

SAFETY DATA SHEET



Revision date: 23-Feb-2015

Version: 1.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Aureomix S 10/10

Trade Name: Aureomix® S 10/10 Granular
Synonyms: Aureomix S 10/10 granular; Chlortetracycline/Sulfamethazine
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product (Feed additive)
Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Grey to brown granular solid

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1A

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

EU Classification:

EU Indication of danger: Toxic to reproduction: Category 1

EU Symbol: T

EU Risk Phrases:
R61 - May cause harm to the unborn child.

Label Elements

Signal Word: Danger
Hazard Statements: H360D - May damage the unborn child
May form combustible dust concentrations in air

ZT00552

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Precautionary Statements: P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Supplemental Hazards: Powdered material may form explosive dust-air mixtures



Other Hazards
Short Term:

May cause eye, skin and respiratory tract irritation . May cause hypersensitivity reactions in susceptible individuals. Signs and symptoms might include skin rash, itching, redness or swelling. May cause stomach irritation, diarrhea, nausea, or vomiting. May cause adverse blood effects .

Long Term:

May cause damage to liver and kidneys , may have the potential to produce effects on the developing fetus.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Calcium carbonate	1317-65-3	215-279-6	Not Listed	Not Listed	<50
Calcium sulfate	7778-18-9	231-900-3	Not Listed	Not Listed	<50
Sulfamethazine	57-68-1	200-346-4	Not Listed	Not Listed	10 g/lb
Chlortetracycline	57-62-5	200-341-7	Repr. Cat.1;R61	Repro. Tox. Cat. 1A (H360)	10 g/lb

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Rice	Proprietary	Not Listed	Not Listed	Not Listed	<50

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions Aggravated by Exposure:** Breathing dust may worsen asthma symptoms.

Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
- Fire / Explosion Hazards:** During processing, dust may form explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Avoid dust formation. Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

- Measures for Cleaning / Collecting:** Contain the source of the spill if it is safe to do so. Avoid generating airborne dust. Collect spilled material by a method that controls dust generation. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal. Clean contaminated surface thoroughly.

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Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Minimize dust generation and accumulation. Use with adequate ventilation. Wash thoroughly after handling. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Keep in a cool, well-ventilated place. Keep away from heat, sparks, flame, and other sources of ignition.

Specific end use(s): Veterinary product (Feed additive)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Calcium carbonate

Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	1.0 fiber/cm ³
	10.0 mg/m ³
Czech Republic OEL - TWA	10.0 mg/m ³
Estonia OEL - TWA	10 mg/m ³
	5 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Hungary OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Romania OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	10 mg/m ³
Switzerland OEL - TWAs	3 mg/m ³

Calcium sulfate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Austria OEL - MAKs	5 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
France OEL - TWA	10 mg/m ³
Germany - TRGS 900 - TWAs	6 mg/m ³
Germany (DFG) - MAK	1.5 mg/m ³
	4 mg/m ³
Hungary OEL - TWA	6 mg/m ³
Ireland OEL - TWAs	10 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Latvia OEL - TWA	4 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	6 mg/m ³
Slovenia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	3 mg/m ³

Sulfamethazine

Latvia OEL - TWA	1 mg/m ³
Lithuania OEL - TWA	1 mg/m ³

Chlortetracycline

Zoetis OEL TWA 8-hr	0.5 mg/m ³
Latvia OEL - TWA	0.1 mg/m ³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Sulfamethazine

Zoetis OEB OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Wear impervious gloves if skin contact is possible.

Eyes:

Safety glasses or goggles

Skin:

Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection:

Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:

Granular solid

Color:

Grey to brown

Odor:

Slight

Odor Threshold:

No data available.

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solvent Solubility:

No data available

Water Solubility:

Slightly Soluble:

pH:

5.5 - 7.5

Melting/Freezing Point (°C):

No data available

Boiling Point (°C):

No data available.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient: (Method, pH, Endpoint, Value)

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electrostatic discharge). Avoid dispersion as a dust cloud. Dust may form explosive mixture in air. Fine particles (such as dusts, mists and vapors) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.
Routes of exposure: inhalation , eye contact , skin contact

Acute Toxicity: (Species, Route, End Point, Dose)

Sulfamethazine

Mouse Oral LD50 50 g/kg

Mouse Sub-tenon injection (eye) LD50 1.06 g/kg

Chlortetracycline

Rat Oral LD50 3000 mg/kg

Inhalation Acute Toxicity

Allergic reactions might occur based on effects of the individual components. Inhalation of dust may cause irritation of the respiratory tract and mucous membranes and allergic reactions in susceptible individuals.

Skin Irritation / Sensitization

May cause allergic reactions in susceptible individuals.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

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11. TOXICOLOGICAL INFORMATION

Chlortetracycline

6 Week(s) Mouse Oral 100 mg/kg/day NOEL No effects at maximum dose
14 Week(s) Mouse Oral 200 mg/kg/day NOEL No effects at maximum dose
14 Week(s) Rat Oral 200 mg/kg/day NOEL No effects at maximum dose

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Sulfamethazine

Reproductive & Fertility Mouse Oral 805 mg/kg/day NOEL Fertility
Embryo / Fetal Development Rat Oral 545 mg/kg/day NOEL Teratogenic
Reproductive & Fertility Rabbit Oral 600 mg/kg/day NOEL Not Teratogenic, Maternal Toxicity, Fetotoxicity

Chlortetracycline

2 Generation Reproductive Toxicity Rat Oral 500 mg/kg/day NOEL Negative

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Sulfamethazine

Bacterial Mutagenicity (Ames) *Salmonella* Negative
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive

Chlortetracycline

In Vitro Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vitro HGPRT Forward Gene Mutation Assay Chinese Hamster Ovary (CHO) cells Negative
In Vitro Unscheduled DNA Synthesis Rat Hepatocyte Negative
In Vivo Chromosome Aberration Rat Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Chlortetracycline

2 Year(s) Rat Oral 700 mg/kg/day NOEL Not carcinogenic

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Sulfamethazine

IARC:

Group 3 (Not Classifiable)

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12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Mobility in Soil:	No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
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14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



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15. REGULATORY INFORMATION

Calcium carbonate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	215-279-6

Calcium sulfate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-900-3

Sulfamethazine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4 Schedule 5
EU EINECS/ELINCS List	200-346-4

Chlortetracycline

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4 Schedule 5
EU EINECS/ELINCS List	200-341-7

Rice

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1A; H360D - May damage the unborn child

Toxic to reproduction: Category 1

R61 - May cause harm to the unborn child.

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Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: New data sheet.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet