

# SAFETY DATA SHEET

## Nilvax<sup>®</sup> Selenised

### Section 1: Identification of the Substance and Supplier

|                            |  |
|----------------------------|--|
| <b>Product name</b>        | <b>Nilvax Selenised</b>  |
| <b>Recommended use</b>     | Combination clostridial vaccine and drench for sheep.  |
| <b>Company details</b>     | <b>Schering-Plough Animal Health Limited</b><br><b>33 Whakatiki Street, Upper Hutt</b><br><br>Phone: 0800 800 543 Fax: 0800 808 100 Website: www.spah.co.nz<br>Hours 8am – 5 pm, Mon – Fri |
| <b>Emergency telephone</b> | <b>0800 764 766 (0800 POISON) 24 hours human health</b><br><b>0800 243 622 (0800 CHEMCALL) 24 hours</b>  |
| <b>Date of preparation</b> | January 2007   |

### Section 2: Hazards Identification

|                                  |  |
|----------------------------------|--|
| <b>Hazard classifications</b>    | 6.1E, 6.5B, 6.6B, 6.9B   |
| <b>Priority identifiers</b>      | <b>Warning – Keep out of reach of children</b>   |
| <b>Secondary identifier</b>      | 6.1E May be harmful if swallowed, inhaled or absorbed through the skin<br>6.5B May cause an allergic skin reaction<br>6.6B Suspected of causing genetic defects<br>6.9B May cause damage to the blood and hematopoietic system through prolonged or repeated oral exposure at high doses |
| <b>Risk &amp; Safety Phrases</b> | R22 Harmful if swallowed<br>R48/22 Harmful: danger of serious damage to health by prolonged exposure if swallowed  |

### Section 3: Composition/Information on Ingredients

| <b>Chemical name</b>                                | <b>CAS number</b> | <b>Concentration</b> |
|---|-------------------|----------------------|
| <i>C. chauvoei</i> whole cell culture (inactivated) | -                 | Varies               |
| <i>C. novyi</i> Type B toxoid (inactivated)         | -                 | Varies               |
| <i>C. perfringens</i> Type D toxoid (inactivated)   | -                 | Varies               |
| <i>C. septicum</i> toxoid (inactivated)             | -                 | Varies               |
| <i>C. tetani</i> toxoid (inactivated)               | -                 | Varies               |
| Levamisole Phosphate                                | 32093-35-9        | 10%                  |
| Sodium selenate                                     | 13410-01-0        | <1%                  |
| Thiomersal (Preservative)                           | 54-64-8           | <1%                  |

**Section 4: First Aid Measures****Necessary first aid measures**

**ACCIDENTAL SELF-INJECTION:** Obtain medical attention - show this SDS. Accidental self injection may lead to an inflammatory response and medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. If possible the application of gentle squeezing pressure with absorbent material (e.g. facial tissues) at the injection site will swab up unabsorbed vaccine. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied.

**SKIN CONTACT:** In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a doctor.

**EYE CONTACT:** In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a doctor.

**INGESTION:** Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Centre. If symptoms persist, consult a doctor.

**INHALATION:** Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a doctor.

**Required instructions**

For advice contact the National Poisons Centre 0800 POISON (0800 764 766) or a doctor.

**Notes for medical personnel**

Accidental self-injection: Treat symptomatically. Some risk of hypersensitivity from injection. Contains safety tested inactivated bacterial toxins. Contamination of the needle must be considered.

Inhalation: remove to fresh air & provide oxygen if breathing is difficult

**Workplace facilities**

Emergency showers and eyewashes may be warranted depending on quantity and type of use.

**Section 5: Fire Fighting Measures****Type of hazard**

Not classified as flammable

**Fire hazard properties**

Not applicable

**Regulatory requirements**

Not applicable

**Extinguishing media and methods**

Carbon dioxide (CO<sub>2</sub>), extinguishing powder or water spray

**Hazchem code**

2X

**Recommended protective clothing**

Wear full protective clothing and self-contained breathing apparatus (SCBA).

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### Section 6: Accidental Release Measures

|                             |  |
|-----------------------------|--|
| <b>Emergency procedures</b> | Wear chemical resistant gloves and overalls, facemask or goggles. Prevent further spillage. Adsorb spilled product and place in sealable container for disposal. Wash down affected area with water plus detergent. Absorb and collect washings and place in the same sealable container for disposal. Seek advice from the local authority regarding disposal. Avoid contamination of any water source or soil with product or empty container. |
|-----------------------------|--|

### Section 7: Handling and Storage

|                                      |  |
|--------------------------------------|--|
| <b>Precautions for safe handling</b> | Avoid contact with skin, eyes, and mucosa. Keep containers adequately sealed during material transfer, transport, or when not in use. See Section 8 (Exposure Controls) for additional guidance. |
| <b>Regulatory requirements</b>       | Emergency response plan required where quantities greater than 1000L are present.  |
| <b>Handling practices</b>            | Avoid contact with skin. Keep containers adequately sealed during material transfer, transport, or when not in use.  |
| <b>Approved handlers</b>             | Not required   |
| <b>Conditions for safe storage</b>   | Store in original container in a cool, dry, ventilated place away from direct heat or direct sunlight. Keep container sealed when not in use.  |
| <b>Store site requirements</b>       | Store between 2 and 8°C. DO NOT FREEZE.<br>Store in dark container or away from light.   |
| <b>Packaging</b>                     | PGIII  |

### Section 8: Exposure Control/Personal Protection

|   |  |
|---|--|
| <b>Workplace exposure standards</b>             | None set for this substance  |
| <b>Application in the workplace</b>             | Ensure adequate ventilation. Keep container sealed when not in use.  |
| <b>Exposure standards outside the workplace</b> | No TEL is set for this substance at this time<br>EEL - not applicable  |
| <b>Personal protection</b>                      | Wear chemical resistant gloves, facemask or goggles.   |
| <b>Engineering controls</b>                     | The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment. |

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### Section 9: Physical and Chemical Properties

|                               |  |
|-------------------------------|--|
| Appearance                    | Clear to turbid, colourless to white, liquid |
| Boiling Point                 | 100°C  |
| Melting/Softening point       | Not applicable                               |
| Vapour Pressure               | Not determined                               |
| Specific Gravity              | 1.0  |
| Solubility (H <sub>2</sub> O) | Soluble                                      |
| Percent Volatiles             | Not determined                               |
| Evaporation Rate              | Not determined                               |

### Section 10: Stability and Reactivity

|   |                                  |
|---|----------------------------------|
| <b>Stability of the substance</b>       | Stable under normal conditions.  |
| <b>Conditions to avoid</b>              | Avoid high temperatures          |
| <b>Material to avoid</b>                | Avoid food products              |
| <b>Hazardous decomposition products</b> | Carbon oxides (CO <sub>x</sub> ) |

### Section 11: Toxicological Information

#### Acute effects for individual ingredients only

|      |  |
|------|--|
| ORAL | Levamisole: LD50 294.12mg/kg bw [ERMA]<br>Sodium selenate: LD50 25mg/kg/bw [INCLASS]<br>Sodium selenate: Toxic by inhalation [INCLASS]<br>Thiomersal: LD50 40mg/kg/bw (rat) [ERMANZ] |
| TEL  | No TEL is set for this substance at this time.   |

#### Chronic/long term effects for individual ingredients only

Levamisole: Levamisole induced chromosome gaps and breaks in human lymphocytes in vitro and in vivo after volunteers were given 2 mg/kg. No chromosomal damage occurred in mice given 2.5 mg/kg subcutaneously. Levamisole; ADI of 0-6 µg/kg based on LOAEL of 1.25 mg/kg/day haemolytic effects in dogs, safety factor of 200. MRLs of 100 µg/kg in muscle, kidney and fat and 100 µg/kg for liver.

Sodium selenate: NOAEL of 0.37mg/kg/bw/day for Hepatotoxicity/ Alimentary system (liver) effects based on [Hayes, W.J., Jr., E.R. Laws, Jr., (eds.). New York, NY: Academic Press, Inc., 1991. 558] [HSDB]

Thiomersal has been documented as a sensitiser. [All references from NTP]

### Section 12: Environmental Information

#### Effects for individual ingredient only

|     |                |
|-----|----------------|
| EEL | Not applicable |
|-----|----------------|

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### Section 13: Disposal Considerations

|                             |  |
|-----------------------------|--|
| <b>Disposal information</b> | <b>Disposal</b><br>Dispose of this product only by using according to the label, or at an approved landfill, or other approved facility. |
|                             | <b>Container Disposal</b><br>Crush or puncture and bury in a suitable landfill.  |
| <b>Reference</b>            | Current version of NZS 8409 Management of Agrichemicals  |

### Section 14: Transport Information

|                             |  |
|-----------------------------|--|
| <b>Relevant information</b> | Not classified as a dangerous good for transport |
|-----------------------------|--|

### Section 15: Regulatory Information

|                               |   |
|-------------------------------|---|
| <b>Regulatory status</b>      | ERMA Approval Code: HSR002293<br>For full listings of controls see <a href="http://www.ermanz.govt.nz">www.ermanz.govt.nz</a><br>ACVM Registration No: A3977<br>For conditions of registration see <a href="http://www.nzfsa.govt.nz/acvm/">www.nzfsa.govt.nz/acvm/</a> |
| <b>HSNO and ACVM controls</b> | <b>Emergency Plan:</b> 1,000 Litres   |

### Section 16: Other Information

|                               |  |
|-------------------------------|--|
| <b>Additional information</b> | ® Registered trademark of Schering-Plough Animal Health Limited. |
|-------------------------------|--|

Schering-Plough urges each user or recipient of this SDS to read the entire data sheet to become aware of the potential hazards associated with this material. This SDS summarises, at the date of issue, our best knowledge of the health and safety hazard information. Although reasonable care has been taken in the preparation of this document, Schering-Plough Animal Health Ltd extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).