

Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g), Rev. 2012 and GHS Rev 03.

Printing date 11/19/2014

Reviewed on 11/19/2014

1 Identification

- **Product identifier**
- **Trade name: Pennox 343**
- **Product description** Water soluble powder.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Pharmgate
Address: 14040 Industrial Rd.
Omaha, NE 68144
Phone: (402) 330-6000
Fax: (402) 330-6004
- **Emergency telephone number:** (800) 832-8303

2 Hazard(s) Identification

- **Classification of the substance or mixture**



GHS08 Health hazard

Repr. 2 H361 Suspected of damaging fertility or the unborn child.



GHS07

Eye Irrit. 2A H319 Causes serious eye irritation.

- **Label elements**

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS07



GHS08

- **Signal word** Warning

- **Hazard-determining components of labeling:**

Oxytetracycline hydrochloride

- **Hazard statements**

Causes serious eye irritation.

Suspected of damaging fertility or the unborn child.

- **Precautionary statements**

Wear eye protection / face protection.

Wash thoroughly after handling.

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

IF exposed or concerned: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Store locked up.

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Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**· **NFPA ratings (scale 0 - 4)**

Health = 1
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = *1
Fire = 0
Reactivity = 0

3 Composition/Information on Ingredients· **Chemical characterization: Mixtures**· **Description:** Mixture of the substances listed below with nonhazardous additions.· **Dangerous Components:**

2058-46-0	Oxytetracycline hydrochloride	◆ Repr. 2, H361	75.6%
590-46-5	Betaine Hydrochloride	◆ Eye Irrit. 2A, H319	24.4%

4 First-aid measures· **Description of first aid measures**· **After inhalation:** Supply fresh air; consult doctor in case of complaints.· **After skin contact:** Generally the product does not irritate the skin.· **After eye contact:**

Rinse opened eye for at least 15 minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** If symptoms persist, consult doctor.· **Most important symptoms and effects, both acute and delayed** No further relevant information available.· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5 Fire-fighting measures· **Extinguishing media**· **Suitable extinguishing agents:**CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.· **Special hazards arising from the substance or mixture** No further relevant information available.· **Advice for firefighters**· **Protective equipment:**

As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

6 Accidental release measures· **Personal precautions, protective equipment and emergency procedures** Not required.· **Environmental precautions:** No special measures required.· **Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (ie. sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

Dispose of the collected material according to regulations.

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- **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 disposal information.

7 Handling and storage

- **Precautions for safe handling**

- Ensure good ventilation/exhaustion at the workplace.
- Open and handle receptacle with care.
- Prevent formation of aerosols.

- **Information about protection against explosions and fires:** Keep protective respiratory device available.

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

- **Storage:**

- **Requirements to be met by storerooms and receptacles:** Store below 104°F or 40°C.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **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 section 7.

- **Control parameters**

- **Components with occupational exposure limits:**

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

- **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

- Keep away from foodstuffs, beverages and feed.
- Immediately remove all soiled and contaminated clothing.
- Wash hands before breaks and at the end of work.
- Store protective clothing separately.
- Avoid contact with the eyes.
- Avoid contact with the eyes and skin.

- **Breathing equipment:** Not required.

- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Select glove material based on penetration times, rates of diffusion and degradation.

- **Material of gloves**

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.

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- **Penetration time of glove material**

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

- **Eye protection:** Tightly sealed goggles

9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form: Powder

Color: Brown

- **Odor:** Mild

- **Odor threshold:** Not determined.

- **pH-value:** Not determined.

- **Change in condition**

Melting point/Melting range: Not determined.

Boiling point/Boiling range: Not determined.

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Not applicable.

- **Ignition temperature:**

Decomposition temperature: Not determined.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

- **Vapor pressure:** Not determined.

- **Density:**

Relative density Not determined.

Vapour density Not determined.

Evaporation rate Not determined.

- **Solubility in / Miscibility with**

Water: Not miscible or difficult to mix.

- **Partition coefficient (n-octanol/water):** Not determined.

- **Viscosity:**

Dynamic: Not determined.

Kinematic: Not determined.

- **Solvent content:**

Organic solvents: 0.0 %

- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.

- **Chemical stability** Stable under normal conditions.

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- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information• **Information on toxicological effects**• **Acute toxicity:**• **LD/LC50 values that are relevant for classification:****2058-46-0 Oxytetracycline hydrochloride**

Oral LD50 6696 mg/kg (mouse)

Inhalative LC50/4 h <200 mg/l (Trout)

• **Primary irritant effect:**• **on the skin:** No irritating effect.• **on the eye:**

Irritating effect.

Causes serious eye irritation.

• **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

• **Carcinogenic categories**• **IARC (International Agency for Research on Cancer)**

None of the ingredients are listed.

Group 1 - Carcinogenic to humans

Group 2A - Probably carcinogenic to humans

Group 2B - Possibly carcinogenic to humans

Group 3 - Not classifiable as to its carcinogenicity to humans

Group 4 - Probably not carcinogenic to humans

• **NTP (National Toxicology Program)**

None of the ingredients are listed.

• **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients are listed.

12 Ecological information• **Toxicity**• **Aquatic toxicity:** No further relevant information available.• **Persistence and degradability** No further relevant information available.• **Bioaccumulative potential** No further relevant information available.• **Mobility in soil** No further relevant information available.• **Additional ecological information:**• **General notes:** Not known to be hazardous to water.• **Results of PBT and vPvB assessment**• **PBT:** Not applicable.• **vPvB:** Not applicable.• **Other adverse effects** No further relevant information available.

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

*** 14 Transport information**

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** Non-Regulated Material
- **Packing group**
- **DOT, ADR, IMDG, IATA** Non-Regulated Material
- **Environmental hazards:**
- **Marine pollutant:** No
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **UN "Model Regulation":**

*** 15 Regulatory information**

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**
- **Section 355 (extremely hazardous substances):**
None of the ingredients are listed.
- **Section 313 (Specific toxic chemical listings):**
None of the ingredients are listed.
- **TSCA (Toxic Substances Control Act):**
All ingredients are listed.
- **Proposition 65**
- **Chemicals known to cause cancer:**
None of the ingredients are listed.
- **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients are listed.
- **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients are listed.
- **Chemicals known to cause developmental toxicity:**
2058-46-0 Oxytetracycline hydrochloride

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- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients are listed.

- **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients are listed.

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients are listed.

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Warning

- **Hazard-determining components of labeling:**

Oxytetracycline hydrochloride

- **Hazard statements**

Causes serious eye irritation.

Suspected of damaging fertility or the unborn child.

- **Precautionary statements**

Wear eye protection / face protection.

Wash thoroughly after handling.

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

IF exposed or concerned: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- **National regulations:**

2058-46-0 | Oxytetracycline hydrochloride

- **State Right to Know**

2058-46-0 | Oxytetracycline hydrochloride

◆ Repr. 2, H361

75.6%

590-46-5 | Betaine Hydrochloride

◆ Eye Irrit. 2A, H319

24.4%

All ingredients are listed.

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

16. Other information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

- **Date of preparation / last revision** 11/19/2014 / 2

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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)

ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

Repr. 2: Reproductive toxicity, Hazard Category 2

*** Data compared to the previous version altered.**SDS created by MSDS Authoring Services www.msdsauthoring.com (877) 204-9106