

SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name	Solupam 5 mg/ml solution for injection for dogs and cats
Synonyms	Multipam
Proper shipping name	Not available
Other means ofidentification	None
1.2 Relevant identified uses of t	the substances or mixture and uses advised against
Recommended uses	For the short term management of convulsive disorders and skeletal muscle spasms of central and peripheral origin. As part of a pre-anaesthetic or sedation protocol. SDS are intended for use in the workplace. For domestic-use products, refer to consumer labels.
Uses advised against	Not for human use
1.3 Details of the supplier of the	e substance or mixture
Registered company name	Dechra Regulatory B.V.
Address	Handelsweg 25 5531 AE Bladel The Netherlands
Telephone	+31 348565858
Fax	Not available
Email	Not available

SECTION 2: HA	AZARDS IDEN	ITIFICATION	
2.1 Classificat	ion of the sul	ostance or mixture	
Poison	s Schedule	Not Applicable	
Cla	ssification ^[1]	Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2A	
1. Classified by Ch	emwatch; 2. Clas	ssification drawn from HCIS; 3. Classification drawn from Regulation (EU)	
No 1272/2008 - An	nex VI		
2.2 Label elem	nents		
Hazard p	oictogram(s)	!	
	Signal word	Warning	
2.3 Hazard stat	tement(s)		
H315	Causes skin	irritation.	
H317	May cause an allergic skin reaction.		
H319	Causes serious eye irritation.		
2.4 Precaution	ary statement	t(s) Prevention	
P280	Wear protect protection.	ive gloves, protective clothing, eye protection and face	

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P261	Avoid breathing mist/vapours/spray.
P264	Wash all exposed external body areas thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the workplace.
2.5 Precaution	ary statement(s) Response
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+	IF IN EYES: Rinse cautiously with water for several minutes. Remove
P338	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.
P362+P364	Take off contaminated clothing and wash it before reuse.
2.6 Precaution	ary statement(s) Storage
Not Applicable	
2.7 Precaution	ary statement(s) Disposal
P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

3.1 Substances		
See section below	for composition of Mix	tures.
3.2 Mixtures		
CAS No	%[weight]	Name
57-55-6	30-60	propylene glycol
64-17-5	1-10	<u>ethano</u> l
532-32-1	1-10	sodium benzoate
100-51-6	1-10	benzyl alcohol
439-14-5	<1	diazepam
65-85-0	<1	benzoic acid
Not Available	balance	Ingredients determined not to be hazardous

SECTION 4: FIRST AID MEASURES

Description of first aid measures

General advice:

Consult a physician. Show this safety data sheet to the doctor in attendance.

Eye contact:

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Skin contact:

Wash off with soap and plenty of water. Consult a physician.

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Inhalation:

Move person to fresh air. If not breathing, give artificial respiration. Consult a physician.

Ingestion:

If swallowed do NOT induce vomiting. Rinse mouth with water. Consult a physician.

Indication of any immediate medical attention and special treatment needed:

Treat symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

HAZCHEM Not Applicable

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, carbon dioxide.

event consider foam, d	ry chemical powder, carbon dioxide.
5.2 Special hazards ar	ising from the substance or mixture
Fire incompatibility:	None known.
5.3 Advice for fire-figh	iters:
Firefighting	Wear breathing apparatus plus protective gloves in the event of a
	fire. Prevent, by any means available, spillage from entering drains
	or water courses. DO NOT approach containers suspected to be hot.
Fire/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.

SECTION 6: ACCII	DENTAL RELEASE MEASURES
6.1 Personal prec	autions, protective equipment and emergency procedures
See Section 8.	
6.2 Environmenta	I precautions
See Section 12.	
6.3 Methods and n	naterial for containment and cleaning up
Minor spills	Clean up all spills immediately. Avoid breathing vapors and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Wipe up. Place in a suitable, labelled container for waste disposal.
Major spills	Clear area of personnel and move upwind. Alert the fire department and

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tell them location and nature of the hazard. Contain and absorb spill with sand, earth, inert material or vermiculite. Prevent spillage from entering drains or watercourse.

SECTION 7: HAND	LING AND STORAGE
7.1 Precautions for	or safe handling
Safe handling	DO NOT allow clothing wet with material to stay in contact with skin. Avoid all personal contact, including inhalation. DO NOT enter confined spaces until atmosphere has been checked. DO NOT allow material to contact humans, exposed food or food utensils. Wear suitable protective gloves and clothing when handling the product. DO NOT eat, drink or smoke when handling the product. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
Other information	Keep out of the reach and sight of children. Store in original containers. Keep containers securely sealed. Store in a cool, dry, well-ventilated area. Observe manufacturer's storage and handling recommendations contained within this SDS.
7.2 Conditions for	safe storage, including any incompatibilities
Suitable	Clear type I glass vial containing 5 ml, 10 ml, 20 ml or 50 ml with a
container	coated bromobutyl rubber stopper and aluminium cap.
Storage incompatibility	Glycols and their ethers undergo violent decomposition in contact with 70% perchloric acid. Alcohols are incompatible with strong acids, acid chlorides, acid anhydrides, oxidising and reducing agents. should not be heated above 49 deg. C. when in contact with aluminium equipment. Avoid oxidising agents, acids, acid chlorides, acid anhydrides, chloroformates.

SECTION 8:	EXPOSURE	CONTROLS / PER	SONAL PRO	TECTION		
8.1 Control	parameters					
Occupation	al Exposure	limits (OEL)				
Ingredient of	lata					
Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	propylene glycol	Propane-1,2-diol: particulates only	10 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	propylene glycol	Propane-1,2-diol total: (vapour & particulates)	150 ppm / 474 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	ethanol	Ethyl alcohol	1000 ppm / 1880 mg/m ³	Not Available	Not Available	Not Available

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Emergency limits				
Ingredient	TEEL-1	TEEL-2	TEEL-2 TEEL-3	
propylene glycol	30 mg/m ³	1,300 m	g/m³	7,900 mg/m ³
ethanol	Not Available		Not Available 15000* ppm	
sodium benzoate	61 mg/m ³	680 mg/	g/m ³ 810 mg/m ³	
benzyl alcohol	30 ppm	52 ppm		
benzoic acid	13 mg/m ³	140 mg/	g/m ³ 830 mg/m ³	
Ingredient	Original IDLH		Revised IDLH	
Not Available for any ingred	ient			
Occupational Exposure B	Banding			
Ingredient	Occupational Ex	cposure	Occupational Exposure Band Limit	
sodium benzoate	E		≤ 0.01 mg/m³	
benzyl alcohol	E		≤ 0.1 ppm	
diazepam	E		≤ 0.01 mg	g/m³
benzoic acid	E		≤ 0.01 mg/m³	
Occupational exposure banding a chemical's potency and the advant occupational exposure band (expected to protect worker healt	erse health outcomes as OEB), which correspond	sociated with e	xposure. The	output of this process is
Appropriate engineering	The basic types of	engineering	controls ar	e: Process controls
controls	which involve chang to reduce the part ventilated areas.	ging the way a	a job activity	y or process is done
Personal protection	None for handling s	mall quantitie	es.	
	When using large q	uantities:		
Eye and face protection	When using large q	uantities wea	ır splash-pr	oof goggles.
Skin protection	See hand protection	n below.		
Hands / feet protection	When using large q e.g. rubber or PVC		ır chemical	protective gloves,
Body protection	When using large q likely, see other pro			y contamination is
Other protection	When using large q	nt needed when handling small quantities. uantities: overalls, P.V.C apron, barrier ng cream, eye wash unit.		

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Yellow-green, clear liquid;

mixes with water

Physical state: Liquid

Odor: Not Available

Odor threshold: Not Available pH (as supplied): 6.2 – 7.2

Melting point / freezing point (degrees C):

Not Available

Initial boiling point and boiling range: Not

Available

Flash point: Not Applicable Evaporation rate: Not Available Flammability: Not Available

Upper / lower flammability or explosive

limits: Not Available

Vapor pressure: Not Available Relative density (at degrees C): Not

Available

Solubility in water and solvents (mg/l): Not

Available

Vapor density: Not Available

Auto ignition temperature (degrees C): Not

Applicable

Decomposition temperature (degrees C):

Not Available

Viscosity (degrees C): Not Available

Explosive properties: None **Oxidizing properties:** None

Partition coefficient: Not Available Molecular weight: Not Applicable

Taste: Not Available

Surface tension: Not Available Volatile component: Not Available

Gas group: Not Available pH as a solution: Not Available

VOC g/L: Not Available

Specific gravity @ 20 degrees C (water =

1): Not Available

10: REACTIVITY AND STABILITITY	
10.1 Reactivity	See Section 7.
10.2 Chemical stability	Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur.
10.3 Possibility of hazardous reactions	See Section 7.
10.4 Conditions to avoid	See Section 7.
10.5 Incompatible materials	See Section 7.
10.6 Hazardous composition	See Section 5.

SECTION 11: TOXICOL	OGICAL INFORMATION
Inhalation:	The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models). Nevertheless inhalation of vapours, fumes or aerosols, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress. In the case of inhalation exposure, seek medical advice immediately and show the package leaflet.
Ingestion:	In the case of accidental oral intake, seek medical advice immediately and show the package leaflet.



ethanol	Inhalation(rat) LC ₅₀ : >44.9 mg/L4h ^[2] Oral (rat) LD ₅₀ : >10400 mg/kg ^[2] Toxicity	Eye (rabbit): 500 mg/24h - mild Eye: no adverse effect observed (not irritating) ^[1] Skin(human):104 mg/3d Intermit Mod Skin (human):500 mg/7days mild Skin: no adverse effect observed (not irritating) ^[1] Irritation
	Dermal (rabbit) LD ₅₀ : 17100 mg/kg ^[1] Inhalation (mouse) LC ₅₀ : 39 mg/l4h ^[2] Oral (rat) LD ₅₀ : >7692 mg/kg ^[1]	Eye (rabbit): 500 mg SEVERE Eye (rabbit):100mg/24hr- moderate Eye: adverse effect observed (irritating) ^[1] Skin (rabbit):20 mg/24hr-moderate Skin (rabbit):400 mg (open)-mild Skin: no adverse effect observed (not irritating) ^[1]
sodium benzoate	Toxicity [1]	Irritation Not Available
	Dermal (rabbit) LD ₅₀ : >2000 mg/kg ^[1] Inhalation (rat) LC ₅₀ : >12.2 mg/L4h ^[1] Oral (mouse) LD ₅₀ : 1600 mg/kg ^[2]	Ttot / trailable



			(not irrita	ting) ^[1]
diazepam	Toxicity		Irritation	
	dermal (mouse) LD ₅₀ : 800 mg/kg ^[2]		Not Available	
	Oral (mouse) LD50: 48 n			
benzoic acid	Toxicity		Irritation	
Value obtained from Europe	Dermal (rabbit) LD ₅₀ : >=2000 mg/kg ^[1] Inhalation (rat) LC ₅₀ : >0.007 mg/l4h ^[2] Oral (rat) LD ₅₀ : 1700 mg/kg ^[2]		Eye (rabbit): 100 mg – SEVERE Eye: adverse effect observed (irritating) ^[1] Skin (human): 22 mg/3d - moderate Skin (rabbit): 500 mg/24h – mild Skin: adverse effect observed (irritating) ^[1] * Value obtained from manufacturer's SDS.	
Unless otherwise specified data	Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances			
Acute Toxicity	×	Carcino	genicity	*
Skin	✓	Reprod	luctivity	*
Irritation/Corrosion		OTOT	0:! -	
Serios Eye Damage/Irritation	✓		- Single opposure	×
Respiratory or Skin	✓	STOT – R		*
Sensitization			posure	•
Mutagenicity		Aspiration		×
 ♣ - Data either not available or does not fill the criteria for classification ✓ - Data available to make classification 				

SECTION 12: ECOLOGICAL INFORMATION					
12.1 Toxicity					
Solupam 5	Endpoint	Test duration	Species	Value	Source
mg/ml solution for injection for dogs and cats	Not available	Not available	Not available	Not available	Not available
propylene glycol	Endpoint	Test duration	Species	Value	Source
	NOEC(ECx)	336h	Algae or other aquatic plants	<5300mg/l	1
	EC ₅₀	72h	Algae or other aquatic plants	19300mg/l	2
	LC ₅₀	96h	Fish	>10000mg/l	2
	EC ₅₀	48h	Crustacea	>114.4mg/L	4
	EC ₅₀	96h	Algae or other aquatic plants	19000mg/l	2
ethanol	Endpoint	Test duration	Species	Value	Source
	EC ₅₀ (ECx)	96h	Algae or other aquatic plants	<0.001mg/L	4
	EC ₅₀	72h	Algae or other aquatic plants	275mg/l	2

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	LC ₅₀	96h	Fish	>100mg/l	2
	EC ₅₀	48h	Crustacea	>79mg/L	4
	EC ₅₀	96h	Algae or other aquatic plants	<0.001mg/L	4
sodium benzoate	Endpoint	Test duration	Species	Value	Source
	NOEC(ECx)	72h	Algae or other aquatic plants	0.09mg/l	2
	EC ₅₀	72h	Algae or other aquatic plants	>30.5mg/l	2
	LC ₅₀	96h	Fish	>100mg/l	2
	EC ₅₀	48h	Crustacea	<650mg/l	1
benzyl alcohol	Endpoint	Test duration	Species	Value	Source
	EC ₅₀	72h	Algae or other aquatic plants	500mg/l	2
	LC ₅₀	96h	Fish	10mg/l	2
	EC ₅₀	48h	Crustacea	230mg/l	2
	NOEC(ECx)	336h	Fish	5.1mg/l	2
	EC ₅₀	96h	Algae or other aquatic plants	76.828mg/l	2
diazepam	Endpoint	Test duration	Species	Value	Source
	NOEC(ECx)	0.17h	Fish	4mg/L	4
	LC ₅₀	96h	Fish	12.57- 12.85mg/l	4
benzoic acid	Endpoint	Test duration	Species	Value	Source
	NOEC(ECx)	72h	Algae or other aquatic plants	0.11mg/l	2
	EC ₅₀	72h	Algae or other aquatic plants	33mg/l	2
	LC ₅₀	96h	Fish	44.6mg/l	2
	EC ₅₀	48h	Crustacea	>120mg/l	2

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

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
propylene glycol	LOW	LOW
ethanol	LOW (Half-life = 2.17 days)	LOW (Half-life = 5.08 days)
benzyl alcohol	LOW	LOW
diazepam	HIGH	HIGH
benzoic acid	LOW	LOW

12.3 Bioaccumulative potential

Ingredient	Bioaccumulation
propylene glycol	LOW (BCF = 1)
ethanol	LOW (LogKOW = -0.31)



benzyl alcohol	LOW (LogKOW = 1.1)		
diazepam	LOW (LogKOW = 2.82)		
benzoic acid	LOW (LogKOW = 1.87)		
12.4 Mobility in soil	12.4 Mobility in soil		
Ingredient	Mobility		
propylene glycol	HIGH (KOC = 1)		
ethanol	HIGH (KOC = 1)		
benzyl alcohol	LOW (KOC = 15.66)		
diazepam	LOW (KOC = 11220)		
benzoic acid	LOW (KOC = 14.49)		

SECTION 13: DISPOSAL CONSIDERATIONS			
13.1 Waste treatment methods			
Product /	DO NOT allow wash water from cleaning or process equipment to enter		
packaging	drains. Observe all federal, state, and local environmental regulations.		
disposal	Contact a licensed professional waste disposal service to dispose of this		
	material. Dissolve or mix the material with a combustible solvent and		
	burn in a chemicalincinerator equipped with an afterburner and scrubber.		
	Recycle containers if possible, or dispose of in an authorised landfill.		

SECTION 14: TRANSPORT INFORMATION			
SECTION 14. TRANSPORT INFORMATION			
Labels required			
Marine pollutant	No		
HAZCHEM	Not Applicable		
Land transport (ADG)			
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			
Not Available for all ingredients			
Transport in bulk in accordance with the ICG Code			
Not Available for all ingredients			

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SECTION 15: REGULATORY INFORMATION

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

Propylene glycol is found on the following regulatory lists

Australian Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) – Schedule 5, Australian Inventory of Industrial Chemicals (AIIC)

ethanol is found on the following regulatory lists

AIIC, Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

Sodium benzoate is found on the following regulatory lists AllC

Benzyl alcohol is found on the following regulatory lists

AIIC, Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

diazepam is found on the following regulatory lists

SUSMP – Schedule 4, Australia Chemicals with non-industrial uses removed from the Australian Inventory of Chemical Substances (old Inventory), Chemical Footprint Project - Chemicals of High Concern List, International Agency for Research on Cancer (IARC) – Agents Classified by the IARC Monographs

Benzoic acid is found on the following regulatory lists

AIIC, Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

15.2 National Inventory Status

10.2 National inventory otatus			
Yes			
Yes			
No (propylene glycol; ethanol; sodium benzoate; benzyl alcohol; diazepam; benzoic acid)			
No (diazepam)			
Yes			
No (diazepam)			
Yes			
Yes			
Yes			
No (diazepam)			
No (diazepam)			

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.

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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

BCF: BioConcentration Factors
BEI: Biological Exposure Index
DSL: Domestic Substances List

NDSL: Non-Domestic Substances List

IECSC: Inventory of Existing Chemical Substance in China 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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