

Safety Data Sheet

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 Document group:
 10-3495-8
 Version number:
 1.02

 Issue Date:
 06/03/2023
 Supersedes date:
 27/05/2021

This Safety Data Sheet has been prepared in accordance with the GHS guidelines & India Hazardous substances (Classification, Labeling & Packaging) Draft Rules 2011.

SECTION 1: Identification

1.1. Product identifier

3M Steri-Gas Sterilisation Cartridges

Product Identification Numbers

70-2007-8377-0 70-2007-8383-8

1.2. Recommended use and restrictions on use

Recommended use

Gas to sterilize in a 3M Steri-Vac(TM) Ethylene Oxide Sterilizer

1.3. Supplier's details

Address: 3M India Limited, plot-48-51, Electronic city, Hosur road, Bangalore-560100

Telephone: 080-45543000, contact Product EHS team

E Mail: productehs.in@mmm.com
Website: http://solutions.3mindia.co.in

1.4. Emergency telephone number

080-45543000 (Contact hours: 8:00 AM to 5:00 PM)

SECTION 2: Hazard identification

Under MSIHC Rules, information is noted below on flammability, acute toxicity and explosivity relevant to this product. In line with international standards, information on other hazard classes and associated precautionary statements relevant to this product are included as well.

2.1. Classification of the substance or mixture

Flammable Gas: Category 1A.
Gas under pressure: Liquefied gas.
Acute Toxicity (oral): Category 3.
Acute Toxicity (inhalation): Category 3.
Skin Corrosion/Irritation: Category 1C.
Serious Eye Damage/Irritation: Category 1.
Germ Cell Mutagenicity: Category 1B.

Carcinogenicity: Category 1A. Reproductive Toxicity: Category 1B.

Specific Target Organ Toxicity (single exposure): Category 1. Specific Target Organ Toxicity (repeated exposure): Category 1. Specific Target Organ Toxicity (single exposure): Category 3. Specific Target Organ Toxicity (single exposure): Category 3. Acute Aquatic Toxicity: Category 3.

2.2. Label elements

Signal Word

Danger

Symbols

Flame | Gas cylinder | Corrosion | Skull and crossbones | Health Hazard |

Pictograms











HAZARD STATEMENTS:

H220 Extremely flammable gas.

H280 Contains gas under pressure; may explode if heated.

H301 + H331 Toxic if swallowed or if inhaled.

H314 Causes severe skin burns and eye damage.

H340 May cause genetic defects.

H350 May cause cancer.

H360 May damage fertility or the unborn child.
H336 May cause drowsiness or dizziness.
H335 May cause respiratory irritation.

H370 Causes damage to organs: respiratory system.

H372 Causes damage to organs through prolonged or repeated exposure: nervous system.

H373 May cause damage to organs through prolonged or repeated exposure: kidney/urinary

tract | sensory organs.

H402 Harmful to aquatic life.

PRECAUTIONARY STATEMENTS

Prevention:

P201 Obtain special instructions before use.

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

No smoking.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P280D Wear protective gloves, protective clothing, and eye/face protection.

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin

with water or shower.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

P377 Leaking gas fire: Do not extinguish, unless leak can be stopped safely.

P381 In case of leakage, eliminate all ignition sources.

Storage:

P403 + P233Store in a well-ventilated place. Keep container tightly closed.

P410 + P403Protect from sunlight. Store in a well-ventilated place.

2.3. Other hazards

May cause frostbite. - May cause chemical gastrointestinal burns.

SECTION 3: Composition/information on ingredients

This material is a substance.

Ingredient	CAS Nbr	% by Wt
Ethylene oxide	75-21-8	100

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

Remove person to fresh air. Get medical attention.

Skin contact

Immediately flush with large amounts of water for at least 15 minutes. Remove contaminated clothing. Get immediate medical attention. Wash clothing before reuse.

Eye contact

Immediately flush with large amounts of water for at least 15 minutes. Remove contact lenses if easy to do. Continue rinsing. Immediately get medical attention.

If swallowed

Rinse mouth. Do not induce vomiting. Get immediate medical attention.

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

Toxic if inhaled. Irritating to the respiratory tract (coughing, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain). Skin burns (localized redness, swelling, itching, intense pain, blistering, and tissue destruction). Serious damage to the eyes (corneal cloudiness, severe pain, tearing, ulcerations, and significantly impaired or loss of vision). Toxic if swallowed. Central nervous system depression (headache, dizziness, drowsiness, incoordination, nausea, slurred speech, giddiness, and unconsciousness). Target organ effects. See Section 11 for additional details. Target organ effects following prolonged or repeated exposure. See Section 11 for additional details.

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 water spray or fog to extinguish, do not use straight streams. If water is not available use dry chemical, CO2, or foam to extinguish. Refer to other precautionary advice in SDS section 5. Use a fire fighting agent suitable for the surrounding fire.

5.2. Special hazards arising from the substance or mixture

Closed containers exposed to heat from fire may build pressure and explode.

Hazardous Decomposition or By-Products Substance

Condition

Carbon monoxide. Carbon dioxide.

During combustion. During combustion.

5.3. Special protective actions for fire-fighters

Leaking gas fire: Do not extinguish, unless leak can be stopped safely. Eliminate all ignition sources if safe to do so. 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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Evacuate area. Eliminate all ignition sources if safe to do so. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. 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 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

If possible, seal leaking container. Place leaking containers in a well-ventilated area, preferably an operating exhaust hood, or if necessary outdoors on an impermeable surface until appropriate packaging for the leaking container or its contents is available. Close cylinder. Place in a metal container approved for transportation by appropriate authorities. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

For industrial/occupational use only. Not for consumer sale or use. Do not use in a confined area with minimal air exchange. Do not handle until all safety precautions have been read and understood. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Take precautionary measures against static discharge. Do not breathe dust/fume/gas/mist/vapours/spray. Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Avoid release to the environment. Wash contaminated clothing before reuse. Eliminate all ignition sources if safe to do so. Avoid contact with oxidising agents (eg. chlorine, chromic acid etc.) Use personal protective equipment (eg. gloves, respirators...) as required. Recommendations for storing Steri-Gas cartridges are stringent. Check your local fire protection codes for additional requirements. Keep all sources of ignition such as matches, lighted cigarettes, sparks and static discharge away from the sterilzer and cartridges. Store cartridges in an upright position. Keep only one day's requirement or a maximum of twelve(12) cartridges (one box) in the immediate sterilizer area. This area needs to have at least ten air changes per hour. Additional Steri-Gas cartridges should be stored in an approved flammable liquid storage cabinet vented to the outside atmosphere, or in an area suitable for storage of flammable liquids appropriately vented to the outside atmosphere, or into a non-recirculating, continuously operating, dedicated exhaust system.

7.2. Conditions for safe storage including any incompatibilities

Store in a well-ventilated place. Keep container tightly closed. Protect from sunlight. Store away from heat. Do not expose to temperatures exceeding 50 C/122 F. Store away from acids. Store away from oxidising agents. Store away from areas where product may come into contact with food or pharmaceuticals.

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
Ethylene oxide	75-21-8 ACGIH T		TWA:1 ppm	A2: Suspected human
				carcin.

ACGIH: American Conference of Governmental Industrial Hygienists

AIHA: American Industrial Hygiene Association

CMRG: Chemical Manufacturer's Recommended Guidelines

TWA: Time-Weighted-Average STEL: Short Term Exposure Limit

CEIL: Ceiling

8.2. Exposure controls

8.2.1. Engineering controls

Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below relevant Exposure Limits and/or control dust/fume/gas/mist/vapours/spray. If ventilation is not adequate, use respiratory protection equipment.

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:

Full face shield.

Indirect vented goggles.

Skin/hand protection

Select and use gloves and/or protective clothing approved to relevant local standards to prevent skin contact based on the results of an exposure assessment. Selection should be based on use factors such as exposure levels, concentration of the substance or mixture, frequency and duration, physical challenges such as temperature extremes, and other use conditions. Consult with your glove and/or protective clothing manufacturer for selection of appropriate compatible gloves/protective clothing. Note: Nitrile gloves may be worn over polymer laminate gloves to improve dexterity. Gloves made from the following material(s) are recommended: Polymer laminate

If this product is used in a manner that presents a higher potential for exposure (eg. spraying, high splash potential etc.), then use of protective coveralls may be necessary. Select and use body protection to prevent contact based on the results of an exposure assessment. The following protective clothing material(s) are recommended: Apron - polymer laminate

Respiratory protection

An exposure assessment may be needed to decide if a respirator is required. If a respirator is needed, use respirators as part of a full respiratory protection program. Based on the results of the exposure assessment, select from the following respirator type(s) to reduce inhalation exposure:

Half facepiece or full facepiece supplied-air respirator

For questions about suitability for a specific application, consult with your respirator manufacturer.

Thermal hazards

Wear cold insulating gloves/face shield/eye protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Gas.
Specific Physical Form:	Compressed gas.
Color	Colorless

0.1	001
Odor	Sweet Odor
Odour threshold	No data available.
рН	7
Melting point/Freezing point: NA	Not applicable.
Boiling point/Initial boiling point/Boiling range	10.6 °C
Flash point	-20 °C [Test Method: Tagliabue closed cup]
Evaporation rate	Not applicable.
Flammability (solid, gas)	Flammable gas: Category 1.
Flammable Limits(LEL)	3 % volume
Flammable Limits(UEL)	100 % volume
Vapour pressure	145,854.3 Pa [@ 20 °C]
Vapor Density and/or Relative Vapor Density	1.49 [<i>Ref Std</i> :AIR=1]
Density	Not applicable.
Relative density	0.87 [Ref Std:WATER=1] [Details:@, 20 °C]
Water solubility	Complete
Solubility- non-water	No data available.
Partition coefficient: n-octanol/water	No data available.
Autoignition temperature	428.9 °C [Details: CONDITIONS: Burns in the absence of air]
Decomposition temperature	Not applicable.
Viscosity/Kinematic Viscosity	Not applicable.
Volatile organic compounds (VOC)	100 %
Percent volatile	100 %
VOC less H2O & exempt solvents	100 %
Molecular weight	No data available.

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 may occur.

10.4 Conditions to avoid

Heat.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Substance

None known.

Condition

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

Toxic if inhaled.

Respiratory tract irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain. May cause additional health effects (see below).

Skin contact

Frostbite: Signs/symptoms may include intense pain, discoloration of skin, and tissue destruction. Corrosive (skin burns): Signs/symptoms may include localised redness, swelling, itching, intense pain, blistering, ulceration, and tissue destruction.

Eve contact

Frostbite: Signs/symptoms may include intense pain, clouding of the cornea, redness, swelling, and blindness. Corrosive (eye burns): Signs/symptoms may include cloudy appearance of the cornea, chemical burns, severe pain, tearing, ulcerations, significantly impaired vision or complete loss of vision.

Ingestion

Toxic if swallowed.

Gastrointestinal corrosion: Signs/symptoms may include severe mouth, throat and abdominal pain, nausea, vomiting, and diarrhea; blood in the faeces and/or vomitus may also be seen.

Additional Health Effects:

Single exposure may cause target organ effects:

Central nervous system (CNS) depression: Signs/symptoms may include headache, dizziness, drowsiness, incoordination, nausea, slowed reaction time, slurred speech, giddiness, and unconsciousness. Respiratory effects: Signs/symptoms may include cough, shortness of breath, chest tightness, wheezing, increased heart rate, bluish coloured skin (cyanosis), sputum production, changes in lung function tests, and respiratory failure.

Prolonged or repeated exposure may cause target organ effects:

Ocular effects: Signs/symptoms may include blurred or significantly impaired vision. Peripheral neuropathy: Signs/symptoms may include tingling or numbness of the extremities, incoordination, weakness of the hands and feet, tremors and muscle atrophy. Kidney/Bladder effects: Signs/symptoms may include changes in urine production, abdominal or lower back pain, increased protein in urine, increased blood urea nitrogen (BUN), blood in urine, and painful urination.

Reproductive/Developmental Toxicity:

Contains a chemical or chemicals which can cause birth defects or other reproductive harm.

Genotoxicity:

Genotoxicity and Mutagenicity: May interact with genetic material and possibly alter gene expression.

Carcinogenicity:

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
Ethylene oxide	Inhalation-	official	LC50 700 ppm
	Gas (4	classifica	
	hours)	tion	
Ethylene oxide	Ingestion	official	LD50 100 mg/kg
		classifica	
		tion	

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Ethylene oxide	Human and	Corrosive
	animal	

Serious Eye Damage/Irritation

Name	Species	Value
Ethylene oxide	similar health	Corrosive
	hazards	

Sensitization:

Skin Sensitisation

Mil Selisiusutoi			
Name	Species	Value	
Ethylene oxide	Human and	Not classified	
	animal		

Respiratory Sensitisation

Name	Species	Value
Ethylene oxide	Human	Not classified

Germ Cell Mutagenicity

Name	Route	Value
Ethylene oxide	In vivo	Mutagenic

Carcinogenicity

Name	Route	Species	Value
Ethylene oxide	Inhalation	Multiple	Carcinogenic.
		animal	
		species	

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure	
			_		Duration	
Ethylene oxide	Inhalation	Toxic to development	Rat	NOAEL 33	during	
				ppm	organogenesis	
Ethylene oxide	Inhalation	Toxic to female reproduction	Rat	NOAEL 33	1 generation	
-		_		ppm		
Ethylene oxide	Inhalation	Toxic to male reproduction	Monkey	LOAEL 50	2 years	
				ppm		

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Ethylene oxide	Inhalation	respiratory system	Causes damage to organs	Human and animal	NOAEL Not available	
Ethylene oxide	Inhalation	central nervous system depression	May cause drowsiness or dizziness	Human	NOAEL Not available	
Ethylene oxide	Inhalation	respiratory irritation	May cause respiratory irritation		NOAEL Not available	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration	
Ethylene oxide	Inhalation	peripheral nervous system	Causes damage to organs through prolonged or repeated exposure	Human and animal	NOAEL Not available		
Ethylene oxide	Inhalation	kidney and/or bladder	May cause damage to organs though prolonged or repeated exposure	Mouse	LOAEL 100 ppm	14 weeks	
Ethylene oxide	Inhalation	eyes	May cause damage to organs though prolonged or repeated exposure	Human and animal	NOAEL Not available		
Ethylene oxide	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification		LOAEL 200 ppm	14 weeks	
Ethylene oxide	Inhalation	endocrine system			NOAEL 100 ppm	2 years	
Ethylene oxide	Inhalation	liver	Not classified	Multiple animal species	NOAEL 841 ppm	not available	
Ethylene oxide	Inhalation	hematopoietic system	Not classified	Mouse	NOAEL 250 ppm	10 weeks	
Ethylene oxide	Inhalation	immune system	Not classified Mouse		LOAEL 200 ppm	14 weeks	
Ethylene oxide	Inhalation	heart	Not classified	Monkey	NOAEL 100 ppm	2 years	

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

Acute aquatic hazard:

GHS Acute 3: Harmful to aquatic life.

Chronic aquatic hazard:

Not chronically toxic to aquatic life by GHS criteria.

Material	Organism	Type	Exposure	Test endpoint	Test result
3M Steri-Gas Sterilisation Cartridges	Water flea	Laboratory	48 hours	N/A	137 mg/l
3M Steri-Gas Sterilisation Cartridges	Fathead minnow	Laboratory	96 hours	N/A	84 mg/l
3M Steri-Gas Sterilisation Cartridges	Goldfish	Laboratory	24 hours	N/A	90 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Ethylene oxide	75-21-8	Experimental	28 days	BOD	107 %BOD/ThOD	OECD 301C - MITI test (I)
		Biodegradation				
Ethylene oxide	75-21-8	Experimental		Hydrolytic half-life	12.9 days (t 1/2)	
		Hydrolysis		(pH 7)		

12.3: Bioaccumulative potential

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Ethylene oxide	75-21-8	Experimental		Log Kow	-0.3	OECD 107 log Kow shke
		Bioconcentration		_		flsk mtd

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

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

Incinerate in a permitted waste incineration facility. As a disposal alternative, utilize an acceptable permitted waste disposal facility. The facility should be equipped to handle gaseous 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.

SECTION 14: Transport Information

Air Transport (IATA)Regulations

Forbidden: Not allowed by the regulatory agency

UN No Not applicable

Proper Shipping Name Not applicable **Hazard Classs/Division** Not applicable

Subsidiary Risk Not applicable **Packing Group:** Not applicable

Marine Transport (IMDG)

UN No UN1040

Proper Shipping Name Ethylene oxide

Hazard Classs/Division 2.3

Subsidiary Risk 2.1

Packing Group: Not applicable

Environmental Hazards: Not applicable

SECTION 15: Regulatory information

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

Global inventory status

Contact 3M for more information.

Applicable Environmental, Health and Safety Regulations

The Manufacture, Storage and Import of Hazardous Chemical Rules, 1989 Hazardous Waste(Management, Handling & Transboundary) Rules, 2008

Hazardous Chemicals (Classification, Packaging and Labelling Draft Rules), 2011

The following ingredients are listed as hazardous on Part II of Schedule I of the India Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) rules

Ethylene oxide

The following ingredients are classified as hazardous based on the criteria listed under Part I of Schedule I of the India Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) rules:

Product is classified as Flammable and Toxic Gas.

SECTION 16: Other information

NFPA Hazard Classification

Health: 4 Flammability: 4 Instability: 3 Special Hazards: None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

Revision information:

Section 2: Hazard - Other information was modified.

Label: GHS Classification information was modified.

Label: GHS Precautionary - Disposal information was deleted.

Label: GHS Precautionary - Prevention information was modified.

Label: GHS Precautionary - Response information was modified. Label: GHS Precautionary - Storage information was modified.

Label: GHS Target Organ Hazard Statement information was modified.

Label: Graphic information was modified.

Label: Signal Word information was modified.

Label: Symbol information was modified.

Section 03: Material is a mixture standard phrase information was modified.

Section 04: First Aid - Symptoms and Effects (GHS) information was added.

Section 4: First aid for skin contact information information was modified.

Section 7: Precautions safe handling information information was modified.

Section 8: Personal Protection - Skin/body information information was added.

Section 8: Skin protection - protective clothing information information was added.

Section 09: Nanoparticle information was deleted.

Section 09: Vapor Density Value information was modified.

Section 11: Health Effects - Eve information information was modified.

Section 11: Health Effects - Ingestion information information was modified.

Section 11: Health Effects - Skin information information was modified.

Section 12: Material ecotoxicity information information was modified.

Section 12: Persistence and Degradability information information was modified.

Section 12:Bioccumulative potential information information was modified.

Section 14: Forbidden (IATA) information was added.

Section 14: IATA Subsidiary Risk information was modified.

Section 14: IATA transport hazard classes information was modified.

Section 14: Proper Shipping Name (IATA) information was modified.

Section 14: UN Number (IATA) information was modified.

Section 15: MSIHC Part I of Schedule I ingredients information was modified.

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