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

1.1 Product identifier

Material Name

Merlin™ One-Step Prep Applicator

Synonyms

605039, 605030

Substance Registration Number(s)

REACH obligation for the substances in this product is under review.

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

Identified uses

Skin preparation antibiotic/antiseptic

Uses advised against

For use under medical supervision only.

1.3 Details of the supplier of the safety data sheet

Covidien, LP

15 Hampshire Street

Mansfield, MA 02048

USA

Phone: +1-(508) 261-8000 (Monday - Friday 8:00 am to 5:00 pm)

Email: customerservice@medtronic.com

1.4 Emergency telephone number

CHEMTREC (800) 424-9300 (for US and Canada), 1(703) 527-3887 (Outside US and Canada) , Collect calls accepted

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flammable Liquids - Category 2

Serious Eye Damage/Eye Irritation - Category 2

Specific Target Organ Toxicity - Single Exposure - Category 3

Hazardous to the Aquatic Environment - Acute - Category 3

2.2 Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard symbols



Signal word

Danger

Hazard statements

H225 Highly flammable liquid and vapor

H319 Causes serious eye irritation

H336 May cause drowsiness or dizziness

H402 Harmful to aquatic life

Precautionary statements

Prevention

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

P271 Use only outdoors or in a well-ventilated area

P280 Wear protective gloves/protective clothing/eye protection/face protection

P261 Avoid breathing dust/fume/gas/mist/vapours/spray

P264 Wash thoroughly after handling

P273 Avoid release to the environment

Response

P370+P378 In case of fire: Use appropriate media to extinguish

P303+P361+P353 IF ON SKIN (or hair): Remove/take off immediately all contaminated clothing. Rinse skin with water/shower

P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing

P312 Call a POISON CENTER or doctor if you feel unwell

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337+P313 If eye irritation persists: Get medical advice/attention

Storage

P402 Store in a dry place

Disposal

P501 Dispose of contents/container in accordance with local/regional/national/international regulations

2.3 Other hazards

No additional information available.

SECTION 3: Composition / information on ingredients

CAS EC No Registration No	Component Name Synonyms	1272/2008 (CLP)	Percent (%)
67-63-0 200-661-7 Not available	Isopropyl alcohol	Flam. Liq. 2 - H225 Eye Dam. 2 - H319 STOT SE 3 - H336	> 60
7553-56-2 231-442-4 Not available	Iodine	Acute Tox. (Dermal) 4 - H312 Acute Tox. (Dust/Mist) 4 - H332 Aquatic Acute 1 - H400	< 1
25322-68-3 500-038-2 Not available	Polyethylene glycol	Note(s): No classification	< 4
7732-18-5 231-791-2 Not available	Water	Note(s): No classification	< 40

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation

It is unlikely that first aid will be required. Remove person to fresh air and keep comfortable for breathing.

Skin

It is unlikely that first aid will be required. If skin irritation occurs, get medical advice/attention.

Eyes

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Ingestion

If swallowed, get medical attention.

4.2 Most Important Symptoms/Effects

Acute

Causes serious eye irritation. May cause drowsiness or dizziness.

Delayed

No information on significant adverse effects.

4.3 Indication of Immediate Medical Attention and Special Treatment

Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use dry chemical, carbon dioxide, alcohol-resistant foam or water spray.

Unsuitable Extinguishing Media

None known.

5.2 Special hazards arising from the substance or mixture

Highly flammable liquid and vapour.

Combustion

Oxides of carbon

5.3 Advice for firefighters

Slight fire hazard. Fire or heat may produce irritating, toxic and/or corrosive gases.

Fire Fighting Measures

Avoid inhalation of material or combustion by-products.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear personal protective clothing and equipment.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and Materials for Containment and Cleaning Up

Clear up spills immediately and dispose of waste safely.

6.4 Reference to other sections

Safe handling: see section 7. Personal protection equipment: see section 8. Disposal: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Keep away from heat/sparks/open flames/hot surfaces.

7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place

Incompatible Materials

Acids, strong oxidizing agents, halogens, aluminum, acid anhydrides

7.3 Specific end use(s)

Skin preparation antibiotic/antiseptic

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Component Exposure Limits

Isopropyl alcohol	67-63-0
Austria:	200 ppm TWA [TMW] (short time value for large casting); 500 mg/m ³ TWA [TMW] (short time value for large casting)
	800 ppm STEL [KZW] 4 X 15 min; 2000 mg/m ³ STEL [KZW] 4 X 15 min; 800 ppm STEL [KZW] (STEL for large casting valid till 12/31/2013) 4 X 30 min; 2000 mg/m ³ STEL [KZW] (STEL for large casting valid till 12/31/2013) 4 X 30 min
Belgium:	200 ppm TWA; 500 mg/m ³ TWA
	400 ppm STEL; 1000 mg/m ³ STEL
Denmark:	200 ppm TWA; 490 mg/m ³ TWA
Finland:	200 ppm TWA; 500 mg/m ³ TWA
	250 ppm STEL; 620 mg/m ³ STEL
France:	400 ppm STEL [VLCT]; 980 mg/m ³ STEL [VLCT]
Germany (TRGS):	200 ppm TWA AGW (The risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed) exposure factor 2; 500 mg/m ³ TWA AGW (The risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed) exposure factor 2
Germany (DFG):	200 ppm TWA MAK; 500 mg/m ³ TWA MAK
	400 ppm Peak; 1000 mg/m ³ Peak
Greece:	400 ppm TWA; 980 mg/m ³ TWA
	500 ppm STEL; 1225 mg/m ³ STEL
Ireland:	200 ppm TWA
	400 ppm STEL
	Potential for cutaneous absorption

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Portugal:	200 ppm TWA [VLE-MP]
	400 ppm STEL [VLE-CD]
Spain:	200 ppm TWA [VLA-ED] (it is prohibited the partial or complete commercialization or use of this substance as a phytosanitary or biocide compound); 500 mg/m3 TWA [VLA-ED] (it is prohibited the partial or complete commercialization or use of this substance as a phytosanitary or biocide compound)
	400 ppm STEL [VLA-EC]; 1000 mg/m3 STEL [VLA-EC]
Sweden:	150 ppm LLV; 350 mg/m3 LLV
	250 ppm STV; 600 mg/m3 STV
United Kingdom:	400 ppm TWA; 999 mg/m3 TWA
	500 ppm STEL; 1250 mg/m3 STEL
Iodine	7553-56-2
Austria:	0.1 ppm TWA [TMW]; 1 mg/m3 TWA [TMW]
	0.1 ppm STEL [KZW]; 1 mg/m3 STEL [KZW]
	0.1 ppm Ceiling; 1 mg/m3 Ceiling
	skin notation
Belgium:	0.01 ppm TWA aerosol and vapor; 0.1 mg/m3 TWA aerosol and vapor
	0.1 ppm STEL vapor; 1 mg/m3 STEL vapor
Denmark:	0.1 ppm Ceiling; 1 mg/m3 Ceiling
Finland:	0.1 ppm STEL; 1.1 mg/m3 STEL
	Potential for cutaneous absorption
France:	0.1 ppm STEL [VLCT]; 1 mg/m3 STEL [VLCT]
Germany (DFG):	skin notation (including inorganic iodide compounds)
Greece:	0.1 ppm TWA; 1 mg/m3 TWA
	0.1 ppm STEL; 1 mg/m3 STEL
Ireland:	0.1 ppm STEL as Fe; 1 mg/m3 STEL
Spain:	0.1 ppm STEL [VLA-EC]; 1 mg/m3 STEL [VLA-EC]
Sweden:	0.1 ppm CLV; 1 mg/m3 CLV

United Kingdom:	0.1 ppm STEL; 1.1 mg/m ³ STEL
Polyethylene glycol	25322-68-3
Austria:	1000 mg/m ³ TWA [TMW] (average molecular weight 200-400) inhalable fraction
	4000 mg/m ³ STEL [KZW] (average molecular weight 200-400) inhalable fraction 4 X 15 min
Germany (TRGS):	1000 mg/m ³ TWA AGW (The risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed, average molecular weight 200-400) inhalable fraction exposure factor 8
Germany (DFG):	1000 mg/m ³ TWA MAK (average molecular weight 200-600) inhalable fraction
	8000 mg/m ³ Peak (average molecular weight 200-600) inhalable fraction

Biological limit value

There are no biological limit values for any of this product's components.

Derived No Effect Levels (DNELs)

No DNELs available.

Predicted No Effect Concentrations (PNECs)

No PNECs available.

8.2 Exposure Controls

Engineering controls

Based on available information, additional ventilation is not required. Ensure compliance with applicable exposure limits.

Eye/face protection

Wear safety glasses with side shields.

Skin Protection

Not required.

Respiratory Protection

No respirator is required under normal conditions of use.

Glove Recommendations

Wear appropriate chemical resistant gloves. Do not wear gloves made of polyvinyl alcohol (PVA).

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	Liquid contents in plastic applicator with dispensing sponge	Physical State	Liquid
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Odor	Pungent, alcohol odor	Color	Reddish
Odor Threshold	Not available	pH	Not available
Melting Point	Not available	Boiling Point	80 °C (176 °F)
Freezing point	Not available	Evaporation Rate	Not available
Boiling Point Range	Not available	Flammability (solid, gas)	Not available
Autoignition	Not available	Flash Point	17 °C (64 °F)
Lower Explosive Limit	Not available	Decomposition	Not available
Upper Explosive Limit	Not available	Vapor Pressure	90 mmHg (approximate)
Vapor Density (air=1)	2.1	Specific Gravity (water=1)	0.889
Water Solubility	Insoluble	Partition coefficient: n-octanol/water	Not available
Viscosity	Not available	Solubility (Other)	Not available
Density	Not available		

9.2 Other information

No additional information available.

SECTION 10: Stability and reactivity

10.1 Reactivity

Not known to occur.

10.2 Chemical stability

Stable under normal conditions of use.

10.3 Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4 Conditions to avoid

Avoid direct sunlight.

10.5 Incompatible materials

Acids, strong oxidizing agents, halogens, aluminum, acid anhydrides

10.6 Hazardous decomposition products

Oxides of carbon

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Component Analysis - LD50/LC50

The components of this material have been reviewed in various sources and the following selected endpoints are published:

Isopropyl alcohol (67-63-0)

Oral LD50 Rat 5045 mg/kg (Safety Data Sheet)

Dermal LD50 Rabbit 12800 mg/kg (Safety Data Sheet)

Inhalation LC50 Rat 1600 ppm 4 h (Safety Data Sheet)

Iodine (7553-56-2)

Oral LD50 Rat 14 g/kg

Polyethylene glycol (25322-68-3)

Oral LD50 Rat 22 g/kg

Dermal LD50 Rabbit >20 mL/kg

Irritation/Corrosivity Data

Causes serious eye irritation. May cause skin irritation.

Respiratory Sensitization

No data available.

Dermal Sensitization

May cause allergic skin reaction.

Germ Cell Mutagenicity

No data available.

Component Carcinogenicity

Isopropyl alcohol	67-63-0
IARC:	Monograph 71 [1999]; Supplement 7 [1987]; Monograph 15 [1977] (Group 3 (not classifiable))

Reproductive toxicity

No data available.

Specific Target Organ Toxicity - Single Exposure

Exposure may stimulate the central nervous system.

Specific Target Organ Toxicity - Repeated Exposure

No target organs identified.

Aspiration hazard

No data available.

SECTION 12: Ecological information

12.1 Toxicity

Avoid release to the environment.

Component Analysis - Aquatic Toxicity

Isopropyl alcohol	67-63-0
Fish:	LC50 96 h Pimephales promelas 9640 mg/L [flow-through]; LC50 96 h Pimephales promelas 11130 mg/L [static]; LC50 96 h Lepomis macrochirus >1400000 µg/L
Algae:	EC50 96 h Desmodesmus subspicatus >1000 mg/L IUCLID; EC50 72 h Desmodesmus subspicatus >1000 mg/L IUCLID
Invertebrate:	EC50 48 h Daphnia magna 13299 mg/L IUCLID

12.2 Persistence and degradability

No information available for the product.

12.3 Bioaccumulative potential

No information available for the product.

12.4 Mobility in soil

No information available for the product.

12.5 Results of PBT and vPvB assessment

EU - Interim Strategy for Management of PBT and vPvB Substances

No components of this material are listed.

12.6 Other adverse effects

No additional information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

Component Marine Pollutants (IMDG)

Not regulated as dangerous goods.

		ADR	RID	ICAO	IATA	ADN	IMDG
14.1	UN Number	Not regulated	Not regulated	Not regulated	Not regulated, as per IATA Special Provision A46	Not regulated	Not regulated
14.2	UN Proper Shipping Name	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3	Transport Hazard Class(es)	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4	Packing Group	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5	Environmental Hazards	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.6	Special Precautions For User	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.7	Transport in Bulk According to Annex II or MARPOL 73/78 and the IBC Code	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.8	Additional information	No additional information available	No additional information available	No additional information available	Consult current IATA regulations prior to shipping by air	No additional information available	No additional information available

International Bulk Chemical Code

This material contains one or more of the following chemicals required by the IBC Code to be identified as dangerous chemicals in bulk.

Polyethylene glycol	25322-68-3
IBC Code:	Category Z

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU - REACH (1907/2006) - Annex XIV List of Substances Subject to Authorization

No components of this material are listed.

EU - REACH (1907/2006) - Article 59(1) Candidate List of Substances Subject to Authorization

No components of this material are listed.

EU - REACH (1907/2006) - Annex XVII Restrictions of Certain Dangerous Substances, Mixtures and Articles

No components of this material are listed.

EU - Biocides (1451/2007) - Existing Active Substance

Isopropyl alcohol	67-63-0
	Present
Iodine	7553-56-2
	Present

Germany Regulations

Germany Water Classification

Isopropyl alcohol (67-63-0)

ID Number 135 , hazard class 1 - low hazard to waters

Iodine (7553-56-2)

ID Number 492 , hazard class 2 - hazard to waters

Polyethylene glycol (25322-68-3)

ID Number 279 , hazard class 1 - low hazard to waters (footnote 11, >=4 EO)

Denmark Regulations

No components of this material are listed.

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out for the substance/mixture.

SECTION 16: Other information

16.1 Indication of changes

New SDS: May 1, 2015

16.2 Key / Legend

ACGIH - American Conference of Governmental Industrial Hygienists; ADR - European Road Transport; AU - Australia; BOD - Biochemical Oxygen Demand; C - Celsius; CA - Canada; CAS - Chemical Abstracts Service; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CLP - Classification, Labelling, and Packaging; CN - China; CPR - Controlled Products Regulations; DFG - Deutsche Forschungsgemeinschaft; DOT - Department of Transportation; DSD - Dangerous Substance Directive; DSL - Domestic Substances List; EEC - European Economic Community; EINECS - European Inventory of Existing Commercial Chemical Substances; EPA - Environmental Protection Agency; EU - European Union; F - Fahrenheit; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; ICAO - International Civil Aviation Organization; IDL - Ingredient Disclosure List; IDLH - Immediately Dangerous to Life and Health; IMDG - International Maritime Dangerous Goods; JP - Japan; Kow - Octanol/water partition coefficient; KR - Korea; LEL - Lower Explosive Limit; LLV - Level Limit Value; LOLI - List Of Lists™ - ChemADVISOR's Regulatory Database; MAK - Maximum Concentration Value in the Workplace; MEL - Maximum Exposure Limits; NFPA - National Fire Protection Agency; NIOSH - National Institute for Occupational Safety and Health; NJTSR - New Jersey Trade Secret Registry; NTP - National Toxicology Program; NZ - New Zealand; OSHA - Occupational Safety and Health Administration; PH - Philippines; RCRA - Resource Conservation and Recovery Act; REACH - Registration, Evaluation, Authorisation, and restriction of Chemicals; RID - European Rail Transport; SARA - Superfund Amendments and Reauthorization Act; STEL - Short-term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; UEL - Upper Explosive Limit; US - United States; WHMIS - Workplace Hazardous Materials Information System

16.3 Key literature references and sources for data

Available upon request.

16.4 Methods Used for Classification of Mixture According to Regulation (EC) No 1272/2008

Available upon request.

16.5 Relevant R-, H- and EUH-phrases (Number and full text)

H319 Causes serious eye irritation

H336 May cause drowsiness or dizziness

H225 Highly flammable liquid and vapor

H400 Very toxic to aquatic life

H312 Harmful in contact with skin

H332 Harmful if inhaled

16.6 Training advice

Read the Safety Data Sheet before handling product.

16.7 Further Information

Disclaimer:

The information and recommendations in this safety data sheet are based on sources believed to be accurate as of the date of issue. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. Covidien LP makes NO WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED and usage of this safety data sheet shall not establish a legal, contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose. Covidien LP assumes no responsibility for injury to vendee or third party person proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Furthermore, Covidien LP assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed. Users should ensure that any use or disposal of the material is in accordance with applicable national, country, federal, state, and local laws, directives, orders and regulations.