SAFETY DATA SHEETS

This SDS packet was issued with item:
078950594

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078950586 078950587 078950588 078950589 078950590 078950591 078950592 078950593

SECTION 1: IDENTIFICATION

1.1 Product identifier	
Product name	Novox® (carprofen tablets) Caplets
Chemical name	carprofen
Synonyms	C_{15}-H_{12}-Cl-N-O_2; 9H-carbazole-2-acetic acid, 6-chloro-alpha-methyl-, (+/-)-; dl-6-chloro-alpha-methylcarbazole-2-acetic acid; C-5720; Carprofena; Imadyl; Rimadyl; NSAID; anti-inflammatory/ analgesic
Proper shipping name	Medicine, solid, toxic, n.o.s. (contains carprofen)
Chemical formula	C_{15}-H_{12}-Cl-N-O_2
Other means ofidentification	Not Available
CAS number	53716-49-7
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses	For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs; for professional use only. Federal law restricts this drug to be used by or on a order of a licensed veterinarian. This SDS is written to address potential worker health and safety issues associated with the handling of the mixture
1.3 Details of the supplier of the substance or mixture	
Registered company name (US)	Vedco, Inc.
Address	5503 Corporate Drive St. Joseph, MO 64507 USA
Telephone	816-238-8840
Fax	Not Available
Email	Not Available
1.4 Emergency telephone numbers	
Dechra (US)	816-238-8840

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Safety Data Sheet according to OSHA HazCom Standard (2012) requirements (GHS.USA)

NFPA 704 diamond

Note: The hazard category numbers found in GHS classification insection 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	Acute Toxicity (Oral) Category 3, Sensitisation (Skin) Category 1, Hazardous to the Aquatic Environment Long-Term Hazard Category 2

2.2 Label elements

Hazard pictogram(s)	
Signal word	Danger
Hazard statement(s)	
H301	Toxic if swallowed.
H317	May cause an allergic skin reaction.
H411	Toxic to aquatic life with long lasting effects.

Hazard(s) not otherwise classified

Not Applicable

Precautionary statement(s) prevention	
P264	Wash all exposed external body areas thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves and protective clothing.

P261	Avoid breathing dust/fumes.
P273	Avoid release to the environment.
P272	Contaminated work clothing must not be allowed out of the workplace.
Precautionary statement(s) response	
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/physician/first aider.
P330	Rinse mouth.
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P391	Collect spillage.
Precautionary statement(s) storage	
P405	Store locked up.
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: INFORMATION ON THE INGREDIENTS

3.1 Substances

CAS No.	% [weight]	Name
53716-49-7	>98	carprofen

3.2 Mixtures

See section above for composition of Substances.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact	Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
Skin contact	Immediately remove all contaminated clothing, including footwear. Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Inhalation	Immediately move exposed subject to fresh air. Immediately notify medical personnel and supervisor.
Ingestion	If swallowed, call a physician immediately. Wash out the mouth with water and notify medical personnel and supervisor.

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

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

Use foam, dry chemical powder, BCF (where regulations permit), carbon dioxide or water spray or fog – large fires only

5.2 Special hazards arising from the substance or mixture

Fire incompatibility	Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

5.3 Special protective actions for fire-fighters:

Firefighting	Wear full body protective clothing with breathing apparatus. Prevent, by any means available, spillage from entering drains or water course. Use fire fighting procedures suitable for surrounding area.. 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	Product itself is not explosive, but dust clouds suspended in are can be explosive. Hazardous conditions will not occur under normal conditions. Combustion products include: carbon monoxide, carbon dioxide, hydrogen chloride, phosgene, nitrogen oxides and other pyrolysis products typical of burning organic material. May emit poisonous fumes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
See Section 8

6.2 Environmental precautions
See Section 12

6.3 Methods and material for containment and cleaning up

Minor spills	Clean up waste regularly and abnormal spills immediately. Avoid breathing dust and contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust. Vacuum up or sweep up. **NOTE:** Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use). Dampen with water to prevent dusting before sweeping. Place in suitable containers for disposal.
Major spills	Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water course. Stop leak if safe to do so. Contain spill with sand, earth or vermiculite. Collect solid residues and seal in labelled drums for disposal. Wash area and prevent runoff into drains.

Personal Protective Equipment advice is contained in Section 8.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe handling	Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. **DO NOT** enter confined spaces until atmosphere has been checked. **DO NOT** allow material to contact humans, exposed food or food utensils. Avoid contact with incompatible materials. When handling, **DO NOT** eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers.
Other information	This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

7.2 Conditions for safe storage, including any incompatibilities

Suitable container	Comply with applicable regulations. Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.
Storage incompatibility	Avoid reaction with oxidising agents.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits (OEL)
INGREDIENT DATA
Not Available

Emergency limits

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

Ingredient	Original IDLH	Revised IDLH
carprofen	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
carprofen	E	≤ 0.01 mg/m³

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

MATERIAL DATA Airborne particulate or vapour must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).	
8.2 Exposure controls	
Appropriate engineering controls	Avoid creating or spreading dust. Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.
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: chemical goggles, face shield, full face shield may be required. Contact lenses may pose a special hazard.
Skin protection	See Hand protection below.
Hands/feet protection	In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.
Body protection	See Other protection below
Other protection	For quantities up to 500 grams a laboratory coat may be suitable. For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. For quantities over 1 kilogram 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	When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if found to be necessary. Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:001, ANSI Z88 or national equivalent).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Solid	Vapor density: NA
Physical state: Solid	Auto ignition temperature (degrees C): NA
Odor: Not Available	Decomposition temperature (degrees C): NA
Odor threshold: NA	Viscosity (degrees C): NA
pH (as supplied): NA	Explosive properties: NA
Melting point / freezing point (degrees C): NA	Oxidizing properties: NA
Initial boiling point and boiling range: NA	Partition coefficient: NA
Flash point: NA	Molecular weight: 273.73
Evaporation rate: NA	Taste: NA
Flammability: Flammable	Surface tension: NA
Upper/lower flammability or explosive limits: NA	Volatile component (%vol): NA
Vapor pressure: NA	Gas group: NA
Relative density (at degrees C): NA	pH as a solution: NA
Solubility in water (mg/l): Partly miscible	VOC g/L: NA
	Specific gravity @ 20 degrees C (water = 1): NA

10: STABILITY AND REACTIVITY

Reactivity	See Section 7
Chemical stability	Product is considered stable. Hazardous polymerization will not occur. Unstable in the presence of incompatible materials
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

Inhalation	The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models). Nevertheless inhalation of dusts, or fumes, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress. Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.
Ingestion	Toxic effects may result from the accidental ingestion of the material; animal experiments indicate that ingestion of less than 40 gram may be fatal or may produce serious damage to the health of the individual.
Skin contact	The material is not thought to be a skin irritant (as classified by EC Directives using animal models). Abrasive damage however, may result from prolonged exposures. Good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
Eye contact	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness. Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.
Chronic	Practical experience shows that skin contact with the material is capable either of inducing a sensitisation reaction in a substantial number of individuals. There is some evidence that human exposure to the material may result in developmental toxicity. Long term exposure to high dust concentrations may cause changes in lung function (i.e. pneumoconiosis) caused by particles less than 0.5 micron penetrating and remaining in the lung.

	Acute toxicity	**Irritation**
carprofen	Oral (Rat) LD50: 74 mg/kg[2]	Not Available

1 Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

CARPROFEN	The following information refers to contact allergens as a group and may not be specific to this product. Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema.

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

	Endpoint	**Test Duration (hr)**	**Species**	**Value**	**Source**
carprofen	Not Available	Not Available	Not Available	Not Available	Not Available

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 aquatic organisms, may cause long-term adverse effects in the aquatic environment.
DO NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.
Wastes resulting from use of the product must be disposed of on site or at approved waste sites.
DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability		
Ingredient	**Persistence: Water/Soil**	**Persistence: Air**
carprofen	HIGH	HIGH
12.3 Bioaccumulative potential		
Ingredient	**Bioaccumulation**	
carprofen	LOW (LogKOW = 3.7888)	
12.4 Mobility in soil		
Ingredient	**Mobility**	
carprofen	LOW (KOC = 816.3)	

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product/ packaging disposal	Disposal of the material must be carried out in accordance with the requirements of the relevant Federal/State Act(s) or Code(s) regulating the disposal of Drugs of Addiction. **DO NOT** allow wash water from cleaning or process equipment to enter drains.

SECTION 14: TRANSPORT INFORMATION

Labels required		
Marine pollutant		
Land transport (US: DOT)		
UN number	3249	
UN proper shipping name	Medicine, solid, toxic, n.o.s. (contains carprofen)	
Transport hazard class(es)	Class	3
	Subrisk	Not Applicable
Packing group	III	
Environmental hazard	Environmentally hazardous	
Special precautions for user	Hazard Label	6.1
	Special provisions	T3, TP33
Land transport (ICAO-IATA / DGR)		
UN number	3249	
UN proper shipping name	Medicine, solid, toxic, n.o.s. (contains carprofen)	
Transport hazard class(es)	ICAO/IATA Class	6.1
	ICAO / IATA Subrisk	Not Applicable
	ERG Code	6L
Packing group	III	
Environmental hazard	Environmentally hazardous	
Special precautions for user	Special provisions	A3
	Cargo Only Packing Instructions	677
	Cargo Only Maximum Qty / Pack	200 kg
	Passenger and Cargo Packing Instructions	670
	Passenger and Cargo Maximum Qty / Pack	100 kg
	Passenger and Cargo Limited Quantity Packing Instructions	Y645
	Passenger and Cargo Limited Maximum Qty / Pack	5 kg
Land transport IMDG-Code / GGVSee)		
UN number	3249	

UN proper shipping name	Medicine, solid, toxic, n.o.s. (contains carprofen)	
Transport hazard class(es)	Class	Class
	Subrisk	Subrisk
Packing group	III	
Environmental hazard	Environmentally hazardous	
Special precautions for user	EMS Number	F-A, S-A
	Special provisions	221 223
	Limited Quantities	5 kg

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
carprofen	Not Applicable

Transport in bulk in accordance with the ICG Code

Product name	Ship type
carprofen	Not Applicable

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.

carprofen is found on the following regulatory lists
FEI Equine Prohibited Substances List - Controlled medication, FEI Equine Prohibited Substances List (EPSL)

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)	Yes
Reproductive toxicity	No
Skin Corrosion or Irritation	No
Respiratory or Skin Sensitization	Yes
Serious eye damage or eye irritation	No
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 reported

National Inventory Status

Australia - AIIC / Australia Non-Industrial Use	Yes

Canada - DSL	No (carprofen)
Canada - NDSL	No (carprofen)
China - IECSC	No (carprofen)
Europe - EINEC / ELINCS /NLP	Yes
Japan - ENCS	No (carprofen)
Korea - KECI	No (carprofen)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (carprofen)
USA - TSCA	No (carprofen)
Taiwan - TCSI	Yes
Mexico - INSQ	No (carprofen)
Vietnam - NCI	Yes
Russia - FBEPH	No (carprofen)

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 require registration

SECTION 16: OTHER INFORMATION

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
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit。
IDLH: Immediately Dangerous to Life or Health Concentrations
ES: Exposure Standard
OSF: Odour Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index
AIIC: Australian Inventory of Industrial Chemicals
DSL: Domestic Substances List
NDSL: Non-Domestic Substances List
IECSC: Inventory of Existing Chemical Substance in China
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European List of Notified Chemical Substances
NLP: No-Longer Polymers
ENCS: Existing and New Chemical Substances Inventory
KECI: Korea Existing Chemicals Inventory
NZIoC: New Zealand Inventory of Chemicals
PICCS: Philippine Inventory of Chemicals and Chemical Substances
TSCA: Toxic Substances Control Act
TCSI: Taiwan Chemical Substance Inventory
INSQ: Inventario Nacional de Sustancias Químicas
NCI: National Chemical Inventory
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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