according to the Hazardous Products Regulations



Betamethasone Cream Formulation

Version Revision Date SDS Number. Date of last issue. 04/04/2023 4.8 09/30/2023 1841217-00016 Date of first issue: 07/19/2017	Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
	4.8	09/30/2023	1841217-00016	Date of first issue: 07/19/2017

SECTION 1. IDENTIFICATION

Product name	:	Betamethasone Cream Formulation
Other means of identification	:	No data available

Manufacturer or supplier's details

Company name of supplier	:	Organon & Co.
Address	:	30 Hudson Street, 33nd floor
		Jersey City, New Jersey, U.S.A 07302
Telephone	:	1-551-430-6000
Emergency telephone	:	1-215-631-6999
E-mail address	:	EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance Reproductive toxicity	GHS classification in accordance with the Hazardous Products Regulations Reproductive toxicity : Category 1B					
Specific target organ toxicity - repeated exposure	:	Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)				
GHS label elements						
Hazard pictograms	:					
Signal Word	:	Danger				
Hazard Statements	:	H360D May damage the unborn child. H372 Causes damage to organs (Pituitary gland, Immune sys- tem, muscle, thymus gland, Blood, Adrenal gland) through pro- longed or repeated exposure.				
Precautionary Statements	:	 Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe vapors. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves, protective clothing, eye protection and face protection. 				
		Response: P308 + P313 IF exposed or concerned: Get medical attention.				

according to the Hazardous Products Regulations



Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.8	09/30/2023	1841217-00016	Date of first issue: 07/19/2017

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

•			
Chemical name	Common	CAS-No.	Concentration (% w/w)
	Name/Synonym		
Petrolatum	White Vaseline	8009-03-8	>= 10 - < 30 *
Paraffin oil	No data availa-	8012-95-1	>= 5 - < 10 *
	ble		>= 5 - < 10
Hexadecan-1-ol. Eth-	No data availa-	9004-95-9	>= 1 - < 5 *
oxylated	ble		>= 1 - < 5
Betamethasone	No data availa-	378-44-9	>= 0.01 - < 0.1 *
	ble		>= 0.01 - < 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.
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. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed Protection of first-aiders	:	May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. 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).

according to the Hazardous Products Regulations



Version 4.8	Revision Date: 09/30/2023		9S Number: 41217-00016	Date of last issue: 04/04/2023 Date of first issue: 07/19/2017
Note	es to physician	:	Treat symptomati	cally and supportively.
SECTION	15. FIRE-FIGHTING ME	ASU	RES	
Suita	able extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical	
Unsı med	uitable extinguishing ia	:	None known.	
Spec fighti	cific hazards during fire	:		explosive mixtures with air. Soustion products may be a hazard to health.
Haza ucts	ardous combustion prod-	:	Carbon oxides	
Spec ods	cific extinguishing meth-	:	cumstances and t Use water spray t	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
	cial protective equipment re-fighters	:		e, wear self-contained breathing apparatus. rective equipment.
SECTION	N 6. ACCIDENTAL RELE	ASI	EMEASURES	
tive e	onal precautions, protec- equipment and emer- cy procedures	:		ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).
Envi	ronmental precautions	:	Prevent spreading oil barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g., by containment or se of contaminated wash water. should be advised if significant spillages
	nods and materials for ainment and cleaning up	:	For large spills, procontainment to kee can be pumped, so container. Clean up remaining absorbent. Local or national no disposal of this may employed in the co determine which may Sections 13 and 1	a absorbent material. rovide diking or other appropriate ep material from spreading. If diked materia store recovered material in appropriate ing materials from spill with suitable regulations may apply to releases and aterial, as well as those materials and items leanup of releases. You will need to regulations are applicable. 5 of this SDS provide information regarding tional requirements.

according to the Hazardous Products Regulations



Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.8	09/30/2023	1841217-00016	Date of first issue: 07/19/2017

SECTION 7. HANDLING AND STORAGE

Technical measures Local/Total ventilation	 See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	 Do not get on skin or clothing. Do not breathe vapors. 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 assessment Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the
Conditions for onfo store so	environment.
Conditions for safe storage	 Keep in properly labeled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	: Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Petrolatum	8009-03-8	TWA (Mist)	5 mg/m³	CA AB OEL
		STEL (Mist)	10 mg/m ³	CA AB OEL
		TWA (Mist)	1 mg/m ³	CA BC OEL
		TWAEV (Mist	5 mg/m ³	CA QC OEL
		- Inhalable	-	
		dust)		
		TWA	5 mg/m ³	ACGIH
		(Inhalable	-	
		particulate		
		matter)		
Paraffin oil	8012-95-1	TWA (Mist)	5 mg/m³	CA AB OEL
		STEL (Mist)	10 mg/m ³	CA AB OEL
		TWA (Mist)	1 mg/m ³	CA BC OEL
		TWAEV (Mist	5 mg/m³	CA QC OEL
		- Inhalable		
		dust)		

according to the Hazardous Products Regulations



Betamethasone Cream Formulation

sion Revision Date: 09/30/2023	-	OS Number: 41217-00016		st issue: 04/04/2023 st issue: 07/19/2017	
			TWA (Inhalable particulate matter)	5 mg/m³	ACGIH
Betamethasone		378-44-9	TWA	1 µg/m3 (OEB 4)	Internal
		Further informa	ation: Skin	c , ,	•
			Wipe limit	10 µg/100 cm ²	Internal
Engineering measures	:	design and op protect produc Essentially no Use closed pr If handled in a cabinet, fume potential exist	erated in accor cts, workers, an open handling ocessing system laboratory, use hood, or other	ms or containment te e a properly designed containment device if tion. If this potential of	ciples to chnologies l biosafety f the
Personal protective equip	oment				
Respiratory protection	:	exposure asse	essment demor	ntilation is not availab istrates exposures ou e respiratory protection	utside the
Filter type Hand protection	:	Combined par	ticulates and o	rganic vapor type	
Material	:	Chemical-resi	stant gloves		
Remarks	:	Consider dout			
Eye protection	:	If the work env mists or aeros Wear a facesh	vironment or ac sols, wear the a nield or other fu	e shields or goggles. tivity involves dusty of ppropriate goggles. Il face protection if th the face with dusts, n	ere is a
Skin and body protection	:	Additional boo task being per disposable su	formed (e.g., slits) to avoid exp its) to avoid exp ite degowning t	bat. buld be used based u leevelets, apron, gau bosed skin surfaces. echniques to remove	ntlets,
Hygiene measures	:	eye flushing s working place When using d Wash contam The effective of engineering or appropriate de industrial hygi	ystems and saf o not eat, drink inated clothing operation of a fa ontrols, proper p egowning and d	before re-use. acility should include personal protective e lecontamination proc , medical surveillance	the review of quipment, edures,

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

according to the Hazardous Products Regulations



Vers 4.8	sion	Revision Date: 09/30/2023		S Number: 1217-00016	Date of last issue: 04/04/2023 Date of first issue: 07/19/2017
	Color		:	No data available)
	Odor		:	No data available)
	Odor Th	hreshold	:	No data available	
	рН		:	5	
	Melting	point/freezing point	:	No data available)
	Initial be range	oiling point and boiling	:	No data available	
	Flash p	oint	:	> 93.3 °C	
	Evapora	ation rate	:	No data available)
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	Not applicable	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	pressure	:	No data available)
	Relative	e vapor density	:	No data available)
	Relative	e density	:	No data available)
	Density	,	:	No data available)
	Solubili Wat	ty(ies) er solubility	:	No data available)
	Partition octanol	n coefficient: n-	:	Not applicable	
		ition temperature	:	No data available)
	Decom	position temperature	:	No data available)
	Viscosi Visc	ty osity, kinematic	:	No data available	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance or	r mixture is not classified as oxidizing.

according to the Hazardous Products Regulations



Betamethasone Cream Formulation

/ersion 1.8	Revision Date: 09/30/2023		S Number: 41217-00016	Date of last issue: 04/04/2023 Date of first issue: 07/19/2017
Partic	le size	:	Not applicable	
SECTION	10. STABILITY AND RE	EAC	TIVITY	
	ivity ical stability bility of hazardous reac-	::	Stable under nor Vapors may form	a reactivity hazard. mal conditions. n explosive mixture with air. trong oxidizing agents.
Incom	tions to avoid patible materials dous decomposition cts	: :	None known. Oxidizing agents No hazardous de	ecomposition products are known.
ECTION	11. TOXICOLOGICAL I	NFC	ORMATION	
Inhala Skin o Ingest	contact	of e	exposure	
	e toxicity assified based on availa	ble	information.	
<u>Produ</u> Acute	<u>uct:</u> oral toxicity	:	Acute toxicity est Method: Calculat	mate: > 2,000 mg/kg on method
<u>Comp</u>	oonents:			
Petro	latum:			
Acute	oral toxicity	:		00 mg/kg est Guideline 401 on data from similar materials
Acute	Acute dermal toxicity		Assessment: The toxicity	00 mg/kg est Guideline 402 substance or mixture has no acute dermal on data from similar materials
	fin oil:			
Acute	oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg
Acute	dermal toxicity	:	LD50 (Rabbit): > Assessment: The toxicity	2,000 mg/kg substance or mixture has no acute dermal

Hexadecan-1-ol. Ethoxylated:

according to the Hazardous Products Regulations



sion	Revision Date: 09/30/2023	SDS Number: 1841217-00016	Date of last issue: 04/04/2023 Date of first issue: 07/19/2017
Acute	oral toxicity	: LD50 (Rat): 2	500 mg/kg
Betar	nethasone:		
Acute	oral toxicity	: LD50 (Rat): >	5,000 mg/kg
		LD50 (Mouse)	: > 4,500 mg/kg
Acute	inhalation toxicity	: LC50 (Rat): 0 Exposure time	
Skin	corrosion/irritation		
Not cl	assified based on ava	ailable information.	
<u>Com</u>	<u>oonents:</u>		
Petro	latum:		
Speci		: Rabbit	
Metho Resul		: OECD Test G : No skin irritati	
Rema			a from similar materials
Paraf	fin oil:		
Speci		: Rabbit	
Resul	t	: No skin irritati	on
Betar	nethasone:		
Speci	es	: Rabbit	
Resul	t	: Mild skin irrita	tion
Not cl	us eye damage/eye assified based on ava		
<u>Comp</u>	<u>oonents:</u>		
	latum:		
Speci Resul		: Rabbit : No eye irritatio	n
Metho		: OECD Test G	
Rema	ırks		a from similar materials
Paraf	fin oil:		
Speci		: Rabbit	
	1	: No eye irritatio	on
Resul	t	. No eye iman	
	τ decan-1-ol. Ethoxyla	,	
	decan-1-ol. Ethoxyla t	ated: : Irritation to ey	es, reversing within 21 days a from similar materials

according to the Hazardous Products Regulations



/ersion I.8	Revision Date: 09/30/2023	SDS Number: 1841217-00016	Date of last issue: 04/04/2023 Date of first issue: 07/19/2017
Betar	nethasone:		
Speci	es	: Rabbit	
Resul		: No eye irritat	ion
Posn	iratory or skin sens	itization	
-	-	IIIZation	
	sensitization assified based on av	ailable information	
-	iratory sensitizatior assified based on av		
<u>Comp</u>	<u>oonents:</u>		
Petro	latum:		
Test 7	Гуре	: Buehler Test	
	s of exposure	: Skin contact	
Speci	•	: Guinea pig	
Resul		: negative	
Rema	ırks	: Based on da	ta from similar materials
Betar	nethasone:		
Route	es of exposure	: Dermal	
Speci		: Guinea pig	
Resul		: Weak sensiti	zer
C a mos			
	cell mutagenicity assified based on av	ailable information	
	oonents:		
	latum:	Test Turner O	
Geno	toxicity in vitro		hromosome aberration test in vitro
		Result: nega	sed on data from similar materials
		Remarks. Da	sed on data nom sinniar materials
Geno	toxicity in vivo	: Test Type: M	ammalian erythrocyte micronucleus test (in vive
		cytogenetic a	issay)
		Species: Mo	JSE
		Application R	coute: Intraperitoneal injection
			CD Test Guideline 474
		Result: nega	
		Remarks: Ba	sed on data from similar materials
Betar	nethasone:		
Geno	toxicity in vitro	: Test Type: B	acterial reverse mutation assay (AMES)
0010		Result: nega	
		T 1 T	
		Test Type: In Result: nega	vitro mammalian cell gene mutation test tive
		Test Type: C	hromosome aberration test in vitro
		, , , , , , , , , , , , , , , , , , ,	

according to the Hazardous Products Regulations



Result: positive Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in viv cytogenetic assay) Species: Mouse Germ cell mutagenicity - : Weight of evidence does not support classification as a gerr cell mutagen. Carcinogenicity : Weight of evidence does not support classification as a gerr cell mutagen. Carcinogenicity : Weight of evidence does not support classification as a gerr cell mutagen. Carcinogenicity : Weight of evidence does not support classification as a gerr cell mutagen. Species : Rat Application Route Species : Rat Application Route Application Route : Ingestion Exposure time Exposure time : 2 Years Result : negative Reproductive toxicity May damage the unborn child. Components: : Petrolatum: : Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials Effects on fetal development : Test Type: Embryo-fetal development Species: Rat Application Route: Skin contact Result: regative Result: regative Remarks: Based on data from similar materials Etfects on fetal development : Species: Rat Application Route: Skin contact Result: regative Developmental Toxicity: LOAE	/ersion .8	Revision Date: 09/30/2023		OS Number: 41217-00016	Date of last issue: 04/04/2023 Date of first issue: 07/19/2017			
cytogenetic assay) Species: Mouse Application Route: Oral Result: equivocal Germ cell mutagenicity Assessment Carcinogenicity Not classified based on available information. Components: Petrolatum: Species Species Carcinogenicity Not classified based on available information. Components: Petrolatum: Species Species Result Result May damage the unborn child. Components: Petrolatum: Effects on fertility Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials Effects on fetal development Species: Rat Application Route: Skin contact Result: megative Remarks: Based on data from similar materials Betamethasone: Effects on fetal development Species: Rat				Result: positive				
Assessment cell mutagen. Carcinogenicity Not classified based on available information. Components: Petrolatum: Species : Rat Application Route : Ingestion Exposure time : 2 Years Result : negative Reproductive toxicity May damage the unborn child. Components: Petrolatum: Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route : Ingestion Result: Regative Remarks: Based on data from similar materials Effects on fetal development : Test Type: Embryo-fetal development Species: Rat Application Route: Skin contact Result: Result: Based on data from similar materials Effects on fetal development : Species: Rat Application Route: Skin contact Result: Result: Based on data from similar materials Effects on fetal development : Species: Rat Application Route: Skin contact Result: Result: Result: Based on data from similar materials Effects on fetal development : Species: Rat Application Route: Skin contact Result: Result: Result: Result: Result: Coust in provide body weight Result: Result: Coust in provide body weight Result: Coust in Route: State Species: Rat Application Route: State Developmental Toxicity: LOAEL: 0.05 mg/kg body weight Result: Malformations were observed.	Geno	Genotoxicity in vivo		cytogenetic assay) Species: Mouse Application Route: Oral				
Not classified based on available information. Components: Petrolatum: Species : Repolication Route : Ingestion Repulation Route : Repoductive toxicity May damage the unborn child. Components: Petrolatum: Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative Reference Reference Result: negative Remarks: Based on data from similar materials Effects on fetal development Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Effects on fetal development Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Effects on fetal development Species: Rat Application Route: Intramuscular Developmental Toxicity: LOAEL: 0.05 mg/kg body weight <t< td=""><td></td><td></td><td>:</td><td></td><td>nce does not support classification as a germ</td></t<>			:		nce does not support classification as a germ			
Somponents: Petrolatum: Species : Rat Application Route : Ingestion Exposure time : 2 Years Result : negative Reproductive toxicity May damage the unborn child. Components: Petrolatum: Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Application Route: Ingestion Result: negative Effects on fetal development : Species: Rat Application Route: Skin contact Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Species: Rat Application Route: Skin contact Result: negative Retamethasone: : Species: Rabbit Application Route: Intramuscular Developmental Toxicity: LOAEL: 0.05 mg/kg body weight Result: Fetotoxicity., Malformations were observed. Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.42 mg/kg body weight	Carci	nogenicity						
Petrolatum Species : Rat Application Route : Ingestion Exposure time : 2 Years Result : negative Reproductive toxicity May damage the unborn child. Components: Petrolatum: Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials Effects on fetal development Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Species: Rat Application Route: Intramuscular Developmental Toxicity: LOAEL: 0.05 mg/kg body weight Result: Fetotoxicity., Malformations were observed. Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.42 mg/kg body weight	Not cl	assified based on availa	able	information.				
Species : Rat Application Route : Ingestion Exposure time : 2 Years Result : negative Reproductive toxicity May damage the unborn child. Components: Petrolatum: : Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials Effects on fetal development : Test Type: Embryo-fetal development Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Effects on fetal development Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Effects on fetal development : Species: Rat Application Route: Intramuscular Developmental Toxicity: LOAEL: 0.05 mg/kg body weight Result: Fetotoxicity., Malformations were observed. Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.42 mg/kg body weight Result: Malformations were observed. Species: Rat Application Route: Subcutaneous	<u>Com</u>	oonents:						
Application Route : Ingestion Exposure time : 2 Years Result : negative Reproductive toxicity May damage the unborn child. May damage the unborn child.	Petro	latum:						
May damage the unborn child. Components: Petrolatum: Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials Effects on fetal development : Test Type: Embryo-fetal development Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Betamethasone: : Effects on fetal development : Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Betamethasone: : Effects on fetal development : Species: Rabbit Application Route: Intramuscular Developmental Toxicity: LOAEL: 0.05 mg/kg body weight Result: Fetotoxicity., Malformations were observed. Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.42 mg/kg body weight Result: Malformations were observed.	Applic Expos	cation Route sure time	:	Ingestion 2 Years				
Components: Petrolatum: Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials Effects on fetal development : Test Type: Embryo-fetal development Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Betamethasone: : Species: Rabbit Application Route: Intramuscular Developmental Toxicity: LOAEL: 0.05 mg/kg body weight Result: Fetotoxicity., Malformations were observed. Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.42 mg/kg body weight Result: Malformations were observed.	Repro	oductive toxicity						
Petrolatum: Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials Effects on fetal development : Test Type: Embryo-fetal development Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Betamethasone: : Effects on fetal development : Species: Rat Application Route: Intramuscular Developmental Toxicity: LOAEL: 0.05 mg/kg body weight Result: Fetotoxicity., Malformations were observed. Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.42 mg/kg body weight Result: Malformations were observed.	May c	damage the unborn child	d.					
Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials Effects on fetal development : Test Type: Embryo-fetal development Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Betamethasone: : Effects on fetal development : Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Betamethasone: : Effects on fetal development : Species: Rabbit Application Route: Intramuscular Developmental Toxicity: LOAEL: 0.05 mg/kg body weight Result: Fetotoxicity., Malformations were observed. Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.42 mg/kg body weight Result: Malformations were observed.	Com	oonents:						
test Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials Effects on fetal development Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Betamethasone: Effects on fetal development Species: Rat Application Route: Intramuscular Developmental Toxicity: LOAEL: 0.05 mg/kg body weight Result: Fetotoxicity., Malformations were observed. Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.42 mg/kg body weight Result: Malformations were observed.	Petro	latum:						
Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials Betamethasone: Effects on fetal development Effects on fetal development : Species: Rabbit Application Route: Intramuscular Developmental Toxicity: LOAEL: 0.05 mg/kg body weight Result: Fetotoxicity., Malformations were observed. Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.42 mg/kg body weight	Effect	s on fertility	:	test Species: Rat Application Rou Result: negative	te: Ingestion			
Effects on fetal development : Species: Rabbit Application Route: Intramuscular Developmental Toxicity: LOAEL: 0.05 mg/kg body weight Result: Fetotoxicity., Malformations were observed. Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.42 mg/kg body weight Result: Malformations were observed. Species: Rat	Effect	s on fetal development	:	Species: Rat Application Rou Result: negative	te: Skin contact			
Application Route: Intramuscular Developmental Toxicity: LOAEL: 0.05 mg/kg body weight Result: Fetotoxicity., Malformations were observed. Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.42 mg/kg body weight Result: Malformations were observed.	Betar	nethasone:						
Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.42 mg/kg body weight Result: Malformations were observed.	Effect	s on fetal development	:	Application Rou Developmental	te: Intramuscular Toxicity: LOAEL: 0.05 mg/kg body weight			
Species: Mouse				Application Rou Developmental	Toxicity: LOAEL: 0.42 mg/kg body weight			
				Species: Mouse	9			

according to the Hazardous Products Regulations



Version 4.8	Revision Date: 09/30/2023		S Number: 41217-00016	Date of last issue: 04/04/2023 Date of first issue: 07/19/2017			
				: Intramuscular oxicity: LOAEL: 1 mg/kg body weight ions were observed.			
Repro sessm	oductive toxicity - As- nent	:	Clear evidence of animal experimer	adverse effects on development, based on tts.			
	-single exposure assified based on avail	lable	information.				
STOT	-repeated exposure						
Cause				system, muscle, thymus gland, Blood, Ad- e.			
<u>Comp</u>	oonents:						
Betan	nethasone:						
	t Organs	:	Pituitary gland, In	nmune system, muscle, thymus gland, Blood,			
Asses	Assessment		Adrenal gland Causes damage to organs through prolonged or repeated exposure.				
Repe	ated dose toxicity						
Comp	oonents:						
Petro	latum:						
			Rat 5,000 mg/kg Ingestion 2 y				
Paraf	fin oil:						
Specie LOAE Applic	es	: : :	Rat, female 161 mg/kg Ingestion 90 Days				
Betan	nethasone:						
Specie LOAE Applic Expos	es	:	Rabbit 0.05 % Skin contact 10 - 30 d Pituitary gland, In	nmune system, muscle			
Expos			Rat 0.05 % Skin contact 8 Weeks thymus gland				
Speci	es	:	Mouse				
			11 / 17				

according to the Hazardous Products Regulations



Betamethasone Cream Formulation

Version 4.8	Revision Date: 09/30/2023		DS Number: 41217-00016	Date of last issue: 04/04/2023 Date of first issue: 07/19/2017
Expo	EL cation Route sure time et Organs	:	0.1 % Skin contact 8 Weeks thymus gland	
Expo		:	Dog 0.05 mg/kg Oral 28 d Blood, thymus gla	and, Adrenal gland

Aspiration toxicity

Not classified based on available information.

Components:

Paraffin oil:

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

Experience with human exposure

Components:

Betamethasone:

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity		
Components:		
Petrolatum:		
Toxicity to fish	 LL50 (Pimephales promelas (fathead minnow)): > 100 mg Exposure time: 96 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 203 Remarks: Based on data from similar materials 	ı/I
Toxicity to daphnia and other aquatic invertebrates	 EC50 (Daphnia magna (Water flea)): > 10,000 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials 	
Toxicity to algae/aquatic plants	 NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials 	=

according to the Hazardous Products Regulations



ersion 8	Revision Date: 09/30/2023		S Number: 41217-00016	Date of last issue: 04/04/2023 Date of first issue: 07/19/2017				
	y to daphnia and other c invertebrates (Chron- city)	:	Exposure time: 27 Test substance: V	nagna (Water flea)): 10 mg/l l d Vater Accommodated Fraction on data from similar materials				
Paraff	in oil:							
Toxicit	y to fish	:	Exposure time: 96 Test substance: V	nus maximus (turbot)): > 100 mg/l 5 h Vater Accommodated Fraction on data from similar materials				
	y to daphnia and other c invertebrates	:	Exposure time: 48 Test substance: V	sa (Calanoid copepod)): > 100 mg/l 3 h Vater Accommodated Fraction on data from similar materials				
Toxicit plants	y to algae/aquatic	:	 EL50 (Skeletonema costatum (marine diatom)): Exposure time: 72 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials 					
			Exposure time: 72 Test substance: V	nema costatum (marine diatom)): > 1 mg/l 2 h Vater Accommodated Fraction on data from similar materials				
Hexad	lecan-1-ol. Ethoxylated	d:						
Toxicit	y to fish	:	LC50 : > 1 - 10 m Exposure time: 96 Remarks: Based					
	y to daphnia and other c invertebrates	:	Exposure time: 48					
Toxicit plants	y to algae/aquatic	:	EC50: > 10 - 100 Exposure time: 72 Remarks: Based					
Betam	ethasone:							
	y to daphnia and other c invertebrates	:	EC50 (Americamy Exposure time: 96					
Toxicit plants	y to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD To					
			NOEC (Pseudokin mg/l Exposure time: 72	rchneriella subcapitata (green algae)): 34 2 h				

according to the Hazardous Products Regulations



Versior 4.8	า	Revision Date: 09/30/2023		9S Number: 41217-00016	Date of last issue: 04/04/2023 Date of first issue: 07/19/2017
				Method: OECD Te Remarks: No toxic	est Guideline 201 city at the limit of solubility.
To icit	-	to fish (Chronic tox-	:	NOEC (Pimephale Exposure time: 32 Method: OECD Te	
				NOEC (Oryzias la Exposure time: 21 Method: OECD Te	
aq		to daphnia and other invertebrates (Chron- y)	:	NOEC (Daphnia n Exposure time: 21 Method: OECD Te	
Ре	ersiste	ence and degradabili	ty		
<u>Cc</u>	ompo	nents:			
Pe	etrolat	tum:			
Bio	odegra	adability	:		31 %
He	exade	can-1-ol. Ethoxylated	:t		
Bio	odegra	adability	:	Result: Readily bid Biodegradation: > Exposure time: 19	> 99 %
Bi	оасси	umulative potential			
<u>Cc</u>	ompo	nents:			
Pa	araffin	oil:			
	artition tanol/	i coefficient: n- water	:	log Pow: > 4 Remarks: Calcula	tion
Be	etame	thasone:			
	artition tanol/	n coefficient: n- water	:	log Pow: 2.11	
	-	/ in soil available			
		dverse effects available			

according to the Hazardous Products Regulations



Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.8	09/30/2023	1841217-00016	Date of first issue: 07/19/2017

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UN number:UN 3082Proper shipping name:ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)Class:9Packing group:IIILabels:9Environmentally hazardous:yesIATA-DGRUN/ID No.:UN/ID No.:UN 3082Proper shipping name:Environmentally hazardous substance, liquid, n.o.s. (Betamethasone)Class:9Packing group:IIILabels:964aircraft):964Packing instruction (passen- ger aircraft):Proper shipping name::Environmentally hazardous:Betamethasone):Class:Packing instruction (passen- ger aircraft):Environmentally hazardous:Environmentally hazardous:Proper shipping name:Environmentally hazardous:ges:IMDG-Code:UN number:Proper shipping name:Environmentally hazardous:Proper shipping name:Class:Packing group:IIILabels:Environmentally hazardous:Benvironmentally hazardous:Benvironmentally hazardous:Benvironmentally hazardous:Benvironmentally hazardous:Benvironmentally haza	UNRTDG		
N.O.S. (betamethasone)Class:9Packing group:Labels:9Environmentally hazardous:VIN/ID No.:VIN/ID No.:Proper shipping name:Class:9Packing group:IIILabels:9Packing group:1IILabels:9Packing instruction (cargo:964aircraft)Packing instruction (passenger aircraft)Proper shipping name:964Bindroff CodeUN number:Proper shipping name:10:964aircraft)Packing instruction (passenger aircraft)Environmentally hazardous:yeesIMDG-CodeUN number:Proper shipping name:Class:9Packing group:Class:9Packing group:10Labels:9Packing group:11Labels:9Packing group:129Packing group:1314141515161617171819 <t< td=""><td>UN number</td><td>:</td><td>UN 3082</td></t<>	UN number	:	UN 3082
Packing group:IIILabels:9Environmentally hazardous:yesIATA-DGRUN 3082UN/ID No.:UN 3082Proper shipping name:Environmentally hazardous substance, liquid, n.o.s. (Betamethasone)Class:9Packing group:IIILabels:MiscellaneousPacking instruction (cargo aircraft):964Packing instruction (passen- ger aircraft):964Packing instruction (passen- ger aircraft):yesIMDG-Code:yesUN number:UN 3082Proper shipping name:ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone)Class:9Packing group:IIILabels:9Packing group:IIILabels:9Ems Code:F-A, S-F	Proper shipping name	:	N.O.S.
Labels:9Environmentally hazardous:yesIATA-DGR	Class	:	9
Environmentally hazardous:yesIATA-DGR:UN/JD No.:UN/3082Proper shipping name:Environmentally hazardous substance, liquid, n.o.s. (Betamethasone)Class:9Packing group:IIILabels:MiscellaneousPacking instruction (cargo:964aircraft):964Packing instruction (passen- ger aircraft):yesIMDG-Code:UN 3082Proper shipping name:ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone)Class:9Packing group:IIILabels:9Proper shipping name:9Environmentally hazardous:9Environmentally hazardous:Environmentally hazardo	Packing group	:	III
IATA-DGRUN/ID No.:UN 3082Proper shipping name:Environmentally hazardous substance, liquid, n.o.s. (Betamethasone)Class:9Packing group:IIILabels:MiscellaneousPacking instruction (cargo aircraft):964Packing instruction (passen- ger aircraft):964Proper shipping name::IMDG-Code:yesUN number:UN 3082Proper shipping name:ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone)Class:9Packing group:IIILabels:9Packing group::Environmentally hazardous::	Labels	:	9
UN/ID No. : UN 3082 Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Betamethasone) Class : 9 Packing group : III Labels : Miscellaneous Packing instruction (cargo : 964 aircraft) Packing instruction (passen- ger aircraft) Environmentally hazardous : 964 IMDG-Code UN number : UN 3082 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone) Class : 9 Packing group : III Labels : 9 Packing group : III	Environmentally hazardous	:	yes
Proper shipping name:Environmentally hazardous substance, liquid, n.o.s. (Betamethasone)Class:9Packing group:IIILabels:MiscellaneousPacking instruction (cargo aircraft):964Packing instruction (passenger aircraft):964Packing instruction (passenger aircraft):yesIMDG-Code:yesUN number:UN 3082Proper shipping name:ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone)Class:9Packing group:IIILabels:9EmS Code::	IATA-DGR		
Class:9Packing group:IIILabels:MiscellaneousPacking instruction (cargo:964aircraft):964Packing instruction (passen- ger aircraft):964Environmentally hazardous:yesIMDG-Code:UN 3082UN number:ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone)Class:9Packing group:IIILabels:9EmS Code:F-A, S-F	UN/ID No.	:	UN 3082
Packing group:IIILabels:MiscellaneousPacking instruction (cargo:964aircraft):964Packing instruction (passen- ger aircraft):964Environmentally hazardous:yesIMDG-Code:yesUN number:UN 3082Proper shipping name:ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone)Class:9Packing group:IIILabels:9EmS Code:F-A, S-F	Proper shipping name	:	(Betamethasone)
Labels:MiscellaneousPacking instruction (cargo:964aircraft):964Packing instruction (passen- ger aircraft):964Environmentally hazardous:yesIMDG-Code:UN number:UN 3082Proper shipping name:ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone)Class:9Packing group:III LabelsLabels:9EmS Code:F-A, S-F		:	
Packing instruction (cargo aircraft)964Packing instruction (passen- ger aircraft)964Environmentally hazardous:964 IMDG-Code UN number:yesIMDG-Code UN number:UN 3082Proper shipping name:ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone)Class:9Packing group:III LabelsLabels:9EmS Code:F-A, S-F		:	
aircraft) Packing instruction (passen- ger aircraft) Environmentally hazardous : yes IMDG-Code UN number : UN 3082 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone) Class : 9 Packing group : III Labels : 9 EmS Code : F-A, S-F		:	
ger aircraft)Environmentally hazardous:IMDG-CodeUN number:Proper shipping name:ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone)Class:Packing group:Labels:EmS Code:F-A, S-F	aircraft)	:	964
IMDG-Code UN number : UN 3082 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone) Class : 9 Packing group : III Labels : 9 EmS Code : F-A, S-F		:	964
UN number : UN 3082 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone) Class : 9 Packing group : III Labels : 9 EmS Code : F-A, S-F	Environmentally hazardous	:	yes
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone) Class : 9 Packing group : III Labels : 9 EmS Code : F-A, S-F	IMDG-Code		
N.O.S. (Betamethasone) Class 9 Packing group 1III Labels 2 EmS Code 5	UN number	:	UN 3082
Class:9Packing group:IIILabels:9EmS Code:F-A, S-F	Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
Class:9Packing group:IIILabels:9EmS Code:F-A, S-F			
Packing group:IIILabels:9EmS Code:F-A, S-F			
Labels : 9 EmS Code : F-A, S-F		•	
EmS Code : F-A, S-F		÷	
		÷	•
		:	
Transport in bulk apporting to Apport II of MARROL 72/79 and the IRC Code		•	•

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

Not applicable for product as supplied.

Domestic regulation

TDG

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

according to the Hazardous Products Regulations



Betamethasone Cream Formulation

Version	Revision Date:		DS Number:	Date of last issue: 04/04/2023
4.8	09/30/2023		41217-00016	Date of first issue: 07/19/2017
Labels ERG C		:	N.O.S. (Betamethasone) 9 III 9 171 yes(Betamethaso	

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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				
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)		
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)		
CA BC OEL	:	Canada. British Columbia OEL		
CA QC OEL	:	Québec. Regulation respecting occupational health and safe- ty, Schedule 1, Part 1: Permissible exposure values for air- borne contaminants		
ACGIH / TWA	:	8-hour, time-weighted average		
CA AB OEL / TWA	:	8-hour Occupational exposure limit		
CA AB OEL / STEL	:	15-minute occupational exposure limit		
CA BC OEL / TWA	:	8-hour time weighted average		
CA QC OEL / TWAEV	:	Time-weighted average exposure value		

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



Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.8	09/30/2023	1841217-00016	Date of first issue: 07/19/2017

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

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	:	09/30/2023 mm/dd/yyyy

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