

SECTION 1: Identification of the substance/mixture and of the company/ undertaking

1.1 Product identifier

Product name : Spirit No-Mix Primer
Product code : Not available.
Product type : Liquid.
Other means of identification : Not available.

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

Product use : Dental product: Primer.
Area of application : Professional applications.

1.3 Details of the supplier of the safety data sheet

Supplier/Manufacturer

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

Distributor

ORMCO B.V.
Basicweg 20
3821 BR Amersfoort
Telephone no.: 00800-3032-3032

e-mail address of person responsible for this SDS : customerservice@ormcoeurope.com

1.4 Emergency telephone number

National advisory body/Poison Centre

Telephone number : United Kingdom (UK) National advisory body/Poison Center: +44 870 600 6266

Supplier

Telephone number : +31 (0) 0800 3032 3032
Hours of operation : 08:00-17:00, European time, GMT+1

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Flam. Liq. 3, H226

Skin Irrit. 2, H315

Eye Irrit. 2, H319

Skin Sens. 1, H317

STOT SE 3, H335

Aquatic Acute 1, H400

The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

Ingredients of unknown toxicity : 80 percent of the mixture consists of component(s) of unknown oral toxicity
80 percent of the mixture consists of component(s) of unknown dermal toxicity
80 percent of the mixture consists of component(s) of unknown inhalation toxicity

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H226 - Flammable liquid and vapour.
H319 - Causes serious eye irritation.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.

Precautionary statements

Prevention : P280 - Wear protective gloves. Wear protective clothing. Wear eye or face protection.
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P273 - Avoid release to the environment.

Response : P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

Storage : P405 - Store locked up.

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

Hazardous ingredients : isobutyl methacrylate

Supplemental label elements : Not applicable.

Spirit No-Mix Primer

SECTION 2: Hazards identification

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

Special packaging requirements

Containers to be fitted with child-resistant fastenings : Not applicable.

Tactile warning of danger : Not applicable.

2.3 Other hazards

Other hazards which do not result in classification : None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

Product/ingredient name	Identifiers	%	Regulation (EC) No. 1272/2008 [CLP]	Type
isobutyl methacrylate	EC: 202-613-0 CAS: 97-86-9 Index: 607-113-00-X	≥75 - ≤90	Flam. Liq. 3, H226 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Acute 1, H400 (M=1) See Section 16 for the full text of the H statements declared above.	[1]

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, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

- [1] Substance classified with a health or environmental hazard
- [2] Substance with a workplace exposure limit
- [3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
- [4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII
- [5] Substance of equivalent concern
- [6] Additional disclosure due to company policy

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

SECTION 4: First aid measures

4.1 Description of 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.
- 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.

4.2 Most important symptoms and effects, both acute and delayed

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
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media** : Use dry chemical, CO₂, water spray (fog) or foam.
- Unsuitable extinguishing media** : Do not use water jet.

5.2 Special hazards arising from the substance or mixture

SECTION 5: Firefighting measures

- Hazards from the substance or mixture** : Flammable liquid and vapour. Runoff to sewer may create fire or explosion hazard. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion. This material is very toxic to aquatic life. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide

5.3 Advice for firefighters

- 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. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.
- 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 mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 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".

6.2 Environmental precautions

- : Low release. Avoid dispersal of spilt 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). Water polluting material. May be harmful to the environment if released in large quantities. Collect spillage.

6.3 Methods and material 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.

6.4 Reference to other sections

- : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

7.1 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 of 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.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in a segregated and approved area. 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. Eliminate all ignition sources. Separate from oxidizing materials. 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 unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Seveso Directive - Reporting thresholds (in tonnes)

Danger criteria

Category	Notification and MAPP threshold	Safety report threshold
P5c: Flammable liquids 2 and 3 not falling under P5a or P5b E1: Hazardous to the aquatic environment - Acute 1 or Chronic 1	5000 100	50000 200

7.3 Specific end use(s)

- Recommendations** : Not available.
- Industrial sector specific solutions** : Not available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

- Recommended monitoring procedures** : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance

SECTION 8: Exposure controls/personal protection

documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available

8.2 Exposure controls

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

Individual protection measures

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

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.

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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state : Liquid. [Clear.]

Colour : Clear.

Odour : Pungent.

Odour threshold : Not available.

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SECTION 9: Physical and chemical properties

pH	: Not available.
Melting point/freezing point	: Not available.
Initial boiling point and boiling range	: Not available.
Flash point	: Closed cup: 42.5°C (Isobutyl Methacrylate)
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not applicable.
Upper/lower flammability or explosive limits	: Not available.
Vapour pressure	: Not available.
Vapour density	: Not available.
Relative density	: 0.9
Solubility(ies)	: Insoluble in the following materials: cold water and hot water.
Partition coefficient: n-octanol/ water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.
Explosive properties	: Not available.
Oxidising properties	: Not available.

9.2 Other information

Solubility in water	: Not available.
Physical/chemical properties comments	: No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability	: The product is stable.
10.3 Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur. Under normal conditions of storage and use, hazardous polymerisation will not occur.
10.4 Conditions to avoid	: Avoid all possible sources of ignition (spark or flame). Do not pressurise, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition.
10.5 Incompatible materials	: Reactive or incompatible with the following materials: oxidizing materials

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SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Conclusion/Summary : Not available.

Acute toxicity estimates

Not available.

Irritation/Corrosion

Conclusion/Summary : Not available.

Sensitisation

Conclusion/Summary : Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Product/ingredient name	Category	Route of exposure	Target organs
isobutyl methacrylate	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

Eye contact : Causes serious eye irritation.

Inhalation : May cause respiratory irritation.

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

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SECTION 11: Toxicological information

- Eye contact** : Adverse symptoms may include the following:
pain or irritation
watering
redness
- Inhalation** : Adverse symptoms may include the following:
respiratory tract irritation
coughing
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

- 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** : Not available.
- 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.

- Other information** : Not available.

SECTION 12: Ecological information

12.1 Toxicity

- Conclusion/Summary** : Not available.

12.2 Persistence and degradability

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SECTION 12: Ecological information

Product/ingredient name	Test	Result	Dose	Inoculum
isobutyl methacrylate	301D Ready Biodegradability - Closed Bottle Test	74.3 % - 28 days	-	-

Conclusion/Summary : Not available.

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
isobutyl methacrylate	-	-	Readily

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
isobutyl methacrylate	2.95	-	low

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

PBT : Not applicable.

vPvB : Not applicable.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised 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.

Hazardous waste : The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Vapour from product residues may create a highly flammable or explosive atmosphere inside the container. Do not cut, weld or grind used containers unless they have been cleaned thoroughly internally. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

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SECTION 13: Disposal considerations

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	UN2283	UN2283	UN2283	UN2283
14.2 UN proper shipping name	ISOBUTYL METHACRYLATE, STABILIZED solution	ISOBUTYL METHACRYLATE, STABILIZED solution	ISOBUTYL METHACRYLATE, STABILIZED solution	Isobutyl methacrylate, stabilized solution
14.3 Transport hazard class(es)	3 	3 	3 	3
14.4 Packing group	III	III	III	III
14.5 Environmental hazards	Yes.	Yes.	Yes.	Yes. The environmentally hazardous substance mark is not required.

Additional information

ADR/RID

: The environmentally hazardous substance mark is not required when transported in sizes of ≤5 L or ≤5 kg.

Hazard identification number 39

Limited quantity 5 L

Tunnel code (D/E)

ADN

: The environmentally hazardous substance mark is not required when transported in sizes of ≤5 L or ≤5 kg.

IMDG

: The marine pollutant mark is not required when transported in sizes of ≤5 L or ≤5 kg.

Emergency schedules F-E, S-D

IATA

: The environmentally hazardous substance mark may appear if required by other transportation regulations.

Quantity limitation Passenger and Cargo Aircraft: 60 L. Packaging instructions: 355. Cargo Aircraft Only: 220 L. Packaging instructions: 366. Limited Quantities - Passenger Aircraft: 10 L. Packaging instructions: Y344.

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

: Not available.

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SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions : Not applicable.
**on the manufacture,
placing on the market
and use of certain
dangerous substances,
mixtures and articles**

Other EU regulations

Europe inventory : Not determined.

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Seveso Directive

This product is controlled under the Seveso Directive.

Danger criteria

Category

P5c: Flammable liquids 2 and 3 not falling under P5a or P5b
E1: Hazardous to the aquatic environment - Acute 1 or Chronic 1

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.

15.2 Chemical safety assessment : This product contains substances for which Chemical Safety Assessments are still required.

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SECTION 15: Regulatory information

15.3 Registration status : Mixture. Information concerning the substance : Contact local supplier or distributor.

SECTION 16: Other information

✔ Indicates information that has changed from previously issued version.

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
vPvB = Very Persistent and Very Bioaccumulative

Key literature references and sources for data : Regulation (EC) No. 1272/2008 [CLP]; European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), concluded in Geneva on 30 September 1957 plus amendments (Uniform text: Journal of Laws 27/2009 pos. 162 plus amendments); Regulation for the transport of dangerous materials on the Rhine (ADN); Occupational exposure limits; International regulations

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Flam. Liq. 3, H226 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Acute 1, H400	On basis of test data Calculation method Calculation method Calculation method Calculation method Calculation method

Full text of abbreviated H statements

H226 H315 H317 H319 H335 H400	Flammable liquid and vapour. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause respiratory irritation. Very toxic to aquatic life.
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Full text of classifications [CLP/GHS]

Aquatic Acute 1, H400 Eye Irrit. 2, H319 Flam. Liq. 3, H226 Skin Irrit. 2, H315 Skin Sens. 1, H317 STOT SE 3, H335	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2 FLAMMABLE LIQUIDS - Category 3 SKIN CORROSION/IRRITATION - Category 2 SKIN SENSITISATION - Category 1 SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE (Respiratory tract irritation) - Category 3
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Training advice : Ensure operatives are trained to minimise exposures. Training staff on good practice.

Date of issue/ Date of revision : 18/05/2017

Date of previous issue : No previous validation

Spirit No-Mix Primer

SECTION 16: Other information

Version : 1

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

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.