

	Version 4.1	Revision Date: 30.09.2023	SDS Number: 402598-00016	Date of last issue: 04.04.2023 Date of first issue: 11.12.2015
--	----------------	---------------------------	-----------------------------	---

### **Section 1: Identification**

Product name	:	Recombinant Bovine Somatotropin Formulation				
Manufacturer or supplier's details						
Company	:	MSD				
Address	:	33 Whakatiki Street - Private Bag 908 Upper Hutt - New Zealand				
Telephone	:	0800 800 543				
Emergency telephone number	:	0800 764 766 (0800 POISON) CHEMCALL)	0800 243 622 (0800			
E-mail address	:	EHSDATASTEWARD@msd.com	n			
Recommended use of the chemical and restrictions on use						
Recommended use Restrictions on use	:	Veterinary product Not applicable				

### Section 2: Hazard identification

GHS Classification Serious eye damage/eye irri- tation	:	Category 2
Skin sensitisation	:	Category 1
Hazardous to the aquatic environment - chronic hazard	:	Category 3
GHS label elements		
Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effects.



Version 4.1	Revision Date: 30.09.2023	SDS Number: 402598-00016	Date of last issue: 04.04.2023 Date of first issue: 11.12.2015
Preca	utionary statements	P264 Wash sk P272 Contami the workplace. P273 Avoid rel	eathing mist or vapours. in thoroughly after handling. nated work clothing should not be allowed out of ease to the environment. otective gloves/ eye protection/ face protection.
		Response: P302 + P352 I P305 + P351 + for several min easy to do. Co P333 + P313 I vice/ attention. P337 + P313 I tention.	F ON SKIN: Wash with plenty of water. - P338 IF IN EYES: Rinse cautiously with water outes. Remove contact lenses, if present and ntinue rinsing. f skin irritation or rash occurs: Get medical ad-
		<b>Disposal:</b> P501 Dispose disposal plant.	of contents/ container to an approved waste

# 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	>= 20 -< 30
Benzyl benzoate	120-51-4	>= 10 -< 20
Benzyl alcohol	100-51-6	>= 10 -< 20

### Section 4: First-aid measures

General advice	vice immedia	f accident or if you feel unwell, seek medical ad- tely. oms persist or in all cases of doubt seek medical
If inhaled	,	nove to fresh air. attention if symptoms occur.
In case of skin contact	Wash with wa	ater and soap as a precaution. attention if symptoms occur.
In case of eye contact		ntact, immediately flush eyes with plenty of water



Version 4.1	Revision Date: 30.09.2023		0S Number: 2598-00016	Date of last issue: 04.04.2023 Date of first issue: 11.12.2015
			for at least 15 mir	suites.
If swallowed		:	If easy to do, rem Get medical atten If swallowed, DO Get medical atten	ove contact lens, if worn.
	t important symptoms effects, both acute and ved	:	May cause an alle Causes serious e	ergic skin reaction. ye irritation.
	ection of first-aiders	:	and use the recor	ers should pay attention to self-protection, nmended personal protective equipment Il for exposure exists (see section 8).
	es to physician	:	Treat symptomati	cally and supportively.
Section	5: Fire-fighting measure	S		
Suita	able extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical	
med		:	None known.	
fight	ardous combustion prod-	:	Exposure to com	bustion products may be a hazard to health.
Spe ods	cific extinguishing meth-	:	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to so.	
	cial protective equipment refighters	:		e, wear self-contained breathing apparatus. tective equipment.
Section	6: Accidental release me	easi	ures	
tive	sonal precautions, protec- equipment and emer- cy procedures	:	Follow safe handl	tective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).
Envi	ronmental 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 o se of contaminated wash water. should be advised if significant spillages

### Methods and materials for : Soak up with inert absorbent material.



Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	402598-00016	Date of first issue: 11.12.2015
conta	inment and cleaning up	ment to keep ma be pumped, stor Clean up remain bent. Local or national posal of this mat employed in the mine which regu Sections 13 and	provide dyking or other appropriate contain- terial from spreading. If dyked material can e recovered material in appropriate container. ing materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- lations are applicable. 15 of this SDS provide information regarding ational requirements.

## Section 7: Handling and storage

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation Advice on safe handling	:	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 practice, based on the results of the workplace exposure as- sessment Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
Conditions for safe storage	:	Keep in properly labelled containers. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents

## Section 8: Exposure controls/personal protection

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis
		exposure)	concentration	



Version 4.1	Revision Date: 30.09.2023	SDS Number: 402598-00016		t issue: 04.04.2023 t issue: 11.12.2015	
Rec	combinant Bovine Somato- bin	- Not Assigned	TWA	OEB 3 (>= 10 < 100 μg/m3)	Internal
Engineering measures : Use a techr less o All er desig prote Conta are re the c tainm		technologies to less quick con All engineering design and op protect produc Containment to are required to	o control airborn nections). g controls shoul erated in accord echnologies sui o control at sour to uncontrolled ces).	controls and manufact the concentrations (e. d be implemented by dance with GMP prin d the environment. table for controlling of the and to prevent mi l areas (e.g., open-fact	g., drip- / facility ciples to compounds gration of
Per	sonal protective equipm	ent			
	spiratory protection Filter type nd protection	sure assessme ommended gu	ent demonstrate idelines, use re	tilation is not availables exposures outside spiratory protection. ganic vapour type	
	Material	: Chemical-resis	stant gloves		
	Remarks e protection	If the work env mists or aeros Wear a facesh	lasses with side vironment or act ols, wear the ap nield or other ful	e shields or goggles. tivity involves dusty oppropriate goggles. I face protection if the he face with dusts, n	ere is a
Ski	n and body protection	: Work uniform Additional bod task being per posable suits)	formed (e.g., slo to avoid expose te degowning te	bat. buld be used based u eevelets, apron, gau ed skin surfaces. echniques to remove	ntlets, dis-

## Section 9: Physical and chemical properties

Appearance	: suspension
Colour	: opaque, yellow
Odour	: musty
Odour Threshold	: No data available
рН	: No data available
Melting point/freezing point	: No data available



Version	Revision Date: 30.09.2023	SDS Number:	Date of last issue: 04.04.2023
4.1		402598-00016	Date of first issue: 11.12.2015

Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n- octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available



Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	402598-00016	Date of first issue: 11.12.2015

### 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 availab	ole	information.
Product:		
Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 2,000 mg/kg

### Components:

components.		
Recombinant Bovine Somate	otro	opin:
Acute inhalation toxicity	:	LC50 (Rat): 30,000 mg/l Exposure time: 1 h Test atmosphere: dust/mist
Benzyl benzoate:		
Acute oral toxicity	:	LD50 (Rat): 1,700 mg/kg
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg

Benzyl alcohol:	
Acute oral toxicity	: LD50 (Rat): 1,620 mg/kg
Acute inhalation toxicity	: LC50 (Rat): > 4.178 mg/l

Method: Calculation method



ersion 1	Revision Date: 30.09.2023		9S Number: 2598-00016	Date of last issue: 04.04.2023 Date of first issue: 11.12.2015
			Exposure time:	4 h
			Test atmosphe	
				Test Guideline 403
Aouto	dormal toxicity		Aquita taxiaity a	atimata: 1 100 mg/kg
Acute	dermal toxicity	:	Method: Experi	stimate: 1,100 mg/kg
				ed on national or regional regulation.
Skin	corrosion/irritation			
Not cl	assified based on ava	ailable	information.	
<u>Comp</u>	oonents:			
Reco	mbinant Bovine Son	natotr	opin:	
Speci		:	Rabbit	
Rema		:	slight irritation	
Benz	yl benzoate:			
Speci			Rabbit	
Metho		÷	OECD Test Gu	ideline 404
Resul		:	No skin irritatio	
Benz	yl alcohol:			
Speci		:	Rabbit	
Metho		:	OECD Test Gu	ideline 404
Resul	t	:	No skin irritatio	n
Serio	us eye damage/eye i	irritati	on	
	es serious eye irritatio			
<u>Comp</u>	oonents:			
Reco	mbinant Bovine Son	natotr	opin:	
Speci	es	:	Rabbit	
Rema	arks	:	slight irritation	
Benz	yl benzoate:			
Speci		•	Rabbit	
Resul		:	No eye irritation	1
Benz	yl alcohol:			
			Rabbit	
Sneci		•		
Speci Resul	t		Irritation to eve	s, reversing within 21 days



	S Number: Dat 2598-00016 Dat
--	---------------------------------

Date of last issue: 04.04.2023 Date of first issue: 11.12.2015

### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

### **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:**

Assessment	:	Probability or evidence of skin sensitisation in humans
Remarks	:	Based on national or regional regulation.

### **Chronic toxicity**

#### Germ cell mutagenicity

Not classified based on available information.

### Components:

Benzyl benzoate:		
Genotoxicity in vitro		Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: In vitro mammalian cell gene mutation test Result: positive Remarks: Based on data from similar materials
		Test Type: Chromosome aberration test in vitro Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	:	Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Benzyl alcohol: Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES)

#### Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative



rsion	Revision Date: 30.09.2023		S Number: 2598-00016	Date of last issue: 04.04.2023 Date of first issue: 11.12.2015
Genot	oxicity in vivo	:	cytogenetic ass Species: Mouse	e ite: Intraperitoneal injection
	n <b>ogenicity</b> assified based on ava	ilable	information.	
<u>Comp</u>	onents:			
Specie Applic	ation Route sure time d	:	Mouse Ingestion 103 weeks OECD Test Gu negative	ideline 451
Not cla	oductive toxicity assified based on ava	ilable	information.	
	oonents:			
-	<b>/l benzoate:</b> s on foetal develop-	:	Test Type: Emb Species: Rat Application Rou Result: negative	0
Benzy	/l alcohol:			
-	s on fertility	:	Species: Rat Application Rou Result: negative	
Effects ment	s on foetal develop-	:	Test Type: Emb Species: Mouse Application Rou Result: negative	ite: Ingestion
	<ul> <li>single exposure</li> <li>assified based on ava</li> </ul>	ilable	information	

## Benzyl benzoate:

Assessment

: May cause respiratory irritation.



Version 4.1	Revision Date: 30.09.2023		9S Number: 2598-00016	Date of last issue: 04.04.2023 Date of first issue: 11.12.2015
Rem	arks	:	Based on nationa	al or regional regulation.
	<b>T - repeated exposure</b> classified based on ava		information.	
Repe	eated dose toxicity			
Com	ponents:			
Reco	ombinant Bovine Som	atotro	opin:	
Spec	cies osure time	:	Rat 90 d	verse effects were reported
Benz	zyl benzoate:			
		:	Rat 781 mg/kg Skin contact 4 Weeks	
Benz	zyl alcohol:			
Spec NOA Appli	ies EL cation Route sure time	:	Rat 1.072 mg/l inhalation (dust/n 28 Days OECD Test Guid	
-	ration toxicity classified based on ava	ilable	information.	
Section 1	2: Ecological informa	tion		
Ecot	oxicity			

Com	ponents:

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



ersion 1	Revision Date: 30.09.2023	-	0S Number: 2598-00016	Date of last issue: 04.04.2023 Date of first issue: 11.12.2015
			Exposure time: 72 Method: OECD Te	
			NOEC (Pseudokir mg/l Exposure time: 72 Method: OECD Te	
	ctor (Acute aquatic tox-	:	1	
	ty to daphnia and other ic invertebrates (Chron- city)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD Te	
Toxici	ty to microorganisms	:	EC50: > 10,000 m Exposure time: 3 Method: ISO 8192	ĥ
Benzy	yl alcohol:			
Toxici	ty to fish	:	LC50 (Pimephales Exposure time: 96	s promelas (fathead minnow)): 460 mg/l s h
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
Toxici plants	ty to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD Te	
			NOEC (Pseudokir mg/l Exposure time: 72 Method: OECD Te	
	ity to daphnia and other ic invertebrates (Chron- city)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD Te	
Persi	stence and degradabili	ity		
Comp	ponents:			
-	<b>yl benzoate:</b> gradability	:	Result: Readily bio Biodegradation: S Exposure time: 28 Method: Directive	94 %



Version 4.1	Revision Date: 30.09.2023		lumber: 8-00016	Date of last issue: 04.04.2023 Date of first issue: 11.12.2015
Benz	yl alcohol:			
	egradability	Bio	sult: Readily odegradation posure time:	
Bioa	ccumulative potential			
<u>Com</u>	ponents:			
Partit	<b>:yl benzoate:</b> tion coefficient: n- nol/water	-	) Pow: 4 ethod: OECD	Test Guideline 117
Benz	yl alcohol:			
Partit	tion coefficient: n- nol/water	: log	9 Pow: 1.05	
Mobi	ility in soil			
No da	ata available			
	r adverse effects			
No da	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.

## Section 14: Transport information

### International Regulations

UNRTDG UN number Proper shipping name Class Subsidiary risk Packing group Labels	<ul> <li>Not applica</li> </ul>	ble ble ble ble
IATA-DGR UN/ID No. Proper shipping name Class Subsidiary risk Packing group	<ul> <li>Not applica</li> <li>Not applica</li> <li>Not applica</li> <li>Not applica</li> <li>Not applica</li> <li>Not applica</li> </ul>	ble ble ble



Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	402598-00016	Date of first issue: 11.12.2015

Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft)	::	Not applicable Not applicable Not applicable
IMDG-Code UN number Proper shipping name Class Subsidiary risk Packing group Labels EmS Code Marine pollutant	:	Not applicable 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 for product as supplied.

#### National Regulations

NZS 5433		
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

#### Section 15: Regulatory information

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

#### HSNO Approval Number

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

### **HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

#### The components of this product are reported in the following inventories:

AICS	:	not determined
------	---	----------------

DSL : not determined



Versio 4.1	n Revision Date: 30.09.2023		DS Number: 2598-00016	Date of last issue: 04.04.2023 Date of first issue: 11.12.2015		
IECSC		:	not determined			
Section 16: Other information						
Revision Date		:	30.09.2023			
Further information						
C	ources of key data used to ompile the Safety Data the sheet	:		data, data from raw material SDSs, OECD arch results and European Chemicals Agen- ropa.eu/		
D	Pate 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 Concentration 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



Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	402598-00016	Date of first issue: 11.12.2015

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.

NZ / EN