

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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<b>Signal Word</b>	: DANGER
<b>Hazard statement(s)</b>	: H314: Causes severe skin burns and eye damage. H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
<b>Precautionary statement(s)</b>	
<b>Prevention</b>	: 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.
<b>Response</b>	: 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.
<b>Storage</b>	: P405: Store locked up.
<b>Disposal</b>	: 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 Subsulfate	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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<b>Following skin</b>	: Immediately flush skin with plenty of water. Remove clothing. Get medical attention immediately. Wash clothing separately before reuse.
<b>Following ingestion</b>	: IF SWALLOWED: Rinse mouth with water. Do NOT induce vomiting.
<b>Following inhalation</b>	: If inhaled, remove victim to fresh air. Seek immediate medical assistance.

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

<b>Eyes</b>	: Causes eye irritation.
<b>Skin</b>	: May cause skin burns.
<b>Ingestion</b>	: Harmful if swallowed.
<b>Inhalation</b>	: Harmful if inhaled

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

<b>Notes to physician</b>	: Corrosive
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### SECTION 5: Fire fighting measures

#### 5.1. Extinguishing media

<b>Extinguishing media</b>	: Water spray, alcohol-resistant foam, dry chemical or carbon dioxide
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#### 5.2. Special hazards arising from the substance or mixture

<b>Hazardous combustion products</b>	: None known.
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#### 5.3. Advice for firefighters

<b>Fire fighting procedures</b>	: General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
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### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

<b>General procedures</b>	: Refer to Section 8 for Personal Protective Equipment.
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#### 6.2. Environmental precautions

<b>Water spill</b>	: Do not allow to enter sewers or drains that may lead to waterways.
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#### 6.3. Methods and material for containment and cleaning up

<b>Small Spill</b>	: Wipe up with cloth, soap and water.
<b>Large Spill</b>	: Collect in tightly closed containers.

#### 6.4. Reference to other sections

<b>Reference to other sections</b>	: NAP
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### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

<b>General procedures</b>	: Avoid contact with eyes, skin and clothing.
<b>Handling</b>	: Use suitable protective equipment.
<b>Storage</b>	: 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**

<b>Dermal LD<sub>50</sub></b>	: > 85900 mg/kg Rabbit
<b>Notes</b>	: ~ 3% of the mixture consists of components of unknown toxicity (Dermal).
<b>Oral LD<sub>50</sub></b>	: > 60000 mg/Kg Rabbit
<b>Notes</b>	: ~19% of the mixture consists of components of unknown toxicity (Oral).
<b>Inhalation LC<sub>50</sub></b>	: > 1000 mg/l/4H Rabbit
<b>Notes</b>	: ~19% of the mixture consists of components of unknown toxicity (Inhalation).
<b>Germ cell mutagenicity</b>	: The components in this product are not reported to produce mutagenic effects in humans.
<b>Carcinogenicity</b>	: None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.
<b>Reproductive toxicity</b>	: The components in this product are not reported to cause reproductive effects in humans.
<b>Other information</b>	: 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 LD<sub>50</sub> (rabbit),  
DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), ORAL LD<sub>50</sub> (rat), INHALATION  
LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat),  
INHALATION LC<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (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 EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), 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.