

SAFETY DATA SHEETS

This SDS packet was issued with item:

077640089

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

077340425 077640147 077640154 077640162 077640188

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/06/2012

SDS No : 7-001.13

Date Revised : 03/18/2015

Revision No : 14

Ultra-Etch®

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

1.1. Product identifier

Product code : UX/10947
Product name : Ultra-Etch®
Product description : Phosphoric Acid dental etchant

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

Relevant identified uses : Professional Dental Acid Etching Solution

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 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 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 : C
R phrases : R34

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

Health : Skin Corrosion, Category 1B

2.2. Label elements

This mixture contains Phosphoric Acid. This material is considered hazardous as defined by the OSHA Hazard Communication Standard (29 CFR 1819.1200)

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : C



Corrosive

R&S statement(s) : R34: Causes burns.

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/06/2012

SDS No : 7-001.13

Date Revised : 03/18/2015

Revision No : 14

Ultra-Etch®**Classification according to Regulation (EC) No 1272/2008 [CLP]**

Hazard pictogram(s)

:



Corrosive

Signal Word

: WARNING

Hazard statement(s)

: H314: Causes severe skin burns and eye damage.

Precautionary statement(s)

Prevention

: P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response

: P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P332+P313: If skin irritation occurs: Get medical advice/attention.

P301: IF SWALLOWED:

P310: Immediately call a POISON CENTER or doctor/physician.

P331: Do NOT induce vomiting.

Storage

: P273: Avoid release to the environment.

Disposal

: P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns

: Corrosive. Will cause eye burns and permanent tissue damage.

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]
Phosphoric Acid	7664-38-2	231-633-2	< 45	C; R34	Skin Corr., Cat. 1B; H314

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

SECTION 4: First aid measures**4.1. Description of first aid measures**

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/06/2012

SDS No : 7-001.13

Date Revised : 03/18/2015

Revision No : 14

Ultra-Etch®

- | | |
|-----------------------------|---|
| Following eyes | : Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Have eyes examined and tested by medical personnel. |
| Following skin | : Wash with soap and water. Get medical attention if irritation develops or persists. |
| Following ingestion | : If swallowed, rinse mouth with water, Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person. |
| 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 | : Causes severe eye burns. |
| Skin | : Corrosive, causes skin burning. |
| Ingestion | : Harmful if swallowed. |
| Inhalation | : None expected for this product. |

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

- | | |
|---------------------------|-------------|
| Notes to physician | : Corrosive |
|---------------------------|-------------|

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 | : Not Determined |
| 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 | : Non-combustible. |

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

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/06/2012

SDS No : 7-001.13

Date Revised : 03/18/2015

Revision No : 14

Ultra-Etch®

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

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 Acid Etching Solution

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 : Gel

Colour : Blue

Odour : Odorless or no characteristic odor

pH : < 1

Solubility in water : Partially soluble in water.

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/06/2012

SDS No : 7-001.13

Date Revised : 03/18/2015

Revision No : 14

Ultra-Etch®

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 strong bases, Metals. Excess heat, exposure to moist air or water.

10.5. Incompatible materials

Incompatible materials : Strong caustics, most metals.

10.6. Hazardous decomposition products

Hazardous decomposition products : Phosphine, oxides of phosphorous, hydrogen gas

Additional information : Reacts with bases to form phosphate salts and is corrosive (especially when hot) to many metals and alloys. Liberates explosive hydrogen gas when reacting with chlorides and stainless steel, and reacts violently with sodium tetrahydroborate. Forms flammable gases with sulfides, mercaptans, cyanides, and aldehydes. Also forms toxic fumes with cyanides, sulfides, fluorides, organic peroxides, and halogenated organics.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Notes : Device is a strong acid and is extremely toxic. It is to be used only as directed with PPE, and only by licensed dental professionals.

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : Not Determined

Aquatic toxicity (acute)

96-hour LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

Persistence and degradability : Not Determined

12.3. Bioaccumulative potential

Bioaccumulative potential : Not Determined

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/06/2012

SDS No : 7-001.13

Date Revised : 03/18/2015

Revision No : 14

Ultra-Etch®

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 : Not defined

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 : 1760

14.2. UN proper shipping name

UN proper shipping name : Corrosive liquid, n.o.s. (Phosphoric acid mixture)

14.3. Transport hazard class(es)

Primary hazard class/division : 8

Hazard classification : 8

14.4. Packing group

Packing group : III

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : N/A

RID - rail : N/A

IMDG - sea : N/A

IATA - air : N/A

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

Transport in bulk : N/A

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

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/06/2012

SDS No : 7-001.13

Date Revised : 03/18/2015

Revision No : 14

Ultra-Etch®**SECTION 16: Other information****Relevant R-phrases and/or H-statements (number and full text)**

: R34: Causes burns.
 Skin Corr., Cat. 1B: Skin Corrosion, Category 1B
 H314: Causes severe skin burns and eye damage.

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 02/25/2015 SDS. Revised: **Section 1:**
 . **Section 2:** . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT -
 SKIN. **Section 10:** HAZARDOUS POLYMERIZATION.

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.

SAFETY DATA SHEET

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

ULTRADENT
PRODUCTS, INC.

Date Issued : 09/06/2012

SDS No : 7-001.15

Date Revised : 12/22/2015

Revision No : 16

Ultra-Etch®

SECTION 1 : Identification of the substance/preparation and of the company/undertaking**1.1. Product identifier**

Product code : UX/10947
Product name : Ultra-Etch®
Product description : Phosphoric Acid dental etchant

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

Relevant identified uses : Professional Dental Acid Etching Solution

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 : C
R phrases : R34

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

Health : Skin Corrosion, Category 1B

2.2. Label elements**Classification according to Directive 1999/45/EC**

Hazard pictogram(s) : C



Corrosive

R&S statement(s) : R34: Causes burns.

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

SAFETY DATA SHEET

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

ULTRADENT
PRODUCTS, INC.

Date Issued : 09/06/2012

SDS No : 7-001.15

Date Revised : 12/22/2015

Revision No : 16

Ultra-Etch®

Hazard pictogram(s)

:



Corrosive

Signal Word

: DANGER

Hazard statement(s)

: H314: Causes severe skin burns and eye damage.

Precautionary statement(s)

Prevention

: P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response

: P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P315: Get immediate 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.
P360: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.
P363: Wash contaminated clothing before reuse.
P301: IF SWALLOWED:
P310: Immediately call a POISON CENTER or doctor/physician.
P330: Rinse mouth.
P331: Do NOT induce vomiting.

Storage

: P273: Avoid release to the environment.

Disposal

: P501: Dispose of in compliance with governmental regulations (EC 1975L0442-20/11/2003).

2.3. Other hazards

Immediate concerns

: Corrosive. Will cause eye burns and permanent tissue damage.

SECTION 3: Composition / Information on Ingredients**3.1. Substances**

Not Applicable

3.2. Mixtures

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use

ULTRADENT
PRODUCTS, INC.

Date Issued : 09/06/2012

SDS No : 7-001.15

Date Revised : 12/22/2015

Revision No : 16

Ultra-Etch®

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Phosphoric Acid	7664-38-2	231-633-2	< 40	C; R34	Skin Corr., Cat. 1B; H314
Cobalt aluminate blue spinel	1345-16-0	310-193-6	< 1	R36/37/38; R22	Skin Irr., Cat. 2; Eye Irr., Cat. 2; STOT SE, Cat. 3; H315; H319; H335

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 with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Have eyes examined and tested by medical personnel.
- Following skin** : Remove contaminated clothing. Wash with soap and water.
- Following ingestion** : If swallowed, rinse mouth with water. Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center if you feel unwell.
- 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** : Causes severe eye burns.
- Skin** : Corrosive, causes skin burning.
- Ingestion** : Harmful if swallowed.
- Inhalation** : None expected for this product.

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

- Notes to physician** : Corrosive

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** : Phosphine, oxides of phosphorous, hydrogen gas

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/06/2012

SDS No : 7-001.15

Date Revised : 12/22/2015

Revision No : 16

Ultra-Etch®**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 : The product is not combustible. Substance does not burn but may decompose upon heating to produce corrosive and/or toxic fumes. Keep product and empty container away from heat and sources of ignition. Use appropriate media for adjacent fire. Cool containers with water.

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 : Not Applicable

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 Acid Etching Solution

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

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/06/2012

SDS No : 7-001.15

Date Revised : 12/22/2015

Revision No : 16

Ultra-Etch®**9.1. Information on basic physical and chemical properties**

Physical state	: Gel
Colour	: Blue
Odour	: Odorless or no characteristic odor
pH	: < 1
Solubility in water	: Partially Soluble

9.2. Other information

Percent volatile	: Not Determined
------------------	------------------

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	: Strong bases, metals, excess heat, exposure to moist air or water
---------------------	---

10.5. Incompatible materials

Incompatible materials	: Strong caustics, most metals.
------------------------	---------------------------------

10.6. Hazardous decomposition products

Hazardous decomposition products	: Phosphine, oxides of phosphorous, hydrogen gas
----------------------------------	--

Additional information	: Reacts with bases to form phosphate salts and is corrosive (especially when hot) to many metals and alloys. Liberates explosive hydrogen gas when reacting with chlorides and stainless steel, and reacts violently with sodium tetrahydroborate. Forms flammable gases with sulfides, mercaptans, cyanides, and aldehydes. Also forms toxic fumes with cyanides, sulfides, fluorides, organic peroxides, and halogenated organics.
------------------------	---

SECTION 11: Toxicological information**11.1. Information on toxicological effects****Acute**

Notes	: Device is a strong acid and is extremely toxic. It is to be used only as directed with PPE, and only by licensed dental professionals.
-------	--

SECTION 12: Ecological information**12.1. Toxicity**

Toxicity	: Not Determined
Aquatic toxicity (acute)	: Do not allow to enter sewers or drains that may lead to waterways.

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/06/2012

SDS No : 7-001.15

Date Revised : 12/22/2015

Revision No : 16

Ultra-Etch®96-hour LC₅₀ : Not Determined48-hour EC₅₀ : Not Determined96-hour EC₅₀ : 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 : Do not flush to sewer.

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 : 1760

14.2. UN proper shipping name

UN proper shipping name : Corrosive liquid, n.o.s. (Phosphoric acid mixture)

14.3. Transport hazard class(es)

Primary hazard class/division : 8

Hazard classification : 8

14.4. Packing group

Packing group : III

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : N/A

RID - rail : N/A

IMDG - sea : N/A

IATA - air : N/A

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

Transport in bulk : N/A

SAFETY DATA SHEET

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



Date Issued : 09/06/2012

SDS No : 7-001.15

Date Revised : 12/22/2015

Revision No : 16

Ultra-Etch®**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 : IARC has identified cobalt and cobalt compounds as "possibly carcinogenic" as a group, however IARC did not specifically identify the cobalt compound in this product as a possible carcinogen.

OSHA- Select Carcinogens: Present

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R22: Harmful if swallowed.
R34: Causes burns.
R36/37/38: Irritating to eyes, respiratory system and skin.
Eye Irr., Cat. 2: Eye Irritation, Category 2
STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Category 3
Skin Corr., Cat. 1B: Skin Corrosion, Category 1B
Skin Irr., Cat. 2: Skin Irritation, Category 2
H314: Causes severe skin burns and eye damage.
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 10/19/2015 SDS. Revised: **Section 1**: MSDS
No. **Section 4**: SKIN. **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.