



Safety Data Sheet

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Document group:	31-4882-2	Version number:	2.00
Revision date:	16/03/2016	Supersedes date:	21/05/2014
Transportation version number:	1.00 (21/05/2014)		

This Safety Data Sheet has been prepared in accordance with the REACH Regulation (EC) 1907/2006 and its modifications.

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

1.1. Product identifier

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

Identified uses

Dental Product

Restrictions on Use

For use only by dental professionals.

1.3. Details of the supplier of the safety data sheet

Address: 3M United Kingdom PLC, 3M Centre, Cain Road, Bracknell, Berkshire, RG12 8HT.
Telephone: +44 (0)1344 858 000
E Mail: tox.uk@mmm.com
Website: www.3M.com/uk

1.4. Emergency telephone number

+44 (0)1344 858 000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

This product is a medical device as defined in Directive 93/42/EEC (MDD), which is invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). Although not required, the classification and label information, as applicable, is provided below.

CLASSIFICATION:

This material is not classified as hazardous according to Regulation (EC) No. 1272/2008, as amended, on classification, labelling, and packaging of substances and mixtures.

2.2. Label elements

3M™ ESPE™ IMPRINT™ 4 REGULAR CATALYST**CLP REGULATION (EC) No 1272/2008**

Not applicable

Notes on labelling

This product contains a substance classified as STOT RE 1. Based on the physical form, exposure by inhalation is not expected.

2.3. Other hazards

For information on hazards and safe use, please consider the corresponding sections of this document.

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EU Inventory	% by Wt	Classification
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2		40 - 60	
Cristobalite	14464-46-1	238-455-4	20 - 40	STOT RE 1, H372 (Self Classified)
Silica, vitreous	60676-86-0	262-373-8	5 - 20	
Siloxanes and Silicones, di-Me, reaction products with silica	67762-90-7		1 - 10	
Siloxanes and silicones, di-Me	63148-62-9		1 - 10	
CI Pig Yellow 109	5045-40-9	225-744-5	< 2	
Tridymite	15468-32-3	239-487-1	< 2	STOT RE 1, H372 (Self Classified)
COBALT TITANATE GREEN SPINEL	68186-85-6	269-047-4	< 0.9	
Quartz	14808-60-7	238-878-4	< 0.3	STOT RE 1, H372 (Self Classified)

Please see section 16 for the full text of any H statements referred to in this section

For information on ingredient occupational exposure limits or PBT or vPvB status, see sections 8 and 12 of this SDS

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

Remove person to fresh air. If you feel unwell, get medical attention.

Skin contact

Wash with soap and water. If signs/symptoms develop, get medical attention.

Eye contact

Flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms persist, get medical attention.

If swallowed

Rinse mouth. If you feel unwell, get medical attention.

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

See Section 11.1 Information on toxicological effects

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

Not applicable

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products

<u>Substance</u>	<u>Condition</u>
Carbon monoxide.	During combustion.
Carbon dioxide.	During combustion.
Irritant vapours or gases.	During combustion.

5.3. Advice for fire-fighters

No special protective actions for fire-fighters are anticipated.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ventilate the area with fresh air. Observe precautions from other sections.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. Dispose of collected material as soon as possible.

6.4. Reference to other sections

Refer to Section 8 and Section 13 for more information

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid prolonged or repeated skin contact. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Avoid contact with oxidising agents (eg. chlorine, chromic acid etc.)

7.2. Conditions for safe storage including any incompatibilities

Store away from heat. Store away from acids. Store away from strong bases. Store away from oxidising agents. Store away from amines.

7.3. Specific end use(s)

See information in Section 7.1 and 7.2 for handling and storage recommendations. See Section 8 for exposure controls and personal protection recommendations.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

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If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
Quartz	14464-46-1	UK HSC	TWA(respirable):0.1 mg/m ³	
Quartz	14808-60-7	UK HSC	TWA(respirable):0.1 mg/m ³	
Quartz	15468-32-3	UK HSC	TWA(respirable):0.1 mg/m ³	
Silica, vitreous	60676-86-0	UK HSC	TWA(as respirable dust):0.08 mg/m ³	
Silicon dioxide	60676-86-0	UK HSC	TWA(as inhalable dust):6 mg/m ³	
Silicon dioxide	67762-90-7	UK HSC	TWA(as inhalable dust):6 mg/m ³ ;TWA(as respirable dust):2.4 mg/m ³	
Cobalt compounds	68186-85-6	UK HSC	TWA(as Co):0.1 mg/m ³	Respiratory Sensitizer
Nickel, water-insoluble inorganic compounds, N.O.S.	68186-85-6	UK HSC	TWA(as Ni):0.5 mg/m ³	Skin notation; Resp Sensitizer
Nickel, water-soluble inorganic compounds, except nickel carbonyl	68186-85-6	UK HSC	TWA(as Ni):0.1 mg/m ³	Skin notation; Resp Sensitizer

UK HSC : UK Health and Safety Commission

TWA: Time-Weighted-Average

STEL: Short Term Exposure Limit

CEIL: Ceiling

Biological limit values

No biological limit values exist for any of the components listed in Section 3 of this safety data sheet.

8.2. Exposure controls

8.2.1. Engineering controls

Use in a well-ventilated area.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:

Safety glasses with side shields.

Skin/hand protection

See Section 7.1 for additional information on skin protection.

Respiratory protection

Respiratory protection is not required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid.
Specific Physical Form:	Paste
Appearance/Odour	Slight characteristic odour; white coloured paste
Odour threshold	No data available.
pH	Not applicable.

Boiling point/boiling range	<i>Not applicable.</i>
Melting point	<i>Not applicable.</i>
Flammability (solid, gas)	Not classified
Explosive properties	Not classified
Oxidising properties	Not classified
Flash point	No flash point
Autoignition temperature	<i>Not applicable.</i>
Flammable Limits(LEL)	<i>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Vapour pressure	<i>No data available.</i>
Relative density	1.2 - 1.4 [<i>Ref Std: WATER=1</i>]
Water solubility	Negligible
Solubility- non-water	<i>No data available.</i>
Partition coefficient: n-octanol/water	<i>No data available.</i>
Evaporation rate	<i>Not applicable.</i>
Vapour density	<i>No data available.</i>
Decomposition temperature	<i>No data available.</i>
Viscosity	<i>No data available.</i>
Density	1.2 g/cm ³ - 1.4 g/cm ³

9.2. Other information

Percent volatile *Not applicable.*

SECTION 10: Stability and reactivity**10.1 Reactivity**

This material may be reactive with certain agents under certain conditions - see the remaining headings in this section

10.2 Chemical stability

Stable.

10.3 Possibility of hazardous reactions

Hazardous polymerisation will not occur.

10.4 Conditions to avoid

Heat.

10.5 Incompatible materials

Amines.
Strong acids.
Strong bases.
Strong oxidising agents.

10.6 Hazardous decomposition products

<u>Substance</u>	<u>Condition</u>
None known.	

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition,

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statements and data presented in Section 11 are based on UN GHS calculation rules and classifications derived from 3M assessments.

11.1 Information on Toxicological effects**Signs and Symptoms of Exposure**

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation

This product may have a characteristic odour; however, no adverse health effects are anticipated.

Skin contact

Contact with the skin during product use is not expected to result in significant irritation.

Eye contact

Contact with the eyes during product use is not expected to result in significant irritation.

Ingestion

Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea.

Additional Health Effects:**Carcinogenicity:**

Exposures needed to cause the following health effect(s) are not expected during normal, intended use:

Contains a chemical or chemicals which can cause cancer.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Siloxanes and silicones, Di-Me, vinyl group-terminated	Dermal	Rabbit	LD50 > 15,440 mg/kg
Siloxanes and silicones, Di-Me, vinyl group-terminated	Ingestion	Rat	LD50 > 15,440 mg/kg
Cristobalite	Dermal		LD50 estimated to be > 5,000 mg/kg
Cristobalite	Ingestion		LD50 estimated to be > 5,000 mg/kg
Silica, vitreous	Dermal	Rabbit	LD50 > 5,000 mg/kg
Silica, vitreous	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Silica, vitreous	Ingestion	Rat	LD50 > 5,110 mg/kg
Siloxanes and Silicones, di-Me, reaction products with silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Siloxanes and Silicones, di-Me, reaction products with silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Siloxanes and Silicones, di-Me, reaction products with silica	Ingestion	Rat	LD50 > 5,110 mg/kg
Tridymite	Dermal		LD50 estimated to be > 5,000 mg/kg
Tridymite	Ingestion		LD50 estimated to be > 5,000 mg/kg
Siloxanes and silicones, di-Me	Dermal	Rabbit	LD50 > 19,400 mg/kg
Siloxanes and silicones, di-Me	Ingestion	Rat	LD50 > 17,000 mg/kg
Quartz	Dermal		LD50 estimated to be > 5,000 mg/kg
Quartz	Ingestion		LD50 estimated to be > 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
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Siloxanes and silicones, Di-Me, vinyl group-terminated	Rabbit	No significant irritation
Cristobalite	Professional judgement	No significant irritation
Silica, vitreous	Rabbit	No significant irritation
Siloxanes and Silicones, di-Me, reaction products with silica	Rabbit	No significant irritation
Tridymite	Professional judgement	No significant irritation
Siloxanes and silicones, di-Me	Rabbit	No significant irritation
Quartz	Professional judgement	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Siloxanes and silicones, Di-Me, vinyl group-terminated	Rabbit	Mild irritant
Silica, vitreous	Rabbit	No significant irritation
Siloxanes and Silicones, di-Me, reaction products with silica	Rabbit	No significant irritation
Siloxanes and silicones, di-Me	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Silica, vitreous	Human and animal	Not sensitising
Siloxanes and Silicones, di-Me, reaction products with silica	Human and animal	Not sensitising

Respiratory Sensitisation

For the component/components, either no data is currently available or the data is not sufficient for classification.

Germ Cell Mutagenicity

Name	Route	Value
Cristobalite	In Vitro	Some positive data exist, but the data are not sufficient for classification
Cristobalite	In vivo	Some positive data exist, but the data are not sufficient for classification
Silica, vitreous	In Vitro	Not mutagenic
Siloxanes and Silicones, di-Me, reaction products with silica	In Vitro	Not mutagenic
Tridymite	In Vitro	Some positive data exist, but the data are not sufficient for classification
Tridymite	In vivo	Some positive data exist, but the data are not sufficient for classification
Quartz	In Vitro	Some positive data exist, but the data are not sufficient for classification
Quartz	In vivo	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Cristobalite	Inhalation	Human and animal	Carcinogenic.
Silica, vitreous	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification

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Siloxanes and Silicones, di-Me, reaction products with silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Tridymite	Inhalation	Human and animal	Carcinogenic.
Quartz	Inhalation	Human and animal	Carcinogenic.

Reproductive Toxicity**Reproductive and/or Developmental Effects**

Name	Route	Value	Species	Test result	Exposure Duration
Silica, vitreous	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Silica, vitreous	Inhalation	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Silica, vitreous	Ingestion	Not toxic to development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis
Siloxanes and Silicones, di-Me, reaction products with silica	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Siloxanes and Silicones, di-Me, reaction products with silica	Ingestion	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Siloxanes and Silicones, di-Me, reaction products with silica	Ingestion	Not toxic to development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis

Target Organ(s)**Specific Target Organ Toxicity - single exposure**

For the component/components, either no data is currently available or the data is not sufficient for classification.

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Cristobalite	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Silica, vitreous	Inhalation	respiratory system silicosis	All data are negative	Human	NOAEL Not available	occupational exposure
Siloxanes and Silicones, di-Me, reaction products with silica	Inhalation	respiratory system silicosis	All data are negative	Human	NOAEL Not available	occupational exposure
Tridymite	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Quartz	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure

Aspiration Hazard

For the component/components, either no data is currently available or the data is not sufficient for classification.

Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

SECTION 12: Ecological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 12 are based on UN GHS calculation rules and classifications derived from 3M assessments.

3M™ ESPE™ IMPRINT™ 4 REGULAR CATALYST**12.1. Toxicity**

No product test data available.

Material	CAS Nbr	Organism	Type	Exposure	Test endpoint	Test result
Siloxanes and Silicones, di-Me, reaction products with silica	67762-90-7		Data not available or insufficient for classification			
Quartz	14808-60-7		Data not available or insufficient for classification			
Silica, vitreous	60676-86-0	Common Carp	Experimental	72 hours	LC50	>10,000 mg/l
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2		Data not available or insufficient for classification			
Cristobalite	14464-46-1		Data not available or insufficient for classification			
Tridymite	15468-32-3		Data not available or insufficient for classification			
Siloxanes and silicones, di-Me	63148-62-9		Data not available or insufficient for classification			
COBALT TITANATE GREEN SPINEL	68186-85-6		Data not available or insufficient for classification			
CI Pig Yellow 109	5045-40-9		Data not available or insufficient for classification			

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Tridymite	15468-32-3	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
COBALT TITANATE GREEN SPINEL	68186-85-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Siloxanes and silicones, Di-Me, vinyl	68083-19-2	Data not available or insufficient for	N/A	N/A	N/A	N/A

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group-terminated		classification				
Quartz	14808-60-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
CI Pig Yellow 109	5045-40-9	Estimated Biodegradation	28 days	BOD	2 % weight	OECD 301C - MITI test (I)
Siloxanes and Silicones, di-Me, reaction products with silica	67762-90-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Siloxanes and silicones, di-Me	63148-62-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silica, vitreous	60676-86-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Cristobalite	14464-46-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.3 : Bioaccumulative potential

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Siloxanes and Silicones, di-Me, reaction products with silica	67762-90-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
COBALT TITANATE GREEN SPINEL	68186-85-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Siloxanes and silicones, di-Me	63148-62-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Tridymite	15468-32-3	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Cristobalite	14464-46-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

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Quartz	14808-60-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silica, vitreous	60676-86-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
CI Pig Yellow 109	5045-40-9	Estimated Bioconcentration		Bioaccumulation factor	21	Estimated: Bioconcentration factor

12.4. Mobility in soil

Please contact manufacturer for more details

12.5. Results of the PBT and vPvB assessment

No information available at this time, contact manufacturer for more details

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

See Section 11.1 Information on toxicological effects

Incinerate in a permitted waste incineration facility. As a disposal alternative, utilize an acceptable permitted waste disposal facility. If no other disposal options are available, waste product may be placed in a landfill properly designed for industrial waste.

The coding of a waste stream is based on the application of the product by the consumer. Since this is out of the control of 3M, no waste code(s) for products after use will be provided. Please refer to the European Waste Code (EWC - 2000/532/EC and amendments) to assign the correct waste code to your waste stream. Ensure national and/or regional regulations are complied with and always use a licensed waste contractor.

EU waste code (product as sold)

180106* Chemicals consisting of or containing dangerous substances.

EU waste code (product container after use)

180107 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transportation information

ADR/IMDG/IATA: Not restricted for transport.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Carcinogenicity**

Ingredient
Cristobalite

CAS Nbr
14464-46-1

Classification
Grp. 1: Carcinogenic to humans

Regulation
International Agency for Research on Cancer

Quartz

14808-60-7

Grp. 1: Carcinogenic to
humansInternational Agency
for Research on Cancer**Global inventory status**

Contact 3M for more information. The components of this material are in compliance with the China "Measures on Environmental Management of New Chemical Substance". Certain restrictions may apply. Contact the selling division for additional information. The components of this product are in compliance with the new substance notification requirements of CEPA.

15.2. Chemical Safety Assessment

Not applicable

SECTION 16: Other information**List of relevant H statements**

H372 Causes damage to organs through prolonged or repeated exposure.

Revision information:

Section 1: Product name information was modified.
Section 1: Restrictions on use information information was added.
Label: CLP Classification information was modified.
Section 02: Label Elements: CLP Medical Device information was added.
Section 2: Other hazards phrase information was modified.
Remark (phrase) information was deleted.
Section 3: Composition/ Information of ingredients table information was modified.
Section 3: Reference to H statement explanation in Section 016 information was added.
Section 3: Reference to R and H statement explanation in Section 16 information was deleted.
Section 3: Reference to section 15 for Nota info information was deleted.
Section 5: Fire - Advice for fire fighters information information was modified.
Section 5: Hazardous combustion products table information was modified.
Section 7: Conditions safe storage information was modified.
Section 7: Precautions safe handling information information was modified.
Section 8: Occupational exposure limit table information was added.
Section 8: Occupational exposure limit table information was modified.
OEL Reg Agency Desc information was modified.
Section 8: Personal Protection - Skin/hand information information was modified.
Section 9: Property description for optional properties information was added.
Section 9: Property description for optional properties information was deleted.
Section 10: Materials to avoid physical property information was modified.
Section 11: Acute Toxicity table information was modified.
Section 11: Aspiration Hazard text information was added.
Section 11: Carcinogenicity Table information was modified.
Section 11: Germ Cell Mutagenicity Table information was modified.
Section 11: Reproductive and/or Developmental Effects text information was added.
Section 11: Reproductive Toxicity Table information was modified.
Section 11: Respiratory Sensitization text information was added.
Section 11: Serious Eye Damage/Irritation Table information was modified.
Section 11: Skin Corrosion/Irritation Table information was modified.
Section 11: Skin Sensitization Table information was modified.
Section 11: Specific Target Organ Toxicity - single exposure text information was added.
Section 11: Target Organs - Repeated Table information was modified.
Section 12: Component ecotoxicity information information was modified.
Section 12: Persistence and Degradability information information was modified.

Section 12: Bioaccumulative potential information was modified.
Section 13: Standard Phrase Category Waste GHS information was modified.
Section 15: Label remarks and EU Detergent information was added.
Section 15: Regulations - Inventories information was modified.
Section 16: List of relevant R phrase information was deleted.
Section 16: List of relevant R-phrases information was deleted.

DISCLAIMER: The information on this Safety Data Sheet is based on our experience and is correct to the best of our knowledge at the date of publication, but we do not accept any liability for any loss, damage or injury resulting from its use (except as required by law). The information may not be valid for any use not referred to in this Data Sheet or use of the product in combination with other materials. For these reasons, it is important that customers carry out their own test to satisfy themselves as to the suitability of the product for their own intended applications.

3M United Kingdom MSDSs are available at www.3M.com/uk