

# SAFETY DATA SHEET

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



Date Issued : 02/24/2014  
SDS No : 161-100.6  
Date Revised : 09/06/2017  
Revision No : 6

## 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 (UR/71041)  
**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 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 3

#### 2.2. Label elements

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

**Hazard pictogram(s)** :    
Corrosive Exclamation mark

**Signal Word** : DANGER

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<b>Hazard statement(s)</b>	: H314: Causes severe skin burns and eye damage. H333: May be harmful if inhaled.
<b>Precautionary statement(s)</b>	
<b>Prevention</b>	: P280: Wear protective gloves/protective clothing/eye protection/face protection. P260: Do not breathe dust/fume/gas/mist/vapours/spray. P264: Wash hands thoroughly after handling.
<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]. P363: Wash contaminated clothing before reuse. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P311: 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. (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]
Phosphoric Acid	7664-38-2	231-633-2	< 40	Skin Corr.,Cat. 1B; H314
Cobalt aluminate blue spinel	1345-16-0	310-193-6	< 1	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; STOT SE,Cat. 3; H315; H319; H335

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

<b>Following eyes</b>	: 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.
<b>Following skin</b>	: Remove contaminated clothing. Wash with soap and water. Get medical attention.

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**Following ingestion** : IF SWALLOWED: Rinse mouth with water. Do NOT induce vomiting.  
**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** : Causes severe eye damage.  
**Skin** : Corrosive, causes skin burning.  
**Ingestion** : Harmful if swallowed.  
**Inhalation** : May be 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** : Phosphine, oxides of phosphorous, hydrogen gas

### 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** : 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** : NAP

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**General procedures** : Avoid contact with eyes, skin and clothing.

**Handling** : Safety glasses should be used by the patient and doctor. Use equipment for eye protection tested and approved under appropriate government standards such as ANSI Z87.1.

**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 Acid Etching Solution

## SECTION 8: Exposure controls / personal protection

### 8.1. Control parameters

Control parameters : Phosphoric Acid CAS: 7664-38-2

Control Parameters	Exposure Limits
OSHA PEL General Industry	1 mg/m <sup>3</sup>
OSHA PEL Construction Industry	1 mg/m <sup>3</sup>
OSHA PEL Shipyard Industry	1 mg/m <sup>3</sup>
NIOSH REL	1 mg/m <sup>3</sup> TWA 3 mg/m <sup>3</sup> STEL
ACGIH TLV	1 mg/m <sup>3</sup> TWA 3 mg/m <sup>3</sup> STEL
CAL/OSHA PEL	1 mg/m <sup>3</sup>

### 8.2. Exposure controls

**Eye/face protection** : Safety glasses (ANSI Z87.1 or equivalent) should be used by the doctor and patient.

**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

### 9.1. Information on basic physical and chemical properties

**Physical state** : Gel  
**Colour** : Blue  
**Odour** : Odorless or no characteristic odor  
**pH** : < 1.0  
**Specific gravity** : 1.0 - 1.4  
**Solubility in water** : Partially soluble in water.

### 9.2. Other information

**Additional information** : No further relevant information available.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

**Reactivity** : Stable

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**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

**Additional information** : Reacts with bases to form phosphate salts and is corrosive (especially when hot) to many metals and alloys. Liberates explosive hydrogen gas when reacting with chlorides and stainless steel, and reacts violently with sodium tetrahydroborate. Forms flammable gases with sulfides, mercaptans, cyanides, and aldehydes. Also forms toxic fumes with cyanides, sulfides, fluorides, organic peroxides, and halogenated organics.

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Acute**

**Dermal LD<sub>50</sub>** : > 5300 mg/kg Rabbit

**Notes** : ~ 2% of the mixture consists of components of unknown toxicity (Dermal).

**Oral LD<sub>50</sub>** : > 2800 mg/kg Rat

**Notes** : < 1% of the mixture consists of components of unknown toxicity (Oral).

**Inhalation LC<sub>50</sub>** : > 0.8 mg/l/4H Rabbit

**Notes** : ~ 2% 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** : Cobalt and Cobalt compounds may cause cancer according to the raw material SDS, IARC monographs, and the NTP.

**Reproductive toxicity** : The components in this product are not reported to cause reproductive effects in humans.

**Other information** : 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**

**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

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**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 : 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 : 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 : European Substances of very high concern (SVHC) according to REACH, Article 57: Contains no SVHC Substances.  
 CAN: All of the raw materials on the formulation list are on the Candian DSL list.

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

### 15.2. Chemical safety assessment

**Chemical safety assessment** : See Section 11

**Additional information** : WARNING! Cobalt and Cobalt Compounds have been identified as potential carcinogens on the raw material SDS, IARC monographs, and NTP.

### SECTION 16: Other information

**Relevant H-statements (number and full-text)** : Eye Irr., Cat. 2: Eye Irritation, Category 2  
STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract 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 12/22/2015 SDS. Revised: **Section 1**: MSDS No, PRODUCT CODE/ PART #. **Section 2**: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4**: INGESTION, INHALATION, SIGNS AND SYMPTOMS OF OVEREXPOSURE ( INHALATION ). **Section 5**: EXTINGUISHING MEDIA, FIRE FIGHTING EQUIPMENT. **Section 6**: . **Section 7**: HANDLING. **Section 8**: PERSONAL PROTECTIVE EQUIPMENT - EYES AND FACE . **Section 9**: COMMENTS, PERCENT VOLATILE, pH, SPECIFIC GRAVITY. **Section 10**: COMMENTS. **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, ECOTOXICOLOGICAL INFORMATION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, 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

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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.