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SECTION 1: IDENTIFICATION				
1.1 Product identifier				
Product name:	Willcain® (Solution for Injection)			
Synonyms:	None			
Proper Shipping name:	Not Available			
Other means of identification:	None			
1.2 Relevant identified uses	of the substances or mixture and uses advised against			
Recommended uses:	For horses, cattle, cats and dogs. For use as a local anaesthetic, by field block or perineural administration, in minor surgical procedures including dehorning and disbudding in cattle.			
Uses advised against:	Not for human use. Do not administer by intravenous, intra-articular or epidural injection. Use with caution in horses due to risk of coat colour at injection site turning permanently white. Care should be taken not to inject the drug into a vein. Vasoconstrictors should be used with caution in lower limb blocks due to the risk of digital ischaemia.			
1.3 Details of the supplier o	f the substance or mixture			
Registered company name:	Dechra Ltd			
Address:	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK			
Telephone:	+44 (0) 1756 791311			
Fax:	+44 (0) 1756 798604			
Email:	Not available			
1.4 Emergency Telephone Numbers				
	+44 (0) 1756 791311			

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SECTION 2: HAZARDS IDENTIFICATION				
2.1 Classification of the sub	ostance or mixture			
DSD Classification (EU):	Not Available			
DPD Classification (EU):	Not Available			
Classification according to regulation (EC) No 1272/2008 [CLP] (EU):				
2.2 Label Elements				
Signal Word:	Not Available			
Hazard Statement(s)				
Not Available				
Additional Statement(s)				
Not Available				
Precautionary Statement(s)	Prevention:			
Not Available				
Precautionary Statement(s)	Response:			
Not Available				
Precautionary Statement(s)	Storage:			
Not Available				
Precautionary Statement(s)	Disposal:			
Not Available				
2.3 Other Hazard Informatio Not Available	on .			

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#### **SECTION 3: INFORMATION ON THE INGREDIENTS** 3.1 Substances See section below for composition of mixtures 3.2 Mixtures Classification according to 1.CAS No Name regulations (EC) No 1272/2008 2.EC Number % w/v [CLP] (EU) 3.Index Number **4.REACH Number** Acute Toxicity (Oral) Category 1.51-05-8 3, Skin Corrosion/Irritation Procaine 2. 200-077-2 Category 2, Eye Irritation hydrochloride 3. Not Available 5 Category 2, Skin Sensitizer 4. 01-2120077479-40-Category 1; H301, H315, H319, XXXX H317<sup>1</sup> N/a N/a Other ingredients

determined not

to be hazardous

**Proprietary** 

SECTION 4: FIRST AID MEASURES					
4.1 Description of first a	4.1 Description of first aid measures				
Eye contact:	Immediately wash off any splashes to the eyes or skin with copious amounts of water. Seek medical attention if irritation occurs, showing the package leaflet or label to the medical practitioner.				
Skin contact:	Immediately wash off any splashes to the eyes or skin with copious amounts of water. Seek medical attention if irritation occurs, showing the package leaflet or label to the medical practitioner.				
Inhalation:	Get medical aid immediately. Remove from exposure to fresh air immediately. If breathing is difficult, give oxygen. Do not use mouth-to-mouth resuscitation. If breathing has ceased apply artificial respiration using oxygen and a suitable mechanical device, such as a bag and a mask.				
Ingestion:	Do not induce vomiting. If victim is conscious and alert, give 2-4 cupfuls of milk or water. Never give anything by mouth to an unconscious person. Get medical aid immediately.				

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Self-Injection:	Take care to avoid accidental self-injection. In the event of accidental self-injection, seek medical attention and show the package leaflet or label to the medical practitioner.			
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 N/a				

SECTION 5: FIRE FIGHTING MEASURES				
5.1 Extinguishing media				
Suitable:	Water spray, dry chemical, alcohol foam or carbon dioxide.			
Unsuitable:	None.			
5.2 Special hazards arising from the substance or mixture				
Fire incompatibility:	None known.			
5.3 Special protective act	ions for fire-fighters:			
Firefighting:	Alert Fire Brigade and tell them location and nature of hazard. Wear full breathing apparatus and self-contained breathing apparatus.			
Fire / explosion hazard:	No known explosive hazards.  Irritating and highly toxic gases may be generated by thermal decomposition or combustion.			

	1		
SECTION 6: ACCIDENTAL RELEASE MEASURES			
6.1 Personal precautions, protective equipment and emergency procedures			
For information on protective equipment, see section 8.			
6.2 Environmental Precautions			
Do not allow product to reach sewage system or any water course.			
6.3 Methods and mat	erial for containment and cleaning up		
Minor Spills:	Absorb solution and place into a suitable clean, dry closed container for disposal.		
Major Spills: Clean up all major spills immediately. Wear protective clothing to avoid contact with the skin and eyes. Absorb solution and place into a suitable clean, dry closed container for disposal.			

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SECTION 7: HANDLING AND STORAGE				
7.1 Precautions for safe handling				
Safe Handling:	Observe manufacturer's storage and handling recommendations. Wear suitable protective equipment when handling the product. Do not eat, drink or smoke when handling the product. Wash hands after use.			
Other Information:	Keep out of the reach and sight of children. Protect from light.			
7.2 Conditions for safe sto	orage, including any incompatibilities			
Suitable Container:	Do not store above 25°C. Following withdrawal of the first dose, use the product within 28 days. Discard unused material. Shelf life of the veterinary medicinal product as packaged for sale: 3 years. Shelf life after first opening the immediate packaging: 28 days.			
Storage incompatibility:	N/a			
7.3 Specific end uses				
Not available				

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION
8.1 Control parameters
DERIVED NO EFFECT LEVEL - DNEL
Not Available
PREDICTED NO EFFECT LEVEL - PNEC
Not Available
OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA:	
Not Available	

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EMERGENCY LIMITS:						
Ingredient	ngredient Material Nan		TEEL-1	TEEL	2	TEEL-3
Not Available	Not Available					
Ingredient		Origi	Original IDLH		Revised IDLH	
Not Available						
8.2 Exposure co	ntrols					
		Prod	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.			
Personal protection:						
Eye and face	e protection:	Safety glasses with side shields / chemical goggles				
Skir	n protection:	See hand protection below				
Hands/ feet protection:		No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves				
Body protection:		Wear appropriate clothing				
Other protection:		No special equipment needed when handling small quantities				
Thermal hazards:		Not applicable				
Respiratory protection:		Not	Not applicable			
<b>8.3 Environmental exposure controls</b> See Section 12						

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## **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

# 9.1 Information on basic physical and chemical properties

**Appearance:** Willcain®: A clean, bright, colourless mobile solution for injection

Procaine hydrochloride: Crystalline powder

Container: 100 ml type I amber glass multidose vial, fitted with a red chlorobutyl bung, with

an aluminium overseal. **Physical state:** Liquid **Odour:** Not available

Odour Threshold: Not available pH (as supplied): Not available

Melting point / freezing point (degrees C): Procaine HCl: 155°C

Initial boiling point and boiling range: Not available

Flash Point: Not available Evaporation rate: Not available Flammability: Not available

Upper/lower flammability or explosive limits: Not available

Vapour pressure: Not available

Relative Density (at degrees C): Not available Solubility in water and solvents (mg/l): Soluble

Vapour density: Not available

Auto ignition temperature (degrees C): Not available Decomposition temperature (degrees C): Not available

Viscosity: (degrees C): Not available Explosive properties: Not available Oxidising properties: Not available Partition Coefficient: Not available

Molecular weight: 272.22
Taste: Not available

Surface tension: Not available Volative component: Not available

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

VOC g/L: Not available

## 9.2 Other information

Not Available

10: REACTIVITY AND STABILITY				
10.1 Reactivity:	See Section 7			
10.2 Chemical stability:	Product is considered stable.			
10.3 Possibility of hazardous reactions:	Stable under normal temperatures and conditions.			
10.4 Conditions to avoid:	Air and light sensitive.			
10.5 Incompatible materials:	See section 7.			

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10.6 Hazardous See Section 5. decomposition:

decomposition.					
SECTION 11: TO	XICOLOGI	CAL INFORMATIO	N		
Inhalation:	May cause respiratory tract irritation.				
	-	• •	dominal pain, nausea and vomiting.		
		e skin irritation.			
Eye contact:	May cause	May cause eye irritation.			
Chronic:	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.				
Willcain <sup>®</sup> :	Acute tox	icity	Irritation		
	Not Availa	ble	Not Available		
Procaine hydrochloride:		Acute toxicity Irritation			
	Oral (rat) I	_D <sub>50</sub> : 200 mg/kg <sup>1</sup>	Not Available		
Legend:	1. Va	lue obtained from mar	nufacturer's SDS		
Skin corrosion / i	irritation:				
Not expected to ca	ause seriou	s skin corrosion or i	rritation.		
Serious eye damage / irritation:					
Not expected to ca	ause seriou	s eye damage or irr	itation.		
Respiratory or sk	kin sensitiz	ation:			
Not expected to be a skin sensitizer.					
Germ cell mutage	enicity:				
Not expected to be	e a mutage	n.			
Carcinogenicity:					
Not expected to be carcinogenic.					
Reproductive toxicity:					
Not expected to have reproductive toxicity.					
STOT – single exposure:					
Not available					
STOT-repeated exposure:					
Not available					

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Aspiration hazard:	SECTION 11: TOXICOLOGICAL INFORMATION
	Aspiration hazard:
Not available	Not available

INOL AVE	
SECTION	ON 12: ECOLOGICAL INFORMATION
Not ex	pected to be an environmental hazard.
12.1 To	oxicity
N/a	
12.2 P	ersistence and degradability
N/a	
12.3 B	ioaccumulative potential
N/a	
12.4 M	obility in Soil
N/a	
12.5 Re	esults of PBT and vPvB assessment
N/a	
12.6 Ot	ther adverse effects
N/a	

SECTION 13: DISPOSAL CONSIDERATIONS				
13.1 Waste treatm	ent methods			
packaging	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.			
	Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.			
	Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.			
Waste Treatment Options:	Not Available			
Sewage Disposal	No environmental effects are anticipated.			

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SECTION 14: TRANSPORT INFORMATION					
SECTION 14. TRANSFORT INFORMATION					
Labels required:		None			
Marine p	ollutant:	NO			
Н	azchem:	Not Applicable			
Land transport (ADR	):	,			
14.1 UN	Number	N/a			
14.2 UN Proper Shipping Name		N/a			
14.3 Transport hazard class(es)		Class		N/a	
		Sub risk		N/a	
14.4 Packing group		N/a			
14.5 Environmental hazards		N/a	N/a		
14.6 Special precautions for user		Special provis	ions	N/a	
		Classification	code	N/a	
		Hazard Label N/a			
		Special provisions N/a			
		Limited quantity N/a			
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code					
Air transport (ICAO-IATA / DGR):					
14.1 UN Number	N/a				
14.2 UN Proper Shipping Name	N/a				
14.3 Transport					
hazard class(es)	ICAO /	IATA Sub risk	N/a		
_	ERG Code N/a				
14.4 Packing group	N/a				
14.5 Environmental hazards					

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	Special provisions	N/a		
precautions for user	Cargo only packing instructions	N/a		
	Cargo only maximun qty/pack	n N/a		
	Passenger and carg packaging instruction			
	Passenger and carg maximum qty/pack	N/a		
	Passenger and carg limited quantity packing instructions	N/a		
	Passenger and carg limited maximum qty/pack	N/a		
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code				
Sea transport (IMDG-Code / GGVSee):				
14.1 UN Number	14.1 UN Number N/a			
14.2 UN Proper Shipping Name	N/a			
14.3 Transport	IMDG Class	N/a		
hazard class(es)	IMDG Sub risk	N/a		
14.4 Packing group	N/a			
14.5 Environmental hazards	N/a			
14.6 Specia precautions fo use	EMS Number	N/a		
	Special provisions	N/a		
	Limited quantities	N/a		
14.7 Transport in bulk according to Annex II of MARPOL73/78 and	N/a			
the IBC Code				

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Inland waterways transport (ADN):				
14.1 UN Number	N/a			
14.2 UN Proper Shipping Name	N/a			
14.3 Transport hazard class(es)	N/a	N/a		
14.4 Packing group	N/a			
14.5 Environmental hazard	N/a			
14.6 Special precautions for user	Classification Code	N/a		
	Special provisions	N/a		
	Limited quantity	N/a		
	Equipment required	N/a		
	Fire cones number	N/a		
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a			

# **SECTION 15: REGULATORY INFORMATION**

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

# PROCAINE HYDROCHLORIDE (51-05-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

- European Customs Inventory of Chemical substances ECICS (English)
- European Union European Inventory of Existing Commercial Chemical Substances (EINECS) (English)

# 15.2 Chemical Safety Assessment

## **ECHA SUMMARY**

Ingredient	CAS number	Index Number	ECHA Dossier
Procaine hydrochloride	51-05-8	Not Available	01-2120077479-40- XXXX

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Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 3, Skin Sens.	GHS06, Dgr	H301, H317
2	Acute Tox. 3, Skin Sens. 1, Acute Tox. 2, Resp. Sens. 1, Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1B	GHS06, Dgr, GHS08	H301, H317, H311, H330, H334, H315, H319

Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification

Australia - AICS	Υ
Canada - DSL	Υ
Canada - NDSL	N (procaine hydrochloride)
China - IECSC	N (procaine hydrochloride)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (procaine hydrochloride)
Korea - KECI	Υ
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

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#### SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS and ECHA.

## Ingredients with multiple CAS numbers:

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices

#### **Definitions and abbreviations**

PC-TWA: Permissible Concentration-Time Weighted Average PC-STEL: Permissible Concentration-Short Term Exposure Limit

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit

#### **Definitions and abbreviations**

PC—TWA: Permissible Concentration-Time Weighted Average PC—STEL: Permissible Concentration-Short Term Exposure Limit

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit

IDLH: Immediately Dangerous to Life or Health Concentrations

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