SAFETY DATA SHEETS

This SDS packet was issued with item:

078949373

N/A

SECTION 1: IDENTIFICATION

1.1 Product identifier	
Product name	Sulforal
Chemical name	Not Applicable
Synonyms	Sulfadimethoxine oral solution
Chemical formula	Not Applicable
Other means of identification	Not Available
1.2 Recommended use of the chemical and restrictions on use	
Relevant identified uses	Veterinary pharmaceutical oral antibacterial solution. Not for human use.
1.3 Details of the supplier of the substance or mixture	
Registered company name (US)	Dechra Veterinary Products
Address	7015 College Blvd Suite 525 Overland Park, KS 66211 USA
Telephone	866-933-2472
Fax	Not Available
Email	Not Available
1.4 Emergency telephone numbers	
Dechra (US)	866-933-2472

SECTION 2: HAZARD(S) IDENTIFICATION

2.1 Classification of the substance or mixture

NFPA 704 diamond

Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Classification	Skin Corrosion/Irritation Category 2, Sensitization (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2A
2.2 Label elements	
Hazard pictogram(s)	
Signal word	**Warning**
Hazard statement(s)	
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
Hazard(s) not otherwise classified	Not Applicable
Precautionary statement(s) Prevention	
P261	Avoid breathing mist/vapours/spray.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
P264	Wash all exposed external body areas thoroughly after handling.
P272	Contaminated work clothing must not be allowed out of the workplace.
Precautionary statement(s) Response	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P302+P352	IF ON SKIN: Wash with plenty of water.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Precautionary statement(s) storage	Not Applicable
Precautionary statement(s) disposal	
P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

See section below for composition of Mixtures

3.2 Mixtures

CAS No.	% [weight]	Name
122-11-2	10-30	sulfadimethoxine
Not Available	balance	Ingredients determined not to be hazardous

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

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

4.2 Most important symptoms and effects, both acute and delayed

See section 11.

4.3 Indication of immediate medical attention and special treatment needed

Treat symptomatically.

In cases of recent sulfonamide overdose, the stomach should be emptied by aspiration and lavage. If kidney function is adequate, a saline purgative, such as sodium sulfate, 30 g in 250 ml water, may be given to promote peristalsis and elimination of sulfonamide in the urine may be assisted by giving alkalies, such as sodium bicarbonate and increasing fluid intake. Severe crystalluria may require ureteric catheterization and irrigation with warm 2.5% sodium bicarbonate solution. Treatment should be continued until it can be assumed that the sulfonamide has been eliminated. The majority of sulfonamides are metabolised to acetylated derivatives which retain the toxicity of the parent compound and thus may indicate more active removal when adverse effects are very severe. Active measures may include forced diuresis, peritoneal dialysis and charcoal hemoperfusion. [*Martindale: The Extra Pharmacopoeia, 28th Ed.*]

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas. Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances. In such an event consider foam, dry chemical powder, or carbon dioxide

5.2 Special hazards arising from the substance or mixture

Fire incompatibility	None known.

5.3 Special protective actions for fire-fighters:

Firefighting	Alert Fire Brigade and tell them location and nature of hazard. Wear full body protective clothing with self-contained breathing apparatus (SCBA). Prevent, by any means available, spillage from entering drains or water course. Avoid spraying water onto liquid pools. **DO NOT** approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire.
Fire / explosion hazard	Under normal conditions of use, this material does not present a significant fire or explosion hazard. The material is not readily combustible under normal conditions. However, it will break down under fire conditions and the organic component may burn. Not considered to be a significant fire risk. Heat may cause expansion or decomposition with violent rupture of containers. Decomposes on heating and may produce toxic fumes of carbon monoxide. May emit acrid smoke. Decomposes on heating and produces toxic fumes of: carbon dioxide, nitrogen oxides, sulfur oxides. other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear appropriate personal protective equipment. Keep personnel away from the clean-up area. Avoid dust formation, dampen with water to prevent dusting before sweeping. Avoid breathing dust, vapors, mist or gas. Ensure adequate ventilation. For personal protection see section 8.

6.2 Environmental precautions

See Section 12.

6.3 Methods and material for containment and cleaning up

Minor spills	All spills should be handled according to site requirements and based on precautions cited in the SDS. 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 vacuum or wet cleaning methods as appropriate.
Major spills	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, vacuuming prior to wet mopping or cleaning is required. Dispose in accordance with local, state and federal regulations regarding health, water and air pollution.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe handling	**DO NOT** allow clothing wet with material to stay in contact with skin. Avoid all personal contact, including skin, eye, and inhalation. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation in places where dust and aerosols are formed. Wear protective clothing when risk of overexposure occurs. **DO NOT** enter confined spaces until atmosphere has been checked. When

	handling, **DO NOT** eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers. Use good occupational work practice. Observe manufacturer's storage and handling recommendations contained within this SDS.
Other information	Store in original containers. Keep containers securely sealed. Store in a cool, dry, well-ventilated area. Store away from incompatible materials and foodstuff containers. Store at room temperature between 15-30°C (59-86°F). Store upright and out of direct sunlight. Store away from ignition sources.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable container	Glass container is suitable for lab quantities and polyethylene/polypropylene container for large quantities. Packing as recommended by manufacturer.
Storage incompatibility	None known.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits (OEL)
INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
US OSHA Permissible Exposure Limits (PELs) Table Z-1	sulfadimethoxine	Particulates Not Otherwise Regulated (PNOR)- Total dust	15 mg/m^3	Not Available	Not Available	Not Available
US OSHA PELs Table Z-1	sulfadimethoxine	PNOR- Respirable fraction	5 mg/m^3	Not Available	Not Available	Not Available
US OSHA PELs Table Z-3	sulfadimethoxine	Inert or Nuisance Dust: Respirable fraction	5 mg/m^3 / 15 mppcf	Not Available	Not Available	Not Available
US OSHA PELs Table Z-3	sulfadimethoxine	Inert or Nuisance Dust: Total Dust	15 mg/m^3 / 50 mppcf	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)	sulfadimethoxine	PNOR	Not Available	Not Available	Not Available	See Appendix D
US OSHA PELs Table Z-1	sulfadimethoxine	PNOR- Total dust	15 mg/m^3	Not Available	Not Available	Not Available

Emergency limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
Sulforal	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
sulfadimethoxine	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
sodium carbonate	E	≤ 0.01 mg/m³
disodium edetate	E	≤ 0.01 mg/m³

Notes: Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical'spotency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposureband (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

MATERIAL DATA

8.2 Exposure controls

Appropriate engineering controls	Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg. When handling quantities up to 500 g in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kg may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kg should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology. Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.
Personal protection	
Eye and face protection	When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs: use chemical goggles or face shields. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants.
Skin protection	See Hand protection below.
Hands/feet protection	The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).
Body protection	See Other protection below.
Other protection	For quantities up to 500 g a laboratory coat may be suitable. For quantities up to 1 kg a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. For quantities over 1 kg and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers. For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection. Eye wash unit.

	Ensure there is ready access to an emergency shower. For Emergencies: Vinyl suit
Respiratory protection	A respirator is not required for routine conditions of use of this product. 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. Type -P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Clear, pale yellow to brown liquid	Vapor density: Not Available
Physical state: Liquid	Auto ignition temperature (°C): Not Available
Odor: Practically no odor	Decomposition temperature (°C): Not Available
Odor threshold: Not Available	Viscosity (°C): Not Available
pH (as supplied): Not Available	Explosive properties: Not Available
Melting point / freezing point (°C): Not Available	Oxidizing properties: Not Available
Initial boiling point and boiling range: Not Available	Partition coefficient: Not Available
Flash point (°C): Not Available	Molecular weight: Not Available
Evaporation rate: Not Available	Taste: Not Available
Flammability: Not Available	Surface tension: Not Available
Upper/lower flammability or explosive limits: Not Available	Volatile component (%vol): Not Available
Vapor pressure: Not Available	Gas group: Not Available
Relative density (Water = 1): Not Available	pH as a solution: Not Available
Solubility in water (mg/l): Miscible	VOC g/L: Not Available
	Specific gravity @ 20°C (water = 1): Not Available

SECTION 10: STABILITY AND REACTIVITY

Reactivity	See Section 7
Chemical stability	Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur.
Possibility of hazardous reactions	See Section 7
Conditions to avoid	See Section 7
Incompatible materials	See Section 7
Hazardous composition	See Section 5

SECTION 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhalation	The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Not normally a hazard due to non-volatile nature of product.
Ingestion	Accidental ingestion of the material may be harmful to the health of the individual.
Skin contact	Evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals.
Eye contact	Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals.
Chronic	Practical experience shows that skin contact is capable either inducing a sensitization reaction in a substantial number of individuals, and/or of producing a positive response in experimental animals. Substances that can cause occupational asthma can induce a state of specific airway hyper-responsiveness. There is some evidence to provide a presumption that human exposure to the material may result in impaired fertility on the basis of: evidence in animal studies. Exposure to the material may cause concerns for humans owing to possible developmental toxic effects, on the basis that similar materials tested in appropriate animal studies.

Sulforal	**Acute toxicity**	**Irritation**
	Not Available	Not Available
sulfadimethoxine	**Acute toxicity**	**Irritation**
	Oral (rabbit) LD_{50}: >1000 mg/kg[2]	Not Available

1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

Acute Toxicity	✘	Carcinogenicity	✘
Skin Irritation/Corrosion	✓	Reproductivity	✘
Serios Eye Damage/Irritation	✓	STOT – Single Exposure	✘
Respiratory or Skin Sensitization	✓	STOT – Repeated Exposure	✘
Mutagenicity	✘	Aspiration Hazard	✘

✘ - Data either not available or does not fill the criteria for classification, ✓ - Data available to make classification.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Sulforal	**Endpoint**	**Test Duration**	**Species**	**Value**	**Source**
	Not Available	Not Available	Not Available	Not Available	Not Available
sulfadimethoxine	**Endpoint**	**Test Duration**	**Species**	**Value**	**Source**
	LC50	96h	Fish	>100mg/l	4
	EC50	48h	Crustacea	151.83-215.9mg/l	4
	EC10(ECx)	168h	Algae or other aquatic plants	0.019-0.097mg/l	4

Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8.Vendor Data

Toxic to soil organisms.

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

Ingredient	**Persistence: Water/Soil**	**Persistence: Air**
sulfadimethoxine	HIGH	HIGH

12.3 Bioaccumulative potential

Ingredient	**Bioaccumulation**
sulfadimethoxine	LOW (LogKOW = 1.2889)

12.4 Mobility in soil

Ingredient	**Mobility**
sulfadimethoxine	LOW (KOC = 883.2)

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product/ packaging disposal	Containers may still present a chemical hazard/ danger when empty. Return to supplier for reuse/ recycling if possible. Otherwise: If container cannot be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. Where possible retain label warnings and SDS and observe all notices pertaining to the product. **DO NOT** allow wash water from cleaning or process equipment to enter drains. Where in doubt contact the responsible authority.

SECTION 14: TRANSPORT INFORMATION

Labels required

Marine pollutant	NO

Land transport (DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	**Group**
sulfadimethoxine	Not Available

Transport in bulk in accordance with ICG Code

Product name	**Group**
sulfadimethoxine	Not Available

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations / legislation specific for thesubstance or mixture

Product regulated by FDA as a veterinary product.

sulfadimethoxine is found on the following regulatory lists

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS), US - Alaska Air Quality Control - Concentrations Triggering an Air Quality Episode for Air Pollutants Other Than PM-2.5, US NIOSH Recommended Exposure Limits (RELs), US OSHA Permissible Exposure Limits (PELs) Table Z-1, US OSHA PELs Table Z-3

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Section 311/312 hazard categories

Flammable (Gases, Aerosols, Liquids, or Solids)	No
Gas under pressure	No
Explosive	No
Self-heating	No
Pyrophoric (Liquid or Solid)	No
Pyrophoric Gas	No
Corrosive to metal	No
Oxidizer (Liquid, Solid or Gas)	No

Organic Peroxide	No
Self-reactive	No
In contact with water emits flammable gas	No
Combustible Dust	No
Carcinogenicity	No
Acute toxicity (any route of exposure)	No
Reproductive toxicity	No
Skin Corrosion or Irritation	Yes
Respiratory or Skin Sensitization	Yes
Serious eye damage or eye irritation	Yes
Specific target organ toxicity (single or repeated exposure)	No
Aspiration Hazard	No
Germ cell mutagenicity	No
Simple Asphyxiant	No
Hazards Not Otherwise Classified	No

US. EPA CERCLA Hazardous Substances and Reportable Quantities (40 CFR 302.4)
None reported

State Regulations
US. California Proposition 65
None listed

National Inventory Status	
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	No (sulfadimethoxine)
Canada - NDSL	No (sulfadimethoxine)
China - IECSC	Yes
Europe - EINEC / ELINCS /NLP	Yes
Japan - ENCS	Yes
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	No (sulfadimethoxine)
Taiwan - TCSI	Yes
Mexico - INSQ	No (sulfadimethoxine)
Vietnam - NCI	Yes
Russia - FBEPH	No (sulfadimethoxine)

Yes = All CAS declared ingredients are on the inventory
No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will requireregistration

SECTION 16: OTHER INFORMATION

Initial date: March 2023

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references. The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average
PC—STEL: Permissible Concentration-Short Term Exposure Limit
IARC: International Agency for Research on Cancer
ACGIH: American Conference of Governmental Industrial Hygienists
IDLH: Immediately Dangerous to Life or Health Concentrations
AIIC: Australian Inventory of Industrial Chemicals
IECSC: Inventory of Existing Chemical Substance in China
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European List of Notified Chemical Substances
ENCS: Existing and New Chemical Substances Inventory
PICCS: Philippine Inventory of Chemicals and Chemical Substances
INSQ: Inventario Nacional de Sustancias Químicas
NCI: National Chemical Inventory
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances
NZIoC: New Zealand Inventory of Chemicals

STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit
ES: Exposure Standard
OSF: Odor Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odor Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index
DSL: Domestic Substances List
NDSL: Non-Domestic Substances List
NLP: No-Longer Polymers
KECI: Korea Existing Chemicals Inventory
TSCA: Toxic Substances Control Act
TCSI: Taiwan Chemical Substance Inventory

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