



Safety Information Sheet for Medical Devices

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Revision date: 29/04/2020 **Supersedes date:** Initial issue.
Transportation version number: 1.00 (29/04/2020)

A safety data sheet is not required for this Product. This Safety Information Sheet has been created on a voluntary basis.

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

1.1. Product identifier

3M™ 2380, 4930, 8692 And 8693 Series Sof-Lex™ Extra Thin Contouring And Polishing Discs

Product Identification Numbers

70-2005-2387-9	70-2005-2388-7	70-2005-2389-5	70-2005-2390-3	70-2005-2391-1
70-2005-2392-9	70-2005-2393-7	70-2005-2394-5	70-2005-2395-2	70-2011-4492-3
70-2011-4493-1	70-2011-4494-9	70-2011-4495-6	70-2011-4500-3	70-2011-4502-9
70-2011-4503-7	70-2011-4512-8	70-2011-4513-6	70-2011-4514-4	70-2011-4515-1
70-2011-4520-1	70-2011-4521-9	70-2011-4522-7	70-2011-4523-5	70-2011-4570-6
70-2011-4571-4	70-2011-4572-2	70-2011-4573-0	70-2011-4578-9	70-2011-4579-7
70-2011-4580-5	70-2011-4581-3			
7000053446	7000053447	7000053448	7000053449	7000053450
7000053451	7000053452	7000053453	7000053454	7100097900
7100097998	7100097997	7100098012	7100098469	7100098470
7100098471	7100100608	7100100609	7100100610	7100100700
7100100779	7100100883	7100100884	7100101225	7100109004
7100109003	7100109002	7100109037	7100109145	7100109146
7100109150	7100109507			

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

Identified uses

Medical device; refer to Instructions for Use

Restrictions on Use

For use only by dental professionals

1.3 Details of the supplier of the safety information sheet for medical devices

Address: 3M Ireland Limited, The Iveagh Building, The Park, Carrickmines, Dublin 18.
Telephone: +353 1 280 3555
E Mail: tox.uk@mmm.com

Website: www.3M.com

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) respectively Regulation (EU) 2017/745 (MDR), 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

CLP REGULATION (EC) No 1272/2008

Not applicable

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	EC No.	% by Wt	Classification
Polyester Film	None		60 - 90	Substance not classified as hazardous
Aluminium oxide Grit and Binder	None		40 - 70	Substance not classified as hazardous

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 SIS

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.

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.

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. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapours, in accordance with good industrial hygiene practice. 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.

SECTION 7: Handling and storage

Refer to Instructions for Use (IFU) for more information.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

No occupational exposure limit values exist for any of the components listed in Section 3 of this SIS.

Biological limit values

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

Appearance

Physical state

Solid.

Colour

Brown, Red, Yellow

Specific Physical Form:

Thin discs

Odor

Slight Odor, Characteristic Odour

pH

Not applicable.

Boiling point/boiling range

Not applicable.

Melting point

No data available.

Flammability (solid, gas)

Not classified

Explosive properties

Not classified

Oxidising properties

Not classified

Flash point

No flash point

Autoignition temperature

No data available.

Flammable Limits(LEL)

Not applicable.

Flammable Limits(UEL)

Not applicable.

Relative density

Not applicable.

Water solubility

Not applicable.

Viscosity

Not applicable.

Density

Not applicable.

9.2. Other information

EU Volatile Organic Compounds

No data available.

Molecular weight

No data available.

Percent volatile

Not applicable.

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is considered to be non reactive under normal use conditions

10.2 Chemical stability

Stable.

10.3 Possibility of hazardous reactions

Hazardous polymerisation will not occur.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

None known.

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 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 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

Dust created by cutting, grinding, sanding, or machining may cause eye irritation: Signs/symptoms may include redness, swelling, pain, tearing, and blurred or hazy vision.

Ingestion

No known health effects.

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

ATE = acute toxicity estimate

Skin Corrosion/Irritation

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

Serious Eye Damage/Irritation

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

Skin Sensitisation

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

Respiratory Sensitisation

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

Germ Cell Mutagenicity

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

Carcinogenicity

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

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

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

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

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

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 SIS for additional toxicological information on this material and/or its components.

The product was evaluated by a toxicologist to be safe for its intended use.

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.

12.1. Toxicity

No product test data available.

12.2. Persistence and degradability

No test data available.

12.3 : Bioaccumulative potential

No test data available.

12.4. Mobility in soil

Please contact manufacturer for more details

12.5. Results of the PBT and vPvB assessment

Not applicable

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Refer to Instructions for Use (IFU) for more information.

EU waste code (product as sold)

070213 Waste plastic

SECTION 14: Transportation information

70-2005-2387-9, 70-2005-2388-7, 70-2005-2389-5, 70-2005-2390-3,
70-2005-2391-1, 70-2005-2392-9, 70-2005-2393-7, 70-2005-2394-5,
70-2005-2395-2, 70-2011-4492-3, 70-2011-4493-1, 70-2011-4494-9,
70-2011-4495-6, 70-2011-4500-3, 70-2011-4501-1, 70-2011-4502-9,
70-2011-4503-7, 70-2011-4512-8, 70-2011-4513-6, 70-2011-4514-4,
70-2011-4515-1, 70-2011-4520-1, 70-2011-4521-9, 70-2011-4522-7,
70-2011-4523-5, 70-2011-4570-6, 70-2011-4571-4, 70-2011-4572-2,
70-2011-4573-0, 70-2011-4578-9, 70-2011-4579-7, 70-2011-4580-5,
70-2011-4581-3

Not hazardous for transportation

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

Global inventory status

Contact the manufacturer for more information

SECTION 16: Other information

Revision information:

Revision information not available

The product to which this Safety Information Sheet applies is classified as a medical device according to the EU Medical Device Regulation EU 2017/745. _x000D_

Medical devices which are invasive or used in direct physical contact with the human body are exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). _x000D_

The EU Medical Device Regulation does not foresee the use of Safety Data sheets for medical devices which are invasive or used in direct physical contact with the human body, as the safe use of the product is described through the Instructions for Use and /or the labelling for the product. Nevertheless, the 3M Safety Information Sheet is provided as a further service to customers to provide additional toxicology and chemical information on the product.

In case of further questions, please contact your 3M representative listed on the Safety Information Sheet.

3M Ireland Safety Information Sheets are available at www.3M.com