

Section 1: IDENTIFICATION

Product Name: Rotary File
Synonyms: Reciprocating File.
Product Use: Cleaning and shaping of root canal.
Restrictions on Use: Not available.
Manufacturer/Supplier: US Endodontics, LLC
2809 W. Walnut Street
Johnson City, TN 37604
Emergency Phone: 423-283-0047
Date of Preparation of SDS: April 13, 2021

Section 2: HAZARD(S) IDENTIFICATION**GHS INFORMATION**

This material is a manufactured article as defined in the OSHA Hazard Communication Standard (29 CFR 1910.1200) and in the Canadian Hazardous Products Act. As supplied, this material is unlikely to pose any health hazards. This SDS contains valuable information critical to safe handling, as well as unusual and unintended exposures.

Classification: Not hazardous according to OSHA criteria (29 CFR 1910.1200).
Not hazardous according to WHMIS 2015 criteria.

LABEL ELEMENTS

Hazard None.

Pictogram(s):

Signal Word: None.

Hazard Not applicable.

Statements:

Precautionary Statements

Prevention: Not applicable.

Response: Not applicable.

Storage: Not applicable.

Disposal: Not applicable.

Hazards Not Otherwise Classified: These files should not be used for nickel-sensitive persons.

Ingredients with Unknown Toxicity: None.

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient(s)	Common name / Synonyms	CAS No.	% wt./wt.
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The blade of the rotary file is made of a Nickel-Titanium alloy. In addition, it includes a silicone stop and a silicone band. The handle of the file is Gold plated, Nickel plated, or Black plated.

Section 4: FIRST-AID MEASURES

- Inhalation:** Not a normal route of exposure.
Acute and delayed symptoms and effects: Not a normal route of exposure.
- Eye Contact:** Not a normal route of exposure. If particles from the treated area come in contact with the eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a poison center or doctor if you feel unwell.
Acute and delayed symptoms and effects: Not a normal route of exposure. Particles resulting from the treatment area may present additional hazards.
- Skin Contact:** No first-aid measures are necessary for handling the file. If particles from the treatment area get on the skin: Wash with plenty of water.
Acute and delayed symptoms and effects: Not expected to adverse effects. **These files should not be used for nickel-sensitive persons.**
- Ingestion:** Not a normal route of exposure. Should the file fracture during treatment and pieces are swallowed, call a poison center or doctor. Should pieces remain lodged in the root canal, they must be removed by dentist.
Acute and delayed symptoms and effects: Not a normal route of exposure. **These files should not be used for nickel-sensitive persons.**
- General Advice:** In case of accident or if you feel unwell, seek medical advice immediately (show the label or SDS where possible).
- Note to Physicians:** Symptoms may not appear immediately.

Section 5: FIRE-FIGHTING MEASURES**FLAMMABILITY AND EXPLOSION INFORMATION**

Not flammable or combustible by OSHA/WHMIS criteria. This product is not expected to burn.

- Sensitivity to Mechanical Impact:** This material is not sensitive to mechanical impact.
Sensitivity to Static Discharge: This material is not sensitive to static discharge. Dust generated may be sensitive to static discharge.

MEANS OF EXTINCTION

- Suitable Extinguishing Media:** Use appropriate extinguishing media for surrounding fire.
Unsuitable Extinguishing Media: Not available.
Products of Combustion: Not available.
Protection of Firefighters: Fire may produce irritating, corrosive and/or toxic gases. Runoff from fire control or dilution water may cause pollution. Wear positive pressure self-contained breathing apparatus (SCBA). Structural firefighters' protective clothing will only provide limited protection.

Section 6: ACCIDENTAL RELEASE MEASURES

- Emergency Procedures:** Keep unauthorized personnel away.
Personal Precautions: Not necessary for the product as supplied.

Environmental Precautions: Not necessary for the product as supplied.

Methods for Containment: Not necessary for the product as supplied.

Methods for Clean-Up: Not necessary for the product as supplied.

Other Information: See Section 13 for disposal considerations.

Section 7: HANDLING AND STORAGE

Handling:

Do not swallow. Wash hands thoroughly after treatment. See Section 8 for information on Personal Protective Equipment.

Storage:

Keep out of the reach of children.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines

Component

No TLV or PEL established for the components of this material.

PEL: Permissible Exposure Limit

TLV: Threshold Limit Value

Engineering Controls: Not normally required.

PERSONAL PROTECTIVE EQUIPMENT (PPE)



Eye/Face Protection:

Wear safety glasses. Use equipment for eye protection that meets the standards referenced by CSA Standard CAN/CSA-Z94.3 and OSHA regulations in 29 CFR 1910.133 for Personal Protective Equipment.

Hand Protection:

Wear protective gloves. Consult manufacturer specifications for further information.

Skin and Body Protection:

Wear protective clothing.

Respiratory Protection:

Not normally required.

General Hygiene Considerations:

Handle according to established industrial hygiene and safety practices. Consult a competent industrial hygienist to determine hazard potential and/or the PPE manufacturers to ensure adequate protection.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

20 mm to 40 mm blade with Gold-plated, Nickel-plated or Black-plated handle. It includes a red silicone stop and a white silicone band. The file weighs < 1 g.

Colour:

Silver blade, with gold-plated, nickel-plated or black-plated handle, and red stop and white band.

Odour:	Odourless.
Odour Threshold:	Not available.
Physical State:	Solid.
pH:	Not available.
Melting Point / Freezing Point:	Not available.
Initial Boiling Point:	Not available.
Boiling Range:	Not available.
Flash Point:	Not available.
Evaporation Rate:	Not available.
Flammability (solid, gas):	See Section 5.
Lower Flammability Limit:	Not available.
Upper Flammability Limit:	Not available.
Vapor Pressure:	Not available.
Vapor Density:	Not available.
Relative Density:	Not available.
Solubilities:	Insoluble in water.
Partition Coefficient: n-Octanol/Water:	Not available.
Auto-ignition Temperature:	Not available.
Decomposition Temperature:	Not available.
Viscosity:	Not available.
Percent Volatile, wt. %:	Not available.
VOC content, wt. %:	Not available.
Density:	Not available.
Coefficient of Water/Oil Distribution:	Not available.

Section 10: STABILITY AND REACTIVITY

Reactivity:	None known.
Chemical Stability:	Stable under normal storage conditions.
Possibility of Hazardous Reactions:	None known.
Conditions to Avoid:	None known.
Incompatible Materials:	None known.
Hazardous Decomposition Products:	None.

Section 11: TOXICOLOGICAL INFORMATION**EFFECTS OF ACUTE EXPOSURE****Product Toxicity**

Oral: Not available.

Dermal: Not available.

Inhalation: Not available.

Component Toxicity

Component	CAS No.	LD₅₀ oral	LD₅₀ dermal	LC₅₀
Aluminum oxide	1344-28-1	Not available.	Not available.	Not available.
Silica, vitreous	60676-86-0	Not available.	Not available.	Not available.

Likely Routes of Exposure: Eye contact. Skin contact. Inhalation. Ingestion.

Target Organs: Skin. Eyes. Gastrointestinal tract. Respiratory system.

Symptoms (including delayed and immediate effects)

Inhalation: Not a normal route of exposure.

Eye: Not a normal route of exposure. Particles resulting from the treatment area may present additional hazards.

Skin: Not expected to adverse effects. **These files should not be used for nickel-sensitive persons.**

Ingestion: Not a normal route of exposure. **These files should not be used for nickel-sensitive persons.**

Skin Sensitization: **These files should not be used for nickel-sensitive persons.**

Respiratory Sensitization: Not available.

Medical Conditions Not available.

Aggravated By Exposure:

EFFECTS OF CHRONIC EXPOSURE (from short and long-term exposure)

Target Organs: Skin. Eyes. Gastrointestinal tract. Respiratory system.

Chronic Effects: Prolonged or repeated contact may dry skin and cause irritation.

Carcinogenicity: As supplied, the material does not pose a cancer hazard.

Mutagenicity: Not available.

Reproductive Effects: Not available.

Developmental Effects

Teratogenicity: Not available.

Embryotoxicity: Not available.

Toxicologically Synergistic Materials: Not available.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: Not available.

Persistence / Degradability: Not available.

Bioaccumulation / Accumulation: Not available.**Mobility in Environment:** Not available.**Other Adverse Effects:** Not available.**Section 13: DISPOSAL CONSIDERATIONS****Disposal Instructions:** Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.**Section 14: TRANSPORT INFORMATION****U.S. Department of Transportation (DOT)****Proper Shipping Name:** Not regulated.**Class:** Not applicable.**UN Number:** Not applicable.**Packing Group:** Not applicable.**Placard(s):** Not applicable.**Canada Transportation of Dangerous Goods (TDG)****Proper Shipping Name:** Not regulated.**Class:** Not applicable.**UN Number:** Not applicable.**Packing Group:** Not applicable.**Placard(s):** Not applicable.**Section 15: REGULATORY INFORMATION****Chemical Inventories****US (TSCA)**

The components of this product are in compliance with the chemical notification requirements of TSCA.

Canada (DSL)

The components of this product are in compliance with the chemical notification requirements of the NSN Regulations under CEPA, 1999.

Federal Regulations**United States**

This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Section 16: OTHER INFORMATION**Disclaimer:**

The information contained in this document applies to this specific material as supplied. It may not be valid for this material if it is used in combination with any other materials. It is the user's responsibility to satisfy oneself as to the suitability and completeness of this information for their own particular use.

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Version: 1.0

GHS SDS Prepared by: **Aegis Regulatory Inc.**
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