SAFETY DATA SHEETS

This SDS packet was issued with item:

071718683

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

071719020

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).

071718741

DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

523899

1. Identification

Product Name	SDS Code Number
DYCAL® Radiopaque Calcium Hydroxide Composition	523899
Substance Identity	Date of Last Revision
DYCAL® Radiopaque Calcium Hydroxide Composition	04/15/11
Manufacturer:	Address
DENTSPLY Caulk	38 West Clarke Avenue
	Milford DE 19963-1805
	http://www.caulk.com 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
Not Applicable	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



WARNING CAUSES SKIN IRRITATION

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 - Base Paste

Hazardous Components	C.A.S. Number	Exposure Limits	%
Calcium Tungstate	7790-75-2	5 mg/M^3	< than 20
Zinc Oxide	1314-13-2	10 mg/M^3	< than 15
Disalicylate ester of 1,3 butylene glycol	73240-13-8	Not Established	< than 50

Other Information: Colorants are synthetic inorganic iron oxides.

3. Composition/Information on Ingredients - Catalyst Paste

Hazardous Components	C.A.S. Number	Exposure Limits	%
Calcium Hydroxide	1305-62-0	5 mg/M^3	< than 55
Zinc Oxide	1314-13-2	10 mg/M^3	< than 15
Titanium Dioxide	13463-67-7	10 mg/M^3	< than 10

3. Hazard Identification

Emergency	Emergency Overview: Material is an irritant.					
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health		
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)	Effect(s)	Target Organ(s)	
Eye	Material may cause irritation.	Single & Repeated	Moderate	Irritation and possible corneal	Not Applicable	
				damage due to the caustic nature of ingredient used in the product.		
Skin	Material may cause irritation.	Single & Repeated	Mild	Irritation or possible allergic	Not Applicable	
				response.		
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Ingestion	Material may cause irritation.	Not Applicable	Mild	Irritation due to the caustic	Not Applicable	
				nature of ingredients used in the		
				product.		
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.						
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 = 1, Fire = 0, Reactivity = 0

4. First Aid Measures

Routes of	First Aid Instructions	Immediate Medical	Delayed Effects		
Exposure		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, If symptoms persist consult physician.	Not Applicable	Not Applicable		
	This may not be of concern when using clinically relevant quantities.				
Ingestion	Rinse out mouth and then drink plenty of water. Consult a physician	Not Applicable	Not Applicable		
	immediately.				
	This may not be of concern when using clinically relevant quantities.				
Other	Not Applicable	Not Applicable	Not Applicable		
Note to Physici	Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.				

5. Fire and Explosion Data

5. The and Explosion Data					
Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air	Autoignition Temperature:	Other: Not		
	LEL: Not Applicable UEL: Not Applicable	Not Applicable	Applicable		
Flame Propagation or Burning Rate (for Solids):	Properties Contributing to Fire Intensity: Not Applicable	Flammability Classification:			
Not Applicable		Not Applicable			
Extinguishing Media: Use fire extinguishing methods suitable to surrounding conditions. Extinguishing Media to Avoid: Not Applicab					
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: Material is a high viscosity paste, but will flow somewhat.				
Spill/Leak Clean-up Procedures and Equipment: 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.				
Evacuation Procedures: Not Applicable Special Instructions: Not Applicable Reporting Requirements: Not Applicable				

7. Handling and Storage

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

Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Store away from food and beverages.

8. Exposure Control / Personal Protection









Individual Protection	Personal Protective Equipment for Normal Use	Personal Protective Equipment for
Measures		Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Not Required. This may not be of concern when using clinically relevant quantities.	Not Applicable
Body Protection	Protective work clothing	Not Applicable
Occupational Exposure Lim	Engineering Controls: Not Applicable	

9. Physical and Chemical Characteristics

Appearance: Base-light yellow colored paste, catalyst-white paste.		Odor: Base odor of cloves, Catalyst Odorless.
Normal Physical State: Paste		Melting Point: Not Applicable
Specific Gravity: Base 2.0 g/cm ³ Catalyst 1.8 g/cm ³	Solubility in Water: Not soluble	pH: Base-Not Applicable, Catalyst- 11.5
Vapor Pressure (mm Hg): Not Applicable		Evaporation Rate (Butyl Acetate =1): Not Applicable
Flashpoint - Method: Not Applicable Flammable (Explosive) Limits in Air		Autoignition Temperature: Not Applicable
	LEL: Not Applicable UEL: Not Applicable	
Other: Not Applicable		

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Not Applicable	
Hazardous Products Produced During Decomposition: Not Applie	eable
Hazardous Polymerization: ☐May Occur ☐May Not Occur	Conditions to Avoid: None known
Stability? ⊠Stable ☐Unstable	Conditions to Avoid: None known

11. Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:

Irritating to skir	Irritating to skin and mucous membranes.					
Emergency Ove	erview: Material is an irritant.					
Routes of		Single, Repeated, or	Severity (Mild, Moderate,	Acute and Chronic Health		
Exposure	Signs and Symptoms	Lifetime Exposure	Severe)	Effect(s)	Target Organ(s)	
Eye	Material may cause irritation.	Single & Repeated	Moderate	Irritation and possible corneal	Not Applicable	
				damage due to the caustic nature		
				of ingredient used in the product.		
Skin	Material may cause irritation.	Single & Repeated	Mild	Irritation or possible allergic	Not Applicable	
				response.		
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Ingestion	Material may cause irritation.	Not Applicable	Mild	Irritation due to the caustic nature	Not Applicable	
				of ingredients used in the product.		
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Medical Conditions Aggregated by Exposure Open seres and wounds of the skin						

Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.

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

NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 0, Reactivity = 0

12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system. Toxic to fish. Also poisonous for fish and plankton in water bodies. Toxic for aquatic organisms.



Danger Hazardous to aquatic life

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.

14.Transport Information

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment	DOT Hazard Class: Not Applicable	UN Number: Not Applicable
method change product classification? No		

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: <u>CERCLA 103 Reportable Quantity</u>: This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

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.

International Regulations: Canadian Environmental Protection Act:

This product is a medical device and not subject to chemical notification requirements.

European Community Labeling. Not a dangerous preparation. These R and S phrases apply to base and catalyst: R36/38 Irritating to eyes and skin. R51/53 Toxic to aquatic organisms, may cause long-term effects in the environment. S26 Incase 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. S37 Wear suitable gloves. S57 Use appropriate container to avoid environmental contamination. S60 This material and its container must be disposed of as hazardous waste. These R and S phrases apply to catalyst: R41 Risk of serious damage to eyes. R50/53 Very toxic to aquatic organisms, may cause long-term effects in the environment. S24 Avoid contact with skin.

European Inventory of New and Existing Chemicals Substances (EINECS):

This product is a medical device and not subject to chemical notification requirements.

Other: Not Applicable

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/International DENTSPLY/Caulk Safety Data Sheet

523899

1. Identification

Product Name	SDS Code Number
DYCAL® Radiopaque Calcium Hydroxide Composition	523899
Substance Identity	Date of Last Revision
DYCAL® Radiopaque Calcium Hydroxide Composition	02/21/14
Manufacturer:	Address
DENTSPLY Caulk	38 West Clarke Avenue
	Milford DE 19963-1805
	http://www.caulk.com 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
Not Applicable	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



WARNING CAUSES SKIN IRRITATION

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 - Base Paste

Hazardous Components	C.A.S. Number	Exposure Limits	%
Calcium Tungstate	7790-75-2	5 mg/M^3	< than 20
Zinc Oxide	1314-13-2	10 mg/M^3	< than 15
Disalicylate ester of 1,3 butylene glycol	73240-13-8	Not Established	< than 50

Other Information: Colorants are synthetic inorganic iron oxides.

3. Composition/Information on Ingredients - Catalyst Paste

Hazardous Components	C.A.S. Number	Exposure Limits	%
Calcium Hydroxide	1305-62-0	5 mg/M^3	< than 55
Zinc Oxide	1314-13-2	10 mg/M^3	< than 15
Titanium Dioxide	13463-67-7	10 mg/M^3	< than 10

3. Hazard Identification

Emergency Overview: Material is an irritant.					
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health	
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)	Effect(s)	Target Organ(s)
Eye	Material may cause irritation.	Single & Repeated	Moderate	Irritation and possible corneal	Not Applicable
				damage due to the caustic nature of ingredient used in the product.	
Skin	Material may cause irritation.	Single & Repeated	Mild	Irritation or possible allergic	Not Applicable
				response.	
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material may cause irritation.	Not Applicable	Mild	Irritation due to the caustic	Not Applicable
				nature of ingredients used in the	
				product.	
Other	Other Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable				Not Applicable
Medical Con	Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.				
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 = 1, Fire = 0, Reactivity = 0

4. First Aid Measures

Routes of	First Aid Instructions	Immediate Medical	Delayed Effects
Exposure		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, If symptoms persist consult physician.	Not Applicable	Not Applicable
	This may not be of concern when using clinically relevant quantities.		
Ingestion	Rinse out mouth and then drink plenty of water. Consult a physician	Not Applicable	Not Applicable
	immediately.		
	This may not be of concern when using clinically relevant quantities.		
Other	Not Applicable	Not Applicable	Not Applicable
Note to Physici	ans (Treating, Testing and Monitoring): Treat symptomatically.	-	·

5. Fire and Explosion Data

5.1 He and Explosion Data			
Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air	Autoignition Temperature:	Other: Not
	LEL: Not Applicable UEL: Not Applicable	Not Applicable	Applicable
Flame Propagation or Burning Rate (for Solids):	Properties Contributing to Fire Intensity: Not Applicable	Flammability Classification:	1
Not Applicable		Not Applicable	
Extinguishing Media: Use fire extinguishing methods suitable to surrounding conditions. Extinguishing Media to Avoid: Not Applicable to Surrounding Conditions.			lot Applicable
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: Material is a high viscosity paste, but will flow somewhat.		
Spill/Leak Clean-up Procedures and Equipment: 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.		
Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable

7. Handling and Storage

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

Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Store away from food and beverages.

8. Exposure Control / Personal Protection









Individual Protection	Personal Protective Equipment for Normal Use	Personal Protective Equipment for
Measures		Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Not Required. This may not be of concern when using clinically relevant quantities.	Not Applicable
Body Protection	Protective work clothing	Not Applicable
Occupational Exposure Lim	its: Not Applicable	Engineering Controls: Not Applicable

9. Physical and Chemical Characteristics

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Appearance: Base-light yellow colored paste, catalyst-white paste.		Odor: Base odor of cloves, Catalyst Odorless.
Normal Physical State: Paste		Melting Point: Not Applicable
Specific Gravity: Base 2.0 g/cm ³ Catalyst 1.8 g/cm ³	Solubility in Water: Not soluble	pH: Base-Not Applicable, Catalyst- 11.5
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1): Not Applicable	Evaporation Rate (Butyl Acetate =1): Not Applicable
Flashpoint - Method: Not Applicable	Flammable (Explosive) Limits in Air	Autoignition Temperature: Not Applicable
	LEL: Not Applicable UEL: Not Applicable	
Other: Not Applicable		

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Not Applicable		
Hazardous Products Produced During Decomposition: Not Applicable		
Hazardous Polymerization: ☐May Occur ☐May Not Occur	Conditions to Avoid: None known	
Stability? ⊠Stable □Unstable	Conditions to Avoid: None known	

11.Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:

Irritating to skin and mucous membranes.							
Emergency Overview: Material is an irritant.							
Routes of		Single, Repeated, or	Severity (Mild, Moderate,	Acute and Chronic Health			
Exposure	Signs and Symptoms	Lifetime Exposure	Severe)	Effect(s)	Target Organ(s)		
Eye	Material may cause irritation.	Single & Repeated	Moderate	Irritation and possible corneal	Not Applicable		
				damage due to the caustic nature			
				of ingredient used in the product.			
Skin	Material may cause irritation.	Single & Repeated	Mild	Irritation or possible allergic	Not Applicable		
				response.			
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable		
Ingestion	Material may cause irritation.	Not Applicable	Mild	Irritation due to the caustic nature	Not Applicable		
				of ingredients used in the product.			
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable		
Medical Conditions Aggregated by Evnogues Open gares and grounds of the skip							

Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.

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

NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 0, Reactivity = 0

12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system. Toxic to fish. Also poisonous for fish and plankton in water bodies. Toxic for aquatic organisms.



Danger Hazardous to aquatic life

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.

14.Transport Information

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment	DOT Hazard Class: Not Applicable	UN Number: Not Applicable
method change product classification? No		

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: <u>CERCLA 103 Reportable Quantity</u>: This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

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.

International Regulations: Canadian Environmental Protection Act:

This product is a medical device and not subject to chemical notification requirements.

European Community Labeling: Not a dangerous preparation. These R and S phrases apply to base and catalyst: R36/38 Irritating to eyes and skin. R51/53 Toxic to aquatic organisms, may cause long-term effects in the environment. S26 Incase 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. S37 Wear suitable gloves. S57 Use appropriate container to avoid environmental contamination. S60 This material and its container must be disposed of as hazardous waste. These R and S phrases apply to catalyst: R41 Risk of serious damage to eyes. R50/53 Very toxic to aquatic organisms, may cause long-term effects in the environment. S24 Avoid contact with skin.

European Inventory of New and Existing Chemicals Substances (EINECS):

This product is a medical device and not subject to chemical notification requirements.

Other: Not Applicable

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.