

Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product, and must be read in conjunction with the Safety Data Sheet (SDS) attached.

Product Name: 3M™ Filtek™ Universal Restorative

Manufacturer: 3M

SDS Expiry: 15 May 2024

Supplier Details: Henry Schein New Zealand
23 William Pickering Drive, Albany
PO Box 101 140, North Shore, Auckland 0745
Ph. 0800 808 855
www.henryschein.co.nz

Emergency Contacts: Poisons/Hazardous Chemical Info Centre – 0800POISON/0800764766 (24 Hours)
Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 6 / 9

HSNO Group Standard: Dental Products Subsidiary Hazard Group Standard 2017 HSR002558

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared on 23 July 2019

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.



Safety Data Sheet

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This Safety Data Sheet has been prepared in accordance with the New Zealand, Hazardous Substances (Safety Data Sheets) Notice 2017.

SECTION 1: Identification

1.1. Product identifier

3M™ Filtek™ Universal Restorative - All shades except Pink Opaquer

Product Identification Numbers

70-2014-0689-2	70-2014-0690-0	70-2014-0691-8	70-2014-0692-6	70-2014-0693-4
70-2014-0694-2	70-2014-0695-9	70-2014-0696-7	70-2014-0697-5	70-2014-0719-7
70-2014-0720-5	70-2014-0721-3	70-2014-0722-1	70-2014-0723-9	70-2014-0724-7
70-2014-0725-4	70-2014-0726-2	70-2014-0727-0	70-2014-0749-4	70-2014-0752-8
70-2014-0765-0	70-2014-0768-4			

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Dental Restorative

For use only by dental professionals.

1.3. Supplier's details

Address: 3M New Zealand Ltd, 94 Apollo Drive, Rosedale 0632, Auckland
Telephone: (09) 477 4040
E Mail: innovation@nz.mmm.com
Website: 3m.co.nz

1.4. Emergency telephone number

24 hr Medical Emergency, National Poisons Centre, 0800 764 766 (0800 POISON)

SECTION 2: Hazard identification

Classified as hazardous in accordance with the relevant criteria of the HSNO Act 1996, the Hazardous Substances (Classification) Notice 2017 and Hazardous Substances (Minimum Degrees of Hazard) Notice 2017.

Refer to Section 14 of this Safety Data Sheet for product Dangerous Goods Classification.

2.1. Classification of the substance or mixture

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GHS	HSNO
Acute Toxicity (oral): Category 5	6.1E Acute toxicity (oral)
Skin Sensitiser: Category 1	6.5B Skin sensitiser
Acute Aquatic Toxicity: Category 2	9.1D Aquatic toxicity (acute)
Chronic Aquatic Toxicity: Category 3	9.1C Aquatic toxicity (chronic)

2.2. Label elements**SIGNAL WORD**

WARNING!

Symbols:

Exclamation mark |

Pictograms**HAZARD STATEMENTS:**

H303	May be harmful if swallowed.
H317	May cause an allergic skin reaction.
H401	Toxic to aquatic life.
H412	Harmful to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS**Prevention:**

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280E	Wear protective gloves.
P272A	Contaminated work clothing must not be allowed out of the workplace.

Response:

P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.
P321	Specific treatment (see Notes to Physician on this label).
P312	Call a POISON CENTRE or doctor/physician if you feel unwell.

Disposal:

P501	Dispose of contents/container in accordance with applicable local/regional/national/international regulations.
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SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	% by Weight
Silane treated ceramic	444758-98-9	40 - 70
Aromatic Urethane Dimethacrylate	1431303-59-1	10 - 30
Diurethane dimethacrylate	72869-86-4	1 - 10
Ytterbium fluoride (YbF ₃)	13760-80-0	1 - 10
1,12-Dodecane Dimethacrylate (DDDMA)	72829-09-5	1 - 5

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Ceramic powder	None	1 - 5
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl)propyl ester, hydrolysis products with silica	248596-91-0	1 - 5
Water	7732-18-5	1 - 5

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

Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. 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. Suitable 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**Substance**

Carbon monoxide.

Carbon dioxide.

Condition

During combustion.

During combustion.

5.3. Special protective actions for fire-fighters

Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

5.4. Hazchem code: Not applicable.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Evacuate area. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapors, in accordance with good industrial hygiene practice. Refer to other sections of this SDS for

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information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

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. Seal the container. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

SECTION 7: Handling and storage

Refer to Section 15 - Controls for more information

7.1. Precautions for safe handling

Avoid breathing of dust created by cutting, sanding, grinding or machining. A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wash contaminated clothing before reuse. Avoid contact with oxidising agents (eg. chlorine, chromic acid etc.) Do not get in eyes.

7.2. Conditions for safe storage including any incompatibilities

Store away from heat. Store away from oxidising agents.

7.3. Certified handler

Not required

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

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
Fluorides	13760-80-0	ACGIH	TWA(as F):2.5 mg/m ³	A4: Not class. as human carcinogen
Fluorides	13760-80-0	New Zealand WES	TWA(as F)(8 hours): 2.5 mg/m ³	

ACGIH : American Conference of Governmental Industrial Hygienists

AIHA : American Industrial Hygiene Association

CMRG : Chemical Manufacturer's Recommended Guidelines

New Zealand WES : New Zealand Workplace Exposure Standards.

TWA: Time-Weighted-Average

STEL: Short Term Exposure Limit

ppm: parts per million

mg/m³: milligrams per cubic metre

CEIL: Ceiling

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.

Refer AS/NZS 1336 - Recommended practices for occupational eye protection and for performance specifications AS/NZS 1337, Parts 1 - 6 - Personal eye-protection.

Skin/hand protection

See Section 7.1 for additional information on skin protection.

Respiratory protection

None 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 acrylate odour, tooth coloured
Odour threshold	<i>No data available.</i>
pH	<i>Not applicable.</i>
Melting point/Freezing point	<i>No data available.</i>
Boiling point/Initial boiling point/Boiling range	<i>Not applicable.</i>
Flash point	No flash point
Evaporation rate	<i>Not applicable.</i>
Flammability (solid, gas)	Not classified
Flammable Limits(LEL)	<i>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Vapour pressure	<i>Not applicable.</i>
Vapour density	<i>Not applicable.</i>
Density	1.9 g/cm ³
Relative density	1.9
Water solubility	Negligible
Solubility- non-water	<i>No data available.</i>
Partition coefficient: n-octanol/water	<i>Not applicable.</i>
Autoignition temperature	<i>No data available.</i>
Decomposition temperature	<i>No data available.</i>
Viscosity	<i>No data available.</i>

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.
High shear and high temperature conditions

10.5 Incompatible materials

Strong oxidising agents.

10.6 Hazardous decomposition products

Substance

Condition

None known.

Refer to Section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labelling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

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

Respiratory tract irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

Skin contact

Contact with the skin during product use is not expected to result in significant irritation. Allergic skin reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

Eye contact

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

Ingestion

May be harmful if swallowed.

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

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	Dermal		No data available; calculated ATE >5,000 mg/kg
Overall product	Ingestion		No data available; calculated ATE 2,000 - 5,000 mg/kg
Silane treated ceramic	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane treated ceramic	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
YTTERBIUM FLUORIDE (YbF3)	Dermal	Professional	LD50 estimated to be > 5,000 mg/kg

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		judgement	
YTTERBIUM FLUORIDE (YbF3)	Ingestion	Rat	LD50 > 5,000 mg/kg
Diurethane dimethacrylate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Diurethane dimethacrylate	Ingestion	Rat	LD50 > 5,000 mg/kg
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl)propyl ester, hydrolysis products with silica	Dermal		LD50 estimated to be > 5,000 mg/kg
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl)propyl ester, hydrolysis products with silica	Ingestion		LD50 estimated to be > 5,000 mg/kg
1,12-DODECANE DIMETHACRYLATE (DDDMA)	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
1,12-DODECANE DIMETHACRYLATE (DDDMA)	Ingestion	similar compounds	LD50 2000-5000 mg/kg
Ceramic powder	Dermal		LD50 estimated to be > 5,000 mg/kg
Ceramic powder	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	No significant irritation
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl)propyl ester, hydrolysis products with silica	Professional judgement	No significant irritation
Ceramic powder	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	Mild irritant
YTTERBIUM FLUORIDE (YbF3)	Professional judgement	Mild irritant
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl)propyl ester, hydrolysis products with silica	Professional judgement	No significant irritation
Ceramic powder	Rabbit	Mild irritant

Skin Sensitisation

Name	Species	Value
Silane treated ceramic	similar compounds	Not classified
Diurethane dimethacrylate	Guinea pig	Sensitising

Respiratory Sensitisation

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

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Name	Route	Value
Ceramic powder	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Silane treated ceramic	Inhalation	similar compounds	Some positive data exist, but the data are not sufficient for classification
Ceramic powder	Inhalation	Multiple animal species	Some positive data exist, but the data are not sufficient for classification

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

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

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

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

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Silane treated ceramic	Inhalation	pulmonary fibrosis	Not classified	similar compounds	NOAEL Not available	
Ceramic powder	Inhalation	pulmonary fibrosis	Not classified	Multiple animal species	NOAEL Not available	
Ceramic powder	Inhalation	respiratory system	Not classified	Human	NOAEL Not available	occupational exposure

Aspiration Hazard

For the component/components, either no data are currently available or the data are 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 be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. Additional information leading to material classification in Section 2 is available upon request. In addition, environmental fate and effects data on ingredients may not be reflected in this section because an ingredient is present below the threshold for labelling, an ingredient is not expected to be available for exposure, or the data is considered not relevant to the material as a whole.

12.1. Toxicity**Ecotoxic to the aquatic environment.**

Acute Aquatic Toxicity: Category 2 (HSNO 9.1D Aquatic toxicity)

Chronic Aquatic Toxicity: Category 3 (HSNO 9.1C Aquatic toxicity)

No product test data available.

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Material	CAS Number	Organism	Type	Exposure	Test endpoint	Test result
Silane treated ceramic	444758-98-9		Data not available or insufficient for classification			
AROMATIC URETHANE DIMETHACRYLATE	1431303-59-1		Data not available or insufficient for classification			
Diurethane dimethacrylate	72869-86-4	Green algae	Endpoint not reached	72 hours	Effect Growth Rate Conc 50%	>100 mg/l
Diurethane dimethacrylate	72869-86-4	Water flea	Experimental	48 hours	EC50	>100 mg/l
Diurethane dimethacrylate	72869-86-4	Zebra Fish	Experimental	96 hours	LC50	10.1 mg/l
Diurethane dimethacrylate	72869-86-4	Green algae	Endpoint not reached	72 hours	Effect Conc. 10% - Growth Rate	>100 mg/l
YTTERBIUM FLUORIDE (YbF3)	13760-80-0		Data not available or insufficient for classification			
1,12-DODECANE DIMETHYCRYLATE (DDDMA)	72829-09-5	Green Algae	Experimental	72 hours	EC50	17 ug/l
1,12-DODECANE DIMETHYCRYLATE (DDDMA)	72829-09-5	Water flea	Experimental	48 hours	EC50	>100 mg/l
1,12-DODECANE DIMETHYCRYLATE (DDDMA)	72829-09-5	Green Algae	Experimental	72 hours	Effect Concentration 10%	6.4 ug/l
Ceramic powder	None		Data not available or insufficient for classification			
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl) propyl ester, hydrolysis products with silica	248596-91-0		Data not available or insufficient for classification			

12.2. Persistence and degradability

Material	CAS Number	Test type	Duration	Study Type	Test result	Protocol
Silane treated ceramic	444758-98-9	Data not availbl-			N/A	

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		insufficient				
AROMATIC URETHANE DIMETHACRYLATE	1431303-59-1	Data not available- insufficient			N/A	
Diurethane dimethacrylate	72869-86-4	Experimental Biodegradation	28 days	CO2 evolution	22 %CO2 evolution/THC O2 evolution (does not pass 10-day window)	OECD 301B - Modified sturm or CO2
YTTERBIUM FLUORIDE (YbF3)	13760-80-0	Data not available- insufficient			N/A	
1,12-DODECANE DIMETHYCRYLATE (DDDMA)	72829-09-5	Experimental Biodegradation	28 days	CO2 evolution	97.3 %CO2 evolution/THC O2 evolution	OECD 301B - Modified sturm or CO2
Ceramic powder	None	Data not available- insufficient			N/A	
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl) propyl ester, hydrolysis products with silica	248596-91-0	Data not available- insufficient			N/A	

12.3 : Bioaccumulative potential

Material	CAS Number	Test type	Duration	Study Type	Test result	Protocol
Silane treated ceramic	444758-98-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
AROMATIC URETHANE DIMETHACRYLATE	1431303-59-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Diurethane dimethacrylate	72869-86-4	Experimental Bioconcentration		Log Kow	3.39	Other methods
YTTERBIUM FLUORIDE (YbF3)	13760-80-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
1,12-DODECANE DIMETHYCRYLATE (DDDMA)	72829-09-5	Estimated Bioconcentration		Bioaccumulation factor	6.6	Estimated: Bioconcentration factor
Ceramic	None	Data not	N/A	N/A	N/A	N/A

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powder		available or insufficient for classification				
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl) propyl ester, hydrolysis products with silica	248596-91-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.4. Mobility in soil

Please contact manufacturer for more details

12.5 Other adverse effects

No information available.

SECTION 13: Disposal considerations**13.1. Disposal methods**

In accordance with the Hazardous Substances (Disposal) Notice 2017 and the relevant criteria of the HSNO Act 1996.

Dispose of completely cured (or polymerized) material in a permitted industrial waste facility. As a disposal alternative, incinerate uncured product in a permitted waste incineration facility. Proper destruction may require the use of additional fuel during incineration processes. If no other disposal options are available, waste product that has been completely cured or polymerized may be placed in a landfill properly designed for industrial waste. Empty drums/barrels/containers used for transporting and handling hazardous chemicals (chemical substances/mixtures/preparations classified as Hazardous as per applicable regulations) shall be considered, stored, treated & disposed of as hazardous wastes unless otherwise defined by applicable waste regulations. Consult with the respective regulating authorities to determine the available treatment and disposal facilities.

Packaging (that may or may not contain any residual substance) may be lawfully disposed of by householders or other consumers through public or commercial waste collection services.

SECTION 14: Transport Information**New Zealand Land Transport Rule: Dangerous Goods - Road/Rail Transport**

UN No.: Not applicable.

Proper Shipping Name: Not applicable.

Class/Division: Not applicable.

Sub Risk: Not applicable.

Packing Group: Not applicable.

Hazchem Code: Not applicable.

IERG: Not applicable.

International Air Transport Association (IATA) - Air Transport

UN No.: Not applicable.

Proper Shipping Name: Not applicable.

Class/Division: Not applicable.

Sub Risk: Not applicable.

Packing Group: Not applicable.

International Maritime Dangerous Goods Code (IMDG) - Marine Transport

UN No.: Not applicable.

Proper Shipping Name: Not applicable.

Class/Division: Not applicable.

Sub Risk: Not applicable.

Packing Group: Not applicable.

Marine Pollutant: Not applicable.

SECTION 15: Regulatory information

HSNO Approval number HSR002558
Group standard name Dental Products (Subsidiary Hazard) Group Standard 2017
HSNO Hazard classification Refer to Section 2: Hazard identification

NZ Inventory of Chemicals (NZIoC) Status

All applicable chemical ingredients in this material are in compliance with NZIoC listing requirements.

Controls in accordance with the Health and Safety at Work (Hazardous Substances) Regulations 2017

Certified handler Not required
Location Compliance Certificate Not required
Hazardous atmosphere zone Not required
Fire extinguishers Not required
Emergency response plan 100 L or 100 kg (for a HSNO 9.1A substance); or 1,000 L or 1,000 kg (for a HSNO 6.1D, 6.5A, 6.5B, 9.1B or 9.1C substance); or 10,000 L or 10,000 kg (for a HSNO 6.6A, 6.8A, 6.9A, 8.3A, 9.1D substance)
Secondary containment 100 L or 100 kg (for a HSNO 9.1A substance); or 1,000 L or 1,000 kg (for a HSNO 6.1D, 6.5A, 6.5B, 9.1B or 9.1C substance); or 10,000 L or 10,000 kg (for a HSNO 6.6A, 6.8A, 6.9A, 8.3A, 9.1D substance)
Tracking Not required
Warning signage 100 L or 100 kg (for a HSNO 9.1A substance); or 1,000 L or 1,000 kg (for a HSNO 8.3A, 9.1B or 9.1C substance); or 10,000 L or 10,000 kg (for a HSNO 6.1D or 9.1D substance)

SECTION 16: Other information

Revision information:

Update to product identification numbers.

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Key to abbreviations and acronyms

GHS means the Globally Harmonised System of Classification and Labelling of Chemicals, 5th revised edition 2013

HSNO means Hazardous Substances and New Organisms Act 1996

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