

# Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

Trade name: **Gel-Etch Etching Gel**

Material.-No.: **OMB #1218-0072**

Specification: **K-872569**

Version 1.0/EN

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Print Date: **01/01/11**

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

**Identification of the substance or preparation:** Gel-Etch Etching Gel

**REACH Registration No:** K-872569 / 2429849

**Use of the substance/preparation:** Etching tooth enamel

**Identified use(s):** Etching gel

**Industry:** Dental Etching Agent

**Professional:** Etching enamel in dentistry

**Private:** N/A – Not intended for private use.

In compliance with the conditions described in the annex to this safety data sheet.

**Function(s) of the substance/the preparation:**

For etching tooth enamel.

**Operational area(s):**

Dentistry

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**EC market placer (manufacturer, importer or distributor):** Temrex Corporation

**Company/undertaking identification:** Temrex Corporation

**E-mail (competent person):** [Tooth112@earthlink.net](mailto:Tooth112@earthlink.net)

**Information contact:** Tel.: (516) 868-6221 / Fax: (516) 868-5700

**EMERGENCY TELEPHONE:** (800) 645-1226

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## 2. HAZARDS IDENTIFICATION

**Classification:** Class IIA Medical Device

**Other Hazards:** May cause burns.

**Information pertaining to special dangers for human and environment:**

Adverse physicochemical effect(s): N/A

Adverse human health effect(s) and symptom(s): N/A

Adverse environmental effect(s): N/A

Other adverse hazard(s): N/A

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## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Chemical characterization (substances):** Water, Alcohol, Phosphoric Acid, Silica, Polyalkylene Ether, FD & C Dye

**Purity:** N/A

**Synonym(s):** N/A

**Stabilizer(s):** N/A

**Hazard(ous) Impurity(ies):** N/A

**Additional Information:**

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## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Chemical characterization (preparation):** N/A

**Hazard(ous) ingredient(s):**

Chemical Name	EC-No.	REACH-No.	Index-No.	CAS-No.	Classification	Remark
Phosphoric Acid	N/A	N/A	N/A	Confid.	IIA	N/A

**Additional information:** CAS-Numbers are confidential.

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## 4. FIRST AID MEASURES

### General information:

No special precautions specified.

### In case of inhalation:

N/A; no harmful effects recorded.

### In case of skin contact:

Wash immediately with copious amounts of water; contact physician if skin is damaged. Damage to tissues on contact. May cause burns.

### In case of eye contact:

Wash immediately with copious amounts of water; contact physician immediately if pain persists or vision is affected.

### In case of ingestion:

Take solution of Sodium Bicarbonate or, if not available, milk; contact physician immediately. DO NOT induce vomiting. Can cause severe damage to digestive system if swallowed in large amounts

### Self-protection of the first aider:

Read product instructions carefully to avoid injury.

### Information to physician:

Symptoms: Skin or eye irritation, possible burns, upset stomach upon swallowing small amounts, or severe digestive damage and discomfort if swallowed in large amounts.

Hazards: May cause burns or poor vision if contact with skin or eyes occurs. Can cause severe damage to digestive tract if swallowed in large amounts.

Treatment: See Item #4 "FIRST AID MEASURES".

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## 5. FIRE-FIGHTING MEASURES

### Suitable extinguishing media:

N/A – Substance is non-flammable.

### Extinguishing media which must not be used for safety reasons:

N/A – Substance is non-flammable.

### Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases:

N/A – Substance is non-flammable.

### Special protective equipment for fire-fighters:

N/A – Substance is non-flammable.

### Additional information:

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## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions:

Be sure to cover all exposed areas of skin to avoid irritation and possible burns.

### Environmental precautions:

N/A – Substance is not an environmental hazard.

### Methods for cleaning up:

Wash spills with copious amounts of water.

### Additional information:

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## 7. HANDLING AND STORAGE

### Handling

#### **Advice on safe handling:**

Implement routine precautions applicable to acids.

#### **Technical measures:**

**Measures to prevent aerosol and dust generation:** N/A – Does not generate aerosol or dust.

**Measures required to protect the environment:** N/A - Substance is not an environmental hazard.

#### **Precautions against fire and explosion:**

N/A – Substance is non-flammable.

#### **Further information:**

### Storage

#### **Technical measures and storage conditions:**

Store material at room temperature.

#### **Hints on storage assembly:**

N/A – Substance should be stored at room temperature.

#### **Further information on storage conditions:**

Recommended storage temperature is between 65°F and 72°F.

#### **Specific use(s):**

Recommendations(s):

Industrial sector specific solutions:

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## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limit values: N/A

Workplace exposure limit value: N/A

Limit value type(country of origin)	Substance	Workplace exposure limit value		EC-No.	CAS-No.	Recommended monitoring procedures	Source	Remark
		Long-term (8 h)	Short-term (15 min)					
-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-

Biological limit value: N/A

Limit value type (country of origin)	Substance	EC-No.	CAS-No.	Investigation parameter	Source	Remark
-	-	-	-	-	-	-

DNEL/PNEC-value(s): N/A

DNEL		Exposure route	Exposure frequency	Remark
Worker	Consumer			
-	-	Oral	Short Term (acute) Long Term (repeated)	-
-	-	Dermal	Short Term (acute) Long Term (repeated)	
-	-	Inhalative	Short Term (acute) Long Term (repeated)	

PNEC			Exposure frequency	Remark
Water	Soil	Air		
-	-	-	Short Term (acute) Long Term (repeated)	-
-	-	-	Short Term (acute) Long Term (repeated)	
-	-	-	Short Term (acute) Long Term (repeated)	

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## **Exposure controls:**

Avoid contact with skin and eyes. Wear protective gloves, if necessary.

## **Occupational exposure controls:**

If needed, wear protective gloves.

## **Personal protections equipment**

### **Respiratory protection:**

N/A

### **Hand protection:**

Protective gloves are recommended to prevent skin irritation.

### **Eye protection:**

Not required. Safety eyewear may be used for protection against splattering of material.

### **Body protection:**

Take necessary precautions to avoid contact with skin.

### **Environmental exposure controls:**

**Water (incl. sewage plant):** N/A

**Soil:** N/A

**Air:** N/A

**Substance control in consumer or downstream products:** N/A

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Appearance

Physical state: Thick, viscous gel form Color: Green

Odor: None

Important health, safety and environmental information:

### Safety relevant basic data

Parameter	Value	Method	Remark
pH (20 °C):	Acidic	-	
Melting point/range ( °C):	-	-	
Boiling point/range ( °C):	>80°C	-	
Flash point ( °C):	-	-	
Ignition temperature ( °C):	-	-	
Vapor pressure ( °C):	-	-	
Density (g/cm <sup>3</sup> ):	-	-	
Bulk density (kg/m <sup>3</sup> ):	-	-	
Water solubility (20 °C in g/l):	Soluble	-	
Partition coefficient n-Octanol/Water (log Po/w)	-	-	
Viscosity, dynamic (mPa s):	-	-	
Dust explosion hazard:	-	-	
Explosion limits:	-	-	
lower:	-	-	

Substance groups relevant properties: N/A

Other information:



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## 10. STABILITY AND REACTIVITY

### Conditions to avoid:

Avoid temperatures above 72°F.

### Materials to avoid:

N/A

### Hazardous decomposition products:

N/A – There are no hazardous by-products.

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## 11. TOXICOLOGICAL INFORMATION

### Toxicokinetics, metabolism and distribution

N/A

### Acute effects (toxicity tests)

N/A

### Acute toxicity

Acute toxicity (effect dose)	Species	Method	Remark
(oral)	-	-	-
(dermal)	-	-	-
(inhalative)	-	-	-

**Specific symptoms in animal studies:** Gel-Etch Etching Gel is not tested on animals.

In case of ingestion: N/A

In case of skin contact: N/A

In case of inhalation: N/A

In case of eye contact: N/A

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**Irritant and corrosive effects:** N/A

	Species	Evaluation	Method	Remark
Skin	-	-	-	-
Eye	-	-	-	-
Respiratory tract	-	-	-	-

### Sensitization

In case of skin contact: N/A

In case of inhalation: N/A

Remark:

Type of toxicity	Effect dose	Exposure time	Species	Evaluation	Method	Remark
Sub-acute oral	-	-	-	-	-	-
Sub-acute dermal	-	-	-	-	-	-
Sub-acute inhalative	-	-	-	-	-	-
Chronic oral	-	-	-	-	-	-
Chronic dermal	-	-	-	-	-	-
Chronic inhalative	-	-	-	-	-	-

### Repeated dose toxicity (sub-acute to chronic)

N/A – There have not been any recorded cases of toxic effects from repeated doses.

### Carcinogenicity, mutagenicity and toxicity for reproduction

Type of toxicity	Effect dose	Exposure time	Species	Evaluation	Method	Remark
Carcinogenicity	-	-	-	-	-	-
Mutagenicity	-	-	-	-	-	-
Reproductive toxicity	-	-	-	-	-	-

**Summarized evaluation of the CMR properties:** N/A

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## Experiences made in practice

Observations relevant to classification: N/A

Other observations: N/A

General remarks: N/A

## 12. ECOLOGICAL INFORMATION

Ecotoxicity: N/A

Acute toxicity	Time	Species	Method	Evaluation	Remark
-	-	-	-	-	-
-	-	-	-	-	-
-	-	-	-	-	-

Mobility: N/A

Known or predicted distribution to environmental compartments: N/A

Surface tension: N/A

Value	at ° C	Concentration	Method	Remark
-	-	-	-	-
-	-	-	-	-
-	-	-	-	-

## Absorption/Desorption

Transport	A/D coefficient Henry constant	log K <sub>oc</sub>	Volatility rate	Method	Hysteresis	Remark
Soil-water	-	-	-	-	-	-
Water-air	-	-	-	-	-	-
Soil-air	-	-	-	-	-	-

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## Persistence and degradability

### Abiotic Degradation

Half-time		Method	Evaluation	Remark
Sea-water	-	-	-	-
Fresh-water	-	-	-	-
Air	-	-	-	-
Soil	-	-	-	-

### Physical- and photo-chemical elimination

Type of elimination	Half-time	Method	Evaluation	Remark
Ozonolyse	-	-	-	-
Oxidation	-	-	-	-
Photo-oxidation	-	-	-	-
De-chlorination	-	-	-	-
Photo-mineralization	-	-	-	-

Biodegradation: N/A

Degradation rate (%)	Time (d)	Method	Evaluation	Remark
-	-	-	-	-
-	-	-	-	-
-	-	-	-	-

### Bioaccumulative potential

Partition coefficient n-octanol/water (log KO/W): N/A

Value	Concentration	pH	° C	Method	Evaluation	Remark
-	-	-	-	-	-	-
-	-	-	-	-	-	-
-	-	-	-	-	-	-

Bioconcentration factor (BCF): N/A

Value	Species	Method	Evaluation	Remark
-	-	-	-	-
-	-	-	-	-
-	-	-	-	-

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Long-term – Ecotoxicity: N/A

Toxicity type	Effect dose		Species	Method	Evaluation	Remark
-	-	-	-	-	-	-
-	-	-	-	-	-	-
-	-	-	-	-	-	-
-	-	-	-	-	-	-
-	-	-	-	-	-	-

Results of PBT assessment: N/A

Other adverse effects: N/A

Overall evaluation: N/A

## 13. DISPOSAL CONSIDERATIONS

Appropriate disposal / Product: Dilute with water.

Waste code(s) / waste designation(s) according to EWC / AVV: N/A

Appropriate packaging: No special methods

Additional information:

## 14. TRANSPORT INFORMATION

Land transport (ADR/RID/GGVSE):

Class: IIA

Classification Code: None

UN-No.: N/A

Packing group: N/A

Hazard label: None

Proper Shipping Name: Gel-Etch Etching Gel

Sea transport (IMDG-Code/GGVSee):

Class: IIA

UN-No.: N/A

Packing group: N/A

EmS: N/A

Proper Shipping Name: Gel-Etch Etching Gel

Marine Pollutant: None

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**Air transport (ICAO-IATA/DGR):**  
Class: **IIA**  
UN-No.: **N/A**  
Packing group: **N/A**  
Proper Shipping Name: **Gel-Etch Etching Gel**

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## 15. REGULATORY INFORMATION

**EU regulations**

**Chemical Safety Assessment:** **N/A**

**Labelling**

**Hazard(s) symbol(s) and hazard(s) statement(s):** **None**

**R-Phrases:** **N/A**

**S-Phrases:** **N/A**

**Special provisions concerning the labeling of certain preparations:** **N/A**

**Authorizations and/or restrictions on use:** **N/A**

**Other EU regulations:** **None**

**Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline):** **N/A**

**National regulations (Germany)**

**Restrictions of occupation:** **None**

**Störfallverordnung (12. BImSchV):** **N/A**

**Wassergefährdungsklasse (water hazard class):** **N/A**

**Technische Anleitung Luft (TA-Luft):** **N/A**

**Other regulations, restrictions and prohibition regulations:** **None**

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## 16. OTHER INFORMATION

**Relevant R-phrases (Number and full text):** None

**Training Instructions:** N/A

**Further information:** None

**Data Sources:** None

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## ANNEX

Will be published as soon as structure is available.