 %	
Solids content:	100.0 %	
· Other information:	No further relevant information available.	
10 Stability and Reactivity		

# 0 Stability and Reactivity

· *Reactivity:* No further relevant information available.

· Chemical stability: Product is stable under normal conditions.

• 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.

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## 1 Toxicological Information

- · Information on toxicological effects:
- · Acute toxicity:
- · LD/LC50 values that are relevant for classification:

# 1314-23-4 Zirconium oxide

Inhalative LC50/96 hours >100 mg/l (Zebra fish)

- Primary irritant effect:
- · On the skin: No irritating effect.
- On the eye: No irritating effect.
- Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

- · Carcinogenic categories:
- · IARC (International Agency for Research on Cancer):

None of the ingredients are listed.

· NTP (National Toxicology Program):

None of the ingredients are listed.

· OSHA-Ca (Occupational Safety & Health Administration):

None of the ingredients are listed.

## 2 Ecological Information

- Toxicity:
- · Aquatic toxicity: No further relevant information available.
- Persistence and degradability: No further relevant information available.
- · Behavior in environmental systems:
- · *Bioaccumulative potential:* No further relevant information available.
- Mobility in soil: No further relevant information available.
- · Additional ecological information:
- · General notes: Not known to be hazardous to water.
- 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:

Observe all federal, state and local environmental regulations when disposing of this material.

- · Uncleaned packaging
- · *Recommendation:* Disposal must be made according to official regulations.

#### 4 Transport Information

- · UN-Number:
- · DOT, ADR/ADN, IMDG, IATA
- UN proper shipping name:
- · DOT, ADR/ADN, IMDG, IATA

Non-Regulated Material

Non-Regulated Material



\*

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• Transport hazard class(es):	
· DOT, ADR/ADN, ADN, IMDG, IATA	
· Class: · Packing group:	Non-Regulated Material
· DOT, ADR/ADN, IMDG, IATA	Non-Regulated Material
· Environmental hazards:	Not applicable.
<ul> <li>Special precautions for user:</li> <li>Transport in bulk according to Annex II</li> </ul>	Not applicable. of
MARPOL73/78 and the IBC Code:	Not applicable.
· UN "Model Regulation":	Non-Regulated Material
15 Regulatory Information	
<ul> <li>Safety, health and environmental regulation</li> <li>No further relevant information available.</li> <li>SARA (Superfund Amendments and Rest</li> </ul>	tions/legislation specific for the substance or mixture: authorization):
<ul> <li>Section 355 (extremely hazardous subs</li> </ul>	tances):
None of the ingredients are listed.	
Section 313 (Specific toxic chemical list	lings):
None of the ingredients are listed.	
TSCA (Toxic Substances Control Act):	
All components have the value ACTIVE.	
Hazardous Air Pollutants	
None of the ingredients are listed.	
California Proposition 65:     Chemicals known to cause cancer:	
None of the ingredients are listed.	
• Chemicals known to cause reproductive	e toxicity for females:
None of the ingredients are listed.	
• Chemicals known to cause reproductive	e toxicity for males:
None of the ingredients are listed.	
· Chemicals known to cause developmen	tal toxicity:
None of the ingredients are listed.	-
· New Jersey Right-to-Know List:	
None of the ingredients are listed.	
· New Jersey Special Hazardous Substan	ce List:
None of the ingredients are listed.	
· Pennsylvania Right-to-Know List:	
None of the ingredients are listed.	
· Pennsylvania Special Hazardous Substa	ance List:
None of the ingredients are listed.	
· Carcinogenic categories:	
· EPA (Environmental Protection Agency)	):
None of the ingredients are listed.	



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#### Trade Name: KTR Pediatric Zirconia Crown

• TLV (Threshold Limit Value established by ACGIH):

1314-23-4 Zirconium oxide

• NIOSH-Ca (National Institute for Occupational Safety and Health):

#### None of the ingredients are listed.

#### GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS). • Hazard pictograms:



## · Signal word: Danger

#### Hazard statements:

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

#### • Precautionary statements:

- P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
- P271 Use only outdoors or in a well-ventilated area.
- P272 Contaminated work clothing must not be allowed out of the workplace.
- P280 Wear protective gloves.
- P284 [In case of inadequate ventilation] wear respiratory protection.

P302+P352 If on skin: Wash with plenty of water.

- P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P304+P341 If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. P312 Call a poison center/doctor if you feel unwell.
- P321 Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P342+P311 If experiencing respiratory symptoms: Call a poison center/doctor.
- P363 Wash contaminated clothing before reuse.
- P403+P233 Store in a well-ventilated place. Keep container tightly closed.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

## · National regulations:

The product is not subject to be labelled according with the prevailing version of the regulations on hazardous substances.

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

16 Other Information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

#### · Contact:

#### • Abbreviations and acronyms:

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation

IATA: International Air Transport Association



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ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA) VOC: Volatile Organic Compounds (USA, EU) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety and Health OSHA: Occupational Safety & Health Administration TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit Sensitization - Respiratory 1: Respiratory sensitisation - Category 1 Sensitization - Skin 1: Skin sensitisation – Category 1 Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3 \* \* Data compared to the previous version altered.

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