

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

- 1.1 Product identifier:** 1920 - Mitomycin C
RTECS: CN0700000
Mitomycin
CAS: 50-07-7
EC: 200-008-6
Index: Non-applicable
REACH:
Other means of identification:
Non-applicable
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: Research use. For professional user only.
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**
GERBU Biotechnik GmbH
69123 Heidelberg - Germany
Phone: +49 6221 7264167
safety@gerbu.de
www.gerbu.de
- 1.4 Emergency telephone number:** Toxicological Information Freiburg
+49 (0) 761 19240

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
CLP Regulation (EC) No 1272/2008:
Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.
Acute Tox. 2: Acute toxicity if swallowed, Category 2, H300
Carc. 2: Carcinogenicity, Category 2, H351
- 2.2 Label elements:**
CLP Regulation (EC) No 1272/2008:
Danger
-
- Hazard statements:**
Acute Tox. 2: H300 - Fatal if swallowed.
Carc. 2: H351 - Suspected of causing cancer.
- Precautionary statements:**

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SECTION 2: HAZARDS IDENTIFICATION (continued)

P201: Obtain special instructions before use.
 P202: Do not handle until all safety precautions have been read and understood.
 P264: Wash thoroughly after handling.
 P270: Do not eat, drink or smoke when using this product.
 P301+P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor.
 P308+P313: IF exposed or concerned: Get medical advice/attention.
 P330: Rinse mouth.
 P501: Dispose of contents/container in accordance with regulations on hazardous waste or packaging and packaging waste respectively.

2.3 Other hazards:

Product fails to meet PBT/vPvB criteria


SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Chemical description: Miscellaneous products

Components:

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 50-07-7 EC: 200-008-6 Index: Non-applicable REACH: Non-applicable	Mitomycin Regulation 1272/2008 Acute Tox. 2: H300; Carc. 2: H351 - Danger	Self-classified  75 - <100 %

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

3.2 Mixture:

Non-applicable

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

Request medical assistance immediately, showing the SDS of this product.

By inhalation:

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes to the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety data Sheet

By eye contact:

This product does not contain substances classified as hazardous for eye contact. Rinse eyes thoroughly for at least 15 minutes with lukewarm water, ensuring that the person affected does not rub or close their eyes.

By ingestion/aspiration:

Request medical assistance immediately, showing the SDS of this product. Induce vomiting (ONLY IF PERSON IS CONSCIOUS!) and then ingest large quantities of liquid to dilute the toxin. Keep the person affected at rest.

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

Acute and delayed effects are indicated in sections 2 and 11.

4.3 Indication of any immediate medical attention and special treatment needed:

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SECTION 4: FIRST AID MEASURES (continued)

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

Unsuitable extinguishing media:

Non-applicable

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

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SECTION 7: HANDLING AND STORAGE (continued)

Due to its inflammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace:

Nuisance dust: Inhalable dust 10 mg/m³ // Respirable dust 4 mg/m³

DNEL (Workers):

Non-applicable

DNEL (General population):

Non-applicable

PNEC:

Non-applicable

8.2 Exposure controls:

A.- General security and hygiene measures in the work place

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory respiratory tract protection	Filter mask for gases and vapours		EN 405:2002+A1:2010	Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment.

C.- Specific protection for the hands



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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	NON-disposable chemical protective gloves		EN ISO 374-1:2016+A1:2018 EN 16523-1:2015+A1:2018 EN 420:2004+A1:2010	The Breakthrough Time indicated by the manufacturer must exceed the period during which the product is being used. Do not use protective creams after the product has come into contact with skin.


D.- Ocular and facial protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Face shield		EN 166:2002 EN 167:2002 EN 168:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory complete body protection	Disposable clothing for protection against chemical risks		EN 13034:2005+A1:2009 EN 168:2002 EN ISO 13982-1:2004/A1:2010 EN ISO 6529:2013 EN ISO 6530:2005 EN 464:1994	For professional use only. Clean periodically according to the manufacturer's instructions.
 Mandatory foot protection	Safety footwear for protection against chemical risk		EN ISO 20345:2011 EN 13832-1:2019	Replace boots at any sign of deterioration.

F.- Additional emergency measures

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	 Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	0 % weight
V.O.C. density at 20 °C:	0 kg/m ³ (0 g/L)
Average carbon number:	Non-applicable
Average molecular weight:	Non-applicable

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C: Solid

Appearance: Not available

*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Colour:	Ultramarine
Odour:	Not available
Odour threshold:	Non-applicable *
Volatility:	
Boiling point at atmospheric pressure:	532 °C
Vapour pressure at 20 °C:	Non-applicable *
Vapour pressure at 50 °C:	Non-applicable *
Evaporation rate at 20 °C:	Non-applicable *
Product description:	
Density at 20 °C:	1900 kg/m ³
Relative density at 20 °C:	1.9
Dynamic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	-0.4
Solubility in water at 20 °C:	5 kg/m ³
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	360 °C
Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *
Flammability:	
Flash Point:	276 °C
Heat of combustion:	Non-applicable *
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *
Explosive:	
Lower explosive limit:	Non-applicable *
Upper explosive limit:	Non-applicable *
9.2 Other information:	
Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

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SECTION 10: STABILITY AND REACTIVITY (continued)

Chemically stable under the conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Avoid direct impact	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity : Can be fatal if consumed. For more information see section 2.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Exposure to this product can cause cancer. For more specific information on the possible health effects see section 2.
IARC: Mitomycin (2B)
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

E- Sensitizing effects:

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensitising effects. For more information see section 3.
- Cutaneous: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- F- Specific target organ toxicity (STOT) - single exposure:
Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- G- Specific target organ toxicity (STOT)-repeated exposure:
 - Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
 - Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- H- Aspiration hazard:
Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Product-specific toxicological information:

Acute toxicity		Genus
LD50 oral	30 mg/kg	Rat

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
	LD50 oral	LD50 dermal	
Mitomycin	5 mg/kg (ATEi)	Non-applicable	
CAS: 50-07-7	Non-applicable	Non-applicable	
EC: 200-008-6	Non-applicable	Non-applicable	

SECTION 12: ECOLOGICAL INFORMATION

- 12.1 Toxicity:**
Not available
- 12.2 Persistence and degradability:**
Not available
- 12.3 Bioaccumulative potential:**
Not available
- 12.4 Mobility in soil:**
Not available
- 12.5 Results of PBT and vPvB assessment:**
Product fails to meet PBT/vPvB criteria
- 12.6 Other adverse effects:**
Not described

SECTION 13: DISPOSAL CONSIDERATIONS

- 13.1 Waste treatment methods:**

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SECTION 13: DISPOSAL CONSIDERATIONS (continued)

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 05 06*	laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals	Dangerous

Type of waste (Regulation (EU) No 1357/2014):

HP6 Acute Toxicity, HP7 Carcinogenic

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC, The Waste Regulations 2011, 2011 No. 988). As under 15 01 (2014/955/EU) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2019 and RID 2019:



- 14.1 **UN number:** UN3462
- 14.2 **UN proper shipping name:** TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S.
- 14.3 **Transport hazard class(es):** 6.1
Labels: 6.1
- 14.4 **Packing group:** II
- 14.5 **Environmental hazards:** No
- 14.6 **Special precautions for user**
Special regulations: 210, 274
Tunnel restriction code: C/E
Physico-Chemical properties: see section 9
Limited quantities: 500 g
- 14.7 **Transport in bulk according to Annex II of Marpol and the IBC Code:** Non-applicable

Transport of dangerous goods by sea:

With regard to IMDG 39-18:



SECTION 14: TRANSPORT INFORMATION (continued)



- 14.1 UN number: UN3462
 14.2 UN proper shipping name: TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S.
 14.3 Transport hazard class(es): 6.1
 Labels: 6.1
 14.4 Packing group: II
 14.5 Marine pollutant: No
 14.6 Special precautions for user
 Special regulations: 210, 274
 EmS Codes: F-A, S-A
 Physico-Chemical properties: see section 9
 Limited quantities: 500 g
 Segregation group: Non-applicable
 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: Non-applicable

Transport of dangerous goods by air:

With regard to IATA/ICAO 2020:



- 14.1 UN number: UN3462
 14.2 UN proper shipping name: TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S.
 14.3 Transport hazard class(es): 6.1
 Labels: 6.1
 14.4 Packing group: II
 14.5 Environmental hazards: No
 14.6 Special precautions for user
 Physico-Chemical properties: see section 9
 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: Non-applicable

SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Seveso III:

Section	Description	Lower-tier requirements	Upper-tier requirements
H2	ACUTE TOXIC	50	200

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc ...):

Non-applicable

Specific provisions in terms of protecting people or the environment:

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**SECTION 15: REGULATORY INFORMATION (continued)**

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG 2009), SI 2009 No 1348

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulations 2011, 2011 No. 1885

Control of Substances Hazardous to Health Regulations 2002 (as amended)

EH40/2005 Workplace exposure limits

The Waste Regulations 2011, 2011 No. 988

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION**Legislation related to safety data sheets:**

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (Regulation (EC) No 2015/830)

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks:

Non-applicable

Texts of the legislative phrases mentioned in section 2:

H300: Fatal if swallowed.

H351: Suspected of causing cancer.

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Acute Tox. 2: H300 - Fatal if swallowed.

Carc. 2: H351 - Suspected of causing cancer.

Advice related to training:

Minimal training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

**SECTION 16: OTHER INFORMATION (continued)**

ADR: European agreement concerning the international carriage of dangerous goods by road
IMDG: International maritime dangerous goods code
IATA: International Air Transport Association
ICAO: International Civil Aviation Organisation
COD: Chemical Oxygen Demand
BOD5: 5-day biochemical oxygen demand
BCF: Bioconcentration factor
LD50: Lethal Dose 50
LC50: Lethal Concentration 50
EC50: Effective concentration 50
Log-POW: Octanol-water partition coefficient
Koc: Partition coefficient of organic carbon

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -