

SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

Date Issued : 09/16/2013
SDS No : 9003975DE
Date Revised : 05/08/2017
Revision No : 3

Haemostatic Gel (20% Ferric sulfate) Kit

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code : 9003975
Product name : Haemostatic Gel (20% Ferric sulfate) Kit
Product description : Hemostatic Solution

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Dental Hemostatic Agent

1.3. Details of the supplier of the safety data sheet

Distributor:

Henry Schein Inc.
135 Duryea Road
Melville, NY 11747 / USA

Authorized EU Representative:

Henry Schein Services GmbH
Monzastrasse 2a
63225 Langen / Germany

Contact:

cbdeurope@henryschein.com
www.henryscheinbrand.com
Tel: +49 6103 757 5000

Responsible for the Safety Data Sheet: Legal Europe Regulatory - cbdeurope@henryschein.com

1.4. Emergency telephone number

Emergency Number INTERNATIONAL: **+49 (0)6132 84463** GBK GmbH (24h 7d/w - 365d/a)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Health

: Skin Corrosion, Category 1
Eye Irritation, Category 2

Environmental

: Acute Hazards to the Aquatic Environment, Category 3
Chronic Hazards to the Aquatic Environment, Category 3

2.2. Label elements

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

Hazard pictogram(s) :



Corrosive



Exclamation
mark

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Signal Word	: DANGER
Hazard statement(s)	: H314: Causes severe skin burns and eye damage. H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
Precautionary statement(s)	
Prevention	: P260: Do not breathe dust/mist. P264: Wash hands thoroughly after handling. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection.
Response	: P301: IF SWALLOWED: P330: Rinse mouth. P331: Do NOT induce vomiting. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P310: Immediately call a POISON CENTER or doctor/physician. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Storage	: P405: Store locked up.
Disposal	: P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-21/11/2003)

2.3. Other hazards

Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Regulation(EC) No 1272/2008 [CLP]
Iron Anion-Sulfate and Sub sulfate	10028-22-5	233-072-9	< 20	Acute Tox. (O), Cat. 4; Eye Irr., Cat. 2; STOT SE, Cat. 3; Aquatic Acute, Cat 3; Aquatic Chronic, Cat 3; H302; H319; H335

For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes	: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
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- Following skin** : Immediately flush skin with plenty of water. Remove clothing. Get medical attention immediately. Wash clothing separately before reuse.
- Following ingestion** : IF SWALLOWED: Rinse mouth with water. Do NOT induce vomiting.
- Following inhalation** : If inhaled, remove victim to fresh air. Seek immediate medical assistance.

4.2. Most important symptoms and effects, both acute and delayed

- Eyes** : Causes eye irritation.
- Skin** : May cause skin burns.
- Ingestion** : Harmful if swallowed.
- Inhalation** : Harmful if inhaled

4.3. Indication of any immediate medical attention and special treatment needed

- Notes to physician** : Corrosive

SECTION 5: Fire fighting measures

5.1. Extinguishing media

- Extinguishing media** : Water spray, alcohol-resistant foam, dry chemical or carbon dioxide

5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : None known.

5.3. Advice for firefighters

- Fire fighting procedures** : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General procedures** : Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions

- Water spill** : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

- Small Spill** : Wipe up with cloth, soap and water.
- Large Spill** : Collect in tightly closed containers.

6.4. Reference to other sections

- Reference to other sections** : NAP

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- General procedures** : Avoid contact with eyes, skin and clothing.
- Handling** : Use suitable protective equipment.
- Storage** : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

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Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Dental Hemostatic Solution

SECTION 8: Exposure controls / personal protection**8.1. Control parameters**

Control parameters : None Required

8.2. Exposure controls

Eye/face protection : Wear eye protection.

Skin protection : Wear suitable protective clothing and gloves.

Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state : Liquid

Colour : Yellow-brown

Odour : Faint metallic

pH : 1.0 to 1.5

Specific gravity : 1.15

9.2. Other information

Additional information : No further relevant information available.

SECTION 10: Stability and reactivity**10.1. Reactivity**

Reactivity : Stable

10.2. Chemical stability

Chemical stability : Sensitive to light.

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

Conditions to avoid : None known.

10.5. Incompatible materials

Incompatible materials : Strong acids, strong bases, and oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

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Acute

Dermal LD₅₀	: > 85900 mg/kg Rabbit
Notes	: ~ 3% of the mixture consists of components of unknown toxicity (Dermal).
Oral LD₅₀	: > 60000 mg/Kg Rabbit
Notes	: ~19% of the mixture consists of components of unknown toxicity (Oral).
Inhalation LC₅₀	: > 1000 mg/l/4H Rabbit
Notes	: ~19% of the mixture consists of components of unknown toxicity (Inhalation).
Germ cell mutagenicity	: The components in this product are not reported to produce mutagenic effects in humans.
Carcinogenicity	: None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.
Reproductive toxicity	: The components in this product are not reported to cause reproductive effects in humans.
Other information	: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.

12.2. Persistence and degradability

Persistence and degradability : Not classified

12.3. Bioaccumulative potential

Bioaccumulative potential : Not classified

12.4. Mobility in soil

Mobility in soil : Not Available

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

12.6. Other adverse effects

Environmental data : No further relevant information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal method : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

SECTION 14: Transport information

14.1. UN number

UN number : 3264

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14.2. UN proper shipping name

UN proper shipping name : Corrosive Liquid, Acidic, Inorganic, N.O.S. (Ferric sulfate mixture)

14.3. Transport hazard class(es)

Primary hazard class/division : 8

Hazard classification : 8

14.4. Packing group

Packing group : II

14.5. Environmental hazards

Marine pollutant #1 : NAP

14.6. Special precautions for user

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

IATA - air : NAP

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : NAP

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

General information : Substances of very high concern (SVHC) according to REACH, Article 57:
Contains no SVHC substances.

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.

SECTION 16: Other information

Relevant H-statements (number and full text) : Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
Aquatic Acute, Cat 3: Acute Hazards to the Aquatic Environment, Category 3
Aquatic Chronic, Cat 3: Chronic Hazards to the Aquatic Environment, Category 3
Eye Irr., Cat. 2: Eye Irritation, Category 2
STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract Category 3
H302: Harmful if swallowed.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 02/24/2015 SDS. Revised: **Section 1: MSDS**

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No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3.
Other hazards. **Section 3:** Wt.%. **Section 4:** EYES, INGESTION,
INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF
OVEREXPOSURE (SKIN), SKIN. **Section 5:** EXPLOSION HAZARDS,
EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT,
SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:**
LARGE SPILL, . **Section 7:** GENERAL PROCEDURES. **Section 8:**
PERSONAL PROTECTIVE EQUIPMENT (RESPIRATORY), . **Section 9:**
COMMENTS, ODOR, PERCENT VOLATILE, pH, PHYSICAL STATE,
SPECIFIC GRAVITY. **Section 10:** CONDITIONS TO AVOID, INCOMPATIBLE
MATERIALS, STABILITY. **Section 11:** ACUTE (DERMAL LD₅₀ (rabbit),
DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION
LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat),
INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE,
GENERAL COMMENTS, CARCINOGENICITY, GERM CELL MUTAGENICITY,
REPRODUCTIVE TOXICITY. **Section 12:** CHEMICAL FATE INFORMATION,
DISTRIBUTION, ENVIRONMENTAL DATA,
BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE),
AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION
12: Ecological information. **Section 14:** VESSEL (IMO/IMDG) - MARINE
POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS
SECTION 14: Transport information, ADR - road, IMDG - sea, IATA -
air. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **Section 16:**
GENERAL STATEMENTS.

General statements

: NAP = Not Applicable
NE = Not Established
TLV = Threshold Limit Value
PEL = Permittable exposure limits
MAK = Maximum Workplace Concentration
STEL = Short-term exposure limit
STEV = Short-term exposure value
TWA = Time Weighted Average
PPE = Personal Protective Equipment

Manufacturer disclaimer

: FOR DENTAL USE ONLY: Use as directed. The information and
recommendations are taken from sources (raw material SDS(s) and
manufacturer's knowledge) believed to be accurate; however, the manufacturer,
makes no warranty with respect to the accuracy of the information or the
suitability of the recommendation and assumes no liability to any user thereof.
Each user should review these recommendations in the specific context of the
intended use and determine whether they are appropriate.