


1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name** TYLO-TEN
- **Article number:** 5727920000
- **Relevant identified uses of the substance or mixture and uses advised against** None.
- **Application of the substance / the mixture** Feed
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
SUPPLIER:
Biesterfeld International GmbH
Ferdinandstr. 41
D-20095 Hamburg
Germany
- **Informing department:**
Dept. QSHE, Mr. P. Tentler, Phone: +49 2224981155; e-mail: sdb@biesterfeld.com
- **Emergency telephone number:**
GIZ-Nord, Göttingen, Germany
Member of EPECS Network
EMERGENCY NUMBER: +49 551 19240

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Xn; Sensitising
R42/43: May cause sensitisation by inhalation and skin contact.
- **Information concerning particular hazards for human and environment:** void
- **Classification system:**
The classification is in line with current EU lists. It is expanded, however, by information from technical literature and by information furnished by supplier companies.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**

GHS08
- **Signal word** Danger
- **Hazard-determining components of labelling:**
Tylosin, phosphate (salt)
- **Hazard statements**
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317 May cause an allergic skin reaction.

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· **Precautionary statements**

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P304+P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P302+P352 IF ON SKIN: Wash with plenty of water.
- P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture consisting of the following components with harmless additives.

· **Dangerous components:**

CAS: 1405-53-4 EINECS: 215-779-4	Tylosin, phosphate (salt) ☒ Xn R42/43; ☒ Xi R36 R53 ☒ Resp. Sens. 1, H334; ☒ Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 4, H413	2,5-10%
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· **Additional information:** For the wording of the listed risk phrases refer to section 16.

4 First aid measures

· **Description of first aid measures**

· **General information**

Personal protection for the First Aider.
Remove contaminated clothing.
If unconscious, place in recovery position and seek medical advice.

· **After inhalation**

Take affected persons into the open air and position comfortably
Supply fresh air. If required, provide artificial respiration. Keep patient warm.

With symptoms:

Call a doctor immediately.

· **After skin contact**

Immediately remove contaminated clothing.

Instantly rinse with water.

Or better;

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

After wide skin contact:

Seek medical treatment.

· **After eye contact**

Use eye protection.

Rinse opened eye for several minutes under running water. If symptoms persist, consult Oculist.

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- **After swallowing**
Rinse out mouth and then drink (two glasses at the most) water.
Do not induce vomiting.
Consult doctor if feeling unwell.
Turn a vomiting person on the side if lying on the back.
If vomiting occurs, the head should be kept low.
- **Information for doctor** The toxicological properties of this material have not been fully investigated.
- **Most important symptoms and effects, both acute and delayed**
Irritations after contact with eyes, skin and mucous membrane.
After inhalation of dust:
Irritating to respiratory tract.
Coughing
Breathing difficulty (dyspnea)
After skin contact:
and
After inhalation:
Allergic reactions
Possible other symptoms are currently not known.
- **Danger**
Slightly irritating on skin and mucous membrane.
Causes serious eye irritation.
After skin contact allergic symptoms possible.
After inhalation allergic symptoms possible.
There are at present no indications to further acute dangers for the health.
Further health dangers cannot be excluded however.
- **Indication of any immediate medical attention and special treatment needed**
Elemental assistance.
Decontamination.
Treat symptomatically and supportively.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents**
CO₂, extinguishing powder or water fog. Fight larger fires with water fog or alcohol-resistant foam.
- **For safety reasons unsuitable extinguishing agents** Water with a full water jet.
- **Special hazards arising from the substance or mixture**
Formation of toxic and corrosive gases during heating or in case of fire.
Can be released in case of fire:
Carbon monoxide and carbon dioxide.
Nitrogen oxides (NO_x)
Phosphorous Oxides (P_xO_y)
Dust explosion hazard!
- **Advice for firefighters**
- **Protective equipment:**
Wear self-contained breathing apparatus.
Wear full protective suit.
- **Additional information**
Collect contaminated fire fighting water separately. It must not enter drains.
Damp down gases/fumes/haze with water spray jet.

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6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.
Use breathing protection against the effects of fumes/dust/aerosol.
Keep away from sources of ignition.
Avoid causing dust.

Ensure adequate ventilation

Bring persons out of danger.

· **Environmental precautions:**

Do not allow to enter sewage systems, water bodies, groundwater or soil.

Inform respective authorities in case product reaches water, sewage system or soil.

· **Methods and material for containment and cleaning up:**

Avoid causing dust.

Ensure adequate ventilation.

Collect mechanically.

Clean up affected area.

May be recycled or disposed of in appropriate containers

Dispose of contaminated material as waste according to item 13.

· **Reference to other sections**

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

7 Handling and storage

· **Handling**

· **Precautions for safe handling**

Keep containers tightly closed.

Prevent formation of dust.

Ensure good ventilation/exhaustion at the workplace.

· **Hygiene measures:**

Keep away from foodstuffs, beverages and feedingstuff.

Instantly remove any soiled and impregnated garments.

Clean skin thoroughly immediately after handling the product.

Do not inhale dust / smoke / mist.

Avoid contact with the eyes and skin.

Do not eat, drink or smoke while working.

· **Information about protection against explosions and fires:**

Substance/product is flammable.

Dust can combine with air to form an explosive mixture.

Fire fighting equipment must be available.

Protect from heat.

Avoid deposition of dust.

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

· **Conditions for safe storage, including any incompatibilities**

· **Storage**

· **Requirements to be met by storerooms and containers:**

Store in original container if possible.

Prevent any penetration into the ground.

· **Information about storage in one common storage facility:**

Store away from foodstuffs.

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Do not store together with materials/products which can form dangerous chemical reactions.

See point 10: stability and reactivity.

· **Further information about storage conditions:**

Store in a dry place. Store in a closed container.

Protect from heat and direct sunlight.

Store container in a well ventilated position.

· **Recommended storage temperature:** >5 °C - <25 °C

· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with critical values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· **DNELs** No data available

· **PNECs** No data available

· **Additional information:** The lists that were valid during the compilation were used as basis.

· **Exposure controls**

· **Personal protective equipment**

· **General protective measures:**

The usual precautionary measures should be adhered to in handling the chemicals.

· **Breathing equipment:**

If used in closed systems or well-ventilated area breathing protection is not necessary.

Required when dusts are generated.



In case of brief exposure or low pollution use breathing filter apparatus. In case of intensive or longer exposure use breathing apparatus that is independent of circulating air.

Filter P2.

or

Filter P3.

· **Protection of hands:**



Chemical-protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Check protective gloves prior to each use for their proper condition.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Preventive skin protection by use of skin-protecting agents is recommended.

· **Material of gloves**

No material can be recommended.

Experience says that polychloroprene, nitrile rubber, butylrubber, fluoro-caoutchouc, and polyvinyl chloride are suitable as glove materials for protection against undissolved solids.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

ASK THE MANUFACTURER FOR SUITABLE MATERIAL.

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· **Penetration time of glove material**

At the permeation time no data are present.

The penetration of the glove material is impossible with dry and not gassing solids.

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Not suitable are gloves made of the following materials:**

Strong gloves

Leather gloves

· **Eye protection:**



Safety glasses with side protection.

· **Body protection:**

Wear dust tight protective clothing.

Apron

Boots

or

Suitable chemical protection suit.

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Granulate, coarse

Colour: Light brown

· **Smell:** unpleasant

· **Odour threshold:** No data available

· **pH-value:** No data available

· **Change in condition**

Melting point/Melting range: No data available

Boiling point/Boiling range: No data available

· **Flash point:** >100 °C

· **Ignition temperature:** No data available

· **Decomposition temperature:** No data available

· **Danger of explosion:** Product does not present an explosion hazard.
Dust explosion hazard!

· **Critical values for explosion:**

Lower: No data available

Upper: No data available

· **Vapour pressure:** No data available

· **Density** No data available

· **Vapour density** Not applicable.

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- **Solubility in / Miscibility with Water:** Insoluble
- **Partition coefficient (n-octanol/water):** No data available
- **Viscosity:**
 - dynamic:** Not applicable.
 - kinematic:** Not applicable.
- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Conditions to be avoided:**
No decomposition if used and stored according to specifications.
To avoid thermal decomposition do not overheat.
Flames, sparks, electrostatic charges.
- **Possibility of hazardous reactions**
The product is not capable of dust explosion in the form supplied; enrichment with fine dust causes risk of dust explosion.
Reacts with strong oxidizing agents.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:**
Poisonous gases/vapours
Corrosive gases/vapours
Inflammable gases/vapours
Can be released in case of fire:
Carbon monoxide (CO) and carbon dioxide (CO₂)
Nitrogen oxides (NO_x)
Phosphorus oxides (e.g. P₂O₅)

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

1405-53-4 Tylosin, phosphate (salt)

Oral	LD50	5000 mg/kg (rodent - rat) (EMEA)
Dermal	LD50	> 2000 mg/kg (rodent - rat) (WHO)
Inhalative	LC50/1h	2060 mg/l (rodent - rat) (Read across, Tylosin Base)

- **Primary irritant effect:**
- **on the skin:**
CAS 1405-53-4:
Skin irritation test (rabbit): Slight irritations (EMEA).
Slightly irritating (no EU classification)
- **on the eye:**
CAS 1405-53-4:
Eye irritation test (rabbit): Irritations (Lit.).
- **Sensitization:**
CAS 1405-53-4:

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Sensitization test (guinea pig): positive

Sensitization possible by inhalation.

Sensitization possible by skin contact.

· **Subacute to chronic toxicity:**

mutagenic activity:

No indication of mutagenic activity.

carcinogenic activity:

No indication of carcinogenic activity.

teratogenic activity:

No indication of teratogenic activity.

fertility impairment:

No indication of reproduction-endangering effect.

· **Additional toxicological information:**

Causes serious eye irritation.

May cause sensitisation by inhalation and skin contact.

The toxicological properties of this material have not been fully investigated.

Further hazardous properties cannot be excluded.

The substance / product should be handled with the care usual when dealing with chemicals.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:** No data available

· **Terrestrial toxicity:** No data available

· **Persistence and degradability** No data available

· **Behaviour in environmental systems:**

· **Bioaccumulative potential** No data available

· **Mobility in soil** No data available

· **Additional ecological information:**

· **AOX-indication:** The product does not contribute to the AOX value of the waste water.

· **General notes:**

Quantitative data on the ecological effect of this product are not available.

At present there are no ecotoxicological assessments.

Do not allow product to reach ground water, water bodies, sewage system or soil.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Disposal must be made according to official regulations.

· **European waste catalogue**

A waste code in accordance with the European Waste Catalogue (EWC) may not be assigned to this product since it admits of a classification only when the consumer uses it for some purpose. In agreement with the waste code must be determined regional waste disposal authority or company.

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- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
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| · UN-Number | |
| · ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · ADR, IMDG, IATA | Void |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | Not dangerous according to the above specifications. |
| · UN "Model Regulation": | - |

15 Regulatory information

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

These statements solely describe the safety demands of the product and base according to the best of our belief on our today's knowledge. They, however, do not represent any assurance towards properties of the product within the sense of liability, resp. guaranty regulations and thus are given without any obligation.

· **Relevant phrases**

- H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H413 May cause long lasting harmful effects to aquatic life.
R36 Irritating to eyes.
R42/43 May cause sensitisation by inhalation and skin contact.
R53 May cause long-term adverse effects in the aquatic environment.

- **Department issuing data specification sheet:** Dept. QSHE
- **Contact:** Mr. Dr. Hollitzer, Fon: +49 4032008284; mailto: sdb@biesterfeld.com

· **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

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ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

Lit.: Literatur

Sources

Information of distributor.

EMA: European Medicines Agency

<http://www.ema.europa.eu/ema/>

ECHA Classification and Labelling

echa.europa.eu/de/view-article/-/journal_content/07005f81-abf1-4081-973b-6c7c526c39df

European chemical Substances Information System

<http://esis.jrc.ec.europa.eu/>

MSDS of different manufacturers.

euSDB - Search Index for Material Safety Data Sheets

<http://www.eusdb.de/>