

Versi 2.5	on	Revision Date: 06.04.2024		S Number: 450-00017	Date of last issue: 30.09.2023 Date of first issue: 11.12.2015
	FION 1 Produc	: IDENTIFICATION t name	:	Recombinant Boy	vine Somatotropin Formulation
ľ	Manufa	acturer or supplier's d	letai	ls	
(Compa	ny	:	Intervet Australia	Pty Limited (trading as MSD Animal Health)
ŀ	Addres	S	:	91-105 Harpin St Bendigo 3550, V	
٦	Telepho	one	:	1 800 033 461	
E	Emerge	ency telephone number	· :	Poisons Informat	ion Centre: Phone 13 11 26
E	E-mail a	address	:	EHSDATASTEW	ARD@msd.com
F	Recom	mended use of the ch	nem	ical and restrictio	ons on use
		mended use tions on use	:	Veterinary produc Not applicable	ct

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification Serious eye damage/eye irri- tation	:	Category 2A
GHS label elements Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H319 Causes serious eye irritation.
Precautionary statements	:	Prevention: P264 Wash skin thoroughly after handling. P280 Wear eye protection/ face protection.
		Response: P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical advice/ at- tention.



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Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Recombinant Bovine Somatotropin	Not Assigned	>= 10 -< 30
Benzyl benzoate	120-51-4	>= 10 -< 30
Benzyl alcohol	100-51-6	>= 10 -< 30

SECTION 4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact	:	Wash with water and soap as a precaution. Get medical attention if symptoms occur.
In case of eye contact	:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Causes serious eye irritation.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod-	:	Carbon oxides



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	ucts				
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray to	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	Special for firefi	protective equipment ghters	:	Evacuate area. In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.
SEC	TION 6	ACCIDENTAL RELE	ASI	E MEASURES	
	Personal precautions, protec- tive equipment and emer- gency procedures		:		ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).
	Environmental precautions		:	Prevent spreading barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g. by containment or oil e of contaminated wash water. should be advised if significant spillages
		s and materials for ment and cleaning up	:	For large spills, pr ment to keep mate be pumped, store Clean up remainin bent. Local or national r posal of this mate employed in the c mine which regula Sections 13 and 1	absorbent material. ovide dyking or other appropriate contain- erial from spreading. If dyked material can recovered material in appropriate container. og materials from spill with suitable absor- egulations may apply to releases and dis- rial, as well as those materials and items leanup of releases. You will need to deter- tions are applicable. 5 of this SDS provide information regarding tional requirements.

SECTION 7. HANDLING AND STORAGE

:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
:	Use only with adequate ventilation.
:	Avoid inhalation of vapour or mist.
	Do not swallow.
	Do not get in eyes.
	Avoid prolonged or repeated contact with skin.
	Wash skin thoroughly after handling.
	Handle in accordance with good industrial hygiene and safety
	:



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Hyg	jiene measures	sessment Take care to prenvironment. If exposure to of flushing system place. When using do Wash contamin The effective of engineering co appropriate de industrial hygie	d on the results of the workplace exposure as- revent spills, waste and minimize release to the chemical is likely during typical use, provide eye ns and safety showers close to the working o not eat, drink or smoke. nated clothing before re-use. peration of a facility should include review of introls, proper personal protective equipment, gowning and decontamination procedures, ene monitoring, medical surveillance and the trative controls.
Cor	nditions for safe storage		ly labelled containers. Jance with the particular national regulations.
Mat	erials to avoid		ith the following product types:

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Recombinant Bovine Somato- tropin	Not Assigned	TWA	OEB 3 (>= 10 < 100 μg/m3)	Internal

Engineering measures :	Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip- less quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face con- tainment devices). Minimize open handling.
Personal protective equipment	
Respiratory protection :	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.

Filter type		ommended guidelines, use respiratory protection.
Hand protection		Combined particulates and organic vapour type
Material	:	Chemical-resistant gloves



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	Remarks Eye protection Skin and body protection		:	If the work environ mists or aerosols, Wear a faceshield potential for direct aerosols. Work uniform or la Additional body ga task being perform posable suits) to a Use appropriate of contaminated clot	ses with side shields or goggles. ment or activity involves dusty conditions, wear the appropriate goggles. d or other full face protection if there is a t contact to the face with dusts, mists, or aboratory coat. arments should be used based upon the ned (e.g., sleevelets, apron, gauntlets, dis- avoid exposed skin surfaces. legowning techniques to remove potentially hing.
SEC		. PHYSICAL AND CHI	EMIC		S
	Appear Colour	ance	•	suspension opaque, yellow	
	Odour				
		Threadeald	•	musty	
		Threshold	:	No data available	
	рН		:	No data available	9
	Melting	point/freezing point	:	No data available	9
	Initial b range	oiling point and boiling	:	No data available	9
	Flash p	oint	:	No data available	9
	Evapor	ation rate	:	No data available	9
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	9
		explosion limit / Upper bility limit	:	No data available	2
		explosion limit / Lower bility limit	:	No data available	9
	Vapour	pressure	:	No data available	9
	Relative	e vapour density	:	No data available	9
	Relative	e density	:	No data available	9



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D	ensity	: No da	ata availabl	e
S	olubility(ies) Water solubility	: No da	ata availabl	e
-	artition coefficient: n- ctanol/water	: No da	ata availabl	e
-	uto-ignition temperature	: No da	ata availabl	e
D	ecomposition temperature	: No da	ata availabl	e
V	iscosity Viscosity, dynamic	: No da	ata availabl	e
	Viscosity, kinematic	: No da	ata availabl	e
E	xplosive properties	: Not e	xplosive	
С	oxidizing properties	: The s	ubstance c	or mixture is not classified as oxidizing.
Ν	lolecular weight	: No da	ata availabl	e
-	article characteristics article size	: No da	ata availabl	e

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition products		None known. Oxidizing agents No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes	: Inhalation Skin contact
	Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity

: Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method



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Acute	e inhalation toxicity	:	Acute toxicity est		
			Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method		
<u>Com</u>	ponents:				
Reco	ombinant Bovine Som	atotr	opin:		
Acute	e inhalation toxicity	:	LC50 (Rat): 30,00 Exposure time: 1 Test atmosphere	h	
Benz	yl benzoate:				
Acute	e oral toxicity	:	LD50 (Rat): 1,70	0 mg/kg	
Acute	e dermal toxicity	:	LD50 (Rabbit): >	2,000 mg/kg	
Benz	yl alcohol:				
Acute	e oral toxicity	:	LD50 (Rat): 1,62	0 mg/kg	
Acute	e inhalation toxicity	:	LC50 (Rat): > 4.1 Exposure time: 4 Test atmosphere Method: OECD T	h	
Not c	corrosion/irritation classified based on avai ponents:	lable	information.		
Reco	ombinant Bovine Som	atotr	opin:		
Spec Rema		:	Rabbit slight irritation		
Benz	yl benzoate:				
Spec Meth Resu	od	:	Rabbit OECD Test Guid No skin irritation	eline 404	
Benz	yl alcohol:				
Spec Meth Resu	ies od	:	Rabbit OECD Test Guid No skin irritation	eline 404	



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Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Recombinant Bovine Somatotropin:				
Species	:	Rabbit		
Remarks	:	slight irritation		

Benzyl benzoate:

Species	:	Rabbit
Result	:	No eye irritation

Benzyl alcohol:

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days
Method	:	OECD Test Guideline 405

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Benzyl benzoate:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Skin contact
Species	:	Mouse
Method	:	OECD Test Guideline 429
Result	:	negative

Benzyl alcohol:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative

Chronic toxicity

Germ cell mutagenicity

Not classified based on available information.



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Comp	oonents:			
Benzy	yl benzoate:			
-	toxicity in vitro	:	Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)
			Result: positive	o mammalian cell gene mutation test on data from similar materials
			Result: negative	nosome aberration test in vitro on data from similar materials
Geno	toxicity in vivo	:	mammalian liver Species: Rat Application Route Result: negative	
Benzy	yl alcohol:			
-	toxicity in vitro	:	Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)
Geno	toxicity in vivo	:	cytogenetic assay Species: Mouse	nalian erythrocyte micronucleus test (in vivo y) e: Intraperitoneal injection
Carci	nogenicity			

Not classified based on available information.

Components:

Benzyl alcohol:

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	103 weeks
Method	:	OECD Test Guideline 451
Result	:	negative

Reproductive toxicity

Not classified based on available information.

Components:

Benzyl benzoate:

Effects on foetal develop-

: Test Type: Embryo-foetal development



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ment			Species: Rat Application Route Result: negative	: Ingestion
Benz	yl alcohol:			
Effect	s on fertility	 Test Type: Fertility/early embryonic developme Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar material 		: Ingestion
Effect ment	s on foetal develop-	:	: Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative	

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Recombinant Bovine Somatotropin:

Species	:	Rat
Exposure time	:	90 d
Remarks	:	No significant adverse effects were reported

Benzyl benzoate:

Species	:	Rat
NOAEL	:	781 mg/kg
Application Route	:	Skin contact
Exposure time	:	4 Weeks

Benzyl alcohol:

Species	:	Rat
NOAEL	:	1.072 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	28 Days
Method	:	OECD Test Guideline 412

Aspiration toxicity

Not classified based on available information.



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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity		
Components:		
Benzyl benzoate: Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): 2.32 mg/l Exposure time: 96 h Method: Regulation (EC) No. 440/2008, Annex, C.1
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 3.09 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 0.475 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 0.247 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.258 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	EC50: > 10,000 mg/l Exposure time: 3 h Method: ISO 8192
Benzyl alcohol:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201



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	ity to daphnia and other tic invertebrates (Chron- icity)		NOEC (Daphnia i Exposure time: 2 ⁻ Method: OECD T	
Persi	istence and degradabi	lity		
Com	ponents:			
	z yl benzoate: egradability	:	Result: Readily bi Biodegradation: Exposure time: 28 Method: Directive	94 %
	yl alcohol: egradability	:	Result: Readily bi Biodegradation: Exposure time: 14	92 - 96 %
Bioa	ccumulative potential			
<u>Com</u>	ponents:			
Partit	yl benzoate: ion coefficient: n- ool/water	:		est Guideline 117
Partit	yl alcohol: ion coefficient: n- nol/water	:	log Pow: 1.05	
	lity in soil ata available			
Othe	r adverse effects ata available			

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods		
Waste from residues	:	Do not dispose of waste into sewer.
		Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste han-
		dling site for recycling or disposal.
		If not otherwise specified: Dispose of as unused product.



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SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG UN number Proper shipping name Class Subsidiary risk Packing group Labels Environmentally hazardous	:	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable no
IATA-DGR UN/ID No. Proper shipping name Class Subsidiary risk Packing group Labels Packing instruction (cargo aircraft)		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
Packing instruction (passen- ger aircraft)	:	Not applicable
IMDG-Code UN number Proper shipping name Class Subsidiary risk Packing group Labels	:	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable

Not applicable Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

: :

Not applicable for product as supplied.

National Regulations

EmS Code

Marine pollutant

ADG		
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Hazchem Code	:	Not applicable

Special precautions for user

Not applicable



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SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mix- ture					
Therapeutic Goods (Poisons : Standard) Instrument	No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)				
Prohibition/Licensing Requirement	ents	There is no applicable prohibition, authorisation and restricted use requirements, including for carcino- gens referred to in Schedule 10 of the model WHS Act and Regula- tions.			
The components of this product are reported in the following inventories:					
AICS	not determined				
DSL	not determined				
IECSC	not determined				

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information

Revision Date Sources of key data used to compile the Safety Data Sheet	:	06.04.2024 Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/
Date format	:	dd.mm.yyyy

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Con-



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centration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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