

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**

Revision Date: **01/04/04**

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

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

Company/undertaking identification: Temrex Corporation

E-mail (competent person): 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

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:

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:

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.

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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)	

Water	PNEC		Exposure frequency	Remark
	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 ³):	-	-	
Bulk density (kg/m ³):	-	-	
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.

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 _{oc}	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**

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

ANNEX

Will be published as soon as structure is available.