SAFETY DATA SHEETS

This SDS packet was issued with item:

078938669

N/A

SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

Contact information

General

Dechra Veterinary Products
7015 College Blvd, Suite 525,
Overland Park, KS 66211
http://www.dechra-us.com

Emergency telephone number

+1 866-933-2472 *Availability: 24 hours/7 days*

Product identifier

Zimeta (dipyrone injection)

Synonyms

Dipyrone, dipyrone sodium, dipyrone sodium monohydrate, metamizole, metamizole sodium monohydrate

Trade names

Zimeta

Chemical family

Mixture - contains a pyrazolone derivative

Relevant identified uses of the substance or mixture and uses advised against

Bulk formulated pharmaceutical mixture for research and development purposes only; dipyrone is indicated for the treatment of fever in horses.

Note

The physical, chemical, toxicological and ecological properties of this mixture have not been fully characterized. This SDS will be revisited as more data become available.

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Globally Harmonized System [GHS]

Skin sensitizer - Category 1B. Respiratory sensitizer - Category 1B.

Label elements

SECTION 2 - HAZARDS IDENTIFICATION …continued

GHS hazard pictogram



GHS signal word Danger

GHS hazard statements H317 - May cause allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

GHS precautionary statements

P261 - Avoid breathing dust/mist/vapors/spray.
P280 - Wear eye/face protection.
P284 - Use respiratory protection.
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P321 - Specific treatment (see First Aid information on product label and/or Section 4 of the SDS).
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention.
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water.

Other hazards Zimeta contains dipyrone, a non-steroidal anti-inflammatory drug (NSAID) that inhibits cyclooxygenase. It has formerly been used in humans for severe pain and fever, and is indicated for veterinary use to treat fever. It is associated with agranulocytosis in humans and may cause allergic reaction. In humans, skin sensitization and respiratory sensitization have been reported with low frequency.

Note This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP) and Hazard Communication Standard No. 1910.1200 (US OSHA).

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	EINECS/ ELINCS#	Amount	GHS Classification
Dipyrone sodium monohydrate	5907-38-0	N/A	35-55%	SS1B: H317; RS1B: H334
Benzyl alcohol (BnOH)	100-51-6	202-859-9	5-20%	ATO4: H302; ATD4: H312; ATI3: H331

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS …continued

Note	The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of GHS classifications.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed	Yes
Eye Contact	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and/or supervisor.
Skin Contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and/or supervisor.
Inhalation	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and/or supervisor.
Ingestion	Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and/or supervisor.
Protection of first aid responders	See Section 8 for Exposure Controls/Personal Protection recommendations.
Most important symptoms and effects, both acute and delayed	See Sections 2 and 11.
Indication of immediate medical attention and special treatment needed, if necessary	Medical conditions aggravated by exposure: None reported. Treat symptomatically and supportively.

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture	No information identified. May emit carbon monoxide, carbon dioxide, nitrogen-, sulfur-, and sodium-containing compounds.
Flammability/ Explosivity	No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.

SECTION 5 - FIREFIGHTING MEASURES …continued

Advice for firefighters

Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe mist/vapors/spray.

Environmental precautions

Do not empty into drains. Avoid release to the environment.

Methods and material for containment and cleaning up

DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent (see Section 9).

Reference to other sections

See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling

Follow recommendations for handling potent pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid breathing vapor/mist/spray. Wash thoroughly after handling.

Conditions for safe storage including any incompatibilities

Store at Controlled Room Temperature 20°C to 25°C (68°F to 77°F); with excursions permitted between 15°C and 30°C (59°F and 86°F). Protect from light.

Specific end use(s)

No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Note

Dispose of broken vials in a sharps container.

Control Parameters/ Occupational Exposure Limit Values

Compound	Issuer	Type	OEL
Benzyl alcohol (BnOH)	AIHA	TWA 8-hour	10 ppm

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION …continued

Exposure/Engineering controls	If vials are crushed/broken and/or if handling bulk liquid: Control exposures to below the OEL (for the active ingredient(s) if available). Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Solutions can be handled outside a containment system or without local exhaust ventilation (LEV). Use engineered LEV and/or enclosure for high-energy operations such as spraying. All containers for solutions and slurries must be covered while being transferred.
Respiratory protection	If vials are crushed/broken and/or if handling bulk liquid: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. Respirators are generally not required. At minimum, a tight-fitting full-face respirator with HEPA filters is required for spill cleanup.
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible.
Skin protection	Wear appropriate work uniform or lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Protective garments are not to be worn in common areas (e.g., cafeterias) or out-doors.
Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Environmental Exposure Controls	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
Other protective measures	Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-doors).

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Liquid
Color	Light yellow to yellow
Odor	No information identified.
Odor threshold	No information identified.
pH	No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES …continued

Melting point/ freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	No information identified.
Vapor density	No information identified.
Relative density	1.16 g/mL
Water solubility	No information identified.
Solvent solubility	No information identified.
Partition coefficient (*n-octanol/water*)	No information identified.
Auto-ignition temperature	No information identified.
Decomposition temperature	No information identified.
Viscosity	No information identified.
Explosive properties	No information identified.
Oxidizing properties	No information identified.

Other information

Molecular formula	Not applicable (Mixture)
Molecular weight	Not applicable (Mixture)

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	Stable under normal temperatures.

SECTION 10 - STABILITY AND REACTIVITY …continued

Possibility of hazardous reactions	No information identified.
Conditions to avoid	No information identified.
Incompatible materials	No information identified.
Hazardous decomposition products	No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Note No data for this mixture were identified. The following data describe the active ingredient and/or the individual ingredients where applicable.

Information on toxicological effects

Route of entry May be absorbed by inhalation, skin contact and ingestion.

Acute toxicity

Compound	Type	Route	Species	Dose
Dipyrone sodium monohydrate	LD_{50}	Oral	Rat	3127 mg/kg
Benzyl alcohol (BnOH)	LC_{50}	Inhalation (4 hour)	Rat	8.8 mg/L
	LD_{50}	Oral	Rat	1230 mg/kg
	LD_{50}	Dermal	Rabbit	2000 mg/kg

Irritation/Corrosion No studies were identified.

Sensitization No studies were identified.

STOT-single exposure Mice administered oral doses of dipyrone sodium demonstrated depressed respiration and sedation at ≥ 100 mg/kg. The NOEL was 10 mg/kg.

STOT-repeated exposure/Repeat-dose toxicity In a 26-week rat study, increased reticulocytes and changes in red blood cells (Heinz bodies) were observed at 900 mg/kg/day IV dipyrone. A NOAEL was not identified in this study. Similar effects were observed in a 4-week rat study. The NOEL was 150 mg/kg/day.

In a 26-week dog study, oral doses of ≥ 300 mg/kg/day dipyrone resulted in increased red blood cell counts and changes to red blood cells (Heinz bodies), changes in serum chemistry, and increased liver and spleen weights in the presence of microscopic effects. The NOAEL was 30 mg/kg/day.

Reproductive toxicity No adverse effects on fertility were observed in rats following oral doses of dipyrone up to 625 mg/kg/day starting 2 weeks prior to mating and throughout pregnancy and lactation in the presence of severe maternal toxicity.

SECTION 11 - TOXICOLOGICAL INFORMATION …continued

Developmental toxicity

In a study in rats administered ≥ 250 mg/kg/day dipyrone orally starting from 2 weeks prior to mating through pregnancy and lactation, reduced pup survival was noted. Significant reductions in the number of pups born per dam were noted at 625 mg/kg/day. The NOEL was 100 mg/kg/day. In a teratology study in rats, no evidence of teratogenicity was observed at oral doses up to 800 mg/kg/day dipyrone in the presence of maternal toxicity. Increased incidence of resorptions with corresponding reductions in the total number of fetuses and numbers of fetuses per dam were observed in rats and rabbits in the presence of maternal toxicity following oral doses of 800 and ≥ 100 mg/kg/day, respectively. Fetal weight reductions were observed in rabbits at 400 mg/kg/day. The NOELs were 400 and 25 mg/kg/day in rats and rabbits, respectively.

Genotoxicity

Dipyrone was negative in one Ames assay, and positive in a number of others reported with limited details. It was also reported to be positive in poorly reported *in vitro* assays in human lymphocytes and in sister chromatid exchange assays in Chinese hamster cells. It was reported to be negative in two *in vivo* mouse micronucleus assays, but positive in a one *in vivo* micronucleus assay with limited reported detail. It was negative in two high quality studies: an *in vitro* HPRT and an *in vivo* mouse micronucleus assay. Overall, when accounting for the quality of the studies and weight of evidence, dipyrone is not expected to be genotoxic.

Carcinogenicity

An increased incidence of benign liver tumors was observed in mice administered ≥ 0.125% dipyrone in water for 78 weeks and in a second study in mice administered 0.75% dipyrone in water for 18 months, but was negative in a third study in mice at 2500 mg/kg/ day in feed for 104 months. No evidence of carcinogenicity was observed in two rat studies at doses up to 145-193 mg/kg/day in feed (for 24 months) or 0.125% in drinking water (no further details identified). Overall, dipyrone is not expected to be carcinogenic. None of the components of the product present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

Aspiration hazard

No data available.

Human health data

See "Section 2 - Other Hazards"

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

Compound	Type	Species	Concentration
Benzyl alcohol (BnOH)	LC_{50} (48h)	*Leuciscus idus* (freshwater fish)	646 mg/L
	LC_{50} (96 hr)	*Pimephales promelas* (freshwater fish)	460 mg/L
	EC_{50} (48 hr)	*Daphnia magna* (crustacea)	23 mg/L
	EC_{50} (48hr)	*E. Coli* (bacteria)	1000 mg/L

Additional toxicity information

No data available.

SECTION 12 - ECOLOGICAL INFORMATION …continued

Persistence and Degradability	Benzyl alcohol is readily biodegradable.
Bioaccumulative potential	Based on a LogP of 1.1 and estimated BCF value of 1.37 L/kg, benzyl alcohol is considered to have no potential for bioaccumulation.
Mobility in soil	No data available.
Results of PBT and vPvB assessment	Not performed.
Other adverse effects	No data available.
Note	The environmental characteristics of this product have not been fully investigated. Releases to the environment should be avoided.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods	Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

SECTION 14 - TRANSPORT INFORMATION

Transport	Based on the available data, this mixture is not regulated as a hazardous material under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
UN number	None assigned.
UN proper shipping name	None assigned.
Transport hazard classes and packing group	None assigned.
Environmental hazards	Based on the available data, this mixture is not regulated as an environmental hazard or a marine pollutant.
Special precautions for users	No special precautions needed.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
Chemical safety assessment	Not conducted.
TSCA status	Drugs are exempt from TSCA.
SARA section 313	Not listed.
California proposition 65	Not listed.
Additional information	No other information identified.

SECTION 16 - OTHER INFORMATION

Full text of H phrases and GHS classifications	ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. ATD4 - Acute Toxicity (Dermal) Category 4. H312 - Harmful in contact with skin. ATI3 - Acute Toxicity (Inhalation) Category 3. H331 - Toxic if inhaled. H317 - May cause an allergic skin reaction. SS1B - Skin sensitizer Category 1B. H334 - May cause allergic or asthmatic symptoms or breathing difficulty if inhaled. RS1B - Respiratory Sensitizer Category 1B.
Sources of data	Information from published literature and internal company data.
Abbreviations	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System

Issue Date	17 December 2020
Revisions	This is the first version of this SDS.
Disclaimer	The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.