

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

Revision Date 19-Mar-2024 Revision Number 3

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

1.1. Product identifier

Product Description: Mitomycin C, 5 mg/ml in DMSO, sterile-filtered

Cat No. : J67460

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

Recommended Use Laboratory chemicals.

Sector of use SU3 - Industrial uses: Uses of substances as such or in preparations at industrial sites

**Product category** PC21 - Laboratory chemicals

**Process categories** PROC15 - Use as a laboratory reagent

**Environmental release category** ERC6a - Industrial use resulting in manufacture of another substance (use of intermediates)

Uses advised against No Information available

1.3. Details of the supplier of the safety data sheet

Company .

Avocado Research Chemicals Ltd. (Part of Thermo Fisher Scientific)

Shore Road, Heysham Lancashire, LA3 2XY, United Kingdom

Office Tel: +44 (0) 1524 850506 Office Fax: +44 (0) 1524 850608

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**

Based on available data, the classification criteria are not met

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#### **Environmental hazards**

Based on available data, the classification criteria are not met

Full text of Hazard Statements: see section 16

#### 2.2. Label elements

None required

#### 2.3. Other hazards

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

Toxic to terrestrial vertebrates

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
Dimethyl sulfoxide	67-68-5	EEC No. 200-664-3	99.54	-
Mitomycin-C	50-07-7	EEC No. 200-008-6	0.455	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 Clean mouth with water and drink afterwards plenty of water. Get medical attention if

symptoms occur.

**Inhalation** Remove to fresh air. Get medical attention immediately if symptoms occur.

Self-Protection of the First Aider No special precautions required.

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

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None reasonably foreseeable.

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

Notes to Physician Treat symptomatically.

## **SECTION 5: FIREFIGHTING MEASURES**

## 5.1. Extinguishing media

## **Suitable Extinguishing Media**

Carbon dioxide (CO 2). Powder. Water spray. In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.

## 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.

## **Hazardous Combustion Products**

Carbon monoxide (CO), Carbon dioxide (CO2), Nitrogen oxides (NOx), Sulfur oxides, Oxides of phosphorus.

## 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

Ensure adequate ventilation. Use personal protective equipment as required.

## 6.2. Environmental precautions

Should not be released into 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.

#### 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

Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Avoid ingestion and inhalation.

#### **Hygiene Measures**

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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

Store in freezer.

Technical Rules for Hazardous Substances (TRGS) 510 Class 10 Storage 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 (Dermal)	Acute effects systemic (Dermal)	Chronic effects local (Dermal)	Chronic effects systemic (Dermal)	
Dimethyl sulfoxide 67-68-5 ( 99.54 )				DNEL = 200mg/kg bw/day	

Component	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
Dimethyl sulfoxide			DNEL = $265 \text{mg/m}^3$	$DNEL = 484mg/m^3$
67-68-5 ( 99.54 )			_	

## **Predicted No Effect Concentration (PNEC)**

See values below.

	Component	Fresh water	Fresh water	Water Intermittent	Microorganisms in	Soil (Agriculture)
L			sediment	sewage treatment		
Γ	Dimethyl sulfoxide	PNEC = 17mg/L	PNEC = 13.4 mg/kg		PNEC = 11mg/L	PNEC = 3.02mg/kg
L	67-68-5 ( 99.54 )		sediment dw			soil dw

Component	Marine water	Marine water sediment	Marine water intermittent	Food chain	Air
Dimethyl sulfoxide	PNEC = 1.7mg/L			PNEC = 0.7g/kg	
67-68-5 ( 99.54 )				food	

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## 8.2. Exposure controls

## **Engineering Measures**

Ensure adequate ventilation, especially in confined areas.

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 Protection** Wear safety glasses with side shields (or goggles) (European standard - EN 166)

**Hand Protection** Protective gloves

Γ	Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
1	Nitrile rubber	See manufacturers	-	EN 374	(minimum requirement)
		recommendations			

Skin and body protection Long sleeved clothing.

Inspect gloves before use.

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

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

In case of insufficient ventilation, wear suitable respiratory equipment Large scale/emergency use

Recommended Filter type: Multi-purpose/ABEK conforming to EN14387

Liquid

Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure Small scale/Laboratory use

limits are exceeded or if irritation or other symptoms are experienced.

When RPE is used a face piece Fit Test should be conducted

No information available. **Environmental exposure controls** 

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

## 9.1. Information on basic physical and chemical properties

**Physical State** Liquid

**Appearance** 

Odor No information available

**Odor Threshold** No data available **Melting Point/Range** No data available No data available **Softening Point** No information available **Boiling Point/Range** No data available Flammability (liquid)

Flammability (solid,gas) Not applicable

**Explosion Limits** No data available

No information available Flash Point Method - No information available

**Autoignition Temperature** No data available **Decomposition Temperature** No data available

pН No information available No data available Viscosity

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Water Solubility Immiscible

Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

Componentlog PowDimethyl sulfoxide-1.35

Vapor PressureNo data availableDensity / Specific GravityNo data available

Bulk DensityNot applicableLiquidVapor DensityNo data available(Air = 1.0)

Particle characteristics Not applicable (liquid)

#### 9.2. Other information

## **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 reactions

Hazardous PolymerizationNo information available.Hazardous ReactionsNone under normal processing.

10.4. Conditions to avoid

Incompatible products. Excess heat.

10.5. Incompatible materials

Oxidizing agent.

## 10.6. Hazardous decomposition products

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

Oxides of phosphorus.

## **SECTION 11: TOXICOLOGICAL INFORMATION**

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

## **Product Information**

(a) acute toxicity;

OralBased on available data, the classification criteria are not metDermalBased on available data, the classification criteria are not metInhalationBased on available data, the classification criteria are not met

## Toxicology data for the components

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Dimethyl sulfoxide	LD50 = 28300 mg/kg (Rat)	LD50 = 40000 mg/kg ( Rat )	LC50 > 5.33 mg/L (Rat) 4 h
Mitomycin-C	LD50 = 30 mg/kg (Rat)	-	-

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(b) skin corrosion/irritation; Based on available data, the classification criteria are not met

Based on available data, the classification criteria are not met (c) serious eye damage/irritation;

(d) respiratory or skin sensitization;

Respiratory Skin

Based on available data, the classification criteria are not met Based on available data, the classification criteria are not met

Based on available data, the classification criteria are not met (e) germ cell mutagenicity;

Based on available data, the classification criteria are not met (f) carcinogenicity;

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

Component	EU	UK	Germany	IARC
Mitomycin-C				Group 2B

Based on available data, the classification criteria are not met (g) reproductive toxicity;

(h) STOT-single exposure; Based on available data, the classification criteria are not met

(i) STOT-repeated exposure: Based on available data, the classification criteria are not met

None known. **Target Organs** 

Based on available data, the classification criteria are not met (j) aspiration hazard;

Symptoms / effects,both acute and No information available.

delayed

## 11.2. Information on other hazards

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

known or suspected endocrine disruptors.

## **SECTION 12: ECOLOGICAL INFORMATION**

## 12.1. Toxicity

**Ecotoxicity effects** 

Component	Freshwater Fish	Water Flea	Freshwater Algae		
Dimethyl sulfoxide	40 g/L LC50 96 h	EC50 24h 7000 mg/L	EC50 96h 12350 - 25500 mg/L		
	33-37 g/L LC50 96 h				

Component	Microtox	M-Factor
Dimethyl sulfoxide	= 16000 mg/L EC50 Pseudomonas putida 16 h	
	= 32 g/L EC50 Tetrahymena pyriformis 24 h	
	= 77 mg/L EC50 Photobacterium phosphoreum 5	
	min	

#### 12.2. Persistence and degradability

Persistence is unlikely. **Persistence** 

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12.3. Bioaccumulative potential Bioaccumulation is unlikely

Component	log Pow	Bioconcentration factor (BCF)
Dimethyl sulfoxide	-1.35	No data available

12.4. Mobility in soil Spillage unlikely to penetrate soil Is not likely mobile in the environment due its low water

solubility.

12.5. Results of PBT and vPvB

assessment

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

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and very bioaccumulative (vPvB).

12.6. Endocrine disrupting

properties

**Endocrine Disruptor Information** 

This product does not contain any known or suspected endocrine disruptors

12.7. Other adverse effects

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

## **SECTION 13: DISPOSAL CONSIDERATIONS**

## 13.1. Waste treatment methods

Waste from Residues/Unused

**Products** 

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Consult local, regional, and national hazardous waste regulations to

ensure complete and accurate classification.

Contaminated Packaging Empty remaining contents. Dispose of in accordance with local regulations. Do not re-use

empty containers.

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

was used.

## **SECTION 14: TRANSPORT INFORMATION**

IMDG/IMO Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

ADR Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

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IATA Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

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
	Dimethyl sulfoxide	67-68-5	200-664-3	ı	-	X	X	KE-32367	X	X
Г	Mitomycin-C	50-07-7	200-008-6	-	-	-	X	-	X	-

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS
Dimethyl sulfoxide	67-68-5	Х	ACTIVE	X	Ī	X	X	X
Mitomycin-C	50-07-7	Х	ACTIVE	-	X	-	X	-

Legend: X - Listed '-' - Not Listed KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

#### Authorisation/Restrictions according to EU REACH

Component	CAS No	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization		REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
Dimethyl sulfoxide	67-68-5	-	Use restricted. See item 75. (see link for restriction details)	-
Mitomycin-C	50-07-7	-	-	-

## **REACH links**

https://echa.europa.eu/substances-restricted-under-reach

## 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
	Dimethyl sulfoxide	67-68-5	Not applicable	Not applicable
I	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

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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** 

Water endangering class = 2 (self classification)

Component	Germany - Water Classification (AwSV)	Germany - TA-Luft Class
Dimethyl sulfoxide	WGK1	
Mitomycin-C	WGK3	

Component	France - INRS (Tables of occupational diseases)
Dimethyl sulfoxide	Tableaux des maladies professionnelles (TMP) - RG 84

#### 15.2. Chemical safety assessment

Chemical Safety Assessment/Reports (CSA/CSR) are not required for mixtures

## **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

CAS - Chemical Abstracts Service

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances IECSC - Chinese Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

Substances List

**ENCS** - Japanese Existing and New Chemical Substances AICS - Australian Inventory of Chemical Substances NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

**DNEL** - Derived No Effect Level RPE - Respiratory Protective Equipment LC50 - Lethal Concentration 50%

NOEC - No Observed Effect Concentration PBT - Persistent, Bioaccumulative, Toxic

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

Predicted No Effect Concentration (PNEC)

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50% POW - Partition coefficient Octanol:Water vPvB - very Persistent, very Bioaccumulative

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ICAO/IATA - International Civil Aviation Organization/International Air

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ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road Transport Association

Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime

Dangerous Goods Code

**OECD** - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

Transport Association

MARPOL - International Convention for the Prevention of Pollution from

Ships

ATE - Acute Toxicity Estimate

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

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards
Health Hazards
Calculation method
Environmental hazards
Cn basis of test data
Calculation method

## **Training Advice**

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

Prepared By Health, Safety and Environmental Department

Revision Date 19-Mar-2024

**Revision Summary** New emergency telephone response service provider.

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

#### Disclaimer

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**