Essex Animal Health Friesoythe
A division of Essex Pharma GmbH
Sedelsberger StraBe 2-4
26169 Friesoythe
Germany

SAFETY DATA SHEET

MSD Animal Health urges each user or recipient of this SDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

SDS NAME: **Sodium Selenite Solutions for Injection**

SYNONYM(S): Sodium Selenite Solutions for Injection
E-SE Injection
BO-SE Injection

SDS Number: SP000363

EMERGENCY NUMBER(S): +1 (908) 423-6000 (24/7/365) English Only

(49) (4491) 294-0 (Essex Animal Health Friesoythe)

EU Transportation Emergencies - Carechem24:
+44 (0)208 762 8322 (24 hours/7 days/week)

INFORMATION: (49) (4491) 294-0 (Essex Animal Health Friesoythe)

MERCK SDS HELPLINE: +1 (908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SDS EMAIL: spmsds@spcorp.com

SECTION 2. HAZARDS IDENTIFICATION

EU CLASSIFICATION(S): Xn;R22

EMERGENCY OVERVIEW

Amber
Viscous liquid
Odor unknown
Harmful if swallowed.
May cause allergic reactions in susceptible individuals.
May be irritating to eyes, skin or respiratory tract.
May cause effects to:
gastrointestinal tract
respiratory system
central nervous system
Harmful to aquatic organisms.
May cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS:

The information presented below pertains to the following individual ingredients, and not to the mixture(s).

Vitamin E may cause skin and eye irritation following acute exposure. Oral ingestion to large amounts may cause diarrhea, abdominal pain, and other gastrointestinal disturbances, blurred vision, dizziness, fatigue and weakness. Contact dermatitis has occurred following topical application.

In animal reproduction studies, Vitamin E has been shown to cause developmental effects; however, there are limited data to show that no malformations were reported in children of women who ingested high daily doses of Vitamin E during pregnancy. Therefore the relevance of the animal data to human experience is inconclusive.

All selenium salts can produce toxicity by ingestion, inhalation, and dermal absorption; however, acute poisonings with selenium and its salts are rare. Selenium dusts may cause severe eye irritation and inhalation may cause headache, cough, nasal discharge, upper respiratory tract irritation, pulmonary edema, nose bleed, olfactory fatigue, and transient difficulty in breathing. Chronic selenium poisoning may cause nausea, vomiting, white streaks in the nails, pallor, upper respiratory irritation, inflammation of the tissue surrounding a fingernail or toenail, hair loss, skin rashes, irritability, fatigue, hyperreflexia, EKG changes, a garlic odor on the breath, and a metallic taste in the mouth.

Benzyl alcohol is corrosive and irritating at high concentrations. It causes eye irritation and can be absorbed through the skin with anesthetic or irritant effect. Acute exposure to benzyl alcohol may cause nausea, vomiting, diarrhea, central nervous system depression, and dizziness. Inhalation of benzyl alcohol or its vapor may cause irritation of upper respiratory tract. When ingested, benzyl alcohol may produce severe irritation of the gastrointestinal tract, followed by nausea, vomiting, cramps and diarrhea; tissue lesions may result. Chronic exposure to benzyl alcohol has been reported to cause allergic contact inflammation. Its effects are presumed to be similar to those effects observed following acute exposure. Prolonged or excessive inhalation may result in headache, nausea, vomiting, and diarrhea. Respiratory stimulation, respiratory and muscular paralysis, convulsions, narcosis, and death may occur following excessive exposure.

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by IARC or EU Directive 90/394 (Annex I) in this mixture.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Veterinary product

CHEMICAL FORMULA: Mixture.

The formulations for these products are proprietary information. These formulations have the same hazardous profile; however, the presence of hazardous ingredients may vary by formulation. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

This formulation may contain some hydrochloric acid and/or sodium hydroxide for pH adjustment.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	EC NUMBER	EU CLASSIFICATION	PERCENT
Vit E Acetate Usp Dl-Alph Toco Acet	7695-91-2	231-710-0		5-5.15

INGREDIENT	CAS NUMBER	EC NUMBER	EU CLASSIFICATION	PERCENT
Sodium Selenite	10102-18-8	233-267-9	T; R23 T+; R28 R31 R43 N; R51-53	0.2-0.5
Benzyl Alcohol	100-51-6	202-859-9	Xn; R20/22	< 10

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

See section 15 for EU hazard classification symbols and risk and safety phrases.

SECTION 4. FIRST AID MEASURES

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 physician.

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 physician.

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 physician.

INGESTION: Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. IMMEDIATELY consult a physician. Do not attempt to give anything by mouth to a seizing, drowsy or unconscious person. If alert, rinse mouth and drink a glass of water.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO2), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:
Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

SPILL RESPONSE / CLEANUP:
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

ENVIRONMENTAL PRECAUTIONS:
Do not allow product to reach ground water, water course, sewage or drainage systems.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

HANDLING:
Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is 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. See Section 8 (Exposure Controls) for additional guidance.

CONDITIONS FOR SAFE STORAGE, INCLUDING ANY IMCOMPATIBILITIES

STORAGE:
Store in a cool, dry, well ventilated area.

SPECIFIC END USE(S)
Refer to Section 1 for identified use(s).

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

EXPOSURE CONTROLS
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.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.
Skin Protection:	Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.
Eye Protection:	Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.
Body Protection:	In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance. In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

EXPOSURE LIMIT VALUES:

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)
Sodium Selenite	10102-18-8	0.2 mg/m^3		

INGREDIENT	CAS NUMBER	EU	Austria	Belgium	Denmark	France
Sodium Selenite	10102-18-8		STEL 0.3 mg/m^3 MAK 0.1 mg/m^3	TWA 0.2 mg/m^3	TWA 0.1 mg/m^3	

INGREDIENT	CAS NUMBER	Germany	Ireland	Italy	Netherlands
Sodium Selenite	10102-18-8	MAK 0.02 mg/m^3 S* Peak 0.16 mg/m^3	TWA 0.1 mg/m^3		

INGREDIENT	CAS NUMBER	Norway	Portugal	Spain	Switzerland	UK:
Sodium Selenite	10102-18-8	STEL 0.15 mg/m^3 TWA 0.05 mg/m^3	TWA 0.2 mg/m^3	VLA-ED 0.1 mg/m^3	STEL 0.16 mg/m^3 S* MAK 0.02 mg/m^3	STEL 0.3 mg/m^3 TWA 0.1 mg/m^3

No exposure limits are available for the active ingredient(s) or any other hazardous ingredient in this formulation.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Viscous liquid
COLOR: Amber
ODOR: Odor unknown
SOLUBILITY:
Water: Not determined

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under conditions specified in Section 7 of this SDS. No hazardous reactions known.

CONDITIONS AND MATERIALS TO AVOID:
Acids.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
No dangerous decomposition is expected if used according to manufacturer's specifications.

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture(s).

ACUTE TOXICITY DATA

SKIN:
Vitamin E: Dermal LD50: > 3000 mg/kg (rat)

Vitamine E acetate was not irritating to the skin of rabbits.

Benzyl alcohol: Dermal LD50: 2000 mg/kg (rabbit)
Benzyl alcohol was moderately irritating to the skin of guinea pigs and rabbits.

EYE:
Vitamin E acetate was not irritating to the eyes of rabbits.

Sodium selenite caused very severe injury to the eyes of rabbits.

Benzyl alcohol was severely irritating to the eyes of rabbits.

ORAL:
Vitamin E Acetate: Oral LD50: > 5000 mg/kg (rat)

Sodium Selenite: Oral LD50: 7 mg/kg (rat)

Benzyl alcohol: Oral LD50: 1230 mg/kg (rat)

DERMAL AND RESPIRATORY SENSITIZATION:
Vitamin E acetate was not a skin sensitizer in guinea pigs.

Benzyl alcohol was not a skin sensitizer in guinea pigs.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Vitamin E acetate did not cause adverse clinical effects in rats given dosages of 500 to 2000 mg/kg for 13 weeks or for 104 weeks. Liver weight changes and minor increases in liver enzymes were noted in the 104-week study.

Sodium Selenite given rats at 6.4 mg/kg (diet) caused significant depression, liver cirrhosis and inlarged spleen, diets containing 8.0 mg/kg caused anemia pancreatic enlargement, elevated serum bilirubin levels and death after 4 weeks. Rats received selenium (as sodium selenate) at a dietary level of 100 ppm ate little food and all died in 8-16 days; all those receiving 50 ppm died in 10-97 days. A dietary level of 15 ppm was tolerated for 72 days or more, but food intake was about half of normal. All rats survived a dietary level of 7.5 ppm (about 0.37 mg/kg/day) for 6 months, and their growth was normal.

Hamsters given dietary levels of 0.1, 1, 5, 10 or 20 ppm selenium for 42 days were not adversely affected at any of the dose levels. Hamsters fed 10 or 20 ppm retained considerable higher levels of selenium in the liver than did the controls. Microscopic examination of the liver revealed degenerative changes in males and females in the 20 ppm group. The nontoxic effect level of selenium fed in the diet for 42 days to hamsters was found to be 10 ppm, (0.7 mg selenium /kg/day).

Benzyl alcohol caused dose-related effects in rats given oral dosages of 50 to 800 mg/kg/day for 13 weeks. Rats showed reductions in weight gain and also signs of staggering, lethargy, and respiratory difficulty, indicating neurotoxicity at the high dosage. Hemorrhages around the mouth and nose, and histological lesions in the brain, thymus, skeletal muscle, and kidney were also noted. Mice tested under similar conditions exhibited similar effects.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Vitamin E acetate was not teratogenic in rats given 22.5 to 2250 mg/kg.

Sodium Selenite injected subcutaneously in female mice on day 12 of gestation, resulted in dose dependent fetocidal effects and fetal growth retardation. Abortions occurred on day 12, at a dose of 58.8 u mol/kg sodium selenite, whereas on day 16 abortions occurred at both 27.2 and 40.0 u mol/kg.

Benzyl alcohol did not affect the gestation index, reproductive index, litter size, average litter weight, or postnatal weight gain or survival when given to rats by gavage during days 6 to15 of gestation.

MUTAGENICITY / GENOTOXICITY:
Vitamin E acetate was negative in a bacterial mutagenicity study (Ames) and in a chromosome aberration study with human lymphocytes.

Benzyl alcohol was negative in bacterial mutagenicity study (Ames) and was positive in a mammalian mutagenicity study (mouse lymphoma).

CARCINOGENICITY:
Vitamin E acetate was not carcinogenic in rats given dosages of 500 to 2000 mg/kg/day for 104 weeks.

The carcinogenicity of selenium compounds has been evaluated in several animal studies. However, the data are conflicting and difficult to interpret because of the anticarcinogenic activity and high toxicity observed with some selenium salts.

Benzyl alcohol was not carcinogenic in a 2 year oral gavage study in rats administered doses of up to 400 mg/kg/day for 5 days a week or in mice at doses up to 200 mg/kg/day for 5 days per week.

SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY

Vitamin E acetate: 96-hr NOEL (zebra fish): > 100 mg/L
Vitamin E acetate: 48-hr NOEL (daphnid): > 100 mg/L
Vitamin E acetate: Algal Growth Inhibition: > 100 mg/L

Benzyl alcohol: 96-hr LC50 (fathead minnow): 460 mg/L
Benzyl alcohol: 48-hr EC50 (daphnid): 400 mg/L
Benzyl alcohol: 96-hr NOEL (E. coli): 1000 ppm

Selenium: 48-hr LC50 (daphnid): 0.43-0.71 mg/L
Selenium: 96-hr LC50 (fathead minnow): 1 mg/L

ENVIRONMENTAL DATA

OTHER INGREDIENT ENVIRONMENTAL DATA:

Vitamin E acetate is not readily biodegradable, but is inherently biodegradable.

Benzyl alcohol is expected to be readily biodegradable. Benzyl alcohol is characterized as a high risk air pollutant because it may emit toxic vapors when heated.

SECTION 13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT METHODS

MATERIAL WASTE:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SPECIAL ENVIRONMENTAL HANDLING PROCEDURES:
Do not allow product to reach ground water, water courses, sewage or drainage systems.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION

The following classification is based on available data and is in accordance with European Union criteria.

EUROPEAN UNION REGULATIONS:

Indication of Danger: Xn - Harmful.

Risk Phrases:
R22 - Harmful if swallowed.

Safety Phrases:
S 2 - Keep out of reach of children.
S46 - If swallowed, seek medical advice immediately and show this container or label.

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we 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).

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