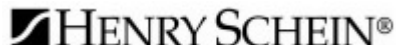


SAFETY DATA SHEET

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



Date Issued : 06/08/2016
SDS No : 184-100.1

Retreat Clear Hemostatic Gel

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

1.1. Product identifier

Product code : VX/22424
Product name : Retreat Clear Hemostatic Gel
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.(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 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 1B
Acute Toxicity (Inhalation), Category 2

2.2. Label elements

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

Hazard pictogram(s) :



Corrosive

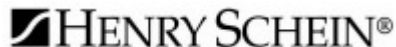
Signal Word : DANGER

Hazard statement(s) : H314: Causes severe skin burns and eye damage.
H335: May cause respiratory irritation.

Precautionary statement(s)

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Prevention	: P280: Wear protective gloves/protective clothing/eye protection/face protection.
Response	: P305: IF IN EYES: P351: Rinse cautiously with water for several minutes. P313: Get medical advice/attention. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P301: IF SWALLOWED: P310: Immediately call a POISON CENTER or doctor/physician. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
Storage	: P273: Avoid release to the environment.
Disposal	: P501: Dispose of in compliance with governmental regulation.(EC1975L0442-20/11/2003)

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]
Aluminum Chloride Hexahydrate	7784-13-6	N/A	< 50	Skin Corr.,Cat. 1B; H314
Sodium borate	1330-43-4	215-540-4	< 1	Eye Irr.,Cat. 2; H319

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes	: Flush eye with water for 15 minutes. Get medical attention.
Following skin	: Wash immediately with plenty of water. Remove contaminated clothing. If irritation persists seek medical attention. Wash contaminated clothing before using them.
Following ingestion	: If swallowed, Do Not Induce Vomiting- Seek Medical Advice.
Following inhalation	: Rest in the fresh air and seek medical advice if necessary.

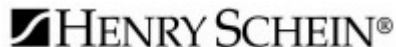
4.2. Most important symptoms and effects, both acute and delayed

Eyes	: Irritating to eyes.
Skin	: Corrosive, causes skin burning.
Ingestion	: May be harmful if swallowed.
Inhalation	: May cause irritation.

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

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Notes to physician : Not Applicable

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media : Water Spray Only

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 small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water.

Large Spill : After removal, flush contaminated area thoroughly with water.

6.4. Reference to other sections

Reference to other sections : Not Applicable

SECTION 7: Handling and storage

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

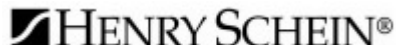
SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Silicon Dioxide CAS: 7631-86-9

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Control Parameters	Exposure Limits
OSHA PEL General Industry	20 mppcf, 80mg/m ³ /%SiO ₂ TWA
OSHA PEL Maritime	20 mppcf TWA
OSHA PEL Construction Industry	20 mppcf TWA
NIOSH REL	6mg/m ³ TWA

Sodium Borate CAS: 1330-43-4

Control Parameters	Exposure Limits
NIOSH REL	1 mg/m ³ TWA
OSHA PEL	none

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

Appearance : Clear

Colour : Colorless to slight yellow

Odour : Odorless or no characteristic odor

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

Conditions to avoid : Not Available

10.5. Incompatible materials

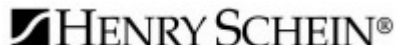
Incompatible materials : Not Available

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : > 66000 mg/kg(rabbit/rat)

Notes : ~50% of the mixture consists of components of unknown toxicity (dermal).

Oral LD₅₀ : > 3800 mg/kg Rat/Mouse/Rabbit

Notes : There are no components of unknown toxicity (oral).

Inhalation LC₅₀ : > 0.1 mg/L/4H Dust/Mist Rat

Notes : ~45% of the mixture consists of components of unknown toxicity (Inhalation).

Reproductive toxicity : WARNING! This product contains a chemical known to cause birth defects or other reproductive harm when used at concentrations over 4.5%: Sodium borate

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 : Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

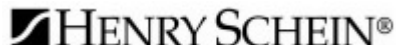
UN number : 1760

14.2. UN proper shipping name

UN proper shipping name : Corrosive liquid, N.O.S. (Aluminum chloride hexahydrate mixture)

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14.3. Transport hazard class(es)

Primary hazard class/division : 8

Hazard classification : 8

14.4. Packing group

Packing group : III

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

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : WARNING! This product contains a chemical known to cause birth defects or other reproductive harm when used at concentrations over 4.5%. Sodium Borate.

SECTION 16: Other information

Relevant H-statements (number and full text) : Eye Irr., Cat. 2: Eye Irritation, Category 2
Skin Corr., Cat. 1B: Skin Corrosion, Category 1B
H314: Causes severe skin burns and eye damage.
H319: Causes serious eye irritation.

Prepared by : Anu Kattoju

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

Additional SDS information : This is the first SDS.

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,

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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.