

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product Name: Iconix Coating
Common Name: Iconix Brackets, Iconix Buccal Tubes
Material: Zirconium Nitride (ZrN)
Restrictions on Use: American Orthodontics' products are used for the treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist. Federal law restricts this device to use by or on the order of a dentist or orthodontist.

EC No.: Information not available.

REACH Registration No.: Information not available.

CAS No. / IUPAC: 25658-42-8 (Zirconium Nitride, ZrN)

1.2 Relevant Identified Uses/ Uses Advised Against

Relevant identified uses: Dental/Orthodontic use only
Uses advised against: Not for Consumer use. Please see "Restrictions on Use"

1.3 Details of the Supplier of the Safety Data Sheet

Company Name:
 American Orthodontics
 3524 Washington Avenue
 Sheboygan, WI 53081
 Phone: 920-457-5051
 Fax: 920-457-1485

E-mail: info@americanortho.com
National Contact: Safety Department

1.4 Emergency Telephone Number

Emergency Response Number:
 920-457-5051
 Only available during office hours: 8:00AM – 5:00PM (Central Time)
 Language of Phone Service: English

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified.

2.1.2 Classification according to Directive 67/548/EEC

Not classified.

2.1.3 Additional information:

The substance does not meet the criteria for classification.

2.2 Label Elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard Pictogram(s)

None.

Signal Word(s): None.

Hazard Statements:

The substance does not meet the criteria for classification.

Precautionary Statements:

Prevention: Observe good industrial hygiene practices.

Response: Wash hands after handling.

Storage: Store away from incompatible materials.

Disposal: Dispose of waste and residues in accordance with local authority requirements.

Supplemental Hazard information (EU):

Information not available.

2.3 Other Hazards

None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

<u>Ingredient(s)</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Wt. % Content (or Range)</u>
Zirconium Nitride (ZrN)	25658-42-8	Not available.	100%

4. FIRST-AID MEASURES

4.1 Description of First-Aid Measures

General Notes

Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

Skin Contact

Wash dust off with soap and water. Get medical attention if irritation develops and persists.

Eye contact

Rinse with water. Get medical attention if irritation develops and persists.

Ingestion/Swallowing

Rinse mouth. Get medical attention if symptoms occur.

Self-Protection of First-Aider

See General Notes.

4.2 Important Symptoms and Effects

Direct contact with eyes may cause temporary irritation.

4.3 Medical Attention & Special Treatment Necessary

Treat symptomatically.

5. FIRE AND EXPLOSION HAZARDS

5.1 Extinguishing Media

Suitable Extinguishing Media:

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Extinguishing Media which should not be used:

Do not use water jet as an extinguisher, as this will spread the fire.

5.2 Special Exposure Hazards from Substance/Mixture

Hazardous Combustion Products:

During fire, gases hazardous to health may be formed.

5.3 Advice for Firefighters

Firefighting Methods:

Use standard firefighting procedures and consider the hazards of other involved materials. Use water spray to cool unopened containers. No unusual fire or explosion hazards noted.

Special protective equipment for fire-fighters:

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment & Emergency Procedures

6.1.1 For Non-Emergency Personnel

Protective Equipment

See Section 8 of the SDS for Exposure Controls and Personal Protection.

Emergency Procedure

Keep unnecessary personnel away.

6.1.2 For Emergency Responders

Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. For personal protection, see Section 8 of the SDS for Exposure Controls and Personal Protection.

6.2 Environmental Precautions

Avoid discharge into drains, water courses or onto the ground.

6.3 Methods & Material for Containment & Cleaning Up

6.3.1 For Containment

Stop the flow of material, if this is without risk.

6.3.2 For Cleaning Up

Following product recovery, flush area with water.

6.3.3 Other Information

See Section 13 of the SDS for Disposal Considerations.

6.4 Reference to other sections

Refer to Sections 8 and 13 for Exposure Controls, Personal Protection, and Disposal Considerations.

7. HANDLING AND STORAGE

7.1 Precautions for Safe-Handling

Protective Measures:

Measures to prevent fire:

Information not available.

Measures to prevent aerosol and dust generation:

Information not available.

Measure to protect the environment

Avoid discharge into drains, water courses or onto the ground.

Advice on General Occupational Hygiene:

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures & Storage Conditions

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters

Component	OSHA PELs (Permissible Exposure Limits)	ACGIH TLVs (Threshold Limit Values)	U.S. NIOSH (Threshold Limit Values)	U.S. CA Code of Regulations (Title 8, Sec. 5155)
Zirconium Nitride (ZrN) CAS# 25658-42-8	5 mg/m ³	10 mg/m ³ STEL 5 mg/m ³ TWA	10 mg/m ³ STEL 5 mg/m ³ TWA	10 mg/m ³ STEL 5 mg/m ³ PEL

Biological Limit Values: No biological exposure limits noted for the ingredient(s).

8.2 Exposure Controls

8.2.1 Appropriate Engineering Controls

Substance/Mixture Related Measures to Prevent Exposure During Identified Uses:

Observe good industrial hygiene practices. Wash hands after handling.

Structural Measures to Prevent Exposure:

Not applicable.

Organizational Measures to Prevent Exposure:

Not applicable.

Technical Measures to Prevent Exposure

Store away from incompatible materials.

8.2.2 Personal Protective Equipment

8.2.2.1 Eye & Face Protection

Wear safety glasses with side shields (or goggles).

8.2.2.2 Skin Protection

Hand Protection

Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.

Other Skin Protection

Wear suitable protective clothing.

8.2.2.3 Respiratory Protection

In case of insufficient ventilation, wear suitable respiratory equipment.

8.2.2.4 Thermal Hazards

Wear appropriate thermal protective clothing, when necessary.

Reference Section 5 for specific personal protective equipment advice.

8.2.3 Environmental Exposure Controls

Substance/Mixture Related Measures to Prevent Exposure

Store away from incompatible materials.

Instruction Measures to Prevent Exposure

Avoid discharge into drains, water courses or onto the ground.

Organizational Measure to Prevent Exposure

Information not available.

Technical Measures to Prevent Exposure

Refer to Section 13 for Disposal Considerations.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance:	Solid.
Odor:	Not applicable.
Odor Threshold:	Not available.
pH:	Not available.
Melting Point/Freezing Point:	Not available.
Initial Boiling Point & Boiling Range:	Not applicable.
Flash Point:	Not available.
Evaporation Rate:	Not available.
Flammability (solid, gas):	Not available.
Upper/Lower Flammability or Explosive Limits:	Not available.
Vapor Pressure:	<0.0000001kPa @ 25°C
Vapor Density:	Not available.
Relative Density:	Not available.
Solubility(ies):	Not available.
Partition Coefficient: n-octanol/water):	Not available.
Auto-Ignition Temperature:	Not applicable.
Decomposition Temperature:	Not available.
Viscosity:	Not available.
Explosive Property:	Not explosive.
Oxidizing:	Not oxidizing.

9.2 Other Information

None.

10. STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport.

10.2 Chemical Stability

Material is stable under normal conditions.

10.3 Conditions of Instability

See Conditions to Avoid and Incompatible Materials.

10.4 Possibility of Hazardous Reactions

No dangerous reaction known under conditions of normal use.

10.5 Conditions to Avoid

Contact with incompatible materials.

10.6 Incompatible Materials

Strong oxidizing agents.

10.7 Hazardous Decomposition Products

No hazardous decomposition products are known.

10.8 Hazardous Polymerization

Information not available.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Information

Acute Toxicity

Not available.

Chronic Health Effects

Information not available.

Skin Corrosion

Prolonged skin contact may cause temporary irritation.

Serious Eye Damage/Irritation

Direct contact with eyes may cause temporary irritation.

Respiratory/Skin Sensitization

Not a respiratory sensitizer. This product is not expected to cause skin sensitization.

Germ Cell Mutagenicity

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive Toxicity

This product is not expected to cause reproductive or developmental effects.

Summary of Evaluation of the CMR properties

Information not available.

STOT-Single Exposure

Not classified.

STOT-Repeated Exposure

Not classified.

Aspiration Hazard

Not an aspiration hazard.

Signs & Symptoms of Exposure

Direct contact with eyes may cause temporary irritation.

Medical Conditions Generally Aggravated by Exposure

Information not available.

Other Potential Health Effects

Prolonged inhalation may be harmful.

11.1.1 Acute Toxicity

Method: Information not available.
 Species: Information not available.
 Routes of Exposure: Information not available.
 Effective Dose: Information not available.
 Exposure Limit: Information not available.
 Results: Information not available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

12.2 Persistence and Degradability

No data is available on the degradability of this product.

12.3 Bio accumulative Potential

No data available.

12.4 Mobility in Soil

No data available.

12.5 Results of PBT and vPvB Assessment

Information not available.

12.6 Other Adverse Effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods

13.1.1 Product/Packaging disposal:

Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Dispose in accordance with all applicable regulations.

Waste Codes/Waste Designations according to LoW: The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

13.1.2 Waste Treatment – relevant information:

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (refer to Section 13.1.1).

13.1.3 Sewage Disposal –relevant information:

Not available.

13.1.4 Other Disposal recommendations:

Contaminated Packaging: Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. TRANSPORTATION INFORMATION

DOT / IATA / IMDF: not regulated as dangerous goods.

14.1 UN Number

Not applicable.

14.2 UN Proper Shipping Name

Not applicable.

14.3 Transport Hazard Class(es)

Not applicable.

14.4 Packing Group

Not applicable.

14.5 Environmental Hazards

Not applicable.

14.6 Special Precautions for User

None.

14.7 Transport in Bulk According to Annex II of MARPOL73/78 and the IBC Code

Not available.

15. REGULATORY INFORMATION

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

EU Regulations

Authorizations and/or restrictions on use: Information not available.

Authorization: Information not available.

Restrictions on use: Information not available.

Other EU Regulations:

Information according to 1999/13/EEC about limitation of emissions of volatile organic compounds (VOC-Guideline): Information not available.

National Regulations (USA):

Federal Regulations:

- This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
- TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) – Not regulated.
- CERCLA Hazardous Substance List (40 CFR 302.4) – Not listed.
- US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) – Not listed.
- Superfund Amendments and Reauthorization Act of 1986 (SARA)
 - o Hazard Categories:
 - Immediate Hazard – No.
 - Delayed Hazard – No.
 - Fire Hazard – No.
 - Pressure Hazard – No.
 - Reactivity Hazard – No.
 - o SARA 302 Extremely hazardous substance – Not listed.
 - o SARA 311/312 Hazardous Chemical – Yes.
 - o SARA 313 (TRI Reporting) – Not regulated.

Other federal regulations:

- Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List – Not regulated.
- Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) – Not regulated.
- Safe Drinking Water Act (SDWA) – Not regulated.

US State regulations:

- US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100) – Not listed.
- US. Massachusetts RTK - Substance List – Not regulated.

- US. New Jersey Worker and Community Right-to-Know Act – Not regulated.
- US. Pennsylvania RTK - Hazardous Substances – Not regulated.
- US. Pennsylvania Worker and Community Right-to-Know Law – Not listed.
- US. Rhode Island RTK – Not regulated.
- US. California Proposition 65: California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) – This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

15.2 Chemical Safety Assessment:

No chemical safety assessment has been carried out for this substance/mixture by the supplier.

16. ADDITIONAL INFORMATION

16.1 Indication of changes/revision to SDS:

1. New format
2. Inclusion of EC Requirements
3. *Revision Date:* 11/16/2018

16.2 Abbreviations and acronyms:

ACGIH – American Conference of Governmental Industrial Hygienists
 CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act (Superfund)
 CFR – Code of Federal Regulations (Federal Drug Administration)
 CMR – Carcinogenic, mutagenic, reprotoxic
 DOT – U.S. Department of Transportation
 IARC – International Agency for Research on Cancer
 IATA – International Air Transport Association
 IMDG – International Maritime Dangerous Goods
 NIOSH – National Institute for Occupational Safety and Health
 NTP – National Toxicology Program
 OSHA – Occupational Safety and Health Administration
 PBT – Persistent, bioaccumulative and toxic
 RTK – Right-to-Know
 STEL – Short-term Exposure Limit
 TSCA – Toxic Substances Control Act
 TWA – Time Weighted Average
 vPvB – very persistent and very bioaccumulative

16.3 Key literature references and sources for data

1. Guidance on the Compilation of Safety Data Sheets; European Chemical Agency (ECHA); Version 2.1, February 2014
2. Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling, and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

16.4 Classification and procedure used to derive classification for mixtures according to Regulation (EC) 1272/2008[CLP]:

None.

Some of the information presented and conclusions drawn herein are from sources other than direct test data on the product itself. The information in the SDS was obtained from sources that we believe are reliable and is believed to be valid and accurate. American Orthodontics, however, makes no warranty, express or implied, regarding its correctness of the information provided.

The conditions or method of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage, or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. If the product is used as a component in another product or used in a way other than recommended by the Company, this SDS information may not be applicable. **Reasonable safety precautions must always be observed.**