

# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C ≥98 %, for biochemistry

article number: **4150**  
Version: **3.0 en**  
Replaces version of: 2021-08-18  
Version: (2)

date of compilation: 2016-01-22  
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## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

Identification of the substance	<b>Mitomycin C</b> ≥98 %, for biochemistry
Article number	4150
Registration number (REACH)	It is not required to list the identified uses because the substance is not subject to registration according to REACH (< 1 t/a).
EC number	200-008-6
CAS number	50-07-7

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

Relevant identified uses:	Laboratory chemical Laboratory and analytical use
Uses advised against:	Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household). Food, drink and animal feeding-stuffs.

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

Carl Roth GmbH + Co. KG  
Schoemperlenstr. 3-5  
D-76185 Karlsruhe  
Germany

**Telephone:** +49 (0) 721 - 56 06 0  
**Telefax:** +49 (0) 721 - 56 06 149  
**e-mail:** [sicherheit@carlroth.de](mailto:sicherheit@carlroth.de)  
**Website:** [www.carlroth.de](http://www.carlroth.de)

Competent person responsible for the safety data sheet: Department Health, Safety and Environment

**e-mail (competent person):** [sicherheit@carlroth.de](mailto:sicherheit@carlroth.de)

### 1.4 Emergency telephone number

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Centre Beaumont Hospital	Beaumont Road	Dublin 9	+353 1 809 2166	<a href="https://www.poisons.ie/">https://www.poisons.ie/</a>

# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C ≥98 %, for biochemistry

article number: 4150

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Cat-egory	Hazard class and category	Hazard statement
3.10	Acute toxicity (oral)	2	Acute Tox. 2	H300
3.6	Carcinogenicity	2	Carc. 2	H351

For full text of abbreviations: see SECTION 16

#### 2.2 Label elements

##### Labelling according to Regulation (EC) No 1272/2008 (CLP)

###### Signal word

**Danger**

###### Pictograms

GHS06, GHS08



###### Hazard statements

H300 Fatal if swallowed  
H351 Suspected of causing cancer

###### Precautionary statements

###### Precautionary statements - prevention

P201 Obtain special instructions before use  
P280 Wear protective gloves/eye protection

###### Precautionary statements - response

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor

###### Precautionary statements - storage

P405 Store locked up

For professional users only

##### Labelling of packages where the contents do not exceed 125 ml

Signal word: **Danger**

Symbol(s)



H300 Fatal if swallowed.  
H351 Suspected of causing cancer.  
P201 Obtain special instructions before use.  
P280 Wear protective gloves/eye protection.  
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.  
P405 Store locked up.

# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C $\geq 98\%$ , for biochemistry

article number: 4150

### 2.3 Other hazards

#### Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

#### Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq 0,1\%$ .

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Name of substance	Mitomycin C
Molecular formula	$C_{15}H_{18}N_4O_5$
Molar mass	334,3 $g/mol$
CAS No	50-07-7
EC No	200-008-6

Substance, Specific Conc. Limits, M-factors, ATE			
Specific Conc. Limits	M-Factors	ATE	Exposure route
-	-	30 $mg/kg$	oral

## SECTION 4: First aid measures

### 4.1 Description of first aid measures



#### General notes

Take off contaminated clothing.

#### Following inhalation

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following skin contact

Rinse skin with water/shower.

#### Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following ingestion

Rinse mouth immediately and drink plenty of water. Call a physician immediately. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

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

Gastrointestinal complaints, Cough, Diarrhoea, Nausea

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

none

# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



**Mitomycin C ≥98 %, for biochemistry**

article number: 4150

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media



#### Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings!  
water, foam, dry extinguishing powder, ABC-powder

#### Unsuitable extinguishing media

water jet

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

Combustible.

#### Hazardous combustion products

In case of fire may be liberated: Nitrogen oxides (NO<sub>x</sub>), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

## SECTION 6: Accidental release measures

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



#### For non-emergency personnel

Use personal protective equipment as required. Avoid contact with skin, eyes and clothes. Do not breathe dust.

### 6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

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

#### Advice on how to contain a spill

Covering of drains. Take up mechanically.

#### Advice on how to clean up a spill

Take up mechanically. Control of dust.

#### Other information relating to spills and releases

Place in appropriate containers for disposal.

### 6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C ≥98 %, for biochemistry

article number: 4150

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Provision of sufficient ventilation. Avoid exposure. Avoid dust formation. Clear contaminated areas thoroughly.

#### Measures to prevent fire as well as aerosol and dust generation

Removal of dust deposits.

#### Advice on general occupational hygiene

When using do not eat or drink. Thorough skin-cleansing after handling the product.

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

Store in a dry place. Keep in a cool place.

#### Incompatible substances or mixtures

Observe hints for combined storage.

#### Consideration of other advice:

Store locked up.

#### Ventilation requirements

Use local and general ventilation.

#### Specific designs for storage rooms or vessels

Recommended storage temperature: 4 °C

#### 7.3 Specific end use(s)

No information available.

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### National limit values

##### Occupational exposure limit values (Workplace Exposure Limits)

Country	Name of agent	CAS No	Identifier	TWA [mg/m <sup>3</sup> ]	STEL [mg/m <sup>3</sup> ]	Ceiling-C [mg/m <sup>3</sup> ]	Notation	Source
IE	dusts, non-specific		OELV	10			i	S.I. No. 619 of 2001
IE	dusts, non-specific		OELV	4			r	S.I. No. 619 of 2001

##### Notation

Ceiling-C Ceiling value is a limit value above which exposure should not occur

i Inhalable fraction

r Respirable fraction

STEL Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

TWA Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C $\geq 98\%$ , for biochemistry

article number: 4150

### 8.2 Exposure controls

#### Individual protection measures (personal protective equipment)

##### Eye/face protection



Use safety goggle with side protection.

##### Skin protection



##### • hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

##### • type of material

NBR (Nitrile rubber)

##### • material thickness

>0,11 mm

##### • breakthrough times of the glove material

>480 minutes (permeation: level 6)

##### • other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

##### Respiratory protection



Respiratory protection necessary at: Dust formation. Particulate filter device (EN 143). P3 (filters at least 99,95 % of airborne particles, colour code: White).

##### Environmental exposure controls

Keep away from drains, surface and ground water.

# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C ≥98 %, for biochemistry

article number: 4150

### SECTION 9: Physical and chemical properties

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

Physical state	solid
Form	powder
Colour	not determined
Odour	odourless
Melting point/freezing point	360 °C (TOXNET)
Boiling point or initial boiling point and boiling range	581,8 °C
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	not determined
Flash point	305,6 °C
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	6 – 8 (in aqueous solution: 5 g/l, 20 °C)
Kinematic viscosity	not relevant
<u>Solubility(ies)</u>	
Water solubility	not determined
Solubility in methanol	10 g/l at 20 °C
<u>Partition coefficient</u>	
Partition coefficient n-octanol/water (log value):	-0,4 (TOXNET)
Vapour pressure	not determined
<u>Density and/or relative density</u>	
Density	not determined
Relative vapour density	Information on this property is not available.
Particle characteristics	No data available.
<u>Other safety parameters</u>	
Oxidising properties	none

#### 9.2 Other information

Information with regard to physical hazard classes:	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics:	There is no additional information.

# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C ≥98 %, for biochemistry

article number: 4150

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

#### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

#### 10.3 Possibility of hazardous reactions

**Violent reaction with:** strong oxidiser

#### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

#### 10.5 Incompatible materials

There is no additional information.

#### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

### SECTION 11: Toxicological information

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

**Classification according to GHS (1272/2008/EC, CLP)**

##### Acute toxicity

Fatal if swallowed.

Acute toxicity					
Exposure route	Endpoint	Value	Species	Method	Source
oral	LD50	30 mg/kg	rat		TOXNET

##### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

##### Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

##### Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

##### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

##### Carcinogenicity

Suspected of causing cancer.

##### Reproductive toxicity

Shall not be classified as a reproductive toxicant.

##### Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).



# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C ≥98 %, for biochemistry

article number: 4150

### Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

### Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

### Symptoms related to the physical, chemical and toxicological characteristics

#### • If swallowed

diarrhoea, vomiting, Liver and kidney damage, nausea, gastrointestinal complaints

#### • If in eyes

Data are not available.

#### • If inhaled

cough, Dyspnoea

#### • If on skin

Data are not available.

#### • Other information

This information is based upon the present state of our knowledge.

### 11.2 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.

### 11.3 Information on other hazards

There is no additional information.

## SECTION 12: Ecological information

### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

### 12.2 Persistence and degradability

Theoretical Oxygen Demand (without nitrification): 1,34 mg/mg

Theoretical Oxygen Demand (with nitrification): 1,657 mg/mg

Theoretical Carbon Dioxide: 1,975 mg/mg

### 12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

n-octanol/water (log KOW)	-0,4 (TOXNET)
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### 12.4 Mobility in soil

Data are not available.

### 12.5 Results of PBT and vPvB assessment

Data are not available.

### 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.

### 12.7 Other adverse effects

Data are not available.

# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C ≥98 %, for biochemistry

article number: 4150

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

##### Sewage disposal-relevant information

Do not empty into drains.

##### Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. Handle contaminated packages in the same way as the substance itself. Completely emptied packages can be recycled.

#### 13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

##### Properties of waste which render it hazardous

**HP 6** acute toxicity

**HP 7** carcinogenic

#### 13.3 Remarks

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Please consider the relevant national or regional provisions. Non-contaminated packages may be recycled.

### SECTION 14: Transport information

#### 14.1 UN number or ID number

ADRRID	UN 3462
IMDG-Code	UN 3462
ICAO-TI	UN 3462

#### 14.2 UN proper shipping name

ADRRID	TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S.
IMDG-Code	TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S.
ICAO-TI	Toxins, extracted from living sources, solid, n.o.s.
Technical name	Mitomycin C

#### 14.3 Transport hazard class(es)

ADRRID	6.1
IMDG-Code	6.1
ICAO-TI	6.1

#### 14.4 Packing group

# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C ≥98 %, for biochemistry

article number: 4150

ADRRID	II
IMDG-Code	II
ICAO-TI	II
<b>14.5 Environmental hazards</b>	non-environmentally hazardous acc. to the dangerous goods regulations

### 14.6 Special precautions for user


Provisions for dangerous goods (ADR) should be complied within the premises.

### 14.7 Maritime transport in bulk according to IMO instruments


The cargo is not intended to be carried in bulk.

### 14.8 Information for each of the UN Model Regulations

#### Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) Additional information

Proper shipping name	TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S.
Particulars in the transport document	UN3462, TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S., (Mitomycin C), 6.1, II, (D/E)
Classification code	T2
Danger label(s)	6.1
	
Special provisions (SP)	210, 274, 802(ADN)
Excepted quantities (EQ)	E4
Limited quantities (LQ)	500 g
Transport category (TC)	2
Tunnel restriction code (TRC)	D/E
Hazard identification No	60

#### Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) Additional information

Classification code	T2
Danger label(s)	6.1
	
Special provisions (SP)	210, 274, 802(ADN)
Excepted quantities (EQ)	E4
Limited quantities (LQ)	500 g
Transport category (TC)	2
Hazard identification No	60

# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C ≥98 %, for biochemistry

article number: 4150

### International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name	TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S.
Particulars in the shipper's declaration	UN3462, TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S., (Mitomycin C), 6.1, II
Marine pollutant	-
Danger label(s)	6.1
Special provisions (SP)	210, 274
Excepted quantities (EQ)	E4
Limited quantities (LQ)	500 g
EmS	F-A, S-A
Stowage category	B

### International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Proper shipping name	Toxins, extracted from living sources, solid, n.o.s.
Particulars in the shipper's declaration	UN3462, Toxins, extracted from living sources, solid, n.o.s., (Mitomycin C), 6.1, II
Danger label(s)	6.1
Special provisions (SP)	A3, A43
Excepted quantities (EQ)	E4
Limited quantities (LQ)	1 kg

## SECTION 15: Regulatory information

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

#### Relevant provisions of the European Union (EU)

#### Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)				
Name of substance	Name acc. to inventory	CAS No	Restriction	No
Mitomycin C	substances in tattoo inks and permanent make-up		R75	75

#### Legend

- R75 1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:  
(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;  
(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;  
(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by

## Mitomycin C ≥98 %, for biochemistry

article number: 4150

### Legend

- weight;
- (d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:
- (i) 0,1 % by weight, if the substance is used solely as a pH regulator;
- (ii) 0,01 % by weight, in all other cases;
- (e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
- (f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:
- (i) "Rinse-off products";
- (ii) "Not to be used in products applied on mucous membranes";
- (iii) "Not to be used in eye products";
- (g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;
- (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.
2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.
3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
- (a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
- (b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.
6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.
7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:
- (a) the statement "Mixture for use in tattoos or permanent make-up";
- (b) a reference number to uniquely identify the batch;
- (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
- (d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
- (e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;
- (f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;
- (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.
- The information shall be clearly visible, easily legible and marked in a way that is indelible.
- The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.
- Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.
- Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.
8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.
9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).
10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C ≥98 %, for biochemistry

article number: 4150

### List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

Not listed.

### Seveso Directive

#### 2012/18/EU (Seveso III)

No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements		Notes
H2	acute toxic (cat. 2 + cat. 3, inhal.)	50	200	41)

#### Notation

- 41) - Category 2, all exposure routes  
- category 3, inhalation exposure route

### Deco-Paint Directive

VOC content	0 %
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### Industrial Emissions Directive (IED)

VOC content	0 %
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### Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

not listed

### Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

not listed

### Water Framework Directive (WFD)

#### List of pollutants (WFD)

Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Mitomycin C	Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment		a)	

#### Legend

- a) Indicative list of the main pollutants

### Regulation on the marketing and use of explosives precursors

not listed

### Regulation on drug precursors

not listed

### Regulation on substances that deplete the ozone layer (ODS)

not listed

### Regulation concerning the export and import of hazardous chemicals (PIC)

not listed

# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C ≥98 %, for biochemistry

article number: 4150

### Regulation on persistent organic pollutants (POP)

not listed

### Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

### National inventories

Country	Inventory	Status
CA	NDSL	substance is listed
EU	ECSI	substance is listed
JP	CSCL-ENCS	substance is listed
MX	INSQ	substance is listed
NZ	NZIoC	substance is listed
TW	TCSI	substance is listed
US	TSCA	substance is listed (ACTIVE)
VN	NCI	substance is listed

#### Legend

CSCL-ENCS	List of Existing and New Chemical Substances (CSCL-ENCS)
ECSI	EC Substance Inventory (EINECS, ELINCS, NLP)
INSQ	National Inventory of Chemical Substances
NCI	National Chemical Inventory
NDSL	Non-domestic Substances List (NDSL)
NZIoC	New Zealand Inventory of Chemicals
TCSI	Taiwan Chemical Substance Inventory
TSCA	Toxic Substance Control Act

## 15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance.

## SECTION 16: Other information

### Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes
14.8		Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)Additional information	yes
14.8		Classification code: T2	yes
14.8		Danger label(s): 6.1	yes
14.8		Danger label(s): change in the listing (table)	yes
14.8		Special provisions (SP): 210, 274, 802(ADN)	yes

# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C ≥98 %, for biochemistry

article number: 4150

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
14.8		Excepted quantities (EQ): E4	yes
14.8		Limited quantities (LQ): 500 g	yes
14.8		Transport category (TC): 2	yes
14.8		Hazard identification No: 60	yes
15.1		National inventories: change in the listing (table)	yes

### Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals



# Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



## Mitomycin C ≥98 %, for biochemistry

article number: 4150

Abbr.	Descriptions of used abbreviations
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
S.I. No. 619 of 2001	Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001
STEL	Short-term exposure limit
SVHC	Substance of Very High Concern
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

### List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H300	Fatal if swallowed.
H351	Suspected of causing cancer.

### Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.