



SECTION 1: IDENTIFICATION	
<b>1.1 Product identifier</b>	
<b>Product name:</b>	Equipalazone® 200 mg/ml solution for injection
<b>Synonyms:</b>	Phenylbutazone
<b>Proper Shipping name:</b>	N/a
<b>Other means of identification:</b>	None
<b>1.2 Relevant identified uses of the substances or mixture and uses advised against</b>	
<b>Recommended uses:</b>	For the treatment of musculoskeletal disorders in horses and ponies where the anti-inflammatory and analgesic properties of phenylbutazone can offer relief against inflammation, pain and lameness (for example, osteoarthritis conditions, acute and chronic laminitis, bursitis and carpalis).
<b>Uses advised against:</b>	<p>Not for human use.</p> <ul style="list-style-type: none"> <li>• The therapeutic index of phenylbutazone is low. Do not exceed the stated dose or the duration of treatment.</li> <li>• Do not administer with other non-steroidal anti-inflammatory agents concurrently or within 24 hours of each other.</li> <li>• Do not use in animals suffering from cardiac, hepatic or renal disease; where there is the possibility of gastrointestinal ulceration or bleeding; where there is evidence of a blood dyscrasia or of hypersensitivity to the product.</li> <li>• Discontinue treatment if no response is evident after four to five days treatment.</li> <li>• The clinical effect of phenylbutazone can be evident for at least three days following cessation of administration. This should be borne in mind when examining horses for soundness.</li> <li>• Use in any animal under six weeks of age or in aged animals may involve additional risks. If such use cannot be avoided, animals may require a reduced dosage and special clinical management.</li> <li>• Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a risk of increased toxicity.</li> <li>• It is preferable that non-steroidal anti-inflammatory drugs, which inhibit prostaglandin synthesis, are not administered to animals undergoing general anaesthesia until fully recovered.</li> <li>• Response to long-term therapy should be monitored at regular intervals by a veterinary practitioner.</li> </ul>



	<p>Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption.          The horse must have been declared as not intended for human consumption under national horse passport legislation.</p> <p><b>NOTE:</b> Some authorities (including the Jockey Club) regard phenylbutazone as a “prohibited substance” under the rules of competition. Therefore, use of this product in a competition horse should be in accordance with the recommendations/ advice of the relevant competition authorities.</p>
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### 1.3 Details of the supplier of the substance or mixture

<b>Registered company name (UK):</b>	Dechra Ltd
<b>Address:</b>	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK
<b>Telephone:</b>	+44 (0) 1756 791311
<b>Fax:</b>	+44 (0) 1756 798604
<b>Website:</b>	www.dechra.com
<b>Email:</b>	Not available

### 1.4 Emergency Telephone Numbers

<b>Dechra:</b>	+44 (0) 1756 791311
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## SECTION 2: HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

<b>Classification according to regulation (EC) No 1272/2008 [CLP] (EU)<sup>1</sup>:</b>	Not available
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### 2.2 Label Elements

<b>Signal Word:</b>	Not applicable
<b>Hazard statement(s):</b>	Not Available
<b>Precautionary Statement(s) Prevention:</b>	Not Available



<b>Precautionary Statement(s) Response:</b>
Not Available
<b>Precautionary Statement(s) Storage:</b>
Not Available
<b>Precautionary Statement(s) Disposal:</b>
Not Available
<b>2.3 Other Hazard Information</b>
Not Available

### SECTION 3: INFORMATION ON THE INGREDIENTS

#### 3.1 Substances

See section below for composition of mixtures

#### 3.2 Mixtures

1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% w/v	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 50-33-9 2. 200-029-0 3. Not Available 4. Not Available	20	Phenylbutazone	Acute toxicity (oral) Category 4, Acute toxicity (dermal) Category 4, Acute toxicity (Inhalation) Category 4, Skin corrosion / irritation Category 2, Eye irritation Category 2, Carcinogenic substance of category 2, Reproductive Toxicity Category 2, STOT - SE (Resp. Irr) Category 3; H302, H312, H332, H315, H319, H351, H361, H335 <sup>[1]</sup>
N/a	Proprietary	Other ingredients determined not to be hazardous	N/a

**Legend:** 1. Classified by Chemwatch

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

<b>Eye contact:</b>	If accidental eye contact occurs, the site should be washed immediately with water. If irritation persists, seek medical attention and show the package leaflet or the label to the medical practitioner.
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<b>Skin contact:</b>	If accidental skin contact occurs, the site should be washed immediately with water. If irritation persists, seek medical attention and show the package leaflet or the label to the medical practitioner.
<b>Inhalation:</b>	Not considered to be a hazard. If concerned, remove from exposure and lie down.
<b>Ingestion:</b>	If the product is ingested, seek medical advice and show the product packaging or label to the medical practitioner.
<b>Self-Injection:</b>	If the product is self-injected, seek medical advice and show the product packaging 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

**Advice to doctors:** gastric lavage (emesis in children) should be performed urgently. Charcoal haemoperfusion has also been shown to be beneficial. Treatment should then be administered symptomatically.

The therapeutic index of phenylbutazone is low. In man, charcoal haemoperfusion in conjunction with dopamine has been used successfully to treat overdose with phenylbutazone, but there is no experience of the use of this technique in the horse.

### SECTION 5: FIRE FIGHTING MEASURES

#### 5.1 Extinguishing media

<b>Suitable:</b>	All systems may be used.
<b>Unsuitable:</b>	None

#### 5.2 Special hazards arising from the substance or mixture

<b>Fire incompatibility:</b>	Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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#### 5.3 Special protective actions for fire-fighters:

<b>Firefighting:</b>	Alert Fire Brigade and tell them location and nature of hazard. Wear full body protective clothing with breathing apparatus. Prevent, by any means available, spillage from entering drains or water course. Use firefighting procedures suitable for surrounding area.
<b>Fire / explosion hazard:</b>	Assumed to be combustible. May emit toxic fumes.



**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**

See section 12

**6.3 Methods and material for containment and cleaning up**  
 Spills are unlikely due to the nature of the product and how it is packaged

<b>Minor Spills:</b>	Absorb liquid for disposal. Control personal contact with the substance, by using protective equipment.
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<b>Major Spills:</b>	Clean up all spills immediately. Control personal contact with the substance, by using protective equipment. Absorb liquid for disposal. Prevent, by any means available, spillage from entering drains or water course.
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**SECTION 7: HANDLING AND STORAGE**

**7.1 Precautions for safe handling**

<b>Safe Handling:</b>	The product should be handled with care at all times to reduce the risk of accidental ingestion, skin contact or self-injection. Wear suitable protection gloves and clothing when handling the product. When handling, <b>DO NOT</b> eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
<b>Other Information:</b>	Keep out of the reach and sight of children.

**7.2 Conditions for safe storage, including any incompatibilities**

<b>Suitable Container:</b>	Store between +2 and +8°C. Protect from light. Shelf life of the veterinary medicinal product as packaged for sale: 3 years. Shelf life after first opening the immediate packaging: 28 days.
<b>Storage incompatibility:</b>	No known incompatibilities.

**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

**EMERGENCY LIMITS:**

Not Available

**8.2 Exposure controls**

**Appropriate engineering controls:** 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 protection:** Safety glasses with side shields / chemical goggles

**Skin 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 applicable

**8.3 Environmental exposure controls**  
 See Section 12

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties**

**Appearance:** Equipalazone: Clear, colourless to pale yellow solution  
 Phenylbutazone: White or off-white crystalline powder  
**Container:** 50ml type I amber glass vials with a bromobutyl rubber closure  
**Physical state:** Liquid  
**Odour:** Not available  
**Odour Threshold:** Not available  
**pH (as supplied):** Not Applicable  
**Melting point / freezing point (degrees C):** 106-108°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):** Practically insoluble  
**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:**  
**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

**SECTION 10: STABILITY AND REACTIVITY**

<b>10.1 Reactivity:</b>	See Section 7.
<b>10.2 Chemical stability:</b>	Stable under normal temperatures and conditions.
<b>10.3 Possibility of hazardous reactions:</b>	The product is not considered to be hazardous if used as per instructions.
<b>10.4 Conditions to avoid:</b>	Protect from light.
<b>10.5 Incompatible materials:</b>	See section 7.



<b>10.6 Hazardous decomposition:</b>	See Section 5.
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SECTION 11: TOXICOLOGICAL INFORMATION		
<b>Inhalation:</b>	Possible allergic reaction.	
<b>Ingestion:</b>	May cause nausea, vomiting, epigastric distress, diarrhoea, oedema, skin rashes, vertigo, headache and blurred vision. Also, gastrointestinal bleeding, ulcerative stomatitis, hepatitis, jaundice, haematuria, nephritis, renal failure and goitre. May cause bone marrow depression, agranulocytosis, aplastic anaemia, leucopaenia, pancytopenia, haemolytic anaemia and thrombocytopenia.	
<b>Skin contact:</b>	Possible allergic reaction.	
<b>Eye contact:</b>	Possible allergic reaction.	
<b>Chronic:</b>	Phenylbutazone may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.	
<b>Phenylbutazone:</b>	<b>Acute Toxicity</b>	<b>Irritation</b>
	Oral (rat) LD <sub>50</sub> : 245 mg/kg <sup>1</sup>	Not Available
<b>Legend:</b>	<i>1.* Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances</i>	

<b>Skin corrosion / irritation:</b>
Not expected to cause serious eye damage or irritation; although contact may produce an allergic reaction.
<b>Serious eye damage / irritation:</b>
Not expected to cause serious eye damage or irritation; although contact may produce an allergic reaction.
<b>Respiratory or skin sensitization:</b>
Not expected to be a skin sensitizer
<b>Germ cell mutagenicity:</b>
Not Available
<b>Carcinogenicity:</b>
Not Available.
<b>Reproductive toxicity:</b>



The safety of phenylbutazone in pregnancy has not been established. The compound has been shown to have no effect on initiation or regularity of the oestrus cycle in the mare. Phenylbutazone has been shown to cross the placenta. Use during pregnancy should be avoided whenever possible, particularly during the first trimester.

**STOT – single exposure:**

Not Available

**STOT – repeated exposure:**

Not Available

**Aspiration hazard:**

Not Available

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1 Toxicity**

Not Available

**DO NOT discharge into sewer or waterways.**

**12.2 Persistence and degradability**

Ingredient	Persistence: Water/Soil	Persistence: Air
Phenylbutazone	HIGH	HIGH

**12.3 Bioaccumulative potential**

Ingredient	Bioaccumulative Potential
Phenylbutazone	LOW (LogKOW = 3.16)

**12.4 Mobility in Soil**

Ingredient	Mobility
Phenylbutazone	LOW (KOC = 15800)

**12.5 Results of PBT and vPvB assessment**

Not Available

**12.6 Other adverse effects**

Not Available

**SECTION 13: DISPOSAL CONSIDERATIONS**

**13.1 Waste treatment methods**

Product / packaging	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance



<b>disposal:</b>	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.
<b>Waste Treatment Options:</b>	Not Available
<b>Sewage Disposal Options:</b>	Not Available

SECTION 14: TRANSPORT INFORMATION	
<b>Labels required:</b>	
<b>Marine pollutant:</b>	N/a
<b>Hazchem:</b>	N/a
<b>Land transport (EU: ADR / US: DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>14.1 UN Number</b>	N/a
<b>14.2 UN Proper Shipping Name</b>	N/a
<b>14.3 Transport hazard class(es)</b>	N/a
	N/a
<b>14.4 Packing group</b>	N/a
<b>14.5 Environmental hazards</b>	N/a
<b>14.6 Special precautions for user</b>	N/a
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a



<b>Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	N/a	N/a
	N/a	N/a
	N/a	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	
<b>14.6 Special precautions for user</b>	N/a	N/a
	N/a	N/a
	N/a	N/a
	N/a	N/a
	N/a	N/a
	N/a	N/a
	N/a	N/a
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	
<b>Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	N/a	N/a
	N/a	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	



<b>14.6 Special precautions for user</b>	N/a	N/a
	N/a	N/a
	N/a	N/a
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	
<b>Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	N/a	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazard</b>	N/a	
<b>14.6 Special precautions for user</b>	N/a	N/a
	N/a	N/a
	N/a	N/a
	N/a	N/a
	N/a	N/a
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	

**SECTION 15: REGULATORY INFORMATION**

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

**PHENYLBUTAZONE (50-33-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS:**

- European Customs of Chemicals ECICS (English)
- European Union - European inventory of existing chemical commodities (EINECS)
- International Agency for Cancer Research (IARC) - Agents Issued by the IARC Monographs
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## 15.2 Chemical Safety Assessment

### ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Phenylbutazone	50-33-9	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 4, Skin Irrit. 2, Skin Sens. 1, Eye Irrit. 2, Resp. Sens. 1, STOT SE 3, Carc. 2	GHS07, GHS08, Dgr	H302, H312, H315, H317, H319, H332, H334, H335, H351
2	Acute Tox. 4, Skin Irrit. 2, Skin Sens. 1, Eye Irrit. 2, Resp. Sens. 1, STOT SE 3, Carc. 2, Acute Tox. 3, Repr. 2	GHS08, Dgr, GHS06, Wng	H312, H315, H317, H319, H332, H334, H335, H351, H301, H361

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

National Inventory	Status
Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (phenylbutazone)
China - IECSC	N (phenylbutazone)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	Y
Korea - KECI	N (phenylbutazone)
New Zealand - NZIoC	Y
Philippines - PICCS	N (phenylbutazone)
USA - TSCA	Y
<b>Legend:</b>	<i>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)</i>

## SECTION 16: OTHER INFORMATION

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

### Other Information

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

IDLH: Immediately Dangerous to Life or Health Concentrations

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