

according to Regulation UK SI 2019/758 and UK SI 2020/1577 as amended

Creation Date 08-Jul-2010

Revision Date 27-Sep-2023

Revision Number 6

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1. Product identifier

Product Description: Cat No. : Synonyms Molecular Formula Mitomycin C 226940000; 226940020 Ametycine. C15 H18 N4 O5

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

Recommended Use	Laboratory chemicals.
Uses advised against	No Information available

#### 1.3. Details of the supplier of the safety data sheet

Company

**UK entity/business name** Fisher Scientific UK Bishop Meadow Road, Loughborough, Leicestershire LE11 5RG, United Kingdom

**EU entity/business name** Thermo Fisher Scientific Janssen Pharmaceuticalaan 3a, 2440 Geel, Belgium

#### E-mail address

begel.sdsdesk@thermofisher.com

#### 1.4. Emergency telephone number

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No. **US**:001-800-424-9300 / **Europe**:001-703-527-3887

## **SECTION 2: HAZARDS IDENTIFICATION**

#### 2.1. Classification of the substance or mixture

CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567

#### Physical hazards

Based on available data, the classification criteria are not met

#### Health hazards

Acute oral toxicity Carcinogenicity Category 4 (H302) Category 2 (H351)

#### **Environmental hazards**

Based on available data, the classification criteria are not met

Full text of Hazard Statements: see section 16

#### 2.2. Label elements



Signal Word

#### Hazard Statements

H302 - Harmful if swallowed

H351 - Suspected of causing cancer

#### **Precautionary Statements**

P201 - Obtain special instructions before use

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

Warning

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

#### 2.3. Other hazards

Substance is not considered persistent, bioaccumulative and toxic (PBT) / very persistent and very bioaccumulative (vPvB)

This product does not contain any known or suspected endocrine disruptors

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.2. Mixtures

Component	CAS No	EC No	Weight %	CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567
Sodium chloride	7647-14-5	231-598-3	96	-
Mitomycin-C	50-07-7	EEC No. 200-008-6	4	Carc. 2 (H351) Acute Tox. 3 (H301)

Full text of Hazard Statements: see section 16

## **SECTION 4: FIRST AID MEASURES**

#### 4.1. Description of first aid measures

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.		
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. Get medical attention immediately if symptoms occur.		
Ingestion	Do NOT induce vomiting. Call a physician or poison control center immediately.		
Inhalation	Remove to fresh air. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Get medical attention immediately if symptoms occur. If not breathing, give artificial respiration.		
Self-Protection of the First Aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.		
4.2. Most important symptoms and effects, both acute and delayed			

No information available.

#### 4.3. Indication of any immediate medical attention and special treatment needed

Notes to Physician	Treat symptomatically.
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## **SECTION 5: FIREFIGHTING MEASURES**

#### 5.1. Extinguishing media

**Mitomycin C** 

#### Suitable Extinguishing Media

Water spray, carbon dioxide (CO2), dry chemical, alcohol-resistant foam.

#### Extinguishing media which must not be used for safety reasons No information available.

#### 5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors. Keep product and empty container away from heat and sources of ignition.

#### Hazardous Combustion Products

Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>).

#### 5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment as required. Ensure adequate ventilation. Avoid dust formation. Avoid contact with skin, eyes or clothing.

#### 6.2. Environmental precautions

Avoid release to the environment. See Section 12 for additional Ecological Information.

#### 6.3. Methods and material for containment and cleaning up

Sweep up and shovel into suitable containers for disposal. Avoid dust formation.

#### 6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

### **SECTION 7: HANDLING AND STORAGE**

#### 7.1. Precautions for safe handling

Use only under a chemical fume hood. Wear personal protective equipment/face protection. Avoid dust formation. Avoid contact with skin, eyes or clothing. Avoid ingestion and inhalation.

#### Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

#### 7.2. Conditions for safe storage, including any incompatibilities

Keep containers tightly closed in a dry, cool and well-ventilated place.

# Technical Rules for Hazardous Substances (TRGS) 510Class 11Storage Class (LGK) (Germany)

#### 7.3. Specific end use(s)

Use in laboratories

## **SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### 8.1. Control parameters

#### Exposure limits List source(s):

#### **Biological limit values**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

#### Derived No Effect Level (DNEL) / Derived Minimum Effect Level (DMEL)

See table for values

Component	Acute effects local	Acute effects	Chronic effects local	Chronic effects
	(Dermal)	systemic (Dermal)	(Dermal)	systemic (Dermal)
Sodium chloride 7647-14-5 ( 96 )		DNEL = 295.52mg/kg bw/day		DNEL = 295.52mg/kg bw/day

Component	Acute effects local	Acute effects	Chronic effects local	Chronic effects

#### **Mitomycin C**

	(Inhalation)	systemic (Inhalation)	(Inhalation)	systemic (Inhalation)
Sodium chloride		DNEL = 2068.62mg/m <sup>3</sup>		DNEL = 2068.62mg/m <sup>3</sup>
7647-14-5 (96)				

#### Predicted No Effect Concentration (PNEC)

See values below.

Component	Fresh water	Fresh water sediment	Microorganisms in sewage treatment	,
Sodium chloride 7647-14-5 ( 96 )	PNEC = 5mg/L		PNEC = 500mg/L	PNEC = 4.86mg/kg soil dw

#### 8.2. Exposure controls

#### Engineering Measures

Use only under a chemical fume hood. Ensure that eyewash stations and safety showers are close to the workstation location. Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

Personal protective equipment	
Eve Drotestien	

Eye Protection		Goggles (European standard - EN 166)		
Hand Protection	Protectiv	e gloves		
	Breakthrough time See manufacturers recommendations	Glove thickness -	EU standard EN 374	Glove comments (minimum requirement)

# Skin and body protection

Inspect gloves before use.

PVC

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Wear appropriate protective gloves and clothing to prevent skin exposure.

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

Respiratory Protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly
Large scale/emergency use	Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced <b>Recommended Filter type:</b> Particulates filter conforming to EN 143
Small scale/Laboratory use	Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. <b>Recommended half mask:-</b> Particle filtering: EN149:2001 When RPE is used a face piece Fit Test should be conducted
Environmental exposure controls	No information available.

# SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1. Information on basic physical and chemical properties

Physical State	Solid	
Appearance Odor Odor Threshold Melting Point/Range Softening Point	Blue Odorless No data available > 360 °C / 680 °F No data available	
Boiling Point/Range Flammability (liquid) Flammability (solid,gas) Explosion Limits	No information available Not applicable No information available No data available	Solid
Flash Point	No information available	Method - No information available
Autoignition Temperature Decomposition Temperature	No data available No data available	
pH	5.5-7.0	saturated solution
Viscosity	Not applicable	Solid
Water Solubility	Soluble	
Solubility in other solvents	No information available	
Partition Coefficient (n-octanol/wate	er)	
Vapor Pressure	No data available	
Density / Specific Gravity	No data available	
Bulk Density	No data available	
Vapor Density	Not applicable	Solid
Particle characteristics	No data available	
9.2. Other information		

Molecular Formula	C15 H18 N4 O5
Molecular Weight	334.32
Evaporation Rate	Not applicable - Solid

# **SECTION 10: STABILITY AND REACTIVITY**

10.1. Reactivity	None known, based on information available
10.2. Chemical stability	Stable under normal conditions.
10.3. Possibility of hazardous react	ions
Hazardous Polymerization Hazardous Reactions	Hazardous polymerization does not occur. None under normal processing.
10.4. Conditions to avoid	Avoid dust formation. Incompatible products. Excess heat. Exposure to light.
10.5. Incompatible materials	Strong oxidizing agents. Strong acids. Strong bases.

#### 10.6. Hazardous decomposition products

Nitrogen oxides (NOx). Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>).

# **SECTION 11: TOXICOLOGICAL INFORMATION**

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

#### **Product Information**

(a) acute toxicity;

OralCategory 4DermalBased on available data, the classification criteria are not metInhalationBased on available data, the classification criteria are not met

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium chloride	LD50 = 3 g/kg (Rat)	LD50 > 10000 mg/kg (Rabbit)	LC50 > 42 mg/L (Rat)1 h
Mitomycin-C	LD50 = 30 mg/kg (Rat)	-	-

(b) skin corrosion/irritation;	No data available
(c) serious eye damage/irritation;	No data available
(d) respiratory or skin sensitization; Respiratory Skin	No data available No data available
(e) germ cell mutagenicity;	No data available
(f) carcinogenicity;	Category 2

The table below indicates whether each agency has listed any ingredient as a carcinogen

Component	EU	UK	Germany	IARC
Mitomycin-C				Group 2B

(g) reproductive toxicity;	No data available
(h) STOT-single exposure;	No data available
(i) STOT-repeated exposure;	No data available
Target Organs	No information available.
(j) aspiration hazard;	Not applicable Solid
Other Adverse Effects	Tumorigenic effects have been reported in experimental animals.
Symptoms / effects,both acute and delayed	No information available.
11.2. Information on other hazards	

**Endocrine Disrupting Properties** Assess endocrine disrupting properties for human health. This product does not contain any known or suspected endocrine disruptors.

### **SECTION 12: ECOLOGICAL INFORMATION**

#### 12.1. Toxicity Ecotoxicity effects

This product contains the following substance(s) which are hazardous for the environment. .

Component	Freshwater Fish	Water Flea	Freshwater Algae
Sodium chloride	Pimephals prome: LC50: 7650	EC50: 1000 mg/L/48h	
	mg/L/96h		

12.2. Persistence and degradability Persistence	Soluble in water, Persistence is unlikely, based on information available.
12.3. Bioaccumulative potential	Bioaccumulation is unlikely
12.4. Mobility in soil	The product is water soluble, and may spread in water systems Will likely be mobile in the environment due to its water solubility. Highly mobile in soils
<u>12.5. Results of PBT and vPvB</u> assessment	Substance is not considered persistent, bioaccumulative and toxic (PBT) / very persistent and very bioaccumulative (vPvB).
<u>12.6. Endocrine disrupting</u> properties Endocrine Disruptor Information	This product does not contain any known or suspected endocrine disruptors
<u>12.7. Other adverse effects</u> Persistent Organic Pollutant Ozone Depletion Potential	This product does not contain any known or suspected substance This product does not contain any known or suspected substance
SE	CTION 13: DISPOSAL CONSIDERATIONS
13.1. Waste treatment methods	
Waste from Residues/Unused Products	Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.
Contaminated Packaging	Dispose of this container to hazardous or special waste collection point.
European Waste Catalogue (EWC)	According to the European Waste Catalog, Waste Codes are not product specific, but application specific.
Other Information	Waste codes should be assigned by the user based on the application for which the product

# **SECTION 14: TRANSPORT INFORMATION**

was used. Do not empty into drains.

#### IMDG/IMO

14.1. UN number

UN2811

Mitomycin C
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14.2. UN proper shipping name Technical Shipping Name 14.3. Transport hazard class(es) 14.4. Packing group	Toxic solid, organic, n.o.s. Mitomycin C 6.1 III
ADR	
<u>14.1. UN number</u> <u>14.2. UN proper shipping name</u> Technical Shipping Name <u>14.3. Transport hazard class(es)</u> <u>14.4. Packing group</u>	UN2811 Toxic solid, organic, n.o.s. Mitomycin C 6.1 III
IATA	
<u>14.1. UN number</u> <u>14.2. UN proper shipping name</u> Technical Shipping Name <u>14.3. Transport hazard class(es)</u> 14.4. Packing group	UN2811 TOXIC SOLID, ORGANIC, N.O.S.* Mitomycin C 6.1 III
14.5. Environmental hazards	No hazards identified
14.6. Special precautions for user	No special precautions required.
14.7. Maritime transport in bulk according to IMO instruments	Not applicable, packaged goods

### **SECTION 15: REGULATORY INFORMATION**

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

#### International Inventories

Europe (EINECS/ELINCS/NLP), China (IECSC), Taiwan (TCSI), Korea (KECL), Japan (ENCS), Japan (ISHL), Canada (DSL/NDSL), Australia (AICS), New Zealand (NZIoC), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	EINECS	ELINCS	NLP	IECSC	TCSI	KECL	ENCS	ISHL
Sodium chloride	7647-14-5	231-598-3	-	-	Х	Х	KE-31387	Х	Х
Mitomycin-C	50-07-7	200-008-6	-	-	-	Х	-	Х	-

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS
Sodium chloride	7647-14-5	Х	ACTIVE	Х	-	Х	Х	Х
Mitomycin-C	50-07-7	Х	ACTIVE	-	Х	-	Х	-

Legend: X - Listed '-' - Not Listed

KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

Not applicable

#### Authorisation/Restrictions according to EU REACH

CAS No REACH (1907/2006) -REACH (1907/2006) -**REACH Regulation (EC** Component Annex XIV - Substances Annex XVII - Restrictions 1907/2006) article 59 -Candidate List of Subject to Authorization on Certain Dangerous Substances of Very High Concern (SVHC) Substances Sodium chloride 7647-14-5 -Mitomycin-C 50-07-7

#### Seveso III Directive (2012/18/EC)

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements
Sodium chloride	7647-14-5	Not applicable	Not applicable
Mitomycin-C	50-07-7	Not applicable	Not applicable

# Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)? Not applicable

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work .

#### National Regulations

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

#### WGK Classification

See table for values

Component	Germany - Water Classification (AwSV)	Germany - TA-Luft Class
Sodium chloride	WGK1	
Mitomycin-C	WGK3	

Component	France - INRS (Tables of occupational diseases)
Sodium chloride	Tableaux des maladies professionnelles (TMP) - RG 78

Component	Switzerland - Ordinance on the Reduction of Risk from handling of hazardous substances preparation (SR 814.81)	Switzerland - Ordinance on Incentive Taxes on Volatile Organic Compounds (OVOC)	Switzerland - Ordinance of the Rotterdam Convention on the Prior Informed Consent Procedure
Sodium chloride 7647-14-5 ( 96 )	Prohibited and Restricted Substances		

#### 15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

### **SECTION 16: OTHER INFORMATION**

#### Full text of H-Statements referred to under sections 2 and 3

H301 - Toxic if swallowed

H351 - Suspected of causing cancer

Legend

#### **Mitomycin C**

CAS - Chemical Abstracts Service	TSCA - United States Toxic Substances Control Act Section 8(b) Inventory	
<b>EINECS/ELINCS</b> - European Inventory of Existing Commercial Chemica Substances/EU List of Notified Chemical Substances	al <b>DSL/NDSL</b> - Canadian Domestic Substances List/Non-Domestic Substances List	
PICCS - Philippines Inventory of Chemicals and Chemical Substances	ENCS - Japanese Existing and New Chemical Substances	
IECSC - Chinese Inventory of Existing Chemical Substances	AICS - Australian Inventory of Chemical Substances	
<b>KECL</b> - Korean Existing and Evaluated Chemical Substances	NZIOC - New Zealand Inventory of Chemicals	
WEL - Workplace Exposure Limit	TWA - Time Weighted Average	
ACGIH - American Conference of Governmental Industrial Hygienists	IARC - International Agency for Research on Cancer	
DNEL - Derived No Effect Level	Predicted No Effect Concentration (PNEC) LD50 - Lethal Dose 50%	
<b>RPE</b> - Respiratory Protective Equipment <b>LC50</b> - Lethal Concentration 50%	EC50 - Effective Concentration 50%	
<b>NOEC</b> - No Observed Effect Concentration	<b>POW</b> - Partition coefficient Octanol:Water	
<b>PBT</b> - Persistent, Bioaccumulative, Toxic	<b>vPvB</b> - very Persistent, very Bioaccumulative	
ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road	ICAO/IATA - International Civil Aviation Organization/International Air Transport Association	
<b>IMO/IMDG</b> - International Maritime Organization/International Maritime Dangerous Goods Code	MARPOL - International Convention for the Prevention of Pollution from Ships	
OECD - Organisation for Economic Co-operation and Development	ATE - Acute Toxicity Estimate	
BCF - Bioconcentration factor	VOC - (Volatile Organic Compound)	
Key literature references and sources for data		
https://echa.europa.eu/information-on-chemicals		
Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS		

#### **Training Advice**

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

Creation Date	08-Jul-2010
Revision Date	27-Sep-2023
Revision Summary	Not applicable.

# This safety data sheet complies with Regulation UK SI 2019/758 and UK SI 2020/1577 as amended.

#### Disclaimer

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. 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. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

# End of Safety Data Sheet