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

Product Identifier

Material Name: New Bronz MG

Trade Name: New Bronz
Synonyms: Newcastle (Kimber strain) - Infectious Bronchitis vaccine, Massachusetts (M41) and Holland serotypes + Mycoplasma gallisepticum inactivated vaccine

Chemical Family: Mixture

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

Intended Use: Veterinary Vaccine

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

Contact E-Mail: VMIPSrecords@zoetis.com

2. HAZARDS IDENTIFICATION

Appearance: Pale yellow to reddish-white opaque liquid

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

EU Classification:
EU Indication of danger: Not classified

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

Short Term: This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection. In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. May produce slight eye irritation.

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
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<td>1403-66-3</td>
<td>215-765-8</td>
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<td>Not Listed</td>
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<th>Ingredient</th>
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<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avian Infectious Bronchitis</td>
<td>NA</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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<td>Massachusetts Serotype</td>
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<td>Not Listed</td>
<td>Not Listed</td>
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<td>Avian Infectious Bronchitis Holland</td>
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<td>Serotype</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<td>Newcastle, Kimber Strain</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Adjuvant - Oil Emulsion</td>
<td>NA</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Mycoplasma Gallisepticum</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: ## Trace

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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: None known

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: Formation of toxic gases is possible during heating or fire.

Products:

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
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. Wipe up with a damp cloth and place in container for disposal. Clean contaminated surface thoroughly.

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
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Prevent environmental releases. Use appropriate personal protective equipment. Avoid accidental injection.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Gentamicin
Bulgaria OEL - TWA: 0.1 mg/m³

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.

Gentamicin
Zoetis OEB: OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

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: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Color: Pale yellow to reddish-white
Odor: Odorless
Molecular Formula: Mixture

Solvent Solubility: No data available
Water Solubility: Miscible
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available
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: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
## 10. STABILITY AND REACTIVITY

| Hazardous Decomposition Products: | No data available |

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

#### General Information:
Toxicological properties of the formulation have not been fully investigated. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. The information included in this section describes the potential hazards of the individual ingredients.

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

#### Amphotericin B

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Para-periosteal</td>
<td>LD50</td>
<td>1.6mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>LD50</td>
<td>&gt; 5000mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Intravenous</td>
<td>LD50</td>
<td>1.2mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Intraperitoneal</td>
<td>LD50</td>
<td>27.7mg/kg</td>
</tr>
</tbody>
</table>

#### Gentamicin

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>6600 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Subcutaneous</td>
<td>LD50</td>
<td>710mg/kg</td>
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<tr>
<td>Mouse</td>
<td>IM</td>
<td>LD50</td>
<td>167 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>IM</td>
<td>LD50</td>
<td>463 mg/kg</td>
</tr>
</tbody>
</table>

### Irritation / Sensitization: (Study Type, Species, Severity)

#### Gentamicin
Eye Irritation  Rabbit  Non-irritating

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

#### Amphotericin B

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
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</thead>
<tbody>
<tr>
<td>30 Day(s)</td>
<td>Dog</td>
<td>Intravenous</td>
<td>37 mg/kg/day</td>
<td>LOAEL</td>
<td>Kidney</td>
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<tr>
<td>2 Month(s)</td>
<td>Dog</td>
<td>Intravenous</td>
<td>16.5 mg/kg/day</td>
<td>LOAEL</td>
<td>Kidney</td>
</tr>
<tr>
<td>13 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>2 mg/kg/day</td>
<td>NOAEL</td>
<td>Male reproductive system, Female reproductive system</td>
</tr>
<tr>
<td>13 Week(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>1.6 mg/kg/day</td>
<td>NOAEL</td>
<td>Male reproductive system, Female reproductive system</td>
</tr>
</tbody>
</table>

#### Gentamicin

Embryo / Fetal Development  Rat  Oral  7.5 mg/kg/day  NOAEL  Not teratogenic, Fetotoxicity
Embryo / Fetal Development  Rabbit  Oral  10 mg/kg/day  NOAEL  Not Teratogenic, Fetotoxicity

### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### Amphotericin B

#### Gentamicin

Embryo / Fetal Development  Rat  Intramuscular  75 mg/kg/day  LOAEL  Developmental toxicity

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

ZT00238
11. TOXICOLOGICAL INFORMATION

Amphotericin B
Bacterial Mutagenicity (Ames)  Salmonella, E. coli  Negative
In Vivo Micronucleus  Mouse  Negative
In Vitro Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Negative

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

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly 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.

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
### 15. REGULATORY INFORMATION

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**
None required

#### Gentamicin

<table>
<thead>
<tr>
<th>Standard for the Uniform Scheduling for Drugs and Poisons:</th>
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</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Australia (AICS): Schedule 4</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>215-765-8</td>
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</tbody>
</table>

#### Avian Infectious Bronchitis Massachusetts Serotype

<table>
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<tr>
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#### Avian Infectious Bronchitis Holland Serotype

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<td>EU EINECS/ELINCS List</td>
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#### Newcastle, Kimber Strain

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#### Adjuvant - Oil Emulsion

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#### Mycoplasma Gallisepticum

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#### Amphotericin B

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</tbody>
</table>

### 16. OTHER INFORMATION

**Data Sources:**
The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.
Reasons for Revision:
Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

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