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Version US-EN-Rev 1

Reviewed on 02/08/2021

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- · Product identifier
- · Trade name: G-CEM ONE™ ADHESIVE ENHANCING PRIMER
- Relevant identified uses of the substance or mixture and uses advised against Dental material

The product is intended for professional use.

- To avoid risks for humans and environment obtain instructions.
- · Application of the substance / the mixture Dental bonding material
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

GC America Inc. 3737 W. 127th Street Alsip, IL 60803 USA

SDS.gcamerica@gc.dental

· Information department: Regulatory Affairs

Emergency telephone number:

During normal opening times (Monday–Friday 8:00 AM–5:00 PM Central Time): +1 (708) 597-0900 Transportation (CHEMTREC®) Emergency Telephone No. +1 (800) 424-9300

2 Hazard(s) identification

Classification of the substance or mixture		
Flam. Liq. 2 H225	Highly flammable liquid and vapor.	
Skin Irrit. 2 H315	Causes skin irritation.	
Eye Irrit. 2A H319	Causes serious eye irritation.	
STOT SE 3 H335-H3	36 May cause respiratory irritation. May cause drowsiness or dizziness.	
STOT RE 1 H372	Causes damage to organs through prolonged or repeated exposure.	

• Additional information:

The information provided is in regards to the toxicity and hazard rating(s) of the individual component(s) in the formulation. The associated risk(s) depends on the route(s) of exposure. The hazard rating system is based entirely on the existence of the risk(s) and does not take into account the likelihood of reduced risk(s) through proper usage and handling.

Avoid use of this product in patients with known allergies to methacrylate monomer, methacrylate polymer, or ethyl alcohol (ethanol).

· Label elements

· GHS label elements

Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012. The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



· Signal word Danger

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(Contd. of page 1) · Hazard-determining components of labeling: ethyl alcohol dimethacrylate** phosphoric acid ester monomer** butylated hydroxytoluene Hazard statements Highly flammable liquid and vapor. Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. May cause drowsiness or dizziness. Causes damage to organs through prolonged or repeated exposure. Precautionary statements Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Do not breathe dust/fume/gas/mist/vapors/spray. Wear protective gloves/protective clothing/eye protection/face protection. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Store locked up. Dispose of contents/container in accordance with local/regional/national/international regulations. · Hazard(s) not otherwise classified (HNOC): Exothermic polymerization. · Additional information: 39 % of the mixture consists of component(s) of unknown toxicity.

- · Other hazards
- Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

· Chemical characterization: Mixtures

• **Description:** Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:		
CAS: 64-17-5	ethyl alcohol	25 – < 50%
	dimethacrylate**	10 – < 25%
	phosphoric acid ester monomer**	5 – < 10%
CAS: 128-37-0	butylated hydroxytoluene	1 – < 2.5%
	initiator**	1 – < 2.5%

· Additional information:

Concentrations of dangerous components are expressed in percent by weight (% w/w).

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

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4 First-aid measures

Description of first aid measures

· General information:

Immediately remove any clothing soiled by the product.

- If symptoms persist consult doctor.
- After inhalation:

Supply fresh air; consult doctor in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Immediately wash with water and soap and rinse thoroughly. Rinse with warm water.

Seek medical treatment.

If symptoms persist consult doctor.

After eye contact:

Protect unharmed eye.

Rinse opened eye for several minutes under running water. Then consult a doctor.

· After swallowing:

Rinse out mouth and then drink plenty of water.

- If symptoms persist consult doctor.
- · Information for doctor:
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire fighting measures that suit the environment.

- For safety reasons unsuitable extinguishing agents: Water with full jet
- Special hazards arising from the substance or mixture In case of fire, the following can be released:

Sulphur dioxide (SO2) Carbon monoxide (CO)

- Carbon dioxide
- Advice for firefighters
- Protective equipment: Wear self-contained respiratory protective device.
- · Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Remove persons from danger area. Keep away from ignition sources Avoid contact with the eyes and skin. Wear protective clothing.

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 Environmental precautions: Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system. Do not allow to penetrate the ground/soil. In case of seepage into the ground inform responsible authorities. Methods and material for containment and cleaning up: Ensure adequate ventilation.
Inform respective authorities in case of seepage into water course or sewage system. Do not allow to penetrate the ground/soil. In case of seepage into the ground inform responsible authorities. Methods and material for containment and cleaning up: Ensure adequate ventilation.
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In case of seepage into the ground inform responsible authorities. Methods and material for containment and cleaning up: Ensure adequate ventilation.
Methods and material for containment and cleaning up: Ensure adequate ventilation.
Ensure adequate ventilation.
Absorb liquid components with liquid-binding material.
Dispose of the collected material according to regulations.
Reference to other sections
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
• Protective Action Criteria for Chemicals
Protective Action Criterion (PAC); Protective Action Criteria (PACs); Lower Explosive Limit (LEL)
* indicates the PAC value is between 10% and up to 50% of the LEL (10% LEL \leq PAC $<$ 50% LEL).
** indicates the PAC value is between 50% and up to 100% of the LEL (50% LEL \leq PAC < 100% LEL).
*** indicates the PAC value is at 100% or more of the LEL (PAC \geq LEL).
excerpt from Introduction to PAC Table 2 – PAC Rev. 29 – May 2016
· PAC-1:
CAS: 64-17-5 ethyl alcohol 1,800 ppm
· PAC-2:
CAS: 64-17-5 ethyl alcohol 3300* ppm
· PAC-3:
CAS: 64-17-5 ethyl alcohol 15000* ppm

7 Handling and storage

· Handling:

Precautions for safe handling

Prevent formation of aerosols.

Ensure good ventilation/exhaustion at the workplace.

Observe instructions for use.

Avoid contact with the eyes and skin.

Use caution when opening. The product is a highly flammable liquid and vapor; keep away from heat, hot surfaces, sparks, flames and other ignitions sources. Use with adequate ventilation. Do not ingest or breathe vapor. Personal Protective Equipment (PPE) such as gloves and safety eyewear are always to be worn. Check bottle with liquid before using. Make sure that upon removal of cap, the bottle opening has no obstructions. Some bottles may contain an insert (as a seal). The insert must be in the cap and not obstructing opening.

In case of contact, flush eyes with water for at least 15 minutes. Get prompt medical attention. If overcome by vapor, move to fresh air. If breathing is difficult, administer oxygen and seek medical attention. If swallowed, dilute by giving water to drink and seek medical attention. In case of contact with skin wash thoroughly with soap and water. Store securely. Store in a well ventilated place. Keep cool. Dispose of all waste according to local regulations.

Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Do not spray on a naked flame or any incandescent material.

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Conditions for safe storage, including any incompatibilities
Storage:
Requirements to be met by storerooms and receptacles: Store in a cool location. Store only in unopened original receptacles.
Information about storage in one common storage facility: Store away from foodstuffs.
Further information about storage conditions: Protect from heat and direct sunlight. Keep receptacle tightly sealed. Observe instructions for use / storage. Store in cool, dry conditions in well sealed receptacles. Store in a cool place.
Specific end use(s) No further relevant information available.
8 Exposure controls/personal protection
Additional information about design of technical systems: No further data; see item 7.

· Control parameters

Components with limit values that require monitoring at the workplace:

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

CAS: 64-17-5 ethyl alcohol

PEL Long-term value: 1900 mg/m³, 1000 ppm

REL Long-term value: 1900 mg/m³, 1000 ppm

TLV Short-term value: 1880 mg/m³, 1000 ppm

Regulatory information

PEL: Guide to Occupational Exposure Values (OSHA PELs)

REL: Guide to Occupational Exposure Values (NIOSH RELs)

TLV: Guide to Occupational Exposure Values (TLV)

- Additional information: The lists that were valid during the creation were used as basis.
- Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Breathing equipment:



Suitable respiratory protective device recommended.

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• Protection of hands:



Protective gloves

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

• Eye protection:



Safety glasses

Information on basic physical and	chemical properties
General Information	
Appearance: Form:	Liquid
Color:	Liquid According to product specification
Odor:	Characteristic
Odor threshold:	Not determined.
pH-value:	Not determined.
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	77 °C (170.6 °F)
Flash point:	11 °C (51.8 °F)
Flammability (solid, gaseous):	Not applicable.
Ignition temperature:	Undetermined.
Decomposition temperature:	Not determined.
Auto igniting:	Product is not self-igniting.
Danger of explosion:	Heating may cause an explosion. Product is not explosive. However, formation of explosive air vapor mixtures are possible.
Explosion limits:	
Lower:	3.5 Vol %
Upper:	15 Vol %
Vapor pressure:	Not determined.

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Safety Data Sheet acc. to OSHA HCS 29 CFR 1910.1200

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Density:	Not determined.	
Relative density	Not determined.	
Vapor density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
Water:	Soluble.	
Partition coefficient (n-octano	I/water): Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
Solvent content:		
Organic solvents:	29.0 %	
Water:	30.0 %	
VOC content:	29.00 %	
Solids content:	3.0 %	
Other information	No further relevant information available.	

10 Stability and reactivity

- · Reactivity Danger of polymerization.
- · Chemical stability Stable at ambient temperature.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions Danger of receptacles bursting because of high vapor pressure if heated. Spontaneous polymerization can be caused in unstabilized product e.g. by ambient heat. Exothermic polymerization. · Conditions to avoid Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
- · Incompatible materials: Reacts with peroxides and other radical forming substances. Reacts with amines. Reacts with heavy metals.
- Hazardous decomposition products: Carbon dioxide Carbon monoxide

11 Toxicological information · Information on toxicological effects · Acute toxicity: · LD/LC50 values that are relevant for classification: CAS: 128-37-0 butylated hydroxytoluene LD50 10700 mg/kg (guinea pig) Oral 1040 mg/kg (mouse) > 2930 mg/kg (rat (f+m)) (Contd. on page 8)

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(Contd. of page 7) Dermal LD50 > 2000 mg/kg (rat (f+m)) · Primary irritant effect: · on the skin: Irritant to skin and mucous membranes. · on the eye: Irritating effect. · Sensitization: No sensitizing effects known. · Symptoms related to the physical, chemical and toxicological characteristics: No further relevant information available. · Subacute to chronic toxicity: No further relevant information available. · Numerical measures of toxicity: ATEmix (Oral) is 5 200 mg/kg bodyweight. ATEmix (Dermal) is >2 229 mg/kg bodyweight. ATEmix is the acute toxicity estimate of the mixture. · Additional toxicological information: The product shows the following dangers according to internally approved calculation methods for preparations: Irritant Carcinogenic categories · IARC (International Agency for Research on Cancer) ethyl alcohol 1 butylated hydroxytoluene 3 · NTP (National Toxicology Program) None of the ingredients is listed. **OSHA-Ca** (Occupational Safety & Health Administration) None of the ingredients is listed. Carcinogenic categories' legend: IARC Group 1: The agent is carcinogenic to humans. IARC Group 2A: The agent is probably carcinogenic to humans. IARC Group 2B: The agent is possibly carcinogenic to humans. IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans. IARC Group 4: The agent is probably not carcinogenic to humans. NTP K: Known to be human carcinogen. NTP R: Reasonably anticipated to be human carcinogen. Additional carcinogenic information: The substance, ethyl alcohol, also known as ethanol, is listed by IARC as a Group 1 carcinogen but in alcoholic beverage consumption. IARC Volume 100E (2012) "Personal Habits and Indoor Combustions" stated in its monograph "Consumption of Alcoholic Beverages" the following evaluation: "Ethanol in alcoholic beverages is carcinogenic to humans (Group 1)." GC products are not consumable alcoholic beverages. · Repeated dose toxicity. No further relevant information available. · CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction) · Germ cell mutagenicity No further relevant information available. · Carcinogenicity No further relevant information available. · Reproductive toxicity No further relevant information available. · Specific target organ toxicity - single exposure No further relevant information available. • Specific target organ toxicity - repeated exposure No further relevant information available. · Aspiration hazard No further relevant information available.

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Toxicity	
Aquatic toxicity:	
CAS: 128-37-0 butylated hydro	oxytoluene
NOEC-value Ecol. other effects	0.07 mg/l (daphnia magna) 21 day, reproductive effects
Persistence and degradability	No further relevant information available.
Behavior in environmental sy	
	further relevant information available.
Mobility in soil No further relev	ant information available.
Ecotoxical effects:	
Remark: Harmful to fish	
Additional ecological informa General notes:	tion:
	regulation, AwSV) (Self-assessment): clearly hazardous to water
	ound water, water course or sewage system.
	small quantities leak into the ground.
Harmful to aquatic organisms	
Results of PBT and vPvB ass	essment
PBT: Not applicable.	
vPvB: Not applicable.	

13 Disposal considerations

· Waste treatment methods

· Recommendation:

Dispose of contents / container in accordance with local / regional / national / international regulations.

- · Uncleaned packagings:
- **Recommendation:** Disposal must be made according to official regulations.
- Recommended cleansing agent: Water, if necessary with cleansing agents.

UN-Number	
DOT, ADR, IMDG, IATA	UN1170
UN proper shipping name	
DOT	Ethanol solutions
ADR	1170 ETHANOL SOLUTION (ETHYL ALCOHO
	SOLUTION)
IMDG	ETHANOL SOLUTION (ETHYL ALCOHO
	SOLUTION)
ΙΑΤΑ	ETHANOL SOLUTION

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Transport hazard class(es)	
DOT	
PLANEE EXIT	
Class Label	3 Flammable liquids 3
ADR	
Class	3 (F1) Flammable liquids
Label	3
· IMDG, IATA	
· Class · Label	3 Flammable liquids 3
Packing group	6
DOT, ADR, IMDG, IATA	II
Environmental hazards:	Not applicable.
Special precautions for user	Warning: Flammable liquids
 Hazard identification number (Kemler code EMS Number: 	e): 33 F-E,S-D
Stowage Category	A
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
·IMDG	
Limited quantities (LQ)	1L Order 50
Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
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ACTIVE

· UN "Model Regulation":

UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II

15 Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture
 SARA (Superfund Amendments and Reauthorization Act)

· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

 Section 313 (Specific toxic chemical listings): initiator**
 TSCA (Toxic Substances Control Act): water, distilled ethyl alcohol

dimethacrylate** ACTIV	
	Έ
butylated hydroxytoluene ACTIV	Έ
initiator** ACTIV	Έ

• Additional information:

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

· Hazardous Air Pollutants

None of the ingredients is listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

The substance ethyl alcohol, also known as ethanol, is on California's Proposition 65 list of "Chemicals Known to the State To Cause Cancer or Reproductive Toxicity" as a developmental toxicant but as "ethyl alcohol in alcoholic beverages." GC products are not consumable alcoholic beverages.

ethyl alcohol

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· EPA carcinogenic categories' legend:

EPA weight-of-evidence (WoE): official codes and categories from EPA's 1986 guidelines and unofficial, derived codes from EPA's standard hazard descriptors from 1996, 1999, and 2005 guidelines A: human carcinogen (1986)

B1: probable human carcinogen - based on limited evidence of carcinogenicity in humans (1986)

B2: probable human carcinogen – based on sufficient evidence of carcinogenicity in animals (1986)

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(Contd. of page 11) C: possible human carcinogen (1986) D: not classifiable as to human carcinogenicity (1986) E: evidence of non-carcinogenicity for humans (1986) CaH: carcinogenic to humans CBD: carcinogenic potential cannot be determined I: data are inadequate for an assessment of human carcinogenic potential II: inadequate information to assess carcinogenic potential K/L: known/likely human carcinogen L: likely to be carcinogenic to humans NL: not likely to be carcinogenic to humans S: suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential SC: suggestive evidence of carcinogenic potential · TLV (Threshold Limit Value) ethyl alcohol A3 butylated hydroxytoluene A4 · ACGIH carcinogenic categories' legend: A1: confirmed human carcinogen A2: suspected human carcinogen A3: confirmed animal carcinogen with unknown relevance to humans A4: not classifiable as a human carcinogen A5: not suspected as a human carcinogen · NIOSH-Ca (National Institute for Occupational Safety and Health) None of the ingredients is listed. **GHS** label elements Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012. The product is classified and labeled according to the Globally Harmonized System (GHS). · Hazard pictograms · Signal word Danger · Hazard-determining components of labeling: ethyl alcohol dimethacrylate** phosphoric acid ester monomer** butylated hydroxytoluene · Hazard statements Highly flammable liquid and vapor. Causes skin irritation. Causes serious eve irritation. May cause respiratory irritation. May cause drowsiness or dizziness. Causes damage to organs through prolonged or repeated exposure. · Precautionary statements Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Do not breathe dust/fume/gas/mist/vapors/spray. Wear protective gloves/protective clothing/eye protection/face protection. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Store locked up. (Contd. on page 13)

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Dispose of contents/container in accordance with local/regional/national/international regulations. • Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

Department issuing SDS: Regulatory Affairs Contact:	
Regulatory Affairs	
Telephone No. +1 (708) 597-0900	
SDS.gcamerica@gc.dental	
Date of preparation / last revision 02/08/2021 / -	
Abbreviations and acronyms:	
GHS: Globally Harmonized System of Classification and Labelling of Chemicals	
HCS: Hazard Communication Standard (USA)	
MSDS: Material Safety Data Sheet	
SDS: Safety Data Sheet ECHA: European Chemicals Agency	
OSHA: Occupational Safety and Health Administration (USA)	
PAC: Protective Action Criterion (USA)	
PACs: Protective Action Criteria (USA)	
HNOC: Hazard Not Otherwise Classified (USA)	
LEL: Lower Explosive Limit	
UEL: Upper Explosive Limit	
OSHA-Ca: Occupational Safety and Health Administration – Carcinogens or potential carcinogens regulated	d (USA)
NIOSH-Ca: National Institute for Occupational Safety and Health – Carcinogen List (USA) NIOSH: National Institute for Occupational Safety and Health (USA)	
TSCA: Toxic Substances Control Act (USA)	
AwSV: Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on fa	acilities for handli
substances that are hazardous to water) (Germany)	
NOEC: No Observed Effect Concentration	
ADR: Accord européen relatif au transport international des marchandises dangereuses par route (E	European Agreeme
concerning the International Carriage of Dangerous Goods by Road)	
IMDG Code: International Maritime Dangerous Goods Code	
DOT: Department of Transportation (USA)	
IATA: International Air Transport Association CAS: Chemical Abstracts Service (division of the American Chemical Society)	
VOC: Volatile Organic Compounds (USA, EU)	
LC50: Lethal concentration, 50 percent	
LD50: Lethal dose, 50 percent	
PBT: Persistent, Bioaccumulative and Toxic	
vPvB: very Persistent and very Bioaccumulative	
TLV: Threshold Limit Value	
PEL: Permissible Exposure Limit	
REL: Recommended Exposure Limit	
Flam. Liq. 2: Flammable liquids – Category 2 Skin Irrit. 2: Skin corrector/irritation – Category 2	
Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A	
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3	
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1	
Sources	
Manufacturers' MSDSs/SDSs	
• OSHA (https://www.osha.gov/dts/chemicalsampling/toc/chmcas.html)	
• PubChem (https://pubchem.ncbi.nlm.nih.gov/)	
• ECHA (http://echa.europa.eu/)	
EnviChem (www.echemportal.org)	
Notes:	
CAS Registry Number® is a Registered Trademark of the American Chemical Society.	
CHEMTREC® is a registered service mark of the American Chemistry Council, Inc.	
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· Disclaimer:

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