

Gonadorelin Formulation

Vers 6.0	ion	Revision Date: 2024/09/28		S Number: 3535-00017	Date of last issue: 2023/12/08 Date of first issue: 2016/04/27
1. PF	RODUC	T AND COMPANY IDE	ENT	IFICATION	
	Product	name	:	Gonadorelin Forr	nulation
	Other m	eans of identification	:	FERTAGYL SYNTHETIC GONADOTROPHIN RELEASIN HORMONE (37210)	
	Manufa	cturer or supplier's d	letai	ils	
	Compar	лу	:	MSD	
	Address	3	:	126 E. Lincoln Av Rahway, New Je	venue rsey U.S.A. 07065
	Telepho	one	:	908-740-4000	
	Emergency telephone number		:	1-908-423-6000	
	E-mail a	address	:	EHSDATASTEW	/ARD@msd.com
	Recom	mended use of the ch	nem	ical and restriction	ons on use
	Recommended use Restrictions on use		:	Veterinary produ Not applicable	ct

2. HAZARDS IDENTIFICATION

GHS Classification		
Skin sensitisation	:	Category 1
Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Endocrine system)
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	 H317 May cause an allergic skin reaction. H361fd Suspected of damaging fertility. Suspected of damaging the unborn child. H372 Causes damage to organs (Endocrine system) through prolonged or repeated exposure if swallowed.



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Ш			
Preca	autionary statements	[:] Prevention:	

Fievendon.
 P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe mist or vapours. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of water. P308 + P313 IF exposed or concerned: Get medical advice/ attention. P333 + P313 If skin irritation or rash occurs: Get medical ad- vice/ attention. P362 + P364 Take off contaminated clothing and wash it before reuse.
Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture :

Components

Chemical name	CAS-No.	Concentration (% w/w)
Benzyl alcohol	100-51-6	>= 1 -< 10
Gonadorelin	34973-08-5	>= 0.001 -< 1

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.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water.



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If swa Most i and ei delaye	e of eye contact llowed important symptoms ffects, both acute and ed ction of first-aiders	: :	Get medical atter Wash clothing be Thoroughly clean Flush eyes with v Get medical atter If swallowed, DO Get medical atter Rinse mouth thor May cause an all Suspected of dar unborn child. Causes damage exposure if swall First Aid respond and use the reco	efore reuse. a shoes before reuse. vater as a precaution. ntion if irritation develops and persists. NOT induce vomiting. ntion. roughly with water. ergic skin reaction. maging fertility. Suspected of damaging the to organs through prolonged or repeated owed. ers should pay attention to self-protection, mmended personal protective equipment
Notoo	to physician	:		al for exposure exists (see section 8). ically and supportively.
notes	1 2		, ,	
	GHTING MEASURES		<i>,</i> ,	
5. FIREFIC		:	Water spray Alcohol-resistant Carbon dioxide ((Dry chemical	
5. FIREFIC	SHTING MEASURES	:	Water spray Alcohol-resistant Carbon dioxide (0	
5. FIREFIG Suitat Unsui media	SHTING MEASURES ble extinguishing media table extinguishing	:	Water spray Alcohol-resistant Carbon dioxide (Dry chemical None known.	
5. FIREFIG Suitat Unsui media Specii fightin	SHTING MEASURES ble extinguishing media table extinguishing	:	Water spray Alcohol-resistant Carbon dioxide (Dry chemical None known.	CO2)
FIREFIC Suitat Unsui media Speci fightin Hazar ucts	SHTING MEASURES ble extinguishing media table extinguishing fic hazards during fire-	:	Water spray Alcohol-resistant Carbon dioxide (Dry chemical None known. Exposure to com Carbon oxides Use extinguishing cumstances and Use water spray	CO2)

tive equipment and emer-		Follow safe handling advice (see section 7) and personal pro-
gency procedures		tective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment.





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		Prevent spreadi barriers). Retain and disp	leakage or spillage if safe to do so. ng over a wide area (e.g. by containment or oil ose of contaminated wash water. s should be advised if significant spillages ined.
Methods and materials for containment and cleaning up		For large spills, ment to keep ma be pumped, stor Clean up remain bent. Local or nationa posal of this ma employed in the mine which regu Sections 13 and	ert absorbent material. provide dyking or other appropriate contain- aterial from spreading. If dyked material can re recovered material in appropriate container. hing materials from spill with suitable absor- al regulations may apply to releases and dis- terial, as well as those materials and items cleanup of releases. You will need to deter- ulations are applicable. I 15 of this SDS provide information regarding mational requirements.

7. HANDLING AND STORAGE

Technical measures Local/Total ventilation Advice on safe handling	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. Use only with adequate ventilation. Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Avoid contact with eyes. 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 Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Gonadorelin	34973-08-5	TWA	0.2 µg/m3 (OEB	Internal





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					5)			
				Wipe limit	2 µg/100 cm ²	Internal		
Engir	neering measures	:			especially in confine concentrations.	ed areas.		
Perso	onal protective equip	ment						
Resp	iratory protection	:	sure assessm	ent demonstrate	tilation is not availat es exposures outsid spiratory protection.	e the rec-		
	lter type protection	:	Organic vapor					
Ma	aterial	:	Chemical-resistant gloves					
Re	emarks	:	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the					
Eye p	protection	:	end of workday. Wear the following personal protective equipment: Safety glasses					
Skin a	and body protection	:	 Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc). 					
Hygie	ene measures	:	If exposure to eye flushing s ing place. When using d Contaminated workplace.	chemical is like ystems and safe o not eat, drink	ly during typical use ety showers close to or smoke. hould not be allowe	the work-		

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available



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	nitial bo ange	piling point and boiling	:	No data available	
F	lash p	oint	:	No data available	•
E	Evapora	ation rate	:	No data available	
F	lamma	ability (solid, gas)	:	Not applicable	
F	lamma	ability (liquids)	:	No data available	•
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
V	/apour	pressure	:	No data available	•
R	Relative	e vapour density	:	No data available	•
D	Density		:	No data available	•
S	Solubilit Wate	ty(ies) er solubility	:	No data available	
	Partitior	n coefficient: n-	:	No data available	
		nition temperature	:	No data available	
D	Decomp	position temperature	:	No data available	•
۷	/iscosit Visc	y osity, dynamic	:	No data available	
	Visc	osity, kinematic	:	No data available	•
E	Explosiv	ve properties	:	Not explosive	
C	Dxidizir	ng properties	:	The substance or	mixture is not classified as oxidizing.
N	/lolecul	ar weight	:	Not applicable	
	Particle Particle	characteristics size	:	No data available	

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Can react with strong oxidizing agents.



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Incom	itions to avoid npatible materials rdous decomposition icts	:	None known. Oxidizing agents No hazardous de	ecomposition products are known.
1. TOXIC	OLOGICAL INFORMAT	101	N	
Inforn expos	nation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact	
	<mark>e toxicity</mark> lassified based on availa	hla	information	
Prod		Die	iniomation.	
	e oral toxicity	:	Acute toxicity esti Method: Calculati	mate: > 2,000 mg/kg on method
<u>Com</u>	ponents:			
Benz	yl alcohol:			
Acute	e oral toxicity	:	LD50 (Rat): 1,200) mg/kg
	inhalation toxicity	:	LC50 (Rat): > 5.4 Exposure time: 4 Test atmosphere: Method: OECD T Assessment: The tion toxicity	h dust/mist
II Gona	dorelin:			
	e oral toxicity	:	LD50 (Rat): > 3,0	00 mg/kg
			LD50 (Mouse): >	4,000 mg/kg
Acute	inhalation toxicity	:	Remarks: No data	a available
Acute	e dermal toxicity	:	Remarks: No data	a available
	corrosion/irritation lassified based on availa	ble	information.	
<u>Com</u>	ponents:			
Benz Speci Metho Resu	bd	:	Rabbit OECD Test Guide No skin irritation	eline 404



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Gona Rema	adorelin: arks	: No	data availa	ble
Not c	ous eye damage/eye lassified based on av		mation.	
	ponents:			
Spec	z yl alcohol: ies	: Rat	obit	
Resu Meth	lt			es, reversing within 21 days uideline 405
	adorelin:	NL	1	
Rema	arks	: No	data availa	DIE
Resp	piratory or skin sens	itisation		
Skin	sensitisation			
	cause an allergic skin	reaction.		
	biratory sensitisatior			
	lassified based on av		mation.	
Com	ponents:			
Bonz	yl alcohol:			
	Type	: Hur	nan repeat	insult patch test (HRIPT)
	sure routes		n contact	
Spec			mans	
Resu	lt	: pos	sitive	
Asse	ssment		bability or e in humans	evidence of low to moderate skin sensitisation
Gona	adorelin:			
Rema	arks	: No	data availa	ble
Germ	n cell mutagenicity			
Not c	lassified based on av	ailable infor	mation.	
<u>Com</u>	ponents:			
Benz	yl alcohol:			
	otoxicity in vitro		st Type: Bac sult: negativ	cterial reverse mutation assay (AMES) /e
Genc	otoxicity in vivo	cyto	st Type: Mai ogenetic as ecies: Mous	



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		Application Ro Result: negativ	ute: Intraperitoneal injection /e
II Gona	dorelin:		
Genotoxicity in vitro		Result: negativ	cterial reverse mutation assay (AMES) /e ed on data from similar materials
		Result: negativ	vitro mammalian cell gene mutation test ve ed on data from similar materials
		Result: negativ	romosome aberration test in vitro /e ed on data from similar materials
	cell mutagenicity -	: Weight of evid cell mutagen.	ence does not support classification as a ge
Carci Not cl	i nogenicity lassified based on ava ponents:	Ū.	
Carci Not cl Com Benz Speci Applic	inogenicity lassified based on ava ponents: yl alcohol: ies cation Route sure time od	Ū.	uideline 451
Carci Not cl Com Benz Speci Applic Expos Metho Resul	inogenicity lassified based on ava ponents: yl alcohol: ies cation Route sure time od	ailable information. : Mouse : Ingestion : 103 weeks : OECD Test Gu	uideline 451
Carci Not cl Com Benz Speci Applic Expos Metho Resul Gona	inogenicity lassified based on ava <u>ponents:</u> yl alcohol: ies cation Route sure time od lt idorelin: ies sure time EL	ailable information. : Mouse : Ingestion : 103 weeks : OECD Test Go : negative : Mouse : 2 Years : 2.4 mg/kg bod : positive	



ersion 0	Revision Date: 2024/09/28	SDS Number: 613535-00017	Date of last issue: 2023/12/08 Date of first issue: 2016/04/27
<u>Com</u>	ponents:		
Benz	yl alcohol:		
Effect	ts on fertility	Species: Rat Application Re Result: negati	ertility/early embryonic development oute: Ingestion ive sed on data from similar materials
Effect ment	ts on foetal develop-	Species: Mou	oute: Ingestion
Gona	dorelin:		
Effect	ts on fertility	Species: Rat, Application Re Fertility: LOAE Result: Effects	oute: Subcutaneous EL: 50 µg/kg
		Species: Rat, Application Ro Fertility: LOAE Result: Effects	oute: Subcutaneous EL: 500 μg/kg
		Species: Rabl Application Re	oute: Subcutaneous EL: 1,000 μg/kg
		Species: Dog Application Re	ertility/early embryonic development , male and female oute: Subcutaneous EL: 107 - 214 μg/kg s on fertility
Effect ment	ts on foetal develop-	Species: Rat Application Ro Developmenta	nbryo-foetal development oute: Subcutaneous al Toxicity: LOAEL: >= 2 μg/kg s on foetal development
		Species: Rabl Application Ro Developmenta	nbryo-foetal development bit oute: Subcutaneous al Toxicity: LOAEL: > 20 μg/kg s on foetal development



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Reproc sessmo	luctive toxicity - As- ent	:	fertility, based o	e of adverse effects on sexual function and on animal experiments., Some evidence of on development, based on animal experi-
STOT	- single exposure			
Not cla	ssified based on ava	ilable	information.	
	 repeated exposure 			
Causes lowed.	s damage to organs	(Endo	crine system) thr	ough prolonged or repeated exposure if swal
	onents:			
Gonad				
Target Assess	Organs	:	Endocrine syste	e to organs through prolonged or repeated
/ 100000		•	exposure.	
Repea	ted dose toxicity			
<u>Comp</u>	onents:			
Benzy	alcohol:			
Specie		:	Rat	
NOAEI	- ation Route	:	1.072 mg/l inhalation (dust	/mist/fumo)
	lion Roule	:	28 Days	/mstrume)
Method		:	OECD Test Gu	ideline 412
Canad				
Gonad Specie			Rat	
NOAEI		÷	0.12 mg/kg	
Applica	ation Route	:	Intramuscular	
	ure time	:	15 Days	
Remar	KS	-	No significant a	dverse effects were reported
Specie		:	Rat	
NOAEI		:	0.072 mg/kg	
Applica	ition Route ure time	÷	Intravenous 15 Days	
Remar	ks	:		dverse effects were reported
IlSpagia	6		Dog	
Specie NOAEI		:	0.12 mg/kg	
	- ation Route	:	Intramuscular	
Exposi	ure time	:	15 Days	
Remar	ks	:	No significant a	dverse effects were reported



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	cation Route sure time	:	0.072 mg/kg Intravenous 15 Days No significant a	dverse effects were reported
-	ration toxicity lassified based on avai	ilahle ii	oformation	
	rience with human ex			
-	ponents:	•		
Gona Inges	adorelin: tion			usea, Abdominal pain, Headache, Palpitation, tion change, bronchospasm, anaphylaxis
2. ECOL				
_				
	oxicity			
	ponents:			
	yl alcohol: ity to fish		LC50 (Pimepha Exposure time:	ales promelas (fathead minnow)): 460 mg/l 96 h
	ity to daphnia and othe tic invertebrates		Exposure time:	n magna (Water flea)): 230 mg/l 48 h Test Guideline 202
Toxic plants	ity to algae/aquatic s		mg/l Exposure time:	kirchneriella subcapitata (green algae)): 770 72 h Test Guideline 201
			mg/l Exposure time:	okirchneriella subcapitata (green algae)): 310 72 h Test Guideline 201
	ity to daphnia and othe tic invertebrates (Chror icity)	า-	Exposure time:	a magna (Water flea)): 51 mg/l 21 d Test Guideline 211
II Persi	istence and degradab	oility		
	ponents:	-		
	yl alcohol:			
	egradability		Result: Readily Biodegradation Exposure time:	



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II				
Bioad	ccumulative potential			
<u>Com</u>	ponents:			
Benz	yl alcohol:			
	ion coefficient: n- ol/water	:	log Pow: 1.05	
Mobi	lity in soil			
No da	ata available			
	r adverse effects ata available			
13. DISPO	SAL CONSIDERATIO	ONS		
Dispo	osal methods			
Waste	e from residues	:		f waste into sewer. cordance with local regulations.
Conta	aminated packaging	:		s should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

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) Packing instruction (passen- ger aircraft)		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
IMDG-Code UN number Proper shipping name Class	:	Not applicable Not applicable Not applicable



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Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Not applicable
Prohibited substances	:	Not applicable
Restricted substances	:	Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable control, Annex I

Type of hazardous materials subject to distribution and : Not applicable control, Annex II

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

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

16. OTHER INFORMATION



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Further information		
Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
Items where changes have been made to the previous version are highlighted in the body of this		

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

Date format : yyyy/mm/dd

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 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





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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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