

SAFETY DATA SHEET

SYSTEM 1+ADHESIVE

Section 1. Identification

Product identifier : SYSTEM 1+ADHESIVE

Product code : Not available.

Other means of : Not available.

identification

Product type : Liquid.

Relevant identified uses of the substance or mixture and uses advised against

Product use : Dental product: Adhesive.

Area of application : Professional applications.

Manufacturer : Ormco Corporation

1332 S. Lone Hill Avenue Glendora, CA 91740-5339 Telephone no.: 1-800-854-1741

e-mail address of person responsible for this SDS

: OrmcoCustCare@sybrondental.com

Emergency telephone number (with hours of operation)

: CHEMTREC® (24 hours) U.S.: 1-800-424-9300 International: +1-703-527-3887

Section 2. Hazard identification

Classification of the substance or mixture

: H330 ACUTE TOXICITY (inhalation) - Category 2

H315 SKIN IRRITATION - Category 2 H319 EYE IRRITATION - Category 2A

H334 RESPIRATORY SENSITIZATION - Category 1

H317 SKIN SENSITIZATION - Category 1A

H335 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory

tract irritation) - Category 3

GHS label elements

Hazard pictograms







Signal word : Danger

Hazard statements : H330 - Fatal if inhaled.

H319 - Causes serious eye irritation.

H315 - Causes skin irritation.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317 - May cause an allergic skin reaction. H335 - May cause respiratory irritation.

Precautionary statements

Prevention: P280 - Wear protective gloves. Wear eye or face protection.

P284 - Wear respiratory protection.

P271 - Use only outdoors or in a well-ventilated area.

P260 - Do not breathe vapor.

P264 - Wash hands thoroughly after handling.

P272 - Contaminated work clothing should not be allowed out of the workplace.

Section 2. Hazard identification

Response

: P304 + P340 + P310 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or physician. P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or physician.

P302 + P352 + P362+P364 - IF ON SKIN: Wash with plenty of soap and water.

Take off contaminated clothing and wash it before reuse.

P333 + P313 - If skin irritation or rash occurs: Get medical attention.

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 - If eye irritation persists: Get medical attention.

Storage

: P405 - Store locked up.

Disposal

: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

Supplemental label elements

: Percentage of the mixture consisting of ingredient(s) of unknown oral toxicity: 37.4% Percentage of the mixture consisting of ingredient(s) of unknown dermal toxicity: 76.

Percentage of the mixture consisting of ingredient(s) of unknown inhalation toxicity: 100%

Health effects are based on the uncured material.

Section 3. Composition/information on ingredients

Substance/mixture

: Mixture

Other means of identification

: Not available.

Ingredient name	% (w/w)	CAS number
Poly(oxy-1,2-ethanediyl), α,α' -[(1-methylethylidene)di-4,1-phenylene]bis [ω -[(2-methyl-1-oxo-2-propen-1-yl)oxy]-	>18.9	41637-38-1
2,2'-ethylenedioxydiethyl dimethacrylate	>16.207	109-16-0
4,4'-methylenedi(cyclohexyl isocyanate)	8.7575	5124-30-1
Silica, amorphous, fumed, crystfree	7	112945-52-5
Silane, dichlorodimethyl-, reaction products with silica	7	68611-44-9
2-hydroxyethyl methacrylate	>4.6373	868-77-9
Polyol	4.495	-
dibenzoyl peroxide	3	94-36-0
2,6-di-tert-butyl-p-cresol	1.0093	128-37-0

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First-aid measures

Description of necessary first aid measures

Eye contact

: No special measures are required. In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if symptoms occur.

Inhalation

: No special measures required. If inhaled, remove to fresh air. Get medical attention if symptoms occur.

Skin contact

: No special measures required. In case of contact, immediately flush skin with plenty of water. Get medical attention if symptoms occur.

Ingestion

: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Get medical attention if adverse health effects persist or are severe.

Most important symptoms/effects, acute and delayed

Section 4. First-aid measures

Potential acute health effects

Eye contact : Causes serious eye irritation.

Fatal if inhaled. May cause respiratory irritation. May cause allergy or asthma Inhalation

symptoms or breathing difficulties if inhaled.

Skin contact : Causes skin irritation. May cause an allergic skin reaction.

: No known significant effects or critical hazards. Ingestion

Over-exposure signs/symptoms

Eye contact : Adverse symptoms may include the following:

> pain or irritation watering redness

Inhalation : Adverse symptoms may include the following:

respiratory tract irritation

coughing

wheezing and breathing difficulties

asthma

Skin contact Adverse symptoms may include the following:

> irritation redness

Ingestion : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed.

The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments : No specific treatment.

Protection of first-aiders : In case of major fire and large quantities: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still

present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it,

or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing

media

: Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing

media

: Do not use water jet.

Specific hazards arising from the chemical

Hazardous thermal

: In a fire or if heated, a pressure increase will occur and the container may burst.

carbon dioxide decomposition products

: Decomposition products may include the following materials:

carbon monoxide nitrogen oxides

halogenated compounds metal oxide/oxides

Special protective actions for fire-fighters

: In case of major fire and large quantities: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Section 5. Fire-fighting measures

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

: Low release. For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely

For emergency responders: Low release. See also the information in "For non-emergency personnel".

Environmental precautions

: Low release. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill

: Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

Large spill

: Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

Section 7. Handling and storage

Precautions for safe handling

Protective measures

No special measures are required for small quantities under normal and intended conditions of product use. For professional use only. Put on appropriate personal protective equipment (see Section 8). Handle with care and dispose in a safe manner.

Advice on general occupational hygiene Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

including any incompatibilities

Conditions for safe storage, : Do not store above the following temperature: 23°C (73.4°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
4,4'-methylenedi(cyclohexyl isocyanate)	CA Alberta Provincial (Canada, 4/2009). 8 hrs OEL: 0.005 ppm 8 hours. 8 hrs OEL: 0.05 mg/m³ 8 hours. CA British Columbia Provincial (Canada, 7/2016). TWA: 0.005 ppm 8 hours. C: 0.01 ppm CA Ontario Provincial (Canada, 7/2015). TWA: 0.01 ppm 8 hours. TWA: 0.05 mg/m³ 8 hours.

dibenzoyl peroxide

2,6-di-tert-butyl-p-cresol

Section 8. Exposure controls/personal protection

CA Quebec Provincial (Canada, 1/2014). Skin sensitizer.

TWAEV: 0.005 ppm 8 hours. TWAEV: 0.054 mg/m³ 8 hours.

CA Saskatchewan Provincial (Canada, 7/2013).

STEL: 0.015 ppm 15 minutes. TWA: 0.005 ppm 8 hours.

CA Alberta Provincial (Canada, 4/2009). Skin sensitizer.

8 hrs OEL: 5 mg/m³ 8 hours.

CA British Columbia Provincial (Canada, 7/2016).

TWA: 5 mg/m³ 8 hours.

CA Ontario Provincial (Canada, 7/2015).

TWA: 5 mg/m³ 8 hours.

CA Quebec Provincial (Canada, 1/2014).

TWAEV: 5 mg/m³ 8 hours.

CA Saskatchewan Provincial (Canada, 7/2013).

STEL: 10 mg/m³ 15 minutes. TWA: 5 mg/m³ 8 hours.

CA Saskatchewan Provincial (Canada, 7/2013).

STEL: 4 mg/m³ 15 minutes. Form: Inhalable fraction and vapour

TWA: 2 mg/m³ 8 hours. Form: Inhalable fraction and vapour

CA Ontario Provincial (Canada, 7/2015). TWA: 2 mg/m³ 8 hours. Form: Inhalable fraction and vapour.

CA British Columbia Provincial (Canada, 7/2016).

TWA: 2 mg/m³ 8 hours. Form: Inhalable vapour and aerosol

CA Alberta Provincial (Canada, 4/2009). Skin sensitizer.

8 hrs OEL: 10 mg/m³ 8 hours.

CA Quebec Provincial (Canada, 1/2014).

TWAEV: 10 mg/m³ 8 hours.

Appropriate engineering controls

Environmental exposure controls

- : No special measures are required for small quantities under normal and intended conditions of product use.
- No special measures are required for small quantities under normal and intended conditions of product use.

<u>Individual protection measures</u>

Hygiene measures

: No special measures are required for small quantities under normal and intended conditions of product use.

Eye/face protection

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection

Section 8. Exposure controls/personal protection

Hand protection

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection

: No special measures are required for small quantities under normal and intended conditions of product use.

Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection

: No special measures are required for small quantities under normal and intended conditions of product use.

Section 9. Physical and chemical properties

Appearance

Physical state : Liquid. [Paste.]

Color : Clear.

Odor : Fruity ester-like [Slight]

: Not available. **Odor threshold** pΗ : Not applicable. **Melting point** : Not applicable. **Boiling point** : Not applicable. : Not applicable. Flash point : Not available. **Evaporation rate** Flammability (solid, gas) : Not applicable. Lower and upper explosive

(flammable) limits

: Not applicable.

Vapor pressure : Negligible Vapor density : Not applicable.

Relative density

Solubility : Insoluble in the following materials: cold water and hot water.

Partition coefficient: n-

octanol/water

: Not available.

Auto-ignition temperature : Not applicable. **Decomposition temperature** : Not applicable. : Not available. **Viscosity** Flow time (ISO 2431) : Not available.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous

reactions

: Under normal conditions of storage and use, hazardous reactions will not occur. Under normal conditions of storage and use, hazardous polymerization will not

occur.

Conditions to avoid : No specific data.

Section 10. Stability and reactivity

Incompatible materials

Elevated temperature. Exposure to light.
 Reactive or incompatible with the following materials: oxidizing materials, reducing materials and moisture.
 Amines

Hazardous decomposition products

: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
2,2'-ethylenedioxydiethyl dimethacrylate	LD50 Oral	Rat	10837 mg/kg	-
4,4'-methylenedi(cyclohexyl isocyanate)	LC50 Inhalation Dusts and mists	Rat	0.295 mg/l	4 hours
,	LD50 Dermal	Rabbit	>10000 mg/kg	-
	LD50 Oral	Rat	9900 mg/kg	-
Silica, amorphous, fumed, crystfree	LD50 Oral	Rat	3160 mg/kg	-
Silane, dichlorodimethyl-, reaction products with silica	LC50 Inhalation Dusts and mists	Rat	450 mg/m³	4 hours
-	LD50 Oral	Rat	>5000 mg/kg	-
2-hydroxyethyl methacrylate	LD50 Oral	Rat	4230 mg/kg	-
dibenzoyl peroxide	LD50 Oral	Rat	6400 mg/kg	_
2,6-di-tert-butyl-p-cresol	LD50 Oral	Rat	890 mg/kg	_

Conclusion/Summary

: Not available.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
4,4'-methylenedi(cyclohexyl isocyanate)	Eyes - Mild irritant	Rabbit	-	100 microliters	-
	Eyes - Severe irritant	Rabbit	-	24 hours 100 microliters	-
	Skin - Moderate irritant	Rabbit	-	24 hours 500 microliters	-
dibenzoyl peroxide	Eyes - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
2,6-di-tert-butyl-p-cresol	Eyes - Moderate irritant	Rabbit	-	24 hours 100 milligrams	-
	Skin - Moderate irritant	Rabbit	-	48 hours 500 milligrams	-

Conclusion/Summary

Skin: Not available.Eyes: Not available.Respiratory: Not available.

Sensitization

Conclusion/Summary

Skin: Not available.Respiratory: Not available.

Mutagenicity

Conclusion/Summary: Not available.

Carcinogenicity

Section 11. Toxicological information

Conclusion/Summary: Not available.

Reproductive toxicity

Conclusion/Summary: Not available.

Teratogenicity

Conclusion/Summary: Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Poly(oxy-1,2-ethanediyl), α,α' -[(1-methylethylidene)di-4,1-phenylene]bis[ω -[(2-methyl-1-oxo-2-propen-1-yl)oxy]-	Category 3	Not applicable.	Respiratory tract irritation
4,4'-methylenedi(cyclohexyl isocyanate)	Category 3	Not applicable.	Respiratory tract irritation
Silica, amorphous, fumed, crystfree	Category 3	Not applicable.	Respiratory tract irritation
2-hydroxyethyl methacrylate	Category 3	Not applicable.	Respiratory tract irritation
Polyol	Category 3	Not applicable.	Respiratory tract irritation
2,6-di-tert-butyl-p-cresol	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely

routes of exposure

: Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

Eye contact : Causes serious eye irritation.

Inhalation : Fatal if inhaled. May cause respiratory irritation. May cause allergy or asthma

symptoms or breathing difficulties if inhaled.

Skin contact: Causes skin irritation. May cause an allergic skin reaction.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Adverse symptoms may include the following:

pain or irritation watering redness

Inhalation : Adverse symptoms may include the following:

respiratory tract irritation

coughing

wheezing and breathing difficulties

asthma

Skin contact: Adverse symptoms may include the following:

irritation redness

Ingestion : No specific data.

<u>Delayed and immediate effects and also chronic effects from short and long term exposure</u> <u>Short term exposure</u>

Section 11. Toxicological information

Potential immediate

effects

: Not available.

Potential delayed effects

: Not available.

Long term exposure

Potential immediate

effects

: Not available.

Potential delayed effects : Not available.

Potential chronic health effects

: Not available. **Conclusion/Summary**

General : Once sensitized, a severe allergic reaction may occur when subsequently exposed

to very low levels.

Carcinogenicity : No known significant effects or critical hazards. Mutagenicity : No known significant effects or critical hazards. **Teratogenicity** : No known significant effects or critical hazards. **Developmental effects** : No known significant effects or critical hazards. **Fertility effects** : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral Inhalation (dusts and mists)	18573.9 mg/kg 0.3695 mg/l

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
4,4'-methylenedi(cyclohexyl isocyanate)	Acute LC50 1.2 mg/l Fresh water	Fish - Brachydanio rerio	96 hours
2-hydroxyethyl methacrylate	Acute LC50 227000 μg/l Fresh water	Fish - Pimephales promelas - Juvenile (Fledgling, Hatchling, Weanling)	96 hours
2,6-di-tert-butyl-p-cresol	Acute EC50 0.48 mg/l Fresh water	Daphnia	48 hours

Conclusion/Summary : Not available.

Persistence and degradability

Product/ingredient name	Test	Result	Dose	Inoculum
Poly(oxy-1,2-ethanediyl), $α,α'$ -[(1-methylethylidene)di-4,1-phenylene]bis[ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]-	OECD 301D Ready Biodegradability - Closed Bottle Test	24 % - Inherent - 28 days	-	-
2,2'-ethylenedioxydiethyl dimethacrylate	OECD 301 B 301B Ready Biodegradability - CO ₂ Evolution Test	85 % - Readily - 28 days	-	-
4,4'-methylenedi(cyclohexyl isocyanate)	301F Ready Biodegradability - Manometric Respirometry	0 % - 28 days	-	-

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Section 12. Ecological information

Ready Biodegradability - Modified MITI	92 to 100 % - 14 days	-	-
Test (I)			

Conclusion/Summary: Not available.

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Poly(oxy-1,2-ethanediyl), α,α' -[(1-methylethylidene)di-4,1-phenylene]bis[ω -[(2-methyl-1-oxo-2-propen-1-yl)oxy]-	-	-	Inherent
2,2'-ethylenedioxydiethyl dimethacrylate 4,4'-methylenedi(cyclohexyl	-		Readily Not readily
isocyanate) 2-hydroxyethyl methacrylate	-		Readily

Bioaccumulative potential

Product/ingredient name	LogPow	BCF	Potential
Poly(oxy-1,2-ethanediyl), α,α' -[(1-methylethylidene)di-4,1-phenylene]bis[ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]-	3.43 to 5.62	-	high
2,2'-ethylenedioxydiethyl dimethacrylate	1.88	-	low
4,4'-methylenedi(cyclohexyl isocyanate)	6.11	10186	high
2-hydroxyethyl methacrylate dibenzoyl peroxide 2,6-di-tert-butyl-p-cresol	0.42 3.2 5.1	- - 330 to 1800	low low high

Mobility in soil

Soil/water partition coefficient (Koc)

: Not available.

Other adverse effects : No

: No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods

: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Section 14. Transport information

	TDG Classification	DOT Classification	ADR/RID	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-	-	-

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Section 14. Transport information

Transport hazard class(es)	-	-	-	-	-
Packing group	-	-	-	-	-
Environmental hazards	No.	No.	No.	No.	No.
Additional information	-	Remarks Exemption 49 CFR 173.4	-	-	-

Special precautions for user : Transport within user's premises: always transport in closed containers that are

upright and secure. Ensure that persons transporting the product know what to do in

the event of an accident or spillage.

Transport in bulk according : Not available.

to Annex II of MARPOL and

the IBC Code

Section 15. Regulatory information

Canadian lists

Canadian NPRI : The following components are listed: 1,1-Methylenebis(4-isocyanatocyclohexane); 2,

6-Di-t-butyl-4-methylphenol; Benzoyl peroxide

CEPA Toxic substances : None of the components are listed.

Canada inventory : Not determined.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol (Annexes A, B, C, E)

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Section 16. Other information

History

Date of issue/Date of

revision

: 12/04/2017

Date of previous issue : No previous validation

Version : 1

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Section 16. Other information

Key to abbreviations

: ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships,

1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

UN = United Nations

HPR = Hazardous Products Regulations

Procedure used to derive the classification

Classification	Justification
ACUTE TOXICITY (inhalation) - Category 2 SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2A RESPIRATORY SENSITIZATION - Category 1 SKIN SENSITIZATION - Category 1A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3	Calculation method

References : HPR = Hazardous Products Regulations

▼ Indicates information that has changed from previously issued version.

Notice to reader

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Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.