SAFETY DATA SHEETS

This SDS packet was issued with item:

071884402

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

071883990 071884410

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).

071884006 071884428 078333230

1. Product and Company Identification

Product Name	SDS Code Number
Xeno® IV One Component Self Etching Dental Adhesive	568890
Trade Name & Synonyms	Date of Last Revision
Xeno® IV One Component Self Etching Dental Adhesive	02/02/11
Manufacturer:	Address
DENTSPLY Caulk	38 West Clarke Avenue
	Milford DE 19963-1805
	http://www.caulk.com
Grades or Minor Variant Identities	Information Telephone Number
Not Applicable	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada)	Emergency Telephone Number
Dental Bonding Agent	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



Warning Highly Flammable Liquid and Vapour



Warning Causes Skin Irritation

Keep away from heat/sparks/open flames / hot surfaces. No smoking.

Keep container tightly closed.
Wear protective gloves/eye protection/face protection.
Ground / Bond container and receiving equipment.
Use explosion-proof electrical lighting equipment.
Use only non-sparking tools.

Take precautionary measures against static discharge.

IF ON SKIN or Hair: Remove / take off immediately all contaminated clothing. Rinse skin with water / shower.

In case of fire: Use CO₂ sand or extinguishing powder.

Wash hands thoroughly after handling.
Wear protective gloves
IF ON SKIN: Wash with plenty of soap and water.
If skin irritation occurs: Get Medical Advice/attention.
Take off contaminated clothing and wash before reuse.

3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
Acetone	67-64-1	500 ppm	< 50
Urethane Dimethacrylate Resin	105883-40-7	Not Applicable	< 15
Dipentaerythritol pentaacrylate phosphate	87699-25-0	Not Applicable	< 15
Polymerizeable dimethacrylate resin	1709-71-3	Not Applicable	< 10
Polymerizeable trimethacrylate resin	3290-92-4	Not Applicable	< 10
Polymerizeable dimethacrylate resin	868-77-9	Not Applicable	< 10

4. First Aid Measures

Routes of	First Aid Instructions	Immediate	Delayed Effects
Exposure		Medical Attention	
Eye	Rinse opened eye for several minutes under running water. If symptoms persist consult physician.	Not Applicable	Not Applicable
Skin	Immediately wash with soap and water and rinse thoroughly	Not Applicable	Not Applicable
Inhalation	Supply fresh air	Not Applicable	Not Applicable
Ingestion	If symptoms persist consult physician	Not Applicable	Not Applicable
Other Not Applicable		Not Applicable	Not Applicable
Note to Phys	icians (Treating, Testing and Monitoring): Treat symptomatically.		

5. Fire and Explosion Data

Flashpoint Method: 2°C (36°F)	Flammable (Explosive) Limits in Air	Autoignition Temperature: Not	Other: Not		
Pensky-Marten Closed Cup	LEL: 2.5 vol. % UEL: 12. 8 vol. %	Applicable	Applicable		
Flame Propagation or Burning Rate	Properties Contributing to Fire Intensity: Not	Flammability Classification: 3			
(for Solids): Not Applicable	Applicable				
Extinguishing Media: CO ₂ , sand or extingu	Extinguishing Media to Avoid: Do not us	e water or water			
with full jet.					
Protection and Procedures for Firefighters:	Firefighters should wear self-contained respiratory protective of	devices.			
Unusual Fire and Explosion Hazards: Forn	nation of toxic gases is possible during heating or in case of fire				

6. Accidental Release Measures

Containment Techniques: Wear protective clothing. Absorb with liquid binding material (sand, vermiculite, diatomite, acid binders, universal binders or sawdust).

Scoop up bulk material and place in a labeled plastic or metal container.

Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing. Absorb with liquid binding material (sand, vermiculite, diatomite, acid binders, universal binders or sawdust). Scoop up bulk material and place in a labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation.

Evacuation Procedures: Not Applicable

Special Instructions: Not Applicable

Reporting Requirements: Not Applicable

7. Handling and Storage

Handling Practices and Warnings: Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.

Storage Practices and Warnings: Store in a well-ventilated place. Keep cool. Store only in the original package. Keep package tightly sealed. Protect from exposure to direct light. Store away from food and beverages.

8. Exposure Control / Personal Protection









Ventilation: None	required during normal intended use of this product	Other Engineering Controls: Not Applicable			
Routes of Entry	Personal Protective Equipment	(PPE) for Normal Use	PPE for Emergencies		
Eye/Face	Safety Gla	sses	Not Applicable		
Skin	in The glove material has to be impermeable and resistant to the product.				
Inhalation	Not required for normal volum	Not required for normal volumes used in Dental office.			
Body Protection	Body Protection Protective work clothing				
General Hygiene Considerations and Work Practices: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at end of work. Avoid contact with the eyes and skin.					
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not Applicable					
Other Protective Measures and Equipment: Not Applicable					

9. Physical and Chemical Characteristics

Appearance: Light yellow liquid.		Odor: Acetone like with characteristic sweet acrylic ester odor.			
Normal Physical State: Low viscosity liquid		Melting Point: Not Determined Boiling Point: 57°C (135°F)		Boiling Point: 57°C (135°F)	
Specific Gravity: ~0.9 g/cm ³	fic Gravity: ~0.9 g/cm ³ Solubility in Water: Partially		pH: 2.5		
Vapor Pressure (mm Hg): Not Applicable		Not Applicable	Evaporation Rate (Butyl Acetate=1): Not Applicable	
Other: Not Applicable				_	

10. Stability and Reactivity Data

	Incompatibility (Materials to Avoid): Visible light, high temperatures, stror	ng acids, strong oxidizing agents.	
	Hazardous Products Produced During Decomposition: Methacrylates, acryl	ates, carbon dioxide, carbon monoxide, peroxides and irritating gases.	
Hazardous Polymerization: ☐May Occur ☐May Not Occur ☐Conditions to Avoid: High Temperatures, ignition sources.			
	Stability? ⊠Stable □Unstable	Conditions to Avoid: High Temperatures, ignition sources.	

11. Toxicological Information

Emergency C	Emergency Overview: Material is flammable. Material is irritating to eyes, respiratory system and skin.				
Toxicity Data, E	pidemiology Studies, Carcinogenicity, 1	Neurological Effects, (Genetic Effects, Repro	oductive Effects, or Structure Activity Data:	
				to the skin in susceptible persons. On the eye the	
irritating effect.	Sensitization: Repeated or prolonged co	ntact with the unpolyn	nerized material may	cause sensitization for persons allergic to acrylate	es and
methacrylates. T	his product shows the following danger	s according to internal	ly approved calculation	on methods for composite materials: Irritant.	
Routes of Signs and Symptoms Single, Repeated, Severity (Mild, Acute and Chronic Health Effect(s)					
Exposure		or Lifetime	Moderate, Severe)		Target
Exposure				Organ(s)	
Eye	Material can cause irritation.	Single	Moderate	Irritation and possible corneal damage	Yes
Skin	Material may be an irritant and may	Single & Repeated	Moderate	Irritation or possible allergic response.	Yes
	be absorbed through the skin.			Severe allergic response may result	

				in breathing difficulties.	
Inhalation	Inhalation of high concentrations may cause central nervous system effects characterized by nausea, headache, dizziness, unconsciousness and coma.	Repeated		Chronic inhalation may cause effects similar to those of acute inhalation. Causes respiratory tract irritation. May cause motor incoordination and speech abnormalities.	Yes
Ingestion	May cause irritation of the digestive tract.	Single & Repeated	Mild	Not Applicable	No
Other: Central nervous system	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable

Medical Conditions Aggravated by Exposure: Open sores and wounds of the skin. Individuals with known sensitivity to methacrylates, acrylates, or urethane dimethacrylate resin used in Dental restorative products.

Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No. All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.

NFPA Hazard Classification Ratings (Scale 0-4) Health = 2, Fire = 3, Reactivity = 0 Specific Hazard = None

12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Harmful to fish. Harmful to aquatic organisms.

13. Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations

Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

RCRA P-Series: None Listed, RCRA U-Series CAS#67-64-1: Waste Number U002 (Ignitable Waste)

14. Transport Information

= 11 = 1 = 1 = 1 = 1			
Regulated for Shipping: Yes Proper Shipping Name: Acetone Sol	Packing Group: II		
Do Changes in Quantities, packaging, or shipment method change	Hazard Class: 3	UN Identification Number: 1090	
product classification? Yes			
Other: Not Applicable			



Flammable Liquid

15. Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.

U.S. Federal Regulations: CERCLA 103 Reportable Quantity: RQ is 5,000 pounds (2268Kg) for CAS# 67-64-1 Acetone. Report spills required under federal, state and local regulations. Many states have more stringent release reporting requirements.

RCRA U-Series Hazardous Waste Code for CAS# 67-64-1 Acetone: U002

Section 313 Toxic Chemicals: This product does not contain any chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372).

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory

U.S. State Regulations California Proposition 65: This product does not contain any chemicals, which are on the California Proposition 65 list.

Federal Regulations: The product has been classified and marked in accordance with directives on hazardous materials. Hazard Symbol: Flammable Water Hazard class1 (Self-assessment): slightly hazardous for water. SARA Codes: CAS # 67-64-1 Acute, chronic, flammable.

International Regulations: Hazard Symbol: Flammable XI F Risk Phrases: R11 Highly Flammable, R36/37/38 Irritating to Eyes, respiratory system and skin. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R67 Vapors may cause drowsiness and dizziness. Safety Phrases: S9 Keep container in well-ventilated place. S16 Keep away from sources of ignition – No Smoking, S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice, S28 After contact with skin wash immediately with plenty of water, S61 Avoid release to the environment.

Other: Canada WHMIS for the acetone, classification of B2, D2B. Acetone CAS#67-64-1 is on the Canadian Ingredient Disclosure List.

16. Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex.

All components are synthetically produced; none are derived from animal products.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

DENTSPLY Milford Safety Data Sheet

1. Product and Company Identification

Product Name	SDS Code Number
Xeno® IV One Component Self Etching Dental Adhesive	568890
Trade Name & Synonyms	Date of Last Revision
Xeno® IV One Component Self Etching Dental Adhesive	11/04/16
Manufacturer:	Address
DENTSPLY Milford	38 West Clarke Avenue
	Milford DE 19963-1805
	http://www.dentsply.com
Grades or Minor Variant Identities	Information Telephone Number
Not Applicable	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada)	Emergency Telephone Number
Dental Bonding Agent	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



Warning Highly Flammable Liquid and Vapour

Keep away from heat/sparks/open flames / hot surfaces. No smoking.

Keep container tightly closed.

Wear protective gloves/eye protection/face protection. Ground / Bond container and receiving equipment. Use explosion-proof electrical lighting equipment.

Use only non-sparking tools.

Take precautionary measures against static discharge.

IF ON SKIN or Hair: Remove / take off immediately all contaminated

clothing. Rinse skin with water / shower. In case of fire: Use CO₂ sand or extinguishing powder.



Wash hands thoroughly after handling.
Wear protective gloves
IF ON SKIN: Wash with plenty of soap and water.
If skin irritation occurs: Get Medical Advice/attention.
Take off contaminated clothing and wash before reuse.

3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
Acetone	67-64-1	500 ppm	< 50
Urethane Dimethacrylate Resin	105883-40-7	Not Applicable	< 15
Dipentaerythritol pentaacrylate phosphate	87699-25-0	Not Applicable	< 15
Polymerizeable dimethacrylate resin	1709-71-3	Not Applicable	< 10
Polymerizeable trimethacrylate resin	3290-92-4	Not Applicable	< 10
Polymerizeable dimethacrylate resin	868-77-9	Not Applicable	< 10

4. First Aid Measures

Routes of	First Aid Instructions	Immediate	Delayed Effects
Exposure		Medical Attention	
Eye	Rinse opened eye for several minutes under running water.	Not Applicable	Not Applicable
	If symptoms persist consult physician.		
Skin	Immediately wash with soap and water and rinse thoroughly	Not Applicable	Not Applicable
Inhalation	Supply fresh air	Not Applicable	Not Applicable
Ingestion	If symptoms persist consult physician	Not Applicable	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable
Note to Physi	icians (Treating, Testing and Monitoring): Treat symptomatically.		

5. Fire and Explosion Data

Flashpoint Method: 2°C (36°F)	Flammable (Explosive) Limits in Air	Autoignition Temperature: Not	Other: Not			
Pensky-Marten Closed Cup	LEL: 2.5 vol. % UEL: 12. 8 vol. %	Applicable	Applicable			
Flame Propagation or Burning Rate	Properties Contributing to Fire Intensity: Not	Flammability Classification: 3				
(for Solids): Not Applicable	Applicable					
Extinguishing Media: CO ₂ , sand or extingu	Extinguishing Media to Avoid: Do not us	e water or water				
with full jet.						
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.						
Unusual Fire and Explosion Hazards: Formation of toxic gases is possible during heating or in case of fire						

6. Accidental Release Measures

Containment Techniques: Wear protective clothing. Absorb with liquid binding material (sand, vermiculite, diatomite, acid binders, universal binders or sawdust).

Scoop up bulk material and place in a labeled plastic or metal container.

Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing. Absorb with liquid binding material (sand, vermiculite, diatomite, acid binders, universal binders or sawdust). Scoop up bulk material and place in a labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation.

Evacuation Procedures: Not Applicable

Special Instructions: Not Applicable

Reporting Requirements: Not Applicable

7. Handling and Storage

Handling Practices and Warnings: Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.

Storage Practices and Warnings: Store in a well-ventilated place. Keep cool. Store only in the original package. Keep package tightly sealed. Protect from exposure to direct light. Store away from food and beverages.

8. Exposure Control / Personal Protection









Ventilation: None re	equired during normal intended use of this product	Other Engineering Controls: Not Applicabl	e	
Routes of Entry	Personal Protective Equipn	nent (PPE) for Normal Use	PPE for Emergencies	
Eye/Face	Safety C	Safety Glasses Not Applicabl		
Skin	The glove material has to be imper	The glove material has to be impermeable and resistant to the product. Not Applicable		
Inhalation	Not required for normal volumes used in Dental office. Not Applicable		Not Applicable	
Body Protection	Protective work clothing Not Applicable		Not Applicable	
General Hygiene Considerations and Work Practices: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing.				
Wash hands before breaks and at end of work. Avoid contact with the eyes and skin.				
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not Applicable				
Other Protective Measures and Equipment: Not Applicable				

9. Physical and Chemical Characteristics

> 1 11 51001 0110 01101111001 011011000					
Appearance: Light yellow liquid.	Odor: Acetone like with characteristic sweet acrylic ester odor.				
Normal Physical State: Low viscosity liq	Melting Point: Not Determined Boiling Point: 57°C (135°F)		Boiling Point: 57°C (135°F)		
Specific Gravity: ~0.9 g/cm ³	Solubility in Water: Partially	pH: 2.5			
Vapor Pressure (mm Hg): Not Applicable Vapor Density (AIR=1)		Not Applicable	Evaporation Rate (1	Butyl Acetate=1): Not Applicable	
Other: Not Applicable					

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Visible light, high temperatures, strong acids, strong oxidizing agents.				
Hazardous Products Produced During Decomposition: Methacrylates, acryl	Hazardous Products Produced During Decomposition: Methacrylates, acrylates, carbon dioxide, carbon monoxide, peroxides and irritating gases.			
Hazardous Polymerization: ☐May Occur ☐May Not Occur ☐Conditions to Avoid: High Temperatures, ignition sources.				
Stability? ⊠Stable ☐Unstable Conditions to Avoid: High Temperatures, ignition sources.				

11. Toxicological Information

Emergency O	Emergency Overview: Material is flammable. Material is irritating to eyes, respiratory system and skin.					
Toxicity Data, E	pidemiology Studies, Carcinogenicity, I	Neurological Effects, C	Genetic Effects, Repro	oductive Effects, or Structure Activity Data:		
Product is an irri	tant to skin and mucous membranes. Th	ne unpolymerized prod	uct may be an irritant	to the skin in susceptible persons. On the eye the	product has an	
irritating effect.	Sensitization: Repeated or prolonged co	ntact with the unpolyn	nerized material may	cause sensitization for persons allergic to acrylate	es and	
methacrylates. T	methacrylates. This product shows the following dangers according to internally approved calculation methods for composite materials: Irritant.					
Routes of	Routes of Signs and Symptoms Single, Repeated, Severity (Mild, Acute and Chronic Health Effect(s)					
Exposure	Exposure or Lifetime Moderate, Severe) Target				Target	
	Exposure Organ(s)					
Eye	Material can cause irritation.	Single	Moderate	Irritation and possible corneal damage	Yes	

Skin	Material may be an irritant and may	Single & Repeated	Moderate	Irritation or possible allergic response.	Yes
	be absorbed through the skin.			Severe allergic response may result	
				in breathing difficulties.	
Inhalation	Inhalation of high concentrations	Repeated	Moderate	Chronic inhalation may cause effects similar to	Yes
	may cause central nervous system			those of acute inhalation. Causes respiratory	
	effects characterized by nausea,			tract irritation. May cause motor incoordination	
	headache, dizziness,			and speech abnormalities.	
	unconsciousness and coma.				
Ingestion	May cause irritation of the digestive	Single & Repeated	Mild	Not Applicable	No
	tract.				
Other: Central	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
nervous system					

Medical Conditions Aggravated by Exposure: Open sores and wounds of the skin. Individuals with known sensitivity to methacrylates, acrylates, or urethane dimethacrylate resin used in Dental restorative products.

NTP?: Not listed Carcinogenicity IARC monographs?: Not listed OSHA regulated?: No. All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.

NFPA Hazard Classification Ratings (Scale 0-4) Health = 2, Fire = 3, Reactivity = 0 Specific Hazard = None

12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Harmful to fish. Harmful to aquatic organisms.

13. Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

RCRA P-Series: None Listed, RCRA U-Series CAS#67-64-1: Waste Number U002 (Ignitable Waste)

14. Transport Information

	_		
Regulated for Shipping: Yes Proper Shipping Name: Acetone Solution			Packing Group: II
Do Changes in Quantities, pac	kaging, or shipment method change	Hazard Class: 3	UN Identification Number: 1090
product classification? Yes			
Other: Not Applicable			



Flammable Liquid

15. Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.

U.S. Federal Regulations: CERCLA 103 Reportable Quantity: RQ is 5,000 pounds (2268Kg) for CAS# 67-64-1 Acetone. Report spills required under federal, state and local regulations. Many states have more stringent release reporting requirements.

RCRA U-Series Hazardous Waste Code for CAS# 67-64-1 Acetone: U002

Section 313 Toxic Chemicals: This product does not contain any chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.

U.S. State Regulations California Proposition 65: This product does not contain any chemicals, which are on the California Proposition 65 list.

Federal Regulations: The product has been classified and marked in accordance with directives on hazardous materials. Hazard Symbol: Flammable Water Hazard class1 (Self-assessment): slightly hazardous for water. SARA Codes: CAS # 67-64-1 Acute, chronic, flammable.

International Regulations: Hazard Symbol: Flammable XI F Risk Phrases: R11 Highly Flammable, R36/37/38 Irritating to Eyes, respiratory system and skin. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R67 Vapors may cause drowsiness and dizziness. Safety Phrases: S9 Keep container in well-ventilated place. S16 Keep away from sources of ignition - No Smoking, S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice, S28 After contact with skin wash immediately with plenty of water, S61 Avoid release to the environment.

Other: Canada WHMIS for the acetone, classification of B2, D2B. Acetone CAS#67-64-1 is on the Canadian Ingredient Disclosure List.

16. Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex.

All components are synthetically produced; none are derived from animal products.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.