according to Regulation (EC) No 1907/2006

# Aflatoxin M1

Revision date: 16.06.2020

Product code: LS-1009

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## SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Aflatoxin M1

## Further trade names

(6aR-cis)-2,3,6a,9a-tetrahydro-9a-hydroxy-4-methoxycyclopenta[c]furo[3',2':4,5]furo[2,3-h] [1]benzopyran-1,11-dione 4-hydroxyaflatoxin B1 Substance name: Aflatoxin M1

oubolanoo namo.	7 (10(0)(11) 11)
CAS No:	6795-23-9
EC No:	229-865-4

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

#### Use of the substance/mixture

Scientific research and development

#### Uses advised against

Do not use for private purposes (household). Active pharmaceutical ingredient. In the food industry and in pharmaceutical preparations

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

Company name:	Iris Biotech GmbH	
Street:	Adalbert-Zoellner-Straße 1	
Place:	D-95615 Marktredwitz, Germany	
Post-office box:	568	
	D-95605 Marktredwitz, Germany	
Telephone:	+49 9231 97121 0	Telefax: +49 9231 97121 99
e-mail:	info@iris-biotech.de	
Contact person:	Compliance Department	Telephone: +49 9231 97121 0
e-mail:	sds@iris-biotech.de	
Internet:	www.iris-biotech.de	
Responsible Department:	Only available during office hours.	
4. Emergency telephone	+49 (0)89 19240 (POISON CENTER M	unich: 24 h)

#### <u>1.4. Emergency teleph</u> number:

## Further Information

Emergency telephone: 24 h (POISON CENTER Munich)

#### **SECTION 2: Hazards identification**

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

# Regulation (EC) No. 1272/2008

Hazard categories: Carcinogenicity: Carc. 1B Germ cell mutagenicity: Muta. 1B Acute toxicity: Acute Tox. 1 Acute toxicity: Acute Tox. 1 Acute toxicity: Acute Tox. 1 Hazard Statements: Fatal if inhaled. Fatal in contact with skin. Fatal if swallowed. May cause genetic defects. May cause cancer.



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## 2.2. Label elements

## Regulation (EC) No. 1272/2008

Signal word:

**Pictograms:** 

Danger



#### **Hazard statements**

H300+H310+H330	Fatal if swallowed, in contact with skin or if inhaled.
H340	May cause genetic defects.
H350	May cause cancer.

#### Precautionary statements

ecautionaly statement	.ə
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P262	Do not get in eyes, on skin, or on clothing.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing
	protection.
P284	Wear respiratory protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P330	Rinse mouth.
P302+P352	IF ON SKIN: Wash with plenty of Water.
P310	Immediately call a POISON CENTER/doctor.
P361+P364	Take off immediately all contaminated clothing and wash it before reuse.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P310	Immediately call a POISON CENTER/doctor.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container to an approved disposal site.

#### Additional advice on labelling

Warning - substance not yet tested completely.

# 2.3. Other hazards

No information available.

# **SECTION 3: Composition/information on ingredients**

# 3.1. Substances

# Chemical characterization

(6aR-cis)-2,3,6a,9a-tetrahydro-9a-hydroxy-4-methoxycyclopenta[c]furo[3',2':4,5]furo[2,3-h] [1]benzopyran-1,11-dione



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#### Hazardous components

CAS No	Chemical name		Quantity	
	EC No	Index No	REACH No	
GHS Classification				
6795-23-9	Aflatoxin M1			<= 100 %
	229-865-4			
	Carc. 1B, Muta. 1B, Acute Tox. 1, Acute Tox. 1, Acute Tox. 1; H350 H340 H330 H310 H300			

Full text of H and EUH statements: see section 16.

Specific Co	Specific Conc. Limits, M-factors and ATE				
CAS No	CAS No EC No Chemical name		Quantity		
	Specific Conc.	Limits, M-factors and ATE			
6795-23-9	-9 229-865-4 Aflatoxin M1		<= 100 % %		
inhalation: ATE = 0,05 mg/l (vapours); inhalation: ATE = 0,005 mg/l (dusts or mists); dermal: ATE = 5 mg/kg; oral: ATE = 0,5 mg/kg					

#### **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

#### **General information**

First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

#### After inhalation

Provide fresh air. No mouth-to-mouth or mouth-to-nose resuscitation. Use Ambu bag or ventilator. Call a physician immediately. Remove casualty to fresh air and keep warm and at rest. In case of irregular breathing or respiratory arrest provide artificial respiration.

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

#### After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Call a physician immediately. After contact with skin, wash immediately with plenty of water and soap.

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

#### After contact with eyes

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist. If product gets into the eye, keep eyelid open and rinse immediately with large quantities of water, for at least 5 minutes. Subsequently consult an ophthalmologist.

#### After ingestion

Rinse mouth immediately and drink 1 glass of of water. Induce vomiting when the affected person is not unconscious. Call a physician immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person or a person with cramps.

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

# 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

Treat symptomatically.

#### **SECTION 5: Firefighting measures**

#### 5.1. Extinguishing media



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### Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings. Water spray. alcohol resistant foam. Dry extinguishing powder. Carbon dioxide (CO2). Sand.

#### Unsuitable extinguishing media

High power water jet.

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

Non-flammable. Thermal decomposition can lead to the escape of irritating gases and vapours.

In case of fire may be liberated: Carbon dioxide (CO2). Carbon monoxide (CO).

#### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

#### Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Usual measures for fire prevention.

#### **SECTION 6: Accidental release measures**

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

#### **General advice**

Avoid dust formation. Do not breathe dust. Avoid contact with skin, eyes and clothes. Use personal protection equipment. Provide adequate ventilation. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin, eyes and clothes. Wear personal protection equipment.

In case of fire: Evacuate area.

#### 6.2. Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

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

#### Other information

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal. Take up mechanically, placing in appropriate containers for disposal. Avoid dust formation. Clear contaminated areas thoroughly.

#### 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

Treat the recovered material as prescribed in the section on waste disposal.

#### **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

#### Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Avoid dust formation. Do not breathe dust. Provide adequate ventilation.

Avoid dust formation. Avoid breathing dust/fume/gas/mist/vapours/spray.

Avoid contact with skin, eyes and clothes.

#### Advice on protection against fire and explosion

Usual measures for fire prevention.

#### Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes. Provide adequate ventilation.



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

#### Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations. Keep container tightly closed in a cool, well-ventilated place. Handle and store contents under inert gas. Protect from moisture.

storage temperature: -20 °C

#### Hints on joint storage

No special measures are necessary.

#### Further information on storage conditions

Protect from direct sunlight. Moisture-sensitive.

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

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

#### **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

#### Additional advice on limit values

To date, no national critical limit values exist.

#### 8.2. Exposure controls



#### Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe dust. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

#### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear eye/face protection.

#### Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. 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. Wear suitable gloves.

#### Skin protection

Use of protective clothing.

#### **Respiratory protection**

In case of inadequate ventilation wear respiratory protection. If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.

#### Environmental exposure controls

Discharge into the environment must be avoided.

#### **SECTION 9: Physical and chemical properties**

## 9.1. Information on basic physical and chemical properties

Physical state:	solid
Colour:	yellow



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Odour:	No data available	
Odour threshold:	not determined	
Changes in the physical state		
Melting point/freezing point:	not determined	
Boiling point or initial boiling point and boiling range:	not determined	
Sublimation point:	not determined	
Softening point:	not determined	
Flash point:	No data available	
Flammability		
Solid/liquid:	not determined	
Gas:	not applicable	
Explosive properties The product is not: Explosive.		
Lower explosion limits:	not determined	
Upper explosion limits:	not determined	
Auto-ignition temperature:	not determined	
Self-ignition temperature		
Solid:	not determined	
Gas:	not applicable	
Decomposition temperature:	not determined	
pH-Value:	not determined	
Water solubility:	No data available	
Solubility in other solvents not determined		
Partition coefficient n-octanol/water:	not determined	
Vapour pressure:	not determined	
Density:	not determined	
Relative vapour density:	not determined	
9.2. Other information		
Information with regard to physical haz	ard classes	
Sustaining combustion:	No data available	
Oxidizing properties No data available		
Other safety characteristics		
Solvent content:	No data available	
Solid content:	not determined	
Evaporation rate:	not determined	
Further Information		
SECTION 10: Stability and reactivity		

# SECTION 10: Stability and reactivity

# 10.1. Reactivity

No data available

## 10.2. Chemical stability

Stable under recommended storage conditions.



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# 10.3. Possibility of hazardous reactions

No data available

#### 10.4. Conditions to avoid

Protect from moisture. Keep away from heat. Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

#### 10.5. Incompatible materials

Oxidizing agents, strong. Reducing agents, strong.

#### 10.6. Hazardous decomposition products

Thermal decomposition can lead to the escape of irritating gases and vapours. In case of fire may be liberated: Carbon dioxide (CO2). Carbon monoxide (CO).

#### Further information

In case of fire: See chapter 5.

#### **SECTION 11: Toxicological information**

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

# Toxicocinetics, metabolism and distribution

No data available

#### Acute toxicity

Fatal if swallowed. Fatal in contact with skin. Fatal if inhaled.

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
6795-23-9	Aflatoxin M1					
	oral	ATE mg/kg	0,5			
	dermal	ATE	5 mg/kg			
	inhalation vapour	ATE	0,05 mg/l			
	inhalation aerosol	ATE mg/l	0,005			

#### Irritation and corrosivity

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

#### Sensitising effects

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

## Carcinogenic/mutagenic/toxic effects for reproduction

May cause genetic defects. (Aflatoxin M1)

May cause cancer. (Aflatoxin M1)

Reproductive toxicity: Based on available data, the classification criteria are not met.

IARC: 1 - Group 1: Carcinogenic to humans (Aflatoxin M1)

#### STOT-single exposure

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

#### STOT-repeated exposure

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

#### Aspiration hazard

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



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#### Specific effects in experiment on an animal

No data available

#### Additional information on tests

Special hazards arising from the substance or mixture. Classification according to Regulation (EC) No 1272/2008 [CLP]: health hazard properties.

## **Practical experience**

No data available

#### **Further information**

RTECS: GY1880000

Caution! To the best of our knowledge the toxicological properties of this material have not been thoroughly investigated.

Handle in accordance with good industrial hygiene and safety practice.

#### **SECTION 12: Ecological information**

#### 12.1. Toxicity

No data available

#### 12.2. Persistence and degradability

No data available

#### 12.3. Bioaccumulative potential

No data available

#### 12.4. Mobility in soil

No data available

#### 12.5. Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

#### 12.7. Other adverse effects

Warning - substance not yet tested completely.

#### Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

#### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

#### Disposal recommendations

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation. Consult the appropriate local waste disposal expert about waste disposal.

Handle contaminated packages in the same way as the substance itself.

Contaminated packaging

Hazardous waste according to Directive 2008/98/EC (waste framework directive).

Handle contaminated packages in the same way as the substance itself.

## **SECTION 14: Transport information**

#### Land transport (ADR/RID)

14.1. UN number or ID number:	UN 3462
14.2. UN proper shipping name:	TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S. (Aflatoxin M1)
14.3. Transport hazard class(es):	6.1
14.4. Packing group:	I
Hazard label:	6.1



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Classification code:	T2	
Special Provisions:	210 274	
Limited quantity:	0	
Excepted quantity: Transport category:	E5 1	
Hazard No:	66	
Tunnel restriction code:	C/E	
Inland waterways transport (ADN)		
<u>14.1. UN number or ID number:</u>	UN 3462	
14.2. UN proper shipping name:	TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S. (Aflatoxin M1)	
14.3. Transport hazard class(es):	6.1	
14.4. Packing group:	I	
Hazard label:	6.1	
	6	
Classification code:	T2	
Special Provisions:	210 274 802	
Limited quantity:	0	
Excepted quantity:	E5	
Marine transport (IMDG)		
14.1. UN number or ID number:		
14.2. UN proper shipping name:	TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S. (Aflatoxin M1)	
<u>14.3. Transport hazard class(es):</u>	6.1	
14.4. Packing group:		
Hazard label:	6.1	
Special Provisions:	210, 274	
Limited quantity:	0	
Excepted quantity: EmS:	E5 F-A, S-A	
Air transport (ICAO-TI/IATA-DGR)		
14.1. UN number or ID number:	UN 3462	
14.2. UN proper shipping name:	TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S. (Aflatoxin M1)	
14.3. Transport hazard class(es):	6.1	
14.4. Packing group:	I	
Hazard label:	6.1	
	6	



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Special Provisions:	A3 A43			
Limited quantity Passenger:	Forbidden			
Passenger LQ:	Forbidden			
Excepted quantity:	E5			
IATA-packing instructions - Passenger:	666			
IATA-max. quantity - Passenger:	5 kg			
IATA-packing instructions - Cargo:	673			
IATA-max. quantity - Cargo:	50 k	g		
14.5. Environmental hazards				
ENVIRONMENTALLY HAZARDOUS:	No			
14.6. Special precautions for user				
Warning: Acute Toxicity.				
14.7. Maritime transport in bulk according	to IMO instruments			
not applicable				
SECTION 15: Regulatory information				
15.1. Safety, health and environmental reg	ulations/legislation specific	for the substance or mixture		
EU regulatory information				
Information according to 2012/18/EU (SEVESO III):	H1 ACUTE TOXIC			
Additional information				
Safety Data Sheet according to Regu	ation (EC) No. 1907/2006 (R	EACH)		
National regulatory information				
Employment restrictions:	'juvenile work protection g restrictions under the Mate	ployment for juveniles according to the uideline' (94/33/EC). Observe employm ernity Protection Directive (92/85/EEC) t ers. Observe employment restrictions for the.	for	
Water hazard class (D):	3 - highly hazardous to wa			
Skin resorption/Sensitization:		outer skin and causes poisoning.		
15.2. Chemical safety assessment				

For this substance a chemical safety assessment has not been carried out.

#### **SECTION 16: Other information**

#### Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonized System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service LC50: Lethal concentration, 50% LD50: Lethal dose, 50% CLP: Classification, labelling and Packaging REACH: Registration, Evaluation and Authorization of Chemicals GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals UN: United Nations CAS: Chemical Abstracts Service



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DNEL: Derived No Effect Level DMEL: Derived Minimal Effect Level PNEC: Predicted No Effect Concentration ATE: Acute toxicity estimate LL50: Lethal loading, 50% EL50: Effect loading, 50% EC50: Effective Concentration 50% ErC50: Effective Concentration 50%, growth rate NOEC: No Observed Effect Concentration BCF: Bio-concentration factor PBT: persistent, bioaccumulative, toxic vPvB: very persistent, very bioaccumulative RID: Regulations concerning the international carriage of dangerous goods by rail ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures) EmS: Emergency Schedules MFAG: Medical First Aid Guide IATA: International Air Transport Association ICAO: International Civil Aviation Organization MARPOL: International Convention for the Prevention of Marine Pollution from Ships IBC: Intermediate Bulk Container SVHC: Substance of Very High Concern For abbreviations and acronyms, see table at http://abbrev.esdscom.eu Relevant H and EUH statements (number and full text)

# H300Fatal if swallowed.H300+H310+H330Fatal if swallowed, in contact with skin or if inhaled.H310Fatal in contact with skin.H330Fatal if inhaled.

H340 May cause genetic defects.

H350 May cause cancer.

#### **Further Information**

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.