

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

077640345

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

077640303 077640337

# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010  
Dental Use

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 09/25/2012  
SDS No : 25-001.11  
Date Revised : 04/20/2017  
Revision No : 12

## UltraSeal XT® Plus

### SECTION 1 : Identification of the substance/preparation and of the company/undertaking

#### 1.1. Product identifier

**Product code** : XA/73401, XB/13560, XR/56303, XT/10952  
**Product name** : UltraSeal XT® Plus  
**Product description** : Light cure pit and fissure sealant and flowable composite

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

**Relevant identified uses** : Professional Dental Pit and Fissure Sealant

#### 1.3. Details of the supplier of the safety data sheet

##### Manufacturer

Ultradent Products, Inc.  
505 W. Ultradent Drive (10200 South)  
South Jordan, UT 84095

##### EC Responsible Person

Ultradent Products GmbH  
Am Westhover Berg 30  
51149 Cologne Germany  
Email: infoDE@ultradent.com  
**Emergency Phone** : +49(0)2203-35-92-0

#### 1.4. Emergency telephone number

**CHEMTREC (NORTH AMERICA)** :(800) 424 - 9300  
**(INTERNATIONAL)** :+1(703) 527 - 3887

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

**Health** : Skin Sensitization, Category 1B

#### 2.2. Label elements

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

**Hazard pictogram(s)** :



Exclamation  
mark

**Signal Word** : WARNING

**Hazard statement(s)** : H317: May cause an allergic skin reaction.

**Precautionary statement(s)**

**Prevention** : P280: Wear protective gloves/protective clothing/eye protection/face protection.  
P261: Avoid breathing dust/fumes/gas/mist/vapours/spray.  
P272: Contaminated work clothing should not be allowed out of the workplace.

**Response** : P302+P352: IF ON SKIN: Wash with plenty of soap and water.

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**Storage** : P333+P313: If skin irritation or rash occurs: Get medical advice/attention.  
P363: Wash contaminated clothing before reuse.

**Disposal** : P273: Avoid release to the environment.  
P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-21/11/2003)

### 2.3. Other hazards

Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

## SECTION 3: Composition / information on ingredients

### 3.1. Substances

Not Applicable

### 3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Regulation(EC) No 1272/2008 [CLP]
Bis-GMA	1565-94-2	216-367-7	< 20	H315; H317; H319
TEGDMA	109-16-0	203-652-6	< 20	Skin Sens.,Cat. 1B; H317
Sodium Monofluorophosphate	10163-15-2	233-433-0	< 1	Acute Tox. (O),Cat. 4; H302

For full text of H-statements: see SECTION 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

**Following eyes** : Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.

**Following skin** : Wash with soap and water. Get medical attention if sensitization or irritation develops or persists. Wash contaminated clothing before reuse.

**Following ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.

**Following inhalation** : Rest in the fresh air and seek medical advice if necessary.

### 4.2. Most important symptoms and effects, both acute and delayed

**Eyes** : Irritating to eyes.

**Skin** : May cause skin irritation and sensitization.

**Ingestion** : May be harmful if swallowed in large quantities.

**Inhalation** : None expected for this product.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Notes to physician** : NAP

## SECTION 5: Fire fighting measures

### 5.1. Extinguishing media

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**Extinguishing media** : Foam, dry chemical, CO<sub>2</sub>

**5.2. Special hazards arising from the substance or mixture**

**Hazardous combustion products** : None known.

**5.3. Advice for firefighters**

**Fire fighting procedures** : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

**SECTION 6: Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**

**General procedures** : Refer to Section 8 for Personal Protective Equipment.

**6.2. Environmental precautions**

**Water spill** : Do not allow to enter sewers or drains that may lead to waterways.

**6.3. Methods and material for containment and cleaning up**

**Small Spill** : Clean up spills immediately, observing precautions in Protective Equipment section.

**Large Spill** : Absorb with inert, damp non-combustible material, then flush area with water.

**6.4. Reference to other sections**

**Reference to other sections** : NAP

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

**General procedures** : Avoid contact with eyes, skin and clothing.

**Handling** : Use suitable protective equipment.

**Storage** : See product labeling.

**7.2. Conditions for safe storage, including any incompatibilities**

**Shelf life** : See product labeling

**7.3. Specific end use(s)**

**Specific end use(s)** : Professional Dental Pit and Fissure Sealant

**SECTION 8: Exposure controls / personal protection**

**8.1. Control parameters**

**Control parameters** : None Required

**8.2. Exposure controls**

**Eye/face protection** : Wear eye protection .

**Skin protection** : Wear suitable protective clothing and gloves.

**Respiratory protection** : Good general ventilation should be sufficient to control airborne levels.

**SECTION 9: Physical and chemical properties**

**9.1. Information on basic physical and chemical properties**

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**UltraSeal XT® Plus**

Physical state : Liquid  
Appearance : Medium viscosity  
Colour : White to tan  
Odour : Acrylic  
pH : NAP (non-aqueous)  
Specific gravity : 1.7 - 1.8

**9.2. Other information**

Additional information : No further relevant information available

**SECTION 10: Stability and reactivity**

**10.1. Reactivity**

Reactivity : Stable

**10.2. Chemical stability**

Chemical stability : Stable when stored and handled under recommended conditions.

**10.3. Possibility of hazardous reactions**

Hazardous polymerization : None

**10.4. Conditions to avoid**

Conditions to avoid : Avoid light exposure.

**10.5. Incompatible materials**

Incompatible materials : Not Determined

**10.6. Hazardous decomposition products**

Hazardous decomposition products : None known.

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Acute**

Dermal LD<sub>50</sub> : > 2600 mg/kg Rabbit/Rat/Mouse

Notes : ~ 75% of the mixture consists of components of unknown toxicity (Dermal).

Oral LD<sub>50</sub> : > 4700 mg/kg Rat

Notes : 68% of the mixture consists of components of unknown toxicity (Oral).

Inhalation LC<sub>50</sub> : Not able to calculate ATE mix (inhalation) due to lack of data on the components.

Germ cell mutagenicity : The components in this product are not reported to produce mutagenic effects in humans.

Carcinogenicity : None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.

Reproductive toxicity : The components in this product are not reported to cause reproductive effects in humans.

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**Other information** : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

**SECTION 12: Ecological information**

**12.1. Toxicity**

**Aquatic toxicity (acute)** : Do not empty into drains or the aquatic environment.

**12.2. Persistence and degradability**

**Persistence and degradability** : Not classified

**12.3. Bioaccumulative potential**

**Bioaccumulative potential** : Not classified

**12.4. Mobility in soil**

**Mobility in soil** : Not Available

**12.5. Results of PBT and vPvB assessment**

**Results of PBT and vPvB assessment** : Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

**12.6. Other adverse effects**

**Environmental data** : No further relevant information available.

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

**Disposal method** : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**SECTION 14: Transport information**

**14.1. UN number**

**UN number** : NAP

**14.2. UN proper shipping name**

**UN proper shipping name** : Not Dangerous Goods

**14.3. Transport hazard class(es)**

**Hazard classification** : NAP

**14.4. Packing group**

**Packing group** : NAP

**14.5. Environmental hazards**

**Marine pollutant #1** : NAP

**14.6. Special precautions for user**

**ADR - road** : NAP

**RID - rail** : NAP

**IMDG - sea** : NAP

**IATA - air** : NAP

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**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Transport in bulk : NAP

**SECTION 15: Regulatory information**

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

**General information** : Substances of very high concern (SVHC) according to REACH, Article 57:  
Contains no SVHC substances.

**General comments** : Please refer to Medical Devices Directive 93/42/EEC.

**15.2. Chemical safety assessment**

**Chemical safety assessment** : See Section 11

**Additional information** : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.  
This product is not considered dangerous for transportation.

**SECTION 16: Other information**

**Relevant H-statements (number and full text)** : Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4  
Skin Sens., Cat. 1B: Skin Sensitization, Category 1B  
H302: Harmful if swallowed.  
H315: Causes skin irritation.  
H317: May cause an allergic skin reaction.  
H319: Causes serious eye irritation.

**Prepared by** : Anu Kattoju

**Revision summary** : This SDS replaces the 07/07/2015 SDS. Revised: **Section 1:** MSDS  
No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3.  
Other hazards. **Section 4:** INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE - SKIN SKIN. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** . **Section 7:** GENERAL PROCEDURES. **Section 8:** . **Section 9:** APPEARANCE, COLOR, COMMENTS, PERCENT VOLATILE, pH, SPECIFIC GRAVITY. **Section 11:** ACUTE ( DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat) ACUTE, GENERAL COMMENTS, CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION 12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **Section 16:** GENERAL STATEMENTS.

**General statements** : NAP = Not Applicable

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NE = Not Established  
TLV = Threshold Limit Value  
PEL = Permittable exposure limits  
MAK = Maximum Workplace Concentration  
STEL = Short-term exposure limit  
STEV = Short-term exposure value  
TWA = Time Weighted Average  
PPE = Personal Protective Equipment

**Manufacturer disclaimer**

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.



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**UltraSeal XT® Plus**

**SECTION 1 : Identification of the substance/preparation and of the company/undertaking**

**1.1. Product identifier**

**Product code** : XA/73401, XB/13560, XR/56303, XT/10952  
**Product name** : UltraSeal XT® Plus  
**Product description** : Light cure pit and fissure sealant and flowable composite

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

**Relevant identified uses** : Professional Dental Pit and Fissure Sealant

**1.3. Details of the supplier of the safety data sheet**

**Manufacturer**

Ultradent Products, Inc.  
505 W. 10200 S.  
South Jordan, UT 84095

**Distributor**

Ultradent Products GmbH  
Am Westhoyer Berg 30  
51149 Cologne Germany  
Email: infoDE@ultradent.com  
**Emergency Phone** : +49(0)2203-35-92-0

**1.4. Emergency telephone number**

**CHEMTREC (NORTH AMERICA)** :(800) 424 - 9300  
**(INTERNATIONAL)** :+1(703) 527 - 3887

**SECTION 2: Hazards identification**

**2.1. Classification of the substance or mixture**

**Classification according to Directive 1999/45/EC**

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

**Danger symbols** : Xi

**R phrases** : R36,R43

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

**Health** : Eye Irritation  
Skin Irritation

**2.2. Label elements**

**Classification according to Directive 1999/45/EC**

**Hazard pictogram(s)** : Xi



Irritant

**R&S statement(s)** : R36: Irritating to eyes.  
R43: May cause sensitization by skin contact.


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

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<b>Hazard pictogram(s)</b>	:	
		Exclamation mark
<b>Signal Word</b>	:	WARNING
<b>Hazard statement(s)</b>	:	H317: May cause an allergic skin reaction. H319: Causes serious eye irritation.
<b>Precautionary statement(s)</b>	:	
<b>Prevention</b>	:	P280: Wear protective gloves/protective clothing/eye protection/face protection.
<b>Response</b>	:	P305: IF IN EYES: P351: Rinse cautiously with water for several minutes. P337+P313: If eye irritation persists: Get medical advice/attention. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P332+P313: If skin irritation occurs: Get medical advice/attention.
<b>Storage</b>	:	P273: Avoid release to the environment.
<b>Disposal</b>	:	P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-10/11/2003)
<b>2.3. Other hazards</b>	:	
<b>Immediate concerns</b>	:	None

**SECTION 3: Composition / information on ingredients**

**3.1. Substances**

Not Applicable

**3.2. Mixtures**

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Bis-GMA	1565-94-2	216-367-7	< 20	Xi; R36/37/38; R22	H315; H319; H317
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	< 20	Xi; R43	Not classified
Aluminum Oxide	1344-28-1	215-691-6	< 10	Xi; R36/37	Not classified
Sodium Monofluorophosphate	10163-15-2	233-433-0	< 1	T; R22; R38	Acute Tox. (O), Cat. 4; H302

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For full text of H-statements and R-phrases: see SECTION 16.

**SECTION 4: First aid measures**

**4.1. Description of first aid measures**

- Following eyes** : Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.
- Following skin** : Wash with soap and water. Get medical attention if irritation develops or persists.
- Following ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.
- Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

**4.2. Most important symptoms and effects, both acute and delayed**

- Eyes** : Irritating to eyes.
- Skin** : May cause sensitization to skin.
- Ingestion** : May be harmful if swallowed in large quantities.
- Inhalation** : None expected for this product.

**4.3. Indication of any immediate medical attention and special treatment needed**

- Notes to physician** : Not Applicable

**SECTION 5: Fire fighting measures**

**5.1. Extinguishing media**

- Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.

**5.2. Special hazards arising from the substance or mixture**

- Hazardous combustion products** : None known.
- Explosion hazards** : Not Determined
- Fire explosion** : Not Determined
- Sensitive to static discharge** : Not Determined
- Sensitivity to impact** : Not Determined

**5.3. Advice for firefighters**

- Fire fighting procedures** : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
- Fire fighting equipment** : Foam, dry chemical, carbon dioxide (CO<sub>2</sub>).

**SECTION 6: Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**

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- General procedures** : Refer to Section 8 for Personal Protective Equipment.
- 6.2. Environmental precautions**
- Water spill** : Do not allow to enter sewers or drains that may lead to waterways.
- 6.3. Methods and material for containment and cleaning up**
- Small spill** : Clean up spills immediately, observing precautions in Protective Equipment section.
- Large spill** : Absorb with inert, damp non-combustible material, then flush area with water.
- 6.4. Reference to other sections**
- Reference to other sections** : Not Applicable

**SECTION 7: Handling and storage**

- 7.1. Precautions for safe handling**
- Handling** : Use suitable protective equipment.
- Storage** : See product labeling.
- 7.2. Conditions for safe storage, including any incompatibilities**
- Shelf life** : See product labeling
- 7.3. Specific end use(s)**
- Specific end use(s)** : Professional Dental Pit and Fissure Sealant

**SECTION 8: Exposure controls / personal protection**

- 8.1. Control parameters**
- Control parameters** : Not Determined
- 8.2. Exposure controls**
- Eye/face protection** : Wear eye protection
- Skin protection** : Wear suitable protective clothing and gloves.
- Respiratory protection** : Good general ventilation should be sufficient to control airborne levels.

**SECTION 9: Physical and chemical properties**

- 9.1. Information on basic physical and chemical properties**
- Physical state** : Liquid
- Appearance** : Tinted Liquid
- Colour** : Dependent upon color shade
- Odour** : Acrylic
- 9.2. Other information**
- Percent volatile** : Not Determined

**SECTION 10: Stability and reactivity**

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**10.1. Reactivity**

Reactivity : Stable

**10.2. Chemical stability**

Chemical stability : Stable when stored and handled under recommended conditions.

**10.3. Possibility of hazardous reactions**

Hazardous polymerization : None

**10.4. Conditions to avoid**

Conditions to avoid : Avoid light exposure.

**10.5. Incompatible materials**

Incompatible materials : Not Determined

**10.6. Hazardous decomposition products**

Hazardous decomposition products : None known.

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Acute**

Notes : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

**SECTION 12: Ecological information**

**12.1. Toxicity**

**Aquatic toxicity (acute)**

96-hour LC<sub>50</sub> : Not Determined

48-hour EC<sub>50</sub> : Not Determined

96-hour EC<sub>50</sub> : Not Determined

**12.2. Persistence and degradability**

Persistence and degradability : Not Determined

**12.3. Bioaccumulative potential**

Bioaccumulative potential : Not Determined

**12.4. Mobility in soil**

Mobility in soil : Not Determined

**12.5. Results of PBT and vPvB assessment**

Results of PBT and vPvB assessment : Not Determined

**12.6. Other adverse effects**

Environmental data : No data available.

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**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

**Disposal method** : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**SECTION 14: Transport information**

**14.1. UN number**

**UN number** : N/A

**14.2. UN proper shipping name**

**UN proper shipping name** : Not Dangerous Goods

**14.3. Transport hazard class(es)**

**Hazard classification** : N/A

**14.4. Packing group**

**Packing group** : N/A

**14.5. Environmental hazards**

**Marine pollutant #1** : N/A

**14.6. Special precautions for user**

**ADR - road** : Not Dangerous Goods

**RID - rail** : Not Dangerous Goods

**IMDG - sea** : Not Dangerous Goods

**IATA - air** : Not Dangerous Goods

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

**Transport in bulk** : Not Dangerous Goods

**SECTION 15: Regulatory information**

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

**RoHS** : Please refer to Medical Devices Directive 93/42/EEC

**15.2. Chemical safety assessment**

**Chemical safety assessment** : See Section 11

**Additional information** : This product is not considered dangerous for transportation

**SECTION 16: Other information**

**Relevant R-phrases and/or H-statements (number and full text)** : R22: Harmful if swallowed.  
 R36/37/38: Irritating to eyes, respiratory system and skin.  
 R36/37: Irritating to eyes and respiratory system.  
 R38: Irritating to skin.  
 R43: May cause sensitization by skin contact.  
 Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4

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H302: Harmful if swallowed.  
 H315: Causes skin irritation.  
 H317: May cause an allergic skin reaction.  
 H319: Causes serious eye irritation.

**Prepared by**

: Anu Kattoju

**Revision summary**

: This SDS replaces the 04/10/2015 SDS. Revised: **Section 1:** Date-  
 Revised. **Section 15:** COMMENTS.

**General statements**

: N/A= Not Applicable

**Manufacturer disclaimer**

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.