

Safety Information Sheet for Medical Devices

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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[™] Cavilon[™] Durable Barrier Cream 3353, 3354, 3355, 3391C, 3391G,3392C, 3392G 3392GS

Product Identification Numbers

70-2011-8797-1 70-2011-8798-9 70-2011-8799-7 GH-6206-0648-9 GH-6206-0650-5

GH-6206-0656-2 UU-0108-8067-0

7100044535 7100040789 7100040788 7100219816 7100235987

7100235986 7100235991

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

Identified uses

Medical device; refer to Instructions for Use

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

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

CLASSIFICATION:

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).

2.2. Label elements

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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

3.1. Substances

Not applicable

3.2. Mixtures

| Ingredient | Identifier(s) | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|--------------------------------|--------------------|------------|--|
| Water | (EC-No.) 231-791-2 | 40 - 60 | Substance not classified as hazardous |
| Coconut Oil | (EC-No.) 232-282-8 | 5 - 13 | Substance not classified as hazardous |
| PPG-15 Stearyl Ether | | 3 - 10 | Substance not classified as hazardous |
| Isopropyl Palmitate | (EC-No.) 205-571-1 | 3 - 10 | Substance not classified as hazardous |
| Glycerin | (EC-No.) 200-289-5 | 3 - 10 | Substance with a national occupational exposure limit |
| Paraffin | (EC-No.) 232-315-6 | 5 - 10 | Substance with a national occupational exposure limit |
| Ester Diisooctyl Adipate | (EC-No.) 203-601-8 | 1 - 5 | Substance not classified as hazardous |
| Poly(dimethylsiloxane) | | 0.5 - 5 | Substance not classified as hazardous |
| White Mineral Oil | (EC-No.) 232-455-8 | 1 - 5 | Asp. Tox. 1, H304 |
| Acrylate Terpolymer | Trade Secret | 1 - 5 | Substance not classified as hazardous |
| Trimethylsiloxysilicate | (EC-No.) 273-530-5 | 0.1 - 3 | Substance not classified as hazardous |
| 2-phenoxyethanol | (EC-No.) 204-589-7 | 0.1 - 2 | Acute Tox. 4, H302 |
| | | | Eye Irrit. 2, H319 |
| Magnesium sulfate heptahydrate | (EC-No.) 231-298-2 | 0.1 - 1 | Substance not classified as hazardous |
| Dehydroacetic Acid | (EC-No.) 208-293-9 | < 0.5 | Acute Tox. 4, H302 |
| benzoic acid | (EC-No.) 200-618-2 | < 0.3 | Skin Irrit. 2, H315 |
| | | | Eye Dam. 1, H318 |
| | | | STOT RE 1, H372 |

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

No need for first aid is anticipated.

Skin contact

No need for first aid is anticipated.

Eye contact

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Immediately flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. Get medical attention.

If swallowed

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

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Use a fire fighting agent suitable for the surrounding fire.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products

Substance

Hydrocarbons. Carbon monoxide Carbon dioxide.

Condition

During combustion. During combustion. 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

Evacuate area. 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. Refer to other sections of this SIS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

6.2. Environmental precautions

Avoid release to the environment. For larger spills, cover drains and build dykes to prevent entry into sewer systems or bodies of water.

6.3. Methods and material for containment and cleaning up

Contain spill. Working from around the edges of the spill inward, cover with bentonite, vermiculite, or commercially available inorganic absorbent material. Mix in sufficient absorbent until it appears dry. Remember, adding an absorbent material does not remove a physical, health, or environmental hazard. Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue with an appropriate solvent selected by a qualified and authorized person. Ventilate the area with fresh air. Read and follow safety precautions on the solvent label and SIS. Seal the container. 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

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 Additional comments CAS Nbr Agency Limit type

3MTM CavilonTM Durable Barrier Cream 3353, 3354, 3355, 3391C, 3391G,3392C, 3392G 3392GS

Glycerin UK HSC TWA(as mist):10 mg/m3

Paraffin UK HSC TWA(as fume):2

mg/m3;STEL(as fume):6

mg/m3

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 information sheet.

8.2. Exposure controls

8.2.1. Engineering controls

No engineering controls required.

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:

Liquid.

Indirect vented goggles.

Applicable Norms/Standards

Use eye protection conforming to EN 166

Skin/hand protection

No chemical protective gloves are required.

Respiratory protection

Physical state

None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Specific Physical Form: Cream Colour White Odor Light Odor Melting point/freezing point No data available. Boiling point/boiling range No data available. Flammability (solid, gas) Not applicable. Flammable Limits(LEL) No data available. Flammable Limits(UEL) No data available. Flash point No flash point Autoignition temperature No data available.

Relative density 0.99 [*Ref Std*:WATER=1]

pН

Kinematic Viscosity 50,505.0505050505 mm²/sec

Water solubility No data available.

Density 0.99 g/ml

9.2. Other information

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9.2.2 Other safety characteristics

EU Volatile Organic Compounds No data available. Evaporation rate No data available. Molecular weight Not applicable. 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 internal hazard assessments.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Signs and Symptoms of Exposure

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

Inhalation

No known health effects.

Skin contact

No health effects are expected.

Eye contact

Severe eye irritation: Signs/symptoms may include significant redness, swelling, pain, tearing, cloudy appearance of the cornea, and impaired vision.

Ingestion

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 >5,000 mg/kg |
| Paraffin | Dermal | Rat | LD50 > 5,000 mg/kg |
| Paraffin | Ingestion | Rat | LD50 > 5,000 mg/kg |
| Glycerin | Dermal | Rabbit | LD50 estimated to be > 5,000 mg/kg |
| Glycerin | Ingestion | Rat | LD50 > 5,000 mg/kg |
| Isopropyl Palmitate | Ingestion | Mouse | LD50 > 5,000 mg/kg |
| Isopropyl Palmitate | Dermal | Professional judgement | LD50 estimated to be > 5,000 mg/kg |
| Ester Diisooctyl Adipate | Dermal | | LD50 estimated to be > 5,000 mg/kg |
| Ester Diisooctyl Adipate | Ingestion | | LD50 estimated to be > 5,000 mg/kg |
| Poly(dimethylsiloxane) | Dermal | Rabbit | LD50 > 19,400 mg/kg |
| White Mineral Oil | Dermal | Rabbit | LD50 > 2,000 mg/kg |
| Poly(dimethylsiloxane) | Ingestion | Rat | LD50 > 17,000 mg/kg |
| White Mineral Oil | Ingestion | Rat | LD50 > 5,000 mg/kg |
| 2-phenoxyethanol | Dermal | Rabbit | LD50 > 2,000 mg/kg |
| 2-phenoxyethanol | Inhalation-Dust/Mist | Rat | LC50 > 1.5 mg/l |
| 2-phenoxyethanol | Ingestion | Rat | LD50 1,260 mg/kg |
| Dehydroacetic Acid | Dermal | | estimated to be > 5,000 mg/kg |
| Dehydroacetic Acid | Inhalation-Dust/Mist | | estimated to be > 12.5 mg/l |
| Dehydroacetic Acid | Ingestion | | estimated to be 300 - 2,000 mg/kg |
| benzoic acid | Dermal | Rabbit | LD50 > 2,000 mg/kg |
| benzoic acid | Inhalation-Dust/Mist (4 hours) | Rat | LC50 > 12.2 mg/l |
| benzoic acid | Ingestion | Rat | LD50 2,565 mg/kg |

ATE = acute toxicity estimate

Skin Corrosion/Irritation

| Name | Species | Value | |
|--------------------------|------------------------|---------------------------|--|
| | | | |
| Paraffin | Rabbit | No significant irritation | |
| Glycerin | Rabbit | No significant irritation | |
| Isopropyl Palmitate | Rabbit | Minimal irritation | |
| Ester Diisooctyl Adipate | Professional judgement | Minimal irritation | |
| Poly(dimethylsiloxane) | Rabbit | No significant irritation | |
| White Mineral Oil | Rabbit | No significant irritation | |
| 2-phenoxyethanol | Rabbit | No significant irritation | |
| benzoic acid | Human | Irritant | |

Serious Eye Damage/Irritation

| Name | Species | Value |
|--------------------------|------------------------|---------------------------|
| | | |
| Paraffin | Rabbit | No significant irritation |
| Glycerin | Rabbit | No significant irritation |
| Isopropyl Palmitate | Rabbit | No significant irritation |
| Ester Diisooctyl Adipate | Professional judgement | Mild irritant |
| Poly(dimethylsiloxane) | Rabbit | No significant irritation |
| White Mineral Oil | Rabbit | Mild irritant |
| 2-phenoxyethanol | Rabbit | Corrosive |
| benzoic acid | Rabbit | Corrosive |

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Skin Sensitisation

| Name | Species | Value |
|-------------------|-------------------------|----------------|
| | | |
| Paraffin | Guinea pig | Not classified |
| Glycerin | Guinea pig | Not classified |
| White Mineral Oil | Guinea pig | Not classified |
| 2-phenoxyethanol | Guinea pig | Not classified |
| benzoic acid | Multiple animal species | Not classified |

Respiratory Sensitisation

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

Germ Cell Mutagenicity

| Germ Cen Mutagement | 1 | |
|---------------------|----------|--|
| Name | Route | Value |
| | | |
| Paraffin | In Vitro | Not mutagenic |
| White Mineral Oil | In Vitro | Not mutagenic |
| benzoic acid | In Vitro | Some positive data exist, but the data are not sufficient for classification |

Carcinogenicity

| Name | Route | Species | Value |
|-------------------|------------|-------------------------|--|
| Paraffin | Ingestion | Rat | Not carcinogenic |
| Glycerin | Ingestion | Mouse | Some positive data exist, but the data are not sufficient for classification |
| White Mineral Oil | Dermal | Mouse | Not carcinogenic |
| White Mineral Oil | Inhalation | Multiple animal species | Not carcinogenic |

Reproductive Toxicity

Reproductive and/or Developmental Effects

| Name | Route | Value | Species | Test result | Exposure Duration | |
|-------------------|-----------|--|---------|-----------------------|----------------------|--|
| Glycerin | Ingestion | Not classified for female reproduction | Rat | NOAEL 2,000 mg/kg/day | 2 generation | |
| Glycerin | Ingestion | Not classified for male reproduction | Rat | NOAEL 2,000 mg/kg/day | 2 generation | |
| Glycerin | Ingestion | Not classified for development | Rat | NOAEL 2,000 mg/kg/day | 2 generation | |
| White Mineral Oil | Ingestion | Not classified for female reproduction | Rat | NOAEL 4,350 mg/kg/day | 13 weeks | |
| White Mineral Oil | Ingestion | Not classified for male reproduction | Rat | NOAEL 4,350 mg/kg/day | 13 weeks | |
| White Mineral Oil | Ingestion | Not classified for development | Rat | NOAEL 4,350 mg/kg/day | during gestation | |
| benzoic acid | Ingestion | Not classified for female reproduction | Rat | NOAEL 900 mg/kg/day | 4 generation | |
| benzoic acid | Ingestion | Not classified for male reproduction | Rat | NOAEL 900 mg/kg/day | 4 generation | |
| benzoic acid | Ingestion | Not classified for development | Rat | NOAEL 900 mg/kg/day | 4 generation | |

Target Organ(s)

Specific Target Organ Toxicity - single exposure

| Name | Route | Target Organ(s) | Value | Species | Test result | Exposure Duration |
|------------------|------------|------------------------|--|------------------------------|---------------------|----------------------|
| 2-phenoxyethanol | Inhalation | respiratory irritation | Some positive data exist, but the data are not sufficient for classification | similar health hazards | NOAEL Not available | |
| benzoic acid | Inhalation | respiratory irritation | Some positive data exist, but the data are not sufficient for classification | similar health hazards | NOAEL Not available | |

Specific Target Organ Toxicity - repeated exposure

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| Name | Route | Target Organ(s) | Value | Species | Test result | Exposure Duration |
|-------------------|------------|---|---|---------|------------------------------|----------------------|
| Paraffin | Ingestion | heart | Some positive data exist, but the data are not sufficient for classification | Rat | NOAEL 15 mg/kg/day | 90 days |
| Paraffin | Ingestion | hematopoietic system liver immune system skin endocrine system bone, teeth, nails, and/or hair muscles nervous system eyes kidney and/or bladder respiratory system vascular system | Not classified | Rat | NOAEL 1,500 mg/kg/day | 90 days |
| Glycerin | Inhalation | respiratory system heart liver kidney and/or bladder | Not classified | Rat | NOAEL 3.91 mg/l | 14 days |
| Glycerin | Ingestion | endocrine system hematopoietic system liver kidney and/or bladder | Not classified | Rat | NOAEL 10,000 mg/kg/day | 2 years |
| White Mineral Oil | Ingestion | hematopoietic system | Not classified | Rat | NOAEL 1,381 mg/kg/day | 90 days |
| White Mineral Oil | Ingestion | liver immune system | Not classified | Rat | NOAEL 1,336 mg/kg/day | 90 days |
| benzoic acid | Dermal | heart skin endocrine system gastrointestinal tract hematopoietic system liver immune system muscles nervous system kidney and/or bladder respiratory system | Not classified | Rabbit | NOAEL 2,500 mg/kg/day | 21 days |
| benzoic acid | Inhalation | respiratory system | Causes damage to organs through prolonged or repeated exposure | Rat | LOAEL 0.025 mg/l | 28 days |
| benzoic acid | Inhalation | heart endocrine system gastrointestinal tract bone, teeth, nails, and/or hair hematopoietic system liver immune system nervous system eyes kidney and/or bladder | Not classified | Rat | NOAEL 1.2 mg/l | 28 days |

Aspiration Hazard

| Name | Value | | | | |
|-------------------|-------------------|--|--|--|--|
| White Mineral Oil | Aspiration hazard | | | | |

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.

11.2. Information on other hazards

This material does not contain any substances that are assessed to be an endocrine disruptor for human health.

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

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No product test data available.

| Material | CAS# | Organism | Туре | Exposure | Test endpoint | Test result |
|-----------------------------|--------------|------------------|---|------------|---------------|---------------|
| Coconut Oil | | | Data not available or insufficient for classification | | | N/A |
| Glycerin | | Bacteria | Experimental | 16 hours | NOEC | 10,000 mg/l |
| Glycerin | | Rainbow trout | Experimental | 96 hours | LC50 | 54,000 mg/l |
| Glycerin | | Water flea | Experimental | 48 hours | LC50 | 1,955 mg/l |
| Isopropyl Palmitate | | Bacteria | Estimated | 18 hours | EC50 | >10 mg/l |
| Isopropyl Palmitate | | Green algae | Estimated | 72 hours | EC50 | >100 mg/l |
| Isopropyl Palmitate | | Water flea | Experimental | 48 hours | EC50 | >=3,000 mg/l |
| Isopropyl Palmitate | | Zebra Fish | Experimental | 96 hours | LC50 | >=10,000 mg/l |
| Isopropyl Palmitate | | Water flea | Estimated | 21 days | NOEC | 100 mg/l |
| Paraffin | | Green algae | Estimated | 96 hours | EC50 | >1,000 mg/l |
| Paraffin | | Rainbow trout | Estimated | 96 hours | LC50 | >1,000 mg/l |
| Paraffin | | Water flea | Estimated | 48 hours | EC50 | >10,000 mg/l |
| PPG-15 Stearyl Ether | | | Data not available or insufficient for classification | | | N/A |
| Acrylate Terpolymer | Trade Secret | | Data not available or insufficient for classification | | | N/A |
| Ester Diisooctyl Adipate | | Activated sludge | Estimated | 3 hours | EC50 | >350 mg/l |
| Ester Diisooctyl Adipate | | Bluegill | Estimated | 96 hours | LC50 | >100 mg/l |
| Ester Diisooctyl Adipate | | Green algae | Estimated | 72 hours | EC50 | >500 mg/l |
| Ester Diisooctyl Adipate | | Water flea | Estimated | 48 hours | EC50 | >500 mg/l |
| Ester Diisooctyl Adipate | | Water flea | Estimated | 21 days | NOEC | >100 mg/l |
| Poly(dimethylsiloxane) | | | Data not available or insufficient for classification | | | N/A |
| White Mineral Oil | | Water flea | Estimated | 48 hours | EL50 | >100 mg/l |
| White Mineral Oil | | Bluegill | Experimental | 96 hours | LL50 | >100 mg/l |
| White Mineral Oil | | Green algae | Estimated | 72 hours | NOEL | 100 mg/l |
| White Mineral Oil | | Water flea | Estimated | 21 days | NOEL | >100 mg/l |
| Trimethylsiloxysilicate | | | Data not available or insufficient for classification | | | N/A |
| 2-phenoxyethanol | | Activated sludge | Experimental | 30 minutes | EC50 | >1,000 mg/l |
| 2-phenoxyethanol | | Fathead minnow | Experimental | 96 hours | LC50 | 344 mg/l |
| 2-phenoxyethanol | | Green algae | Experimental | 72 hours | EC50 | >100 mg/l |
| 2-phenoxyethanol | | Scud | Experimental | 96 hours | LC50 | 357 mg/l |

| Fathead minnow Green algae | Experimental Experimental | 34 days | NOEC | 24 mg/l |
|-----------------------------|--|---|---|--|
| Green algae | Experimental | | | |
| | _ | 72 hours | NOEC | 46 mg/l |
| Water flea | Experimental | 21 days | NOEC | 9.43 mg/l |
| Algae other | Estimated | 72 hours | IC50 | 2,490 mg/l |
| Fathead minnow | Estimated | 96 hours | LC50 | 5,770 mg/l |
| Water flea | Estimated | 48 hours | EC50 | 704 mg/l |
| Algae other | Estimated | 72 hours | IC10 | 88 mg/l |
| Green Algae | Experimental | 72 hours | EC50 | 32.1 mg/l |
| Water flea | Experimental | 48 hours | EC50 | >100 mg/l |
| Green Algae | Experimental | 72 hours | EC10 | 23.9 mg/l |
| Activated sludge | Experimental | 3 hours | EC50 | >1,000 mg/l |
| Bluegill | Experimental | 96 hours | LC50 | 44.6 mg/l |
| Water flea | Experimental | 48 hours | EC50 | 860 mg/l |
| | Algae other Fathead minnow Water flea Algae other Green Algae Water flea Green Algae Activated sludge Bluegill | Algae other Estimated Fathead minnow Estimated Water flea Estimated Algae other Estimated Green Algae Experimental Water flea Experimental Green Algae Experimental Activated sludge Experimental Bluegill Experimental | Algae other Estimated 72 hours Fathead minnow Estimated 96 hours Water flea Estimated 48 hours Algae other Estimated 72 hours Green Algae Experimental 72 hours Water flea Experimental 48 hours Green Algae Experimental 72 hours Activated sludge Experimental 3 hours Bluegill Experimental 96 hours | Algae other Estimated 72 hours IC50 Fathead minnow Estimated 96 hours LC50 Water flea Estimated 48 hours EC50 Algae other Estimated 72 hours IC10 Green Algae Experimental 72 hours EC50 Water flea Experimental 48 hours EC50 Green Algae Experimental 48 hours EC50 Green Algae Experimental 72 hours EC10 Activated sludge Experimental 3 hours EC50 Bluegill Experimental 96 hours LC50 |

12.2. Persistence and degradability

| Material | CAS Nbr | Test type | Duration | Study Type | Test result | Protocol |
|--------------------------------|--------------|-----------------------------------|----------|---------------|-----------------------|---|
| Coconut Oil | | Data not availbl- insufficient | | | N/A | |
| Glycerin | | Experimental Biodegradation | 14 days | BOD | 63 % BOD/ThBOD | OECD 301C - MITI test (I) |
| Isopropyl Palmitate | | Experimental Biodegradation | 28 days | BOD | 91.3 % weight | OECD 301B - Modified sturm or CO2 |
| Paraffin | | Estimated Biodegradation | 28 days | BOD | 40 % weight | OECD 301F - Manometric respirometry |
| PPG-15 Stearyl Ether | | Data not availbl- insufficient | | | N/A | |
| Acrylate Terpolymer | Trade Secret | Data not availbl- insufficient | | | N/A | |
| Ester Diisooctyl Adipate | | Estimated Biodegradation | 28 days | BOD | 90-100 % BOD/ThBOD | OECD 301F - Manometric respirometry |
| Poly(dimethylsiloxane) | | Data not availbl- insufficient | | | N/A | |
| White Mineral Oil | | Experimental Biodegradation | 28 days | CO2 evolution | 0 % weight | OECD 301B - Modified sturm or CO2 |
| Trimethylsiloxysilicate | | Data not availbl- insufficient | | | N/A | |
| 2-phenoxyethanol | | Experimental Biodegradation | 28 days | BOD | 90 % BOD/ThBOD | OECD 301F - Manometric respirometry |
| Magnesium sulfate heptahydrate | | Data not availbl- insufficient | | | N/A | |
| Dehydroacetic Acid | | Experimental Biodegradation | 28 days | BOD | 70 % BOD/ThBOD | OECD 301F - Manometric respirometry |
| benzoic acid | | Experimental Biodegradation | 14 days | BOD | 85 % BOD/ThBOD | OECD 301C - MITI test (I) |

12.3 : Bioaccumulative potential

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| Material | Cas No. | Test type | Duration | Study Type | Test result | Protocol |
|-----------------------------------|--------------|---|----------|------------------------|-------------|---|
| Coconut Oil | | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Glycerin | | Experimental Bioconcentration | | Log Kow | -1.76 | Non-standard method |
| Isopropyl Palmitate | | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Paraffin | | Estimated Bioconcentration | | Log Kow | 10.2 | Estimated: Octanol- water partition coefficient |
| PPG-15 Stearyl Ether | | Estimated Bioconcentration | | Bioaccumulation factor | 6.5 | Estimated: Bioconcentration factor |
| Acrylate Terpolymer | Trade Secret | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Ester Diisooctyl Adipate | | Estimated BCF - Bluegill | 28 days | Bioaccumulation factor | 27 | Non-standard method |
| Poly(dimethylsiloxane) | | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| White Mineral Oil | | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Trimethylsiloxysilicate | | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| 2-phenoxyethanol | | Experimental Bioconcentration | | Log Kow | 1.2 | EC A.8 Partition Coefficient |
| Magnesium sulfate heptahydrate | | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Dehydroacetic Acid | | Estimated Bioconcentration | | Log Kow | 0.78 | Estimated: Octanol- water partition coefficient |
| benzoic acid | | Experimental Bioconcentration | | Log Kow | 1.88 | Non-standard method |

12.4. Mobility in soil

| Material | Cas No. | Test type | Study Type | Test result | Protocol |
|--------------------------|---------|-------------------------------|------------|-------------|-----------------------------------|
| Glycerin | | Estimated Mobility in Soil | Koc | <1 l/kg | Episuite TM |
| Isopropyl Palmitate | | Estimated Mobility in Soil | Koc | 40,000 l/kg | Episuite TM |
| Ester Diisooctyl Adipate | | Estimated Mobility in Soil | Koc | 33,000 l/kg | Episuite TM |
| 2-phenoxyethanol | | Experimental Mobility in Soil | Koc | 41 l/kg | OECD 121 Estim. of Koc by HPLC |
| Dehydroacetic Acid | | Estimated Mobility in Soil | Koc | 10 l/kg | Episuite TM |

12.5. Results of the PBT and vPvB assessment

This material does not contain any substances that are assessed to be a PBT or vPvB

12.6. Endocrine disrupting properties

This material does not contain any substances that are assessed to be an endocrine disruptor for environmental effects

12.7. Other adverse effects

No information available.

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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)

180107 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transportation information

Not hazardous for transportation.

| | Ground Transport (ADR) | Air Transport (IATA) | Marine Transport (IMDG) |
|---|--|--|--|
| 14.1 UN number | No data available. | No data available. | No data available. |
| 14.2 UN proper shipping name | No data available. | No data available. | No data available. |
| 14.3 Transport hazard class(es) | No data available. | No data available. | No data available. |
| 14.4 Packing group | No data available. | No data available. | No data available. |
| 14.5 Environmental hazards | No data available. | No data available. | No data available. |
| 14.6 Special precautions for user | Please refer to the other sections of the SDS for further information. | Please refer to the other sections of the SDS for further information. | Please refer to the other sections of the SDS for further information. |
| 14.7 Transport in bulk according to Annex II of Marpol 73/78 and IBC Code | No data available. | No data available. | No data available. |
| Control Temperature | No data available. | No data available. | No data available. |
| Emergency Temperature | No data available. | No data available. | No data available. |
| ADR Classification Code | No data available. | No data available. | No data available. |
| IMDG Segregation Code | No data available. | No data available. | No data available. |

Please contact the address or phone number listed on the first page of the SDS for additional information on the transport/shipment of the material by rail (RID) or inland waterways (ADN).

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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

List of relevant H statements

| H302 | Harmful if swallowed. |
|------|--|
| H304 | May be fatal if swallowed and enters airways. |
| H315 | Causes skin irritation. |
| H318 | Causes serious eye damage. |
| H319 | Causes serious eye irritation. |
| H372 | Causes damage to organs through prolonged or repeated exposure |

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 United Kingdom Safety Information Sheets are available at www.3M.com/uk

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