

Safety Data Sheet

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

Trade name: Copalite Dental Cavity Varnish

Material.-No.: **OMB #1218-0072** Version 1.0/EN

Print Date: January 10th 2014

Specification:

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

Identification of the substance or preparation:

Copalite Cavity Dental Varnish

REACH Registration No: N/A (Grandfathered product)

Use of the substance/preparation:

Identified use(s):

Industry: Dental Varnish

Professional: Used during minor Dental Cleaning and Restorative procedures

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:

Dental Varnishing procedure

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: See section 14 for details

Other Hazards:

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): Ethyl Ether, Chloroform, Resin

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):

Hazard(ous) ingredient(s):

Chemical Name	EC-No.	REACH-No.	Index-No.	CAS-No.	Classification	Remark
Ethyl Ether				60297	B	
Chloroform				67663	D	

Additional information:

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4. FIRST AID MEASURES

General information:

Ether is volatile. Capable of producing CO and CO₂ during inflammation

In case of inhalation: Induce Vomiting with Ipecac syrup

In case of skin contact: Wash off immediately

In case of eye contact: Move patient to safe area, and Flush eyes with water for 15 minutes

In case of ingestion: Induce Vomiting with Ipecac syrup

Self-protection of the first aider: Wear Latex gloves to avoid exposure

Information to physician:

Symptoms: N/A

Hazards: N/A

Treatment N/A

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5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:

Open windows and exhaust fans

Extinguishing media which must not be used for safety reasons:

N/A

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

Wipe all spilt surfaces and areas with isopropyl alcohol.

Special protective equipment for fire-fighters:

N/A

Additional information:

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: N/A

Environmental precautions: Follow OSHA regulations

Methods for cleaning up: See above sections (use Isopropyl alcohol)

Additional information:

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7. HANDLING AND STORAGE

Handling

Advice on safe handling:

Due to evaporation, keep bottle tightly sealed during use and transport

Technical measures:

Measures to prevent aerosol and dust generation:

Measures required to protect the environment:

Precautions against fire and explosion:

Keep away from flames, Keep containers tightly sealed

Further information:

Storage

Store at room temperatures. See section 14 for more information

Technical measures and storage conditions:

Class # 3, UN Packing group II

Hints on storage assembly:

N/A

Further information on storage conditions:

N/A

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:

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
BGW (DE)						

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: N/A

Occupational exposure controls: N/A

Personal protections equipment

Respiratory protection: Mask/ Mouth protector

Hand protection: Latex gloves

Eye protection: Plastic Goggles

Body protection: Lab overcoat

Environmental exposure controls:

Water (incl. sewage plant):

Soil:

Air:

Substance control in consumer or downstream products:



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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state:

Color:

Odor:

Important health, safety and environmental information:

Safety relevant basic data:

Parameter	Value	Method	Remark
pH (20 °C):	-		
Melting point/range (°C):	n/a Liquid form		
Boiling point/range (°C):	39.3 degrees C		
Flash point (°C):	-45 degrees C		
Ignition temperature (°C):	-		
Vapor pressure (°C):	760 mm		
Density (g/cm ³):	-		
Bulk density (kg/m ³):	-		
Water solubility (20 °C in g/l):	Insoluble		
Partition coefficient n-Octanol/Water (log Po/w)			
Viscosity, dynamic (mPa s):			
Dust explosion hazard:			
Explosion limits:			
lower:			

Substance groups relevant properties:

Other information:



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10. STABILITY AND REACTIVITY

Conditions to avoid:

Avoid temperatures above 74 degrees Fahrenheit

Materials to avoid: N/A

Hazardous decomposition products: N/A

11. TOXICOLOGICAL INFORMATION

Toxicokinetics, metabolism and distribution

Acute effects (toxicity tests)

Acute toxicity

Acute toxicity (effect dose)	Species	Method	Remark
LD50 (oral)	Rat		
LD50 (dermal)	Rabbit		
LC50 (inhalative)	Rat		

Specific symptoms in animal studies:

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:

	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)

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:



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Experiences made in practice

Observations relevant to classification:

Other observations:

General remarks:

12. ECOLOGICAL INFORMATION

Ecotoxicity: N/A

Acute toxicity	Time	Species	Method	Evaluation	Remark
LC50	96 h	Fish			
EC50	48 h	Daphnia			
IC50	72 h	Algae			

Mobility: N/A

Known or predicted distribution to environmental compartments:

Surface tension:

Value	at ° C	Concentration	Method	Remark

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Persistence and degradability N/A

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:

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

Bioaccumulative potential

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

Value	Concentration	pH	° C	Method	Evaluation	Remark

Bioconcentration factor (BCF):

Value	Species	Method	Evaluation	Remark

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Long-term – Ecotoxicity: N/A

Toxicity type	Effect dose	Species	Method	Evaluation	Remark
Sub-acute	NOEC	Fish			
	NOEC	Daphnia			
	NOEC	Bird			
Sub-chronic					
Chronic fish					

Results of PBT assessment:

Other adverse effects:

Overall evaluation:

13. DISPOSAL CONSIDERATIONS

Appropriate disposal / Product: OSHA regulations

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

Appropriate packaging: N/A

Additional information:

14. TRANSPORT INFORMATION

Land transport (ADR/RID/GGVSE):

Class: **3**

Classification Code:

UN-No.: **1993**

Packing group: **II**

Hazard label: 2 (Hazardous)

Proper Shipping Name: Copalite Dental Cavity varnish

Sea transport (IMDG-Code/GGVSee): SAME AS ABOVE

Class:

UN-No.:

Packing group:

EmS:

Proper Shipping Name:

Marine Pollutant:

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Air transport (ICAO-IATA/DGR):

Class:

UN-No.:

Packing group:

Proper Shipping Name:

15. REGULATORY INFORMATION

EU regulations

Chemical Safety Assessment: N/A

Labelling N/A

Hazard(s) symbol(s) and hazard(s) statement(s): N/A

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: N/A

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

National regulations (Germany) N/A

Restrictions of occupation: N/A

Störfallverordnung (12. BImSchV): N/A

Wassergefährdungsklasse (water hazard class): N/A

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

Other regulations, restrictions and prohibition regulations: N/A

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16. OTHER INFORMATION

Relevant R-phrases (Number and full text): N/A

Training Instructions: N/A

Further information: N/A

Data Sources: N/A

ANNEX

Will be published as soon as structure is available.