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



Date Issued : 7/9/2014

SDS No: 307-100.2

HS Retreat™ Hemostatic Gel

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

1.1. Product identifier

Product code : VS/64500

Product name : HS Retreat™ Hemostatic Gel

Product description: Hemostatic gel

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.(manufacturer) 135 Duryea Road Melville, NY 11747 USA

EC/REP

HENRY SCHEIN U.K. HOLDINGS LTD. MEDCARE HOUSE, CENTURION CLOSE GILLINGHAM BUSINESS PARK GILLINGHAM, ME8 0SB U.K.

Emergency Phone: 001-703-527-3887 **E-Mail**: cbdeurope@henryschein.de

1.4. Emergency telephone number

CHEMTREC (NORTH AMERICA) :(800) 424 - 9300 (INTERNATIONAL) :+1(703) 527 - 3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 1999/45/EC

Danger symbols : Xn

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xn



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

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Hazard pictogram(s)

Exclamation

mark

: WARNING Signal Word

: H302: Harmful if swallowed. Hazard statement(s)

:

Precautionary statement(s)

General : P301: IF SWALLOWED:

P331: Do NOT induce vomiting.

P310: Immediately call a POISON CENTER or doctor/physician.

P305: IF IN EYES:

P315: Get immediate medical advice/attention.

P333+P313: If skin irritation or rash occurs: Get medical

advice/attention.

2.3. Other hazards

Immediate concerns : R36/38: Irritating to eyes and skin.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Iron Anion-Sulfate and Subsulfate	10028-22-5	233-072-9	< 25	Xn; R22; R36/38	H302; H290; H317; H314; H335; H332; H318

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

SECTION 4: First aid measures

4.1. Description of first aid measures

: Immediately flush eyes with plenty of water for at least 15 minutes. Following eyes

Get immediate medical attention.

Following skin : Wash with soap and water.

Following ingestion : If swallowed, rinse mouth with water, Do NOT Induce Vomiting. Give

victim a glass of water or milk. Call a physician or poison control

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center immediately. Never give anything by mouth to an unconscious

person.

Following inhalation: No specific treatment is necessary since this material is not likely to be

hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other

symptoms develop.

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

Eyes: Irritating to eyes.

Skin : Prolonged or exposure may cause skin irritation

Ingestion : Harmful if swallowed.

Inhalation : None expected for this product.

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

Notes to physician : Not Applicable

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media: Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

Explosion hazards : Not Determined
Fire explosion : Not Determined
Sensitive to static discharge : Not Determined
Sensitivity to impact : Not Determined

5.3. Advice for firefighters

Fire fighting procedures : As in any fire, wear self-contained breathing apparatus pressure

demand, (MSHA/NIOSH) approved or equivalent) and full protective

gear.

Fire fighting equipment : Water spray, alcohol - resistant foam, dry chemical or carbon dioxide

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 spillWipe up with cloth, soap and water.Large spillCollect in tightly closed containers.

6.4. Reference to other sections

Reference to other sections: Not Applicable

SECTION 7: Handling and storage

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7.1. Precautions for safe handling

Handling : Use suitable protective equipment.

Storage: See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s): Professional Dental Hemostatic Agent

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters: Not Determined

8.2. Exposure controls

Eye/face protection: Wear eye protection

Skin protection : S36/37: Wear suitable protective clothing and gloves.

Respiratory protection: Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Gel

Colour : Yellowish-brown
Odour : Slight iron odor
Solubility in water : Partially Soluble

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity: Yes

10.2. Chemical stability

Chemical stability : Sensitive to light.

10.3. Possibility of hazardous reactions

Hazardous polymerization: No

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

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Hazardous decomposition

products

: None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Notes: Device is biocompatible when used as directed by dental professionals

per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : Not Determined

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

96-hour LC50: Not Determined48-hour EC50: Not Determined96-hour EC50: Not Determined

12.2. Persistence and degradability

Persistence and degradability: Not Determined

12.3. Bioaccumulative potential

Bioaccumulative potential : Not Determined

12.4. Mobility in soil

Mobility in soil : Not Determined

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB

assessment

: Not Determined

12.6. Other adverse effects

Environmental data : Not 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

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)

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Hazard classification : 8

14.4. Packing group

: II Packing group

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : N/A RID - rail : N/A IMDG - sea : N/A IATA - air : N/A

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

Transport in bulk : N/A

SECTION 15: Regulatory information

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

RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

Chemical safety assessment : Not Determined

SECTION 16: Other information

Relevant R-phrases and/or Hstatements (number and full

text)

: R22: Harmful if swallowed.

R36/38: Irritating to eyes and skin. H290: May be corrosive to metals.

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

H332: Harmful if inhaled.

H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

General statements : NA = Not Applicable

Additional SDS information

Manufacturer disclaimer

: Revision #:1

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material MSDS(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.