Safety Data Sheet (SDS)

1 Identification

· Product identifier
  · Trade name: NEOMYCIN/OXYTETRACYCLINE 50/50
  · Product description Type A Medicated Article-For use in the manufacture of medicated animal feeds.

· 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. 1B H360 May damage fertility or the unborn child.

  · GHS07

  Skin Irrit. 2 H315 Causes skin irritation.
  Skin Sens. 1 H317 May cause an allergic skin reaction.
  STOT SE 3 H335 May cause respiratory irritation.

  Eye Irrit. 2B H320 Causes 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 Danger

· Hazard-determining components of labeling:
  Neomycin, sulfate (salt)
  calcium carbonate

· Hazard statements
  Causes skin and eye irritation.
  May cause an allergic skin reaction.
  May damage fertility or the unborn child.
  May cause respiratory irritation.

· Precautionary statements
  Avoid breathing dust/fume/gas/mist/vapors/spray
  Use only outdoors or in a well-ventilated area.

(Contd. on page 2)
Trade name: NEOMYCIN/OXYTETRACYCLINE 50/50

Wear protective gloves. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. 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. Specific treatment (see on this label). IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a poison center/doctor if you feel unwell. Wash contaminated clothing before reuse. IF exposed or concerned: Get medical advice/attention. If skin irritation or rash occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. If on skin: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. Store locked up. Store in a well-ventilated place. Keep container tightly closed. Dispose of contents/container in accordance with local/regional/national/international regulations.

**Classification system:**

**NFPA ratings (scale 0 - 4)**

000 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:**

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Substance</th>
<th>Percent</th>
<th>Health Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>471-34-1</td>
<td>Calcium carbonate</td>
<td>0.2-80.3%</td>
<td>Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320</td>
</tr>
<tr>
<td>1405-10-3</td>
<td>Neomycin, sulfate (salt)</td>
<td>12.9%</td>
<td>Repr. 1B, H360; Skin Irrit. 2, H315; Skin Sens. 1, H317; Eye Irrit. 2B, H320</td>
</tr>
<tr>
<td>8042-47-5</td>
<td>Mineral Oil</td>
<td>0.2-2.0%</td>
<td></td>
</tr>
</tbody>
</table>

**4 First-aid measures**

**Description of first aid measures**

**After inhalation:** In case of unconsciousness, place patient securely on side position for transportation.

**After skin contact:** Immediately wash with water and soap and rinse thoroughly.

**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. (Contd. on page 3)
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:**
  - Dispose contaminated material as waste according to section 13.
  - Ensure adequate ventilation.
  - Dispose of the collected material according to regulations.
- **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** Open and handle receptacle with care.
- **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 at 77°F or 25°C with excursions permitted to 98.6°F or 37°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:**
    | Component       | Long-term value       |
    |-----------------|-----------------------|
    | 471-34-1 calcium carbonate | Long-term value: 15* 5** mg/m³ |
    |                 | *total dust **respirable fraction |
    | PEL             | REL Long-term value: 10* 5** mg/m³ |
    |                 | *total dust **respirable fraction |
    | TLV             | TLV withdrawn         |

(Contd. on page 4)
Trade name: NEOMYCIN/OXYTETRACYCLINE 50/50

<table>
<thead>
<tr>
<th>8042-47-5 Mineral Oil</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH TLV</td>
</tr>
<tr>
<td>Short-term value: 10 mg/m³</td>
</tr>
<tr>
<td>Long-term value: 5 mg/m³</td>
</tr>
<tr>
<td>OSHA PEL</td>
</tr>
<tr>
<td>Long-term value: 5 mg/m³</td>
</tr>
</tbody>
</table>

- 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 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.
  - 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: Meal
    - Color: Yellow
  - Odor: No data available
  - Odor threshold: Not determined.
  - pH-value: Not applicable.
  - Change in condition:
    - Melting point/Melting range: Not determined.
    - Boiling point/Boiling range: Not determined.
  - Flash point: Not applicable.
  - Flammability (solid, gaseous): Not determined.
10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal conditions.
- **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**:
    | Substance | Oral LD50/LC50 |
    |-----------|---------------|
    | 471-34-1 calcium carbonate | 6450 mg/kg (rat) |
    | 1405-10-3 Neomycin, sulfate (salt) | 2880 mg/kg (mouse) |
    | | 2750 mg/kg (rat) |
  - **Primary irritant effect**
    - **on the skin**: Irritant to skin and mucous membranes.
May cause an allergic skin reaction.

- **on the eye:**
  - Irritating effect.
  - Causes serious eye irritation.
- **Sensitization:** Sensitization possible through skin contact.
- **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.

**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: Non-Regulated Material

Environmental hazards:

Marine pollutant: No

Special precautions for user: Not applicable.

Transport in bulk according to Annex II of MARPOL 73/78 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:
1405-10-3 Neomycin, sulfate (salt)
79-57-2 oxytetracycline

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).
Safety Data Sheet (SDS)

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Hazard pictograms

GHS07  GHS08

Signal word Danger

Hazard-determining components of labeling:
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calcium carbonate

Hazard statements
Causes skin and eye irritation.
May cause an allergic skin reaction.
May damage fertility or the unborn child.
May cause respiratory irritation.

Precautionary statements
Avoid breathing dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area.
Wear protective gloves.
Wash thoroughly after handling.
Contaminated work clothing must not be allowed out of the workplace.
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.
Specific treatment (see on this label).
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
Call a poison center/doctor if you feel unwell.
Wash contaminated clothing before reuse.
IF exposed or concerned: Get medical advice/attention.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
If on skin: Wash with plenty of water.
Take off contaminated clothing and wash it before reuse.
Store locked up.
Store in a well-ventilated place. Keep container tightly closed.
Dispose of contents/container in accordance with local/regional/national/international regulations.

National regulations:
The product is subject to be labeled according with the prevailing version of the regulations on hazardous substances.

State Right to Know

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<td>79-57-2</td>
<td>oxytetracycline</td>
<td>&lt;12.3%</td>
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<td>8042-47-5</td>
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All ingredients are listed.
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 11/14/2014 / -

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
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2B: Serious eye damage/eye irritation, Hazard Category 2B
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
Repr. 1B: Reproductive toxicity, Hazard Category 1B
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

* Data compared to the previous version altered.*

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