



Safety Data Sheet

M III® with Gentamicin

Ref. 13515/0001, 13515/0001RU, 13515/0003,
13515/0005, 13515/0005RU, 13515/0010,
13515/0010RU, 13515/0083, 13515/0083MX,
13515/4001, 13515/4083, 13515/9001, 13535/3001BR,
13535/3005BR, 13535/3010BR, 13535/3100BR

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Version 2
Issue date:
08.03.2018

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

1.1. Product identifier:

M III® with Gentamicin

Article number: 13515/0001, 13515/0001RU, 13515/0003, 13515/0005, 13515/0005RU, 13515/0010, 13515/0010RU, 13515/0083, 13515/0083MX, 13515/4001, 13515/4083, 13515/9001, 13535/3001BR, 13535/3005BR, 13535/3010BR, 13535/3100BR

1.2. Relevant identified uses of the mixture and uses advised against:

In vitro cell culture for professional use.

The product is a veterinary product. Such products are exempted from Regulation 1272/2008/EC. According to Regulation 1907/2006/EC it is not necessary to provide safety data sheet for such products. The below information for the safe use of the product are only for informative purposes.

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

Minitüb GmbH

Hauptstr. 41 81184 Tiefenbach

Germany

Tel.: + 49 87 09 9229 0

Fax: + 49 87 09 9229 39

1.3.1. Responsible person: Dr. Christian Simmet
E-mail: minitube@minitube.de

1.4. Emergency telephone number: (+49) 0 8709 9229 0

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the mixture:

Classification according to Regulation 1272/2008/EC (CLP):

Not considered as hazardous mixture.

Warning **H statements:** none.

2.2. Label elements:

Warning **H statements:** none.

EUH 208 – Contains Gentamicin, sulfate (salt). May produce an allergic reaction.

EUH 210 – Safety data sheet available on request.

Precautionary **P statements:** none.

2.3. Other hazards:

The product has no other known specific hazards for human or environment.
The product does not meet the criteria for PBT or vPvB substances.



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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance:
Not applicable.

3.2. Mixture:

Description	CAS number	EU number	REACH reg. nr.	Conc. (%)	Classification: 1272/2008/EC (CLP)		
					Hazard pict.	Hazard cat.	H phrase
Gentamicin, sulfate (salt)*	1405-41-0	215-778-9	-	0,5 - < 1	GHS08 Danger	Skin Sens. 1 Resp. Sens. 1 Repr. 2	H317 H334 H361d

*: Classification provided by the manufacturer, the substance is not listed at Annex VI of Regulation 1272/2008/EC.

For the full text of H phrases: see Section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures:

IN CASE OF INGESTION:

Measures:

- Obtain immediate medical attention and show him the label.
- Place the victim into comfortable position.
- Do not give the victim anything orally, and do not induce vomiting if the victim is unconscious.

IN CASE OF INHALATION:

Measures:

- Take the victim into fresh air, loosen his clothes and let him rest.
- If necessary, administer artificial respiration.
- Obtain immediate medical attention and show him the safety data sheet or the label.

IN CASE OF SKIN CONTACT:

Measures:

- Remove the contaminated clothes.
- Wash the skin surface with plenty of water and soap (for 15 minutes).
- Obtain medical help.

IN CASE OF EYE CONTACT:

Measures:

- In case of contact with eyes flush with water holding eyelids apart and moving the eyeballs (for at least 15 minutes).
- Obtain medical help.

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

No data available.

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

No data available.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media:

5.1.1. Suitable extinguishing media:

Water fog, foam, dry chemical, carbon dioxide.

Choose extinguishing media depending on surrounding fire.

5.1.2. Unsuitable extinguishing media:

None known.

5.2. Special hazards arising from the substance or mixture:



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The formation of dangerous decomposition products greatly depends on the circumstances of the combustion. A complex mixture of airborne solid, liquid and gas substances may occur, such as carbon monoxide, carbon dioxide and unidentified compounds.

In case of fire, smoke and other combustion products may be formed, the inhalation of such combustion products can have serious adverse effects on health.

5.3. Advise for fire fighters:

Wear full protective clothing and self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures:

6.1.1 For non-emergency personnel:

Keep unprotected people away, allow only well trained experts wearing suitable protective clothing to abide in the field of accident.

6.1.2. For emergency responders:

Avoid contact with skin, eyes and clothing.

Avoid inhalation of dust.

Wear appropriate personal protective equipment.

Ensure adequate ventilation.

6.2. Environmental precautions:

Dispose the spillage and the resulting waste according to the applicable environmental regulations. Do not allow the product and the resulting waste to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.

6.3. Methods and material for containment and cleaning up:

Collect the spilled mixture mechanically, then place the collected waste into appropriate, labelled, closable hazardous waste container till proper removal/disposal.

6.4. Reference to other sections:

For further and detailed information see section 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling:

Observe conventional hygiene precautions.

Avoid contact with skin, eyes and clothing.

Avoid inhalation and breathing dust.

Observe the pertinent regulations on industrial safety and basic hygiene rules.

Technical measures:

Ensure adequate ventilation.

Precautions against fire and explosion:

No special measures required.

7.2. Conditions for safe storage, including any incompatibilities:

Technical measures and storage condition:

Keep in original, closed and appropriately labelled container.

The place of storage has to be properly ventilated and cleanable.

Store in cool and dry place.

Incompatible materials: none known.

Packaging material: no special prescriptions.

7.3. Specific end use(s):

No specific instructions available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters:

Occupational exposure limit values (91/322/EEC, 98/24/EC, 2000/39/EC):

The components of the mixture are not regulated with exposure limit value.

DNEL		Routes of exposure	Exposure frequency:	Remarks:
Worker	Consumer			



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no data available	no data available	Dermal	Short term (acute) Long term (repeated)	no data available
no data available	no data available	Inhalative	Short term (acute) Long term (repeated)	no data available
no data available	no data available	Oral	Short term (acute) Long term (repeated)	no data available

PNEC			Exposure frequency:	Remarks:
Water	Soil	Air		
no data available	no data available	no data available	Short term (single use) Long term (continuous)	no data available
no data available	no data available	no data available	Short term (single use) Long term (continuous)	no data available
no data available	no data available	no data available	Short term (single use) Long term (continuous)	no data available

8.2. Exposure controls:

In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.

8.2.1 Appropriate engineering controls:

In pursuance of work is proper foresight needed to avoid leaking onto clothes and floors and to avoid contact with eyes and skin.

Ensure adequate ventilation.

8.2.2. Individual protection measures, such as personal protective equipment:

1. Eye/face protection: normally not necessary.
2. Skin protection:
 - a. Hand protection: use appropriate protective gloves (EN 374).
 - b. Other: use appropriate protective clothes.
3. Respiratory protection: normally not necessary.
4. Thermal hazard: none known.

8.2.3. Environmental exposure controls:

No specific prescription.

The requirements detailed in Section 8 assume skilled work under normal conditions and usage of the product for appropriate aims. If conditions differ from normal or work is carried out under extreme conditions an expert's advice should be sought out before deciding upon further protective measures.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties:

Parameter	Test method:	Remarks:
1. Appearance:		off-white powder
2. Odour:		light pungent
3. Odour threshold:		no data available
4. pH value:		no data available
5. Melting point/ freezing point:		no data available
6. Initial boiling point/boiling range:		no data available
7. Flash point:		no data available
8. Evaporation rate:		no data available
9. Flammability (solid, gas):		no data available
10. Upper/lower flammability or explosive limits:		no data available
11. Vapour pressure:		no data available
12. Vapour density:		no data available
13. Relative density:		no data available
14. Solubility(ies):		no data available



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15. Partition coefficient: n-octanol/water: no data available
16. Self-ignition temperature: no data available
17. Degradation temperature: no data available
18. Viscosity: no data available
19. Explosive properties: no data available
20. Oxidizing properties: no data available

- 9.2. Other information:
No data available.

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:
None known.
10.2. Chemical stability:
Stable within normal temperature and general work conditions.
10.3. Possibility of hazardous reactions:
None known.
10.4. Conditions to avoid:
Avoid inhalation and breathing dust.
10.5. Incompatible materials:
None known.
10.6. Hazardous decomposition products:
None known.

SECTION 11: TOXICOLOGICAL INFORMATION

- 11.1. Information on toxicological effects:
Acute toxicity: based on the information available, the criteria for classification is not fulfilled.
Skin corrosion/irritation: based on the information available, the criteria for classification is not fulfilled.
Serious eye damage/eye irritation: based on the information available, the criteria for classification is not fulfilled.
Respiratory or skin sensitisation: contains Gentamicin, sulfate (salt). May produce an allergic reaction.
Germ cell mutagenicity: based on the information available, the criteria for classification is not fulfilled.
Carcinogenicity: based on the information available, the criteria for classification is not fulfilled.
Reproductive toxicity: based on the information available, the criteria for classification is not fulfilled.
STOT-single exposure: based on the information available, the criteria for classification is not fulfilled.
STOT-repeated exposure: based on the information available, the criteria for classification is not fulfilled.
Aspiration hazard: based on the information available, the criteria for classification is not fulfilled.
- 11.1.1. For substances subject to registration, brief summaries of the information derived from the test conducted:
No data available.
- 11.1.2. Relevant toxicological properties of the hazardous substances:
No data available.
- 11.1.3. Information on likely routes of exposure:
Ingestion, inhalation, skin contact, eye contact.
- 11.1.4. Symptoms related to the physical, chemical and toxicological characteristics:
No data available.
- 11.1.5. Delayed and immediate effects as well as chronic effects from short and long-term exposure:
Contains Gentamicin, sulfate (salt). May produce an allergic reaction.
- 11.1.6. Interactive effects:
No data available.
- 11.1.7. Absence of specific data:
No information.
- 11.1.8. Other information:
No data available.

SECTION 12: ECOLOGICAL INFORMATION

- 12.1. Toxicity:
No data available about the product.
The classification of this mixture was performed based on the calculation method detailed in "General Classification guideline for mixtures of the EU" in the latest valid version.
Not classified as hazardous for the environment.



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- 12.2. Persistence and degradability:
No data available.
- 12.3. Bioaccumulation potential:
No data available.
- 12.4. Mobility in soil:
No data available.
- 12.5. Results of PBT and vPvB assessment:
No data available.
- 12.6. Other adverse effects:
No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

- 13.1. Waste treatment methods:
Disposal according to the local regulations.
- 13.1.1. Information regarding the disposal of the product:
No special recommendation from the manufacturer.
Do not dispose together with household waste.
European Waste Code:
For this product no waste disposal key according the European Waste Catalogue (EWC) can be determined, as only the purpose of application defined by the user enables an allocation. The EWC codes indicated below are only recommendations, but they may have to be changed due to special circumstances, in such cases new classification may be needed.
- 13.1.2. Information regarding the disposal of the packaging:
Dispose according to the relevant regulations.
- 13.1.3. Physical/chemical properties that may affect waste treatment options shall be specified:
None known.
- 13.1.4. Sewage disposal:
None known.
- 13.1.5. Special precautions for any recommended waste treatment:
No data available.

SECTION 14: TRANSPORT INFORMATION

Not dangerous good in sense of the transport regulations.

- 14.1. UN Number:
None.
- 14.2. UN proper shipping name:
None.
- 14.3. Transport hazard class(es):
None.
- 14.4. Packaging group:
None.
- 14.5. Environmental hazard:
No relevant information available.
- 14.6. Special precautions for user:
No relevant information available.
- 14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code:
Not applicable.

SECTION 15: REGULATORY INFORMATION

- 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:
REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC



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REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

15.2. Chemical safety assessment: no information available.

SECTION 16: OTHER INFORMATION

Information regarding the revision of the safety data sheet: none.

Full text of the abbreviations in the safety data sheet:

DNEL: Derived no effect level. PNEC: Predicted no effect concentration. CMR effects: carcinogenicity, mutagenicity and toxicity for reproduction. PBT: Persistent, bioaccumulative and toxic. vPvB: Very Persistent, Very Bioaccumulative. n.d.: not defined. n.a.: not applicable.

Data sources: information submitted by the manufacturer.

Methods used for the classification according to Regulation 1272/2008/EC: not classified based on the calculation method of the known hazards of the ingredients.

Relevant H-Phrases (number and full text) of Section 2 and 3:

H317 – May cause an allergic skin reaction.

H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H361d – Suspected of damaging the unborn child.

EUH 208 – Contains Gentamicin, sulfate (salt). May produce an allergic reaction.

EUH 210 – Safety data sheet available on request.

Training advice: no data available.

This safety data sheet had been prepared on the basis of information provided by the manufacturer/supplier and conform to the relevant regulations.

The information, data and recommendations contained herein are provided in good faith, obtained from reliable sources and believed to be true and accurate as of the date issued; however, no representation is made as to the comprehensiveness of the information. The SDS shall be used only as a guide for handling the product; in the course of handling and using the product other considerations may arise or be required.

Users are cautioned to determine the appropriateness and applicability of the above information to their particular circumstances and purposes and assume all risk associated with the use of this product. It is the responsibility of the user to fully comply with local, national and international regulations concerning the use of this product.

