

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 23 October 2018 Revision date: 23 October 2018 Version: 1.0

SECTION 1: Identification

Identification

Product form : Mixture Trade name : EdaeMIX

Recommended use and restrictions on use

Use of the substance/mixture : Endodontic irrigant used to remove smear layer and to disinfect instrumented canal systems

Supplier

Inter-Med, Inc. / Vista Dental Products

2200 South Street Racine, WI 53404 T: (877)-418-4782

Emergency telephone number

Emergency number : 800-424-9300 (North America) / +1 (703) 527-3887 (International)

SECTION 2: Hazard(s) identification

Classification of the substance or mixture

GHS-US classification

Skin corrosion/irritation Category 2 Causes skin irritation Serious eye damage/eye irritation Category 2A Causes serious eye irritation

GHS Label elements, including precautionary statements

GHS-US labeling

Hazard pictograms (GHS-US)



Signal word (GHS-US) : Warning

Hazard statements (GHS-US) Causes skin irritation

Causes serious eye irritation

Precautionary statements (GHS-US) Wash hands thoroughly after handling.

Wear eye protection, protective gloves. If on skin: Wash with plenty of water

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present

and easy to do. Continue rinsing

If skin irritation occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

Other hazards which do not result in classification

No additional information available

Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

Substances

Not applicable

3.2. **Mixtures**

Name	Product identifier	%	GHS-US classification
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate	(CAS-No.) 6381-92-6	10.4	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335

23 October 2018 EN (English US) Page 1

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Name	Product identifier	%	GHS-US classification
sodium hydroxide, caustic soda	(CAS-No.) 1310-73-2	< 2	Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314 Eye Dam. 1, H318
Alcohols, C9-11, ethoxylated	(CAS-No.) 68439-46-3	1.14	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318

Full text of hazard classes and H-statements : see section 16

SECTION 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. Give artificial respiration if

necessary. If you feel unwell, seek medical advice.

First-aid measures after skin contact : Rinse immediately with plenty of water for 15 minutes. Get medical advice if skin irritation

persists.

First-aid measures after eye contact : Rinse immediately with plenty of water for 15 minutes. Remove contact lenses, if present and

easy to do. Continue rinsing. If eye irritation persists: Get medical advice and attention.

First-aid measures after ingestion : Rinse mouth. Do not induce vomiting. Get medical advice/attention.

4.2. Most important symptoms and effects (acute and delayed)

Symptoms/effects after inhalation : Not expected to present a significant inhalation hazard under anticipated conditions of normal

use.

Symptoms/effects after skin contact : Causes skin irritation.

Symptoms/effects after eye contact : Causes serious eye irritation.

Symptoms/effects after ingestion : Not expected to present a significant ingestion hazard under anticipated conditions of normal

use. On ingestion in large quantities: May cause irritation to the digestive tract.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

Unsuitable extinguishing media : None known.

5.2. Specific hazards arising from the chemical

Fire hazard : On combustion, forms: carbon oxides (CO and CO2).

Explosion hazard : No direct explosion hazard.

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

5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions : Exercise caution when fighting any chemical fire.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing

apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid all unnecessary exposure.

6.1.1. For non-emergency personnel

Protective equipment : Use personal protective equipment as required. For further information refer to section 8:

"Exposure controls/personal protection".

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. In case of inadequate

ventilation wear respiratory protection.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect

spillage

Other information : Dispose of materials or solid residues at an authorized site.

23 October 2018 EN (English US) 2/7

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13: "Disposal considerations".

SECTION 7: Handling and storage

Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with eyes. Wear personal protective

equipment.

: Do not eat, drink or smoke when using this product. Always wash hands after handling the Hygiene measures

product. Wash contaminated clothing before reuse. Handle in accordance with good industrial

hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

Incompatible materials : None known.

SECTION 8: Exposure controls/personal protection

Control parameters

Alcohols, C9-11, ethoxylated (68439-46-3)			
Not applicable			
sodium hydroxide, caustic soda (1310-73-2)			
ACGIH	Local name	Sodium hydroxide	
ACGIH	ACGIH Ceiling (mg/m³)	2 mg/m³	
ACGIH	Remark (ACGIH)	URT, eye, & skin irr	
ACGIH	Regulatory reference	ACGIH 2018	
OSHA	OSHA PEL (TWA) (mg/m³)	2 mg/m³	
OSHA	Regulatory reference (US-OSHA)	OSHA	
NIOSH	US-NIOSH chemical category	SK: DIR(COR) Apr 2011	
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)			

Not applicable

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers

should be available in the immediate vicinity of any potential exposure.

Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Hand protection:

Impermeable protective gloves

Eye protection:

Safety glasses with side shields

Respiratory protection:

No respiratory protection needed under normal use conditions

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical state : Liquid Color : Colorless Odor characteristic Odor threshold : No data available

рΗ : 6.8 - 7.5 Melting point : Not applicable

23 October 2018 EN (English US) 3/7

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Relative evaporation rate (butyl acetate=1) : No data available
Flammability (solid, gas) : Not applicable.
Vapor pressure : No data available
Relative vapor density at 20 °C : No data available

Relative density : 1.06

: No data available Solubility : No data available Log Pow : No data available Auto-ignition temperature Decomposition temperature : No data available Viscosity, kinematic No data available : No data available Viscosity, dynamic **Explosion limits** : No data available Explosive properties : No data available Oxidizing properties : No data available

9.2. Other information

No additional information available

SECTION 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

Hazardous polymerization will not occur.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature. On combustion, forms: carbon oxides (CO and CO2).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)

Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)

Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

Alcohols, C9-11, ethoxylated (68439-46-3)		
LD50 oral rat	1400 mg/kg	
LD50 dermal rabbit	> 2000 mg/kg	
sodium hydroxide, caustic soda (1310-73-2)		
LD50 oral rat	140 - 340 mg/kg	
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)		
ATE US (oral)	500 mg/kg body weight	
ATE US (dermal)	1100 mg/kg body weight	
ATE US (gases)	4500 ppmV/4h	
ATE US (vapors)	11 mg/l/4h	
ATE US (dust, mist)	1.5 mg/l/4h	

23 October 2018 EN (English US) 4/7

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Skin corrosion/irritation : Causes skin irritation.

pH: 7 - 7.5

Serious eye damage/irritation : Causes serious eye irritation.

pH: 7 - 7.5

Respiratory or skin sensitization : Not classified (Based on available data, the classification criteria are not met) Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met) Carcinogenicity : Not classified (Based on available data, the classification criteria are not met) Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met) : Not classified (Based on available data, the classification criteria are not met) Specific target organ toxicity - single exposure

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)

Specific target organ toxicity - single exposure May cause respiratory irritation.

Specific target organ toxicity - repeated

exposure

: Not classified (Based on available data, the classification criteria are not met)

Aspiration hazard Viscosity, kinematic : Not classified (Based on available data, the classification criteria are not met) : No data available

Likely routes of exposure

: Inhalation. Ingestion. Skin and eye contact.

Symptoms/effects after inhalation

: Not expected to present a significant inhalation hazard under anticipated conditions of normal

Symptoms/effects after skin contact

: Causes skin irritation.

Symptoms/effects after eye contact

: Causes serious eye irritation.

Symptoms/effects after ingestion : Not expected to present a significant ingestion hazard under anticipated conditions of normal

use. On ingestion in large quantities: May cause irritation to the digestive tract.

SECTION 12: Ecological information

Toxicity

Ecology - general : This material has not been tested for environmental effects.

12.2. Persistence and degradability

No additional information available

Bioaccumulative potential

No additional information available

Mobility in soil

No additional information available

Other adverse effects

No additional information available

SECTION 13: Disposal considerations

Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not regulated

Transportation of Dangerous Goods

Not regulated

23 October 2018 EN (English US) 5/7

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Transport by sea

Not regulated

Air transport

Not regulated

SECTION 15: Regulatory information

15.1. US Federal regulations

Alcohols, C9-11, ethoxylated (68439-46-3)		
Listed on the United States TSCA (Toxic Substances Control Act) inventory		
EPA TSCA Regulatory Flag XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).		
sodium hydroxide, caustic soda (1310-73-2)		
Listed on the United States TSCA (Toxic Substances Control Act) inventory		
CERCLA RQ	1000 lb	

15.2. International regulations

CANADA

Alcohols, C9-11, ethoxylated (68439-46-3)

Listed on the Canadian DSL (Domestic Substances List)

sodium hydroxide, caustic soda (1310-73-2)

Listed on the Canadian DSL (Domestic Substances List)

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

sodium hydroxide, caustic soda (1310-73-2)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

National regulations

Alcohols, C9-11, ethoxylated (68439-46-3)

Listed on the AICS (Australian Inventory of Chemical Substances)

Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Listed on the Korean ECL (Existing Chemicals List)

Listed on NZIoC (New Zealand Inventory of Chemicals)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Listed on the TCSI (Taiwan Chemical Substance Inventory)

sodium hydroxide, caustic soda (1310-73-2)

Listed on the AICS (Australian Inventory of Chemical Substances)

Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory

Listed on the Japanese ISHL (Industrial Safety and Health Law)

Listed on the Korean ECL (Existing Chemicals List)

Listed on NZIoC (New Zealand Inventory of Chemicals)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Japanese Poisonous and Deleterious Substances Control Law

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Listed on CICR (Turkish Inventory and Control of Chemicals)

Listed on the TCSI (Taiwan Chemical Substance Inventory)

23 October 2018 EN (English US) 6/7

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)

Listed on the AICS (Australian Inventory of Chemical Substances)

Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Listed on NZIoC (New Zealand Inventory of Chemicals)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Listed on the TCSI (Taiwan Chemical Substance Inventory)

15.3. US State regulations

No additional information available

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision date : 23 October 2018

Full text of H-phrases:

H302	Harmful if swallowed	
H312	Harmful in contact with skin	
H314	Causes severe skin burns and eye damage	
H315	Causes skin irritation	
H318	Causes serious eye damage	
H319	Causes serious eye irritation	
H332	Harmful if inhaled	
H335	May cause respiratory irritation	

SDS US (GHS HazCom 2012)

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

23 October 2018 EN (English US) 7/7