according to Regulation (EC) No. 453/2010

Dental Use



Date Issued: 02/24/2014 **SDS No**: 161-100.5

Date Revised: 12/22/2015

Revision No: 5

Henry Schein Natural Elegance Etch Gel Kit; Henry Schein Natural Elegance Bulk Syringe

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

1.1. Product identifier

Product code : 112-6978, 112-6979

Product name : Henry Schein Natural Elegance Etch Gel Kit; Henry Schein Natural Elegance

Bulk Syringe

Product description : Phosphoric acid dentin etchant

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

Relevant identified uses : Professional Dental Acid Etching Solution

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

: The mixture has been assessed and/or tested for its physical, health and

environmental hazards and the following classification applies.

Danger symbols : C R phrases : R34

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

Health : Skin Corrosion, Category 1B

2.2. Label elements

Classification according to Directive 1999/45/EC

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Hazard pictogram(s)

R&S statement(s) : R34: Causes burns. 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.

Precautionary statement(s)

Prevention : P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response : P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P315: Get immediate medical advice/attention.

P302+P352: IF ON SKIN: Wash with plenty of soap and water. P332+P313: If skin irritation occurs: Get medical advice/attention.

P360: Rinse immediately contaminated clothing and skin with plenty of water

before removing clothes.

P363: Wash contaminated clothing before reuse.

P301: IF SWALLOWED:

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

P330: Rinse mouth.

P331: Do NOT induce vomiting.

Storage : P273: Avoid release to the environment.

Disposal : P501: Dispose of in compliance with governmental regulations (EC 1975L0442-

20/11/2003).

2.3. Other hazards

Immediate concerns : Corrosive. Will cause eye burns and permanent tissue damage.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

according to Regulation (EC) No. 453/2010

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Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008 [CLP]
Phosphoric Acid	7664-38-2	231-633-2	< 40	C; R34	Skin Corr.,Cat. 1B; H314
Cobalt aluminate blue spinel	1345-16-0	310-193-6	< 1	R36/37/38; R22	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; STOT SE,Cat. 3; H315; H319; H335

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes : Immediately flush with plenty of water. After initial flushing, remove any contact

lenses and continue flushing for at least 15 minutes. Have eyes examined and

tested by medical personnel.

Following skin : Remove contaminated clothing. Wash with soap and water. Get medical

attention.

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 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 : Causes severe eye burns.

Skin: Corrosive, causes skin burning.

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 : Corrosive

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

Hazardous combustion products: Phosphine, oxides of phosphorous, hydrogen gas

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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.

Fire fighting equipment : The product is not combustible. Substance does not burn but may decompose

upon heating to produce corrosive and/or toxic fumes. Keep product and empty container away from heat and sources of ignition. Use appropriate media for

adjacent fire. Cool containers with water.

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 : Clean up spills immediately, observing precautions in Protective Equipment

section.

Large spill : Absorb with inert, damp non-combustible material, then flush area 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

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

Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Dental Acid Etching Solution

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: Wear suitable protective clothing and gloves.

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

of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

according to Regulation (EC) No. 453/2010

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9.1. Information on basic physical and chemical properties

Physical state : Gel
Colour : Blue

Odour : Odorless or no characteristic odor

Solubility in water: Partially soluble in water.

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 : Avoid strong bases, metals, excess heat, exposure to moist air or water.

10.5. Incompatible materials

Incompatible materials: Strong caustics, most metals.

10.6. Hazardous decomposition products

Hazardous decomposition products : Phosphine, oxides of phosphorous, hydrogen gas

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Notes : Device is a strong acid and is extremely toxic. It is to be used only as directed

with PPE, and only by licensed dental professionals.

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

according to Regulation (EC) No. 453/2010

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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 defined

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. (Phosphoric acid mixture)

14.3. Transport hazard class(es)

Hazard classification : 8

14.4. Packing group

Packing group : III

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 : See Section 11

Additional information : IARC has identified cobalt and cobalt compounds as "possibly carcinogenic" as

according to Regulation (EC) No. 453/2010

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a group, however IARC did not specifically identify the cobalt compound in this product as a possible carcinogen.

OSHA- Select Carcinogens: Present

SECTION 16: Other information

Relevant R-phrases and/or Hstatements (number and full text) : R22: Harmful if swallowed.

R34: Causes burns.

R36/37/38: Irritating to eyes, respiratory system and skin.

Eye Irr., Cat. 2: Eye Irritation, Category 2

STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Category 3

Skin Corr., Cat. 1B: Skin Corrosion, Category 1B Skin Irr., Cat. 2: Skin Irritation, Category 2

H314: Causes severe skin burns and eye damage.

H315: Causes skin irritation. H319: Causes serious eye irritation. H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

Revision summary

: This SDS replaces the 02/23/2015 SDS. Revised: **Section 1**: GENERAL USE, MSDS No. **Section 2**: . **Section 4**: INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE - INHALATION. **Section 5**: EXPLOSION HAZARDS, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT,

HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. Section 7: GENERAL PROCEDURES, HANDLING, STORAGE, . Section 8: PERSONAL

PROTECTIVE EQUIPMENT - RESPIRATORY. Section 10: HAZARDOUS

POLYMERIZATION, STABLE. Section 12: ECOTOXICOLOGICAL

INFORMATION.

General statements

: N/A= Not Applicable

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.