Material Safety Data Sheet

STAFAC™ 22, 44

1. Product and company identification

<table>
<thead>
<tr>
<th>Product name</th>
<th>STAFAC™ 22, 44</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonym</td>
<td>Virginiamycin</td>
</tr>
<tr>
<td>Material uses</td>
<td>Antibiotic agent.</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Phibro Animal Health</td>
</tr>
<tr>
<td></td>
<td>65 Challenger Rd,</td>
</tr>
<tr>
<td></td>
<td>3rd Flr, Ridgefield Park,</td>
</tr>
<tr>
<td></td>
<td>NJ 07660-2103, USA</td>
</tr>
<tr>
<td>Distributor</td>
<td>Bio Agri Mix LP</td>
</tr>
<tr>
<td></td>
<td>11 Ellens Street</td>
</tr>
<tr>
<td></td>
<td>PO Box # 399</td>
</tr>
<tr>
<td></td>
<td>Mitchell, ON N0K 1N0</td>
</tr>
<tr>
<td></td>
<td>(519) 348 9865</td>
</tr>
<tr>
<td>Code</td>
<td>8810 013; 8811 013; 8900 013</td>
</tr>
<tr>
<td>MSDS authored by</td>
<td>KMK Regulatory Services Inc.</td>
</tr>
<tr>
<td>In case of emergency</td>
<td>(519) 348 9865 (Technical information within normal business hours).</td>
</tr>
<tr>
<td>Product type</td>
<td>Solid.</td>
</tr>
</tbody>
</table>

2. Hazards identification

- **Color**: Brown.
- **Physical state**: Solid. [Granular powder.]
- **Odor**: Characteristic fermentation odor.
- **Signal word**: CAUTION!
- **Hazard statements**: MAY CAUSE EYE IRRITATION. MAY CAUSE TARGET ORGAN DAMAGE, BASED ON ANIMAL DATA.
- **Precautions**: Avoid contact with eyes. Wash thoroughly after handling.
- **Routes of entry**: Dermal contact. Eye contact. Inhalation. Ingestion.
- **Potential acute health effects**:
  - **Inhalation**: No known significant effects or critical hazards.
  - **Ingestion**: No known significant effects or critical hazards.
  - **Skin**: No known significant effects or critical hazards.
  - **Eyes**: Slightly irritating to the eyes.
- **Potential chronic health effects**:
  - **Chronic effects**: Repeated or prolonged exposure to the substance can produce liver damage.
  - **Carcinogenicity**: Studies to evaluate the chronic toxicity and/or carcinogenic potential of virginiamycin have been conducted in mice and rats. In a 2-year oral toxicity study in mice, virginiamycin was given in the diet at dose levels of 25, 75 or 1000 mg/kg/day. No drug-related effects were observed in the mortality, physical observations, body weight, blood or clinical chemistry data or gross or microscopic pathology. The NOAELs for toxicity and carcinogenicity in this study were determined to be 1000 mg/kg/day. In rats, virginiamycin was administered orally in the diet at doses of 25, 50 or 250 mg/kg/day for males and 25, 50 or 300 mg/kg/day for females for 24 months. At dose levels greater than 50 mg/kg/day, reduced body weights, increased food consumption values, and
2. Hazards identification

Changes in some clinical chemistry parameters were observed in males, but not in females. There were no neoplastic or non-neoplastic findings noted at any dose level that were of toxicological or oncogenic significance. Based on these findings, the NOAEL for toxicity in this study was determined to be 50 mg/kg/day. The NOAEL for carcinogenicity was determined to be greater than 300 mg/kg/day.

Mutagenicity: Virginiamycin was not mutagenic in the Ames test, unscheduled DNA synthesis (UDS), sister chromatid exchange (SCE), or micronucleus tests. It was, however, mutagenic in the mouse lymphoma test and the Chinese hamster ovary assay.

Teratogenicity: Virginiamycin teratogenicity was evaluated in rats at dose levels of 25, 65 or 200 mg/kg/day and in mice at doses of 25, 160 or 1000 mg/kg/day on days 6 through 15 of gestation. In rats, the high-dose (200 mg/kg/day) reduced maternal weight gains and was slightly embryotoxic, affecting pre-implantation loss, but was neither fetotoxic nor teratogenic. No evidence of maternal, embryo or fetus-toxicity or teratogenicity was observed at doses of 25 and 75 mg/kg. The maternal and the fetal NOAELs were 75 mg/kg/day or greater. In mice, no evidence of maternal toxicity or effects on resorption incidence, fetal weight or external, visceral or skeletal development of fetuses were observed at any dose level. The maternal and the fetal NOAELs were 1000 mg/kg/day or greater.

Developmental effects: The subchronic toxicity of virginiamycin was evaluated in rates for three months and in dogs for three and six months. No apparent drug-related effects were seen at any dose level in either species upon administration of virginiamycin at doses of 5, 22.5 and 100 mg/kg for 3 months; the NOAEL in these two studies was 100 mg/kg/day. In a six month toxicity study virginiamycin was given to dogs once daily at dose levels of 25, 200 or 750 mg/kg. No treatment-related effects were seen for the low and middle dose groups. In the high-dose group, treatment-related effects were vomiting, reduced body weight gain and food consumption, blood parameters changes, and reversible proliferated bile duct epithelium adjacent to the liver. The NOAEL in this study was 200 mg/kg/day.

Fertility effects: In a two-generation oral reproductive toxicity study in rats, virginiamycin was administered in the diet at dose levels of 25, 65 or 300 mg/kg/day for ten weeks prior to mating, throughout the mating, gestation and lactation, and during the rest interval between litters. (The high-dose (300 mg/kg/day) was reduced to 100 mg/kg/day in both sexes during mating and in females throughout gestation and lactation as well). No treatment-related effects were observed on survival, mating or pregnancy indexes for adult animals, litter data, pup viability, or pup survival. The NOAEL for reproductive effects in this study was 100 mg/kg/day.

Other potential effects: Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Target organs: May cause damage to the following organs: liver.

Over-exposure signs/symptoms

Inhalation: No specific data.
Ingestion: No specific data.
Skin: No specific data.
Eyes: Adverse symptoms may include the following:
irritation
watering
redness

Medical conditions aggravated by over-exposure: Pre-existing disorders involving any target organs mentioned in this MSDS as being at risk may be aggravated by over-exposure to this product.

See toxicological information (Section 11)
3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Name</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>Trade secret</td>
</tr>
<tr>
<td>Virginiamycin</td>
<td>11006-76-1</td>
<td>Trade secret</td>
</tr>
<tr>
<td>White mineral oil</td>
<td>8042-47-5</td>
<td>Trade secret</td>
</tr>
</tbody>
</table>

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

4. First aid measures

**Eye contact**
- Immediately flush eyes with plenty of water for at least 20 minutes, occasionally lifting the upper and lower eyelids. Get medical attention.

**Skin contact**
- In case of contact, immediately flush skin with plenty of water for at least 20 minutes. Get medical attention.

**Inhalation**
- Move exposed person to fresh air. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Get medical attention.

**Ingestion**
- Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention immediately.

**Protection of first-aiders**
- No action shall be taken involving any personal risk or without suitable training.

**Notes to physician**
- No specific treatment. Treat symptomatically.

5. Fire-fighting measures

**Flammability of the product**
- No specific fire or explosion hazard.

**Extinguishing media**
- Suitable
- Use an extinguishing agent suitable for the surrounding fire.
- Not suitable
- None known.

**Hazardous decomposition products**
- Decomposition products may include the following materials:
  - Carbon dioxide
  - Carbon monoxide

**Special protective equipment for fire-fighters**
- Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

6. Accidental release measures

**Personal precautions**
- Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment (see Section 8).

**Environmental precautions**
- Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

**Spill**
- Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see section 1 for emergency contact information and section 13 for waste disposal.

7. Handling and storage

**Handling**
- Put on appropriate personal protective equipment (see Section 8). Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Do not ingest. Avoid contact with eyes, skin and clothing. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
7. Handling and storage

**Storage**

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

8. Exposure controls/personal protection

### Occupational exposure limits

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>List name</th>
<th>TWA (8 hours) ppm</th>
<th>STEL (15 mins) ppm</th>
<th>Ceiling ppm</th>
<th>Form: [a] Respirable fraction [b] Total dust [c] Total dust</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>US ACGIH 11/2006</td>
<td>5</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>AB 6/2008</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>ON 6/2008</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>QC 6/2008</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Virginiamycin</td>
<td>Phibro</td>
<td>3</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>White mineral oil</td>
<td>-</td>
<td>-</td>
<td>5</td>
<td>-</td>
<td>10</td>
</tr>
</tbody>
</table>

Consult local authorities for acceptable exposure limits.

**Recommended monitoring procedures**

Personal, workplace atmospheric or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment.

**Engineering measures**

Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits.

**Hygiene measures**

Ensure that eyewash stations and safety showers are close to the workstation location. Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period.

**Respiratory**

Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

**Hands**

Use gloves appropriate for work or task being performed. Recommended: Natural rubber (latex).

**Eyes**

Safety eyewear should be used when there is a likelihood of exposure. Recommended: Safety glasses with side shields.

**Skin**

Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Environmental exposure controls**

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

9. Physical and chemical properties

**Physical state**

Solid. [Granular powder.]

**Color**

Brown.

**Odor**

Characteristic fermentation odor.

**Taste**

Bitter. [Strong]

**Solubility**

Very slightly soluble in the following materials: cold water and hot water.
10. Stability and reactivity

Chemical stability: The product is stable.
Conditions to avoid: No specific data.
Materials to avoid: Reactive or incompatible with the following materials: oxidizing materials and alkalis.
Hazardous decomposition products: Under normal conditions of storage and use, hazardous decomposition products should not be produced.
Possibility of hazardous reactions: Under normal conditions of storage and use, hazardous reactions will not occur.
Hazardous polymerization: Under normal conditions of storage and use, hazardous polymerization will not occur.

11. Toxicological information

Acute toxicity

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Result</th>
<th>Species</th>
<th>Dose</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>LD50 Oral</td>
<td>Rat</td>
<td>6450 mg/kg</td>
<td>-</td>
</tr>
<tr>
<td>Virginiamycin</td>
<td>LD50 Oral</td>
<td>Rat</td>
<td>10000 mg/kg</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>LD50 Oral</td>
<td>Mouse</td>
<td>&gt;5000 mg/kg</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>LD50 Oral</td>
<td>Dog</td>
<td>&gt;4000 mg/kg</td>
<td>-</td>
</tr>
</tbody>
</table>

Chronic toxicity: No specific data.

12. Ecological information

Environmental effects: Not established

Aquatic ecotoxicity

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Result</th>
<th>Species</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>Acute LC50 &gt;56000000 ug/L</td>
<td>Fish - Gambusia affinis - Adult</td>
<td>96 hours</td>
</tr>
</tbody>
</table>

13. Disposal considerations

Waste disposal: The generation of waste should be avoided or minimized wherever possible. This material and its container must be disposed of in a safe way. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Empty containers or liners may retain some product residues. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor.

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Refer to Section 7: HANDLING AND STORAGE and Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION for additional handling information and protection of employees.

14. Transport information

TDG/IMDG/IATA: Not regulated.

15. Regulatory information

WHMIS (Canada): Not controlled under WHMIS (Canada).
Canadian lists: CEPA Toxic substances: None of the components are listed.
Canadian ARET: None of the components are listed.
Canadian NPRI: The following components are listed: White mineral oil (Petroleum)
Alberta Designated Substances: None of the components are listed.
Ontario Designated Substances: None of the components are listed.
Quebec Designated Substances: None of the components are listed.

Canada inventory: Not determined.

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.
16. Other information

Date of issue : 12/01/2010
Date of previous issue: 11/15/2010
Version: 2.1

Notice to reader
To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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