

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

1.1 Product identifier

Product name : System 1+ Activator
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: Orthodontic Appliance
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

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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]

Eye Dam. 1, H318

Skin Sens. 1, H317

Aquatic Chronic 3, H412

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

Ingredients of unknown toxicity : 8.2 percent of the mixture consists of component(s) of unknown oral toxicity
89.6 percent of the mixture consists of component(s) of unknown dermal toxicity
89.6 percent of the mixture consists of component(s) of unknown inhalation toxicity

Ingredients of unknown ecotoxicity : Contains 89.6 % of components with unknown hazards to the aquatic environment

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 : Danger

Hazard statements : H318 - Causes serious eye damage.
H317 - May cause an allergic skin reaction.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements

Prevention : P280 - Wear protective gloves. Wear eye or face protection.
P273 - Avoid release to the environment.

Response : P305 + P351 + P310 - IF IN EYES: Rinse cautiously with water for several minutes.
Immediately call a POISON CENTER or physician.

Storage : Not applicable.

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

Hazardous ingredients : 2,2'-ethylenedioxydiethyl dimethacrylate
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]
bismethacrylate
2,2'-[(4-methylphenyl)imino]bisethanol

Supplemental label elements : Not applicable.

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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
2,2'-ethylenedioxydiethyl dimethacrylate	EC: 203-652-6 CAS: 109-16-0	≥50 - ≤75	Skin Sens. 1B, H317	[1]
(1-methylethylidene)bis[4, 1-phenyleneoxy(2-hydroxy-3, 1-propanediyl)] bismethacrylate	EC: 216-367-7 CAS: 1565-94-2	<10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317	[1]
2,2'-[(4-methylphenyl)imino] bisethanol	EC: 221-359-1 CAS: 3077-12-1	≤10	Acute Tox. 4, H302 Eye Dam. 1, H318	[1]
oxybenzone	EC: 205-031-5 CAS: 131-57-7	≤1	Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (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

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SECTION 3: Composition/information on ingredients

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
watering
redness
- Inhalation** : No specific data.
- Skin contact** : Adverse symptoms may include the following:
pain or irritation
redness
blistering may occur
- Ingestion** : Adverse symptoms may include the following:
stomach pains

4.3 Indication of any immediate medical attention and special treatment needed

- 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.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : Do not use water jet.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : In a fire or if heated, a pressure increase will occur and the container may burst. This material is harmful to aquatic life with long lasting effects. 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
nitrogen oxides

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.

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.

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.

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SECTION 6: Accidental release measures

- 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

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 unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

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

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SECTION 8: Exposure controls/personal protection

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 and/or face shield. If inhalation hazards exist, a full-face respirator may be required instead.

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.
Colour : Clear.
Odour : Slight
Odour threshold : Not available.

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SECTION 9: Physical and chemical properties

pH	: Not applicable.
Melting point/freezing point	: Not available.
Initial boiling point and boiling range	: Not available.
Flash point	: Not applicable.
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not applicable.
Upper/lower flammability or explosive limits	: Not applicable
Vapour pressure	: Not available.
Vapour density	: Not available.
Relative density	: 1
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	: Elevated temperature (26.7°C (80°F)). Protect from moisture. Exposure to light.
10.5 Incompatible materials	: No specific data.

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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

Product/ingredient name	Result	Species	Dose	Exposure
2,2'-ethylenedioxydiethyl dimethacrylate	LD50 Oral	Rat	10837 mg/kg	-
2,2'-[(4-methylphenyl)imino] bisethanol	LD50 Oral	Rat	970 mg/kg	-
oxybenzone	LD50 Oral	Rat	7400 mg/kg	-

Conclusion/Summary : Not available.

Acute toxicity estimates

Route	ATE value
Oral	12125 mg/kg

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)

Not available.

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

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SECTION 11: Toxicological information

- Eye contact** : Causes serious eye damage.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : 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
watering
redness
- Inhalation** : No specific data.
- Skin contact** : Adverse symptoms may include the following:
pain or irritation
redness
blistering may occur
- Ingestion** : Adverse symptoms may include the following:
stomach pains

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.

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SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
oxybenzone	Acute EC50 13.87 µg/l Marine water	Algae - Isochrysis galbana - Exponential growth phase	72 hours
	Acute EC50 1.87 mg/l Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 3.8 mg/l Fresh water	Fish - Oryzia latipes	96 hours
	Chronic EC10 3.69 µg/l Marine water	Algae - Isochrysis galbana - Exponential growth phase	72 hours
	Chronic NOEC 90 µg/l Fresh water	Fish - Oryzias latipes - Adult	28 days

Conclusion/Summary : Not available.

12.2 Persistence and degradability

Product/ingredient name	Test	Result	Dose	Inoculum
2,2'-ethylenedioxydiethyl dimethacrylate	OECD 301 B 301B Ready Biodegradability - CO2 Evolution Test	85 % - Readily - 28 days	-	-

Conclusion/Summary : Not available.

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
2,2'-ethylenedioxydiethyl dimethacrylate	-	-	Readily
oxybenzone	-	-	Readily

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
2,2'-ethylenedioxydiethyl dimethacrylate	1.88	-	low
2,2'-[(4-methylphenyl)imino] bisethanol	1.09	-	low
oxybenzone	3.79	39 to 160	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.

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SECTION 12: Ecological information

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. Avoid dispersal of spill material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.

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 not controlled under the Seveso Directive.

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.

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

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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); European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN); Occupational exposure limits; International regulations

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

Classification	Justification
Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Chronic 3, H412	Calculation method Calculation method Calculation method

Full text of abbreviated H statements

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Full text of classifications [CLP/GHS]

Acute Tox. 4, H302 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Aquatic Chronic 3, H412 Eye Dam. 1, H318 Eye Irrit. 2, H319 Skin Irrit. 2, H315 Skin Sens. 1, H317 Skin Sens. 1B, H317	ACUTE TOXICITY (oral) - Category 4 SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 3 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2 SKIN CORROSION/IRRITATION - Category 2 SKIN SENSITISATION - Category 1 SKIN SENSITISATION - Category 1B
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Training advice : Ensure operatives are trained to minimise exposures. Training staff on good practice.

Date of issue/ Date of revision : 10/01/2018

Date of previous issue : No previous validation

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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.