

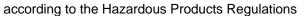
according to the Hazardous Products Regulations

Buserelin Formulation

Vers 3.0	sion	Revision Date: 09/28/2024		OS Number: 1696-00021	Date of last issue: 07/06/2024 Date of first issue: 05/03/2016
SEC	TION 1	. IDENTIFICATION			
Product name Other means of identification		-	Buserelin Formulation RECEPTAL (A004062) RECEPTAL SYNTHETIC GONADOTROPHIN RELEASING HORMONE (36019)		
Manufacturer or supplier's o		deta	nils		
Company name of supplier Address			 Merck & Co., Inc 126 E. Lincoln Avenue Rahway, New Jersey U.S.A. 07065 		
Telephone Emergency telephone E-mail address			: 908-740-4000 : 1-908-423-6000 : EHSDATASTEWARD@merck.com		
Recommended use of the c		hen	nical and restriction	ons on use	
Recommended use Restrictions on use		:	Veterinary produc Not applicable	ot	

SECTION 2. HAZARDS IDENTIFICATION

dan	ce with the Hazardous Products Regulations			
:	Sub-category 1B			
:				
:	Warning			
:	H317 May cause an allergic skin reaction.			
:	Prevention: P261 Avoid breathing mist or vapors. P272 Contaminated work clothing should not be allowed out of			
	the workplace. P280 Wear protective gloves.			
	Response:			
	P302 + P352 IF ON SKIN: Wash with plenty of water. P333 + P313 If skin irritation or rash occurs: Get medical atten- tion.			
	P362 + P364 Take off contaminated clothing and wash it before reuse.			
	Disposal: P501 Dispose of contents and container to an approved waste disposal plant.			





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Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Benzyl alcohol	Benzenemetha- nol	100-51-6	>= 1 - < 5 *
Buserelin	No data availa- ble	68630-75-1	>= 0 - < 0.1 *

Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical advice 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	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
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	:	May cause an allergic skin reaction.
Protection of first-aiders Notes to physician	:	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). Treat symptomatically and supportively.
Notes to physician	•	rical symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.



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	Specific hazards during fire fighting		:	Exposure to comb	Exposure to combustion products may be a hazard to health.	
	Hazardous combustion prod- ucts		:	Carbon oxides		
	Specific extinguishing meth- ods		:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.		
	Special protective equipment for fire-fighters		:	In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.	
SEC	TION 6.	ACCIDENTAL RELE	ASI	EMEASURES		
1	Personal precautions, protec- tive equipment and emer- gency procedures		:		ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).	
"	Environmental precautions		:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment of oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.		
		s and materials for ment and cleaning up	:	For large spills, pr	absorbent material. ovide diking or other appropriate ep material from spreading. If diked material	

SECTION 7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE
		CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not get on skin or clothing.
11		Avoid breathing mist or vapors.

container.

absorbent.

can be pumped, store recovered material in appropriate

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

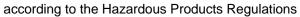
employed in the cleanup of releases. You will need to

Sections 13 and 15 of this SDS provide information regarding

determine which regulations are applicable.

certain local or national requirements.

Clean up remaining materials from spill with suitable





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		Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and saf practice, based on the results of the workplace exposure assessment Take care to prevent spills, waste and minimize release to environment.		
Cond	litions for safe storage		y labeled containers. ance with the particular national regulations.	
Materials to avoid			h the following product types:	

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Buserelin	68630-75-1	TWA	0.1 μg/m3 (OEB 5)	Internal
		Wipe limit	1 µg/100 cm ²	Internal

Engineering measures	:	Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. No open handling permitted. Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.
Personal protective equipme	nt	
Respiratory protection :		If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type Hand protection	:	Organic vapor Type
Material	:	Chemical-resistant gloves
Remarks Eye protection	:	Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

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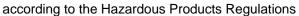


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Skin and body protection		Additional body task being perfo disposable suits Use appropriate	: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.			
Hygiene measures		eye flushing sys working place. When using do Contaminated v	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. Contaminated work clothing should not be allowed out of the workplace.			
		Wash contamin The effective op engineering cor appropriate deg industrial hygier	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.			

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid, Aqueous solution
Color	:	colorless
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	5.7 - 6.3
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
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
Vapor pressure	:	No data available
Relative vapor density	:	No data available





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	Relativ	e density	:	No data available	9
	Density		:	1.004 g/cm ³	
	Solubility(ies) Water solubility		:	soluble	
	Partitio octano	n coefficient: n-	:	No data available	9
		nition temperature	:	Not applicable	
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ity cosity, kinematic	:	No data available	e
	Explos	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	ılar weight	:	Not applicable	
	Particle Particle	e characteristics e size	:	No data available	9

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

Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

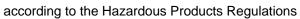
Acute toxicity

Not classified based on available information.

Product:

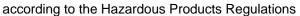
Acute oral toxicity

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





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<u>Com</u>	oonents:			
Benz	yl alcohol:			
Acute	oral toxicity	:	LD50 (Rat): 1,200	mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 5.4 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: The substance or mixture has no acute inhal tion toxicity	
Buse	relin:			
Acute	oral toxicity	:	LD50 (Rat): 400 n	ng/kg
			LD50 (Mouse): >	1,000 mg/kg
	toxicity (other routes of nistration)	:	LD50 (Rat): 36 mg Application Route	
			LD50 (Rat): > 500 Application Route	
			LD50 (Mouse): 56 Application Route	
			LD50 (Dog): > 10 Application Route	
Not cl	corrosion/irritation lassified based on availa conents:	ble	information.	
Benz	yl alcohol:			
Speci		:	Rabbit OECD Test Guide	line 404
Metho Resul		:	No skin irritation	sine 404
Buse	relin:			
Speci		÷	Rabbit	
Resu		:	No skin irritation	
Not cl	us eye damage/eye irri lassified based on availa conents:			
Benz	yl alcohol:			
Speci Resul Metho	es It	:	Rabbit Irritation to eyes, I OECD Test Guide	reversing within 21 days line 405





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Buserelin:

Species Result	:	Rabbit
Result	:	No eye irritation

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:

Benzyl alcohol:

Test Type Routes of exposure Species Result	 Human repeat insult patch test (HRIPT) Skin contact Humans positive
Assessment	: Probability or evidence of low to moderate skin sensitization rate in humans

Buserelin:

Routes of exposure Species Result	: Dermal
Species	: Guinea pig
Result	: Not a skin sensitizer.

Germ cell mutagenicity

Not classified based on available information.

Components:

Benzyl alcohol:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative
Buserelin:	
Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: unscheduled DNA synthesis assay Result: negative

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Genoto	09/28/2024		0S Number: 1696-00021	Date of last issue: 07/06/2024 Date of first issue: 05/03/2016
	oxicity in vivo	:	cytogenetic assay Species: Mouse	nalian erythrocyte micronucleus test (in vivo /) : Intraperitoneal injection
	ogenicity ssified based on availa	able	information	
	onents:			
	alcohol:			
Species		:	Mouse	
Applica	tion Route	:	Ingestion	
	ire time	:	103 weeks	
Method Result	1	:	OECD Test Guide negative	
Busere	lin-			
Species		•	Rat	
	tion Route	÷	Subcutaneous	
	ure time	:	24 Months	
Result	Organs	÷	negative	cervix), Pituitary gland, Testes
Not clas	ductive toxicity ssified based on availa	able	information.	
<u>Compc</u>	onents:			
	alcohol:			
	alcohol: on fertility	:	Species: Rat Application Route Result: negative	y/early embryonic development : Ingestion on data from similar materials
Effects	on fertility	:	Species: Rat Application Route Result: negative Remarks: Based	: Ingestion on data from similar materials
Effects		:	Species: Rat Application Route Result: negative Remarks: Based Test Type: Embry Species: Mouse	: Ingestion on data from similar materials ro-fetal development
Effects	on fertility	:	Species: Rat Application Route Result: negative Remarks: Based Test Type: Embry	: Ingestion on data from similar materials ro-fetal development
Effects	on fertility on fetal development	:	Species: Rat Application Route Result: negative Remarks: Based Test Type: Embry Species: Mouse Application Route	: Ingestion on data from similar materials ro-fetal development
Effects	on fertility on fetal development	:	Species: Rat Application Route Result: negative Remarks: Based Test Type: Embry Species: Mouse Application Route Result: negative	: Ingestion on data from similar materials ro-fetal development : Ingestion
Effects	on fertility on fetal development	:	Species: Rat Application Route Result: negative Remarks: Based Test Type: Embry Species: Mouse Application Route Result: negative	: Ingestion on data from similar materials ro-fetal development
Effects	on fertility on fetal development	:	Species: Rat Application Route Result: negative Remarks: Based Test Type: Embry Species: Mouse Application Route Result: negative Test Type: Fertilit Species: Rat Application Route	: Ingestion on data from similar materials ro-fetal development : Ingestion y/early embryonic development : Subcutaneous
Effects	on fertility on fetal development	:	Species: Rat Application Route Result: negative Remarks: Based Test Type: Embry Species: Mouse Application Route Result: negative Test Type: Fertilit Species: Rat	: Ingestion on data from similar materials ro-fetal development : Ingestion y/early embryonic development : Subcutaneous 0.2 μg/kg
Effects	on fertility on fetal development	:	Species: Rat Application Route Result: negative Remarks: Based Test Type: Embry Species: Mouse Application Route Result: negative Test Type: Fertilit Species: Rat Application Route Fertility: LOAEL: (Result: Effects on	: Ingestion on data from similar materials ro-fetal development : Ingestion y/early embryonic development : Subcutaneous 0.2 μg/kg fertility.
Effects	on fertility on fetal development	:	Species: Rat Application Route Result: negative Remarks: Based Test Type: Embry Species: Mouse Application Route Result: negative Test Type: Fertilit Species: Rat Application Route Fertility: LOAEL: (Result: Effects on	 : Ingestion on data from similar materials ro-fetal development : Ingestion y/early embryonic development : Subcutaneous 0.2 µg/kg fertility. y/early embryonic development male

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				Fertility: LOAEL: > Result: Effects on	
				Test Type: Fertility Species: Mouse, f Application Route Fertility: LOAEL: 1 Result: Effects on	: Subcutaneous I00 μg/kg
	Effects	on fetal development	:	Species: Rat Application Route Developmental To	o-fetal development : Intravenous injection oxicity: LOAEL: 0.4 μg/kg body weight kic effects., Effects on early embryonic
				Species: Rabbit Developmental To	o-fetal development oxicity: LOAEL: 0.1 μg/kg body weight kic effects., No specific developmental
				Species: Mouse Developmental To	o-fetal development oxicity: NOAEL: 0.1 μg/kg body weight kic effects., No effects on F1 offspring.
	Reprod sessme	luctive toxicity - As-	:	May damage fertil	lity.
I		single exposure ssified based on availa	ble	information.	
	STOT-I	repeated exposure			
	_	ssified based on availa ed dose toxicity	ble	information.	
	-	onents:			
	Benzyl	alcohol:			
		- tion Route ire time	:	Rat 1.072 mg/l inhalation (dust/m 28 Days OECD Test Guide	
	Busere	elin:			
	Species LOAEL Applica Exposu	tion Route	:	Rat 0.5 ug/kg/day Subcutaneous 14 Days	
	Species	8	:	Rat	
				10 / 14	

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Expo	EL cation Route sure time et Organs	: 0.05 ug/kg/da : Subcutaneou : 28 Days : Testis	
		: Rabbit : 20 ug/kg/day : 4 Weeks : Prostate, Pitu	itary gland, Testis
		: Monkey : 5 ug/kg/day : 1 y : Ovary, Pituita	ry gland
Expo		: Dog : 0.05 mg/kg : Subcutaneou : 30 Days : Pituitary glan	
Expo		: Dog : 0.05 mg/kg : Subcutaneou : 6 Months : Reproductive	
-	ration toxicity lassified based on avai	lable information.	
	rience with human ex		
Com	oonents:		
Buse			
Inhala	ation	effects, reduc turbance, me Remarks: Ma	nale reproductive effects, female reproductive eed libido, Headache, Rash, Gastrointestinal dis- ntal depression, Local irritation y damage fertility. man Evidence

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Benzyl alcohol:

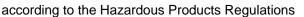
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
	:	EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202

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Toxici plants	ity to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD To	
			NOEC (Pseudokin mg/l Exposure time: 72 Method: OECD Te	
	ty to daphnia and other ic invertebrates (Chron- city)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD To	
Buse	relin:			
Ecoto	oxicology Assessment			
Acute	aquatic toxicity	:	No data available	
Chror	nic aquatic toxicity	:	No data available	
Persi	stence and degradabili	ty		
<u>Comp</u>	oonents:			
Benz	yl alcohol:			
Biode	gradability	:	Result: Readily bi Biodegradation: 9 Exposure time: 14	92 - 96 %
Bioac	cumulative potential			
Com	oonents:			
Partiti	yl alcohol: on coefficient: n- ol/water	:	log Pow: 1.05	
	l ity in soil Ita available			
	adverse effects Ita available			

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 handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.





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Inter	national Regulations	5	
UNR Not re	TDG egulated as a danger	ous good	
	-DGR		

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

TDG

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION

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



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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

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/
Revision Date Date format	:	09/28/2024 mm/dd/yyyy

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

CA / Z8