This SDS packet was issued with item:

078073831

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078946834 078946852

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078073849



Vers 3.1	ion	Revision Date: 04/12/2018	-	0S Number: 8853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016	
SECTION 1. IDENTIFICATION						
	Product name		:	Clotrimazole / Gentamicin / Betamethasone (0.1%) Formula- tion		
	Manufa	acturer or supplier's	deta	nils		
	Company name of supplier		:	Merck & Co., Inc		
	Address		:	2000 Galloping Hill Road Kenilworth - New Jersey - U.S.A. 07033		
	Telephone		:	908-740-4000		
	Telefax		:	908-735-1496		
	Emergency telephone		:	1-908-423-6000		
	E-mail address		:	EHSDATASTEWARD@merck.com		
	Recom	mended use of the c	hen	nical and restriction	ons on use	
	Recommended use		:	Veterinary produc	t	

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200 Reproductive toxicity : Category 1A						
Specific target organ systemic toxicity - repeated exposure	:	Category 1 (Pituitary gland, Immune system, muscle, thymus, Blood, Adrenal gland)				
Specific target organ systemic toxicity - repeated exposure (Oral)	:	Category 2 (Liver, Kidney, Adrenal gland)				
GHS label elements Hazard pictograms	:					
Signal Word	:	Danger				
Hazard Statements	:	 H360Df May damage the unborn child. Suspected of damaging fertility. H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus, Blood, Adrenal gland) through prolonged or repeated exposure. H373 May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed. 				



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 3.1	Revision Date: 04/12/2018	SDS Number: 808853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
Preca	autionary Statements	P202 Do not h and understoo P260 Do not b P264 Wash sk P270 Do not e	reathe mist or vapors. in thoroughly after handling. at, drink or smoke when using this product. otective gloves/ protective clothing/ eye protection/
		Response: P308 + P313 I attention.	F exposed or concerned: Get medical advice/
		Storage: P405 Store loc	sked up.
		Disposal: P501 Dispose posal plant.	of contents/ container to an approved waste dis-
Othe	r hazards		

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	8042-47-5	>= 90 - <= 100
Clotrimazole	23593-75-1	>= 1 - < 5
Gentamicin	1403-66-3	>= 0.1 - < 1
Betamethasone	378-44-9	>= 0.1 - < 1

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.



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Versio 3.1	on	Revision Date: 04/12/2018		98 Number: 8853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016		
Ir	n case	of eye contact	:		water as a precaution. ntion if irritation develops and persists.		
lf	If swallowed		:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.			
а		portant symptoms ects, both acute and l	:	 May damage the unborn child. Suspected of damaging ty. Causes damage to organs through prolonged or repeat exposure. 			
Ρ	Protecti	on of first-aiders	:	and use the reco	ders should pay attention to self-protection, ommended personal protective equipment al for exposure exists.		
N	lotes to	o physician	:	Treat symptoma	tically and supportively.		
SECTION 5. FIRE-FIGHTING MEASURES							
S	Suitable	e extinguishing media	:	Water spray Alcohol-resistan Carbon dioxide (Dry chemical			
	Jnsuita nedia	ble extinguishing	:	None known.			
	Specific ghting	hazards during fire	:	Exposure to con	bustion products may be a hazard to health.		
	lazard cts	ous combustion prod-	:	Carbon oxides			
	Specific ds	extinguishing meth-	:	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. aged containers from fire area if it is safe to do		
		protective equipment ighters	:		re, wear self-contained breathing apparatus. otective equipment.		

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : tive equipment and emer- gency procedures		Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions :	:	Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so.



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 3.1	Revision Date: 04/12/2018	SDS Number: 808853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
		oil barriers). Retain and dispo	ng over a wide area (e.g., by containment or ose of contaminated wash water. should be advised if significant spillages ined.
	ods and materials for nment and cleaning up	For large spills, p containment to k can be pumped, container. Clean up remain absorbent. Local or national disposal of this r employed in the determine which Sections 13 and	ert absorbent material. provide diking or other appropriate teep material from spreading. If diked material store recovered material in appropriate ing materials from spill with suitable I regulations may apply to releases and naterial, as well as those materials and items cleanup of releases. You will need to regulations are applicable. 15 of this SDS provide information regarding national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures		See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe vapors or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Take care to prevent spills, waste and minimize release to the 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 Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters



04/12/2018	808853-00009		t issue: 07/22/2016	
Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	TWA (Mist)	5 mg/m ³	OSHA Z-1
		TWA (Inhal- able fraction)	5 mg/m ³	ACGIH
		TWA (Mist)	5 mg/m³	NIOSH RI
		ST (Mist)	10 mg/m ³	NIOSH RI
Clotrimazole	23593-75-1	TWA	0.2 mg/m3 (OEB 2)	Internal
Gentamicin	1403-66-3	TWA	0.1 mg/m3 (OEB 2)	Internal
Betamethasone	378-44-9	TWA	1 µg/m3 (OEB 4)	Internal
	Further inform			
		Wipe limit	10 µg/100 cm ²	Internal
	cabinet, fum potential exis	e hood, or other o	a properly designed containment device if ion. If this potential c or benchtops.	the
Personal protective equipme	nt			
Respiratory protection	maintain vap concentratio unknown, ap Follow OSH/ use NIOSH/I by air purifyin hazardous c supplied res release, exp	oor exposures bel ns are above reco propriate respirat A respirator regula MSHA approved in ng respirators aga hemical is limited pirator if there is a osure levels are us where air purify	ntilation is recommer ow recommended lim commended limits or a cory protection should ations (29 CFR 1910 respirators. Protection ainst exposure to any . Use a positive pres any potential for uncount unknown, or any other ing respirators may r	nits. Where are d be worn. 0.134) and on provided y sure air ontrolled er
Hand protection				
Material	: Chemical-re	sistant gloves		
Remarks	: Consider do	uble gloving.		
Eye protection	If the work e mists or aero	nvironment or act psols, wear the ap shield or other ful	shields or goggles. ivity involves dusty c propriate goggles. I face protection if the	ere is a



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 3.1	Revision Date: 04/12/2018	SDS Number: 808853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016		
		aerosols.			
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		located close to When using do r Wash contamina The effective op engineering cont appropriate dego	flushing systems and safety showers are the working place. not eat, drink or smoke. ated clothing before re-use. eration of a facility should include review of trols, proper personal protective equipment, owning and decontamination procedures, e monitoring, medical surveillance and the ative controls.		

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	No data available
Odor	:	No information available.
Odor Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 3.1	Revision Date: 04/12/2018		S Number: 3853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016		
Rel	Relative density		No data available	e		
Der	Density		No data available	e		
	Solubility(ies) Water solubility		No data available	e		
	tition coefficient: n- anol/water	:	Not applicable			
Aut	Autoignition temperature		No data available	Э		
Dec	Decomposition temperature		No data available			
	cosity Viscosity, kinematic	:	No data available	e		
Exp	plosive properties	:	Not explosive			
Oxi	dizing properties	:	The substance o	r mixture is not classified as oxidizing.		
Par	ticle size	:	Not applicable			

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac- tions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	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:



Version 3.1	Revision Date: 04/12/2018		98 Number: 8853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016		
Acu	te oral toxicity	:	Acute toxicity estine Method: Calculation	mate: > 5,000 mg/kg on method		
Acu	te inhalation toxicity	:	Acute toxicity estii Exposure time: 4 Test atmosphere: Method: Calculatio	h dust/mist		
Acu	Acute dermal toxicity		Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method			
<u>Cor</u>	nponents:					
Whi	ite mineral oil (petroleum	ו):				
	te oral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg		
Acu	te inhalation toxicity	:	LC50 (Rat): > 5 m Exposure time: 4 Test atmosphere: Assessment: The tion toxicity	ĥ		
Acu	te dermal toxicity	:	LD50 (Rabbit): > 2 Assessment: The toxicity	2,000 mg/kg substance or mixture has no acute dermal		
Clo	trimazole:					
Acu	te oral toxicity	:	LD50 (Rat): 708 n	ng/kg		
			LD50 (Mouse): 76	61 mg/kg		
			LD50 (Rabbit): > 7	1,000 mg/kg		
Acu	te inhalation toxicity	:	LC50 (Rat): > 0.73 Exposure time: 4 Test atmosphere:	h		
Acu	te dermal toxicity	:	LD50 (Mouse): 92	23 mg/kg		
Ger	ntamicin:					
	te oral toxicity	:	LD50 (Rat): 8,000) - 10,000 mg/kg		
			LD50 (Mouse): 10),000 mg/kg		
Acu	te inhalation toxicity	:	LC50 (Rat): > 0.2 Exposure time: 4 Test atmosphere: Remarks: No mor	h		
	te toxicity (other routes of ninistration)	:	LD50 (Rat): 67 - 9 Application Route			



Version 3.1	Revision Date: 04/12/2018		OS Number: 8853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
			LD50 (Rat): 371 Application Route	
			LDLo (Monkey): Application Route	
Beta	methasone:			
Acute	e oral toxicity	:	LD50 (Rat): > 5,0	000 mg/kg
			LD50 (Mouse): >	4,500 mg/kg
Acute	e inhalation toxicity	:	LC50 (Rat): 0.4 r Exposure time: 4	
-	corrosion/irritation	vilabla	information	
	ponents:			
	e mineral oil (petrole	um).		
Spec		:	Rabbit	
Resu		:	No skin irritation	
Clotr	imazole:			
Spec		:	Rabbit	
Resu	llt	:	No skin irritation	
Gent	amicin:			
Spec		:	Rabbit	
Resu	llt	:	Mild skin irritant	
Beta	methasone:			
Spec		:	Rabbit	
Resu	lit	:	Mild skin irritatior	1
Serio	ous eye damage/eye i	irritati	on	
Not c	lassified based on ava	ailable	information.	
<u>Com</u>	ponents:			
Whit	e mineral oil (petrole	um):		
Spec Resu		:	Rabbit No eye irritation	
1.630	in the second	•		
	imazole:			
Spec Resu		:	Rabbit Mild eye irritation	
11630	in.	•		



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

ersion I	Revision Date: 04/12/2018	-	S Number: 3853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
Gent	amicin:			
Spec Resu		:	Rabbit Mild eye irritant	
Beta	methasone:			
Spec Resu		:	Rabbit No eye irritation	
Resp	piratory or skin sens	itizatio	n	
-	sensitization	ailable	information.	
Resp	piratory sensitization	n		
Not c	classified based on av	ailable	information.	
<u>Com</u>	ponents:			
Whit	e mineral oil (petrole	eum):		
		:	Buehler Test Skin contact Guinea pig negative	
Gent	amicin:			
Rem	arks	:	No data available	
Beta	methasone:			
Route Spec Resu		:	Dermal Guinea pig Weak sensitizer	
	n cell mutagenicity classified based on av	ailable	information.	
<u>Com</u>	ponents:			
Whit	e mineral oil (petrole	eum):		
	otoxicity in vitro	:	Test Type: In vitro Result: negative	o mammalian cell gene mutation test
Genc	otoxicity in vivo	:	cytogenetic assay Species: Mouse Application Route Method: OECD T Result: negative	nalian erythrocyte micronucleus test (in vivo y) e: Intraperitoneal injection est Guideline 474 on data from similar materials

Clotrimazole:



Versior 3.1	n Revision Date: 04/12/2018		9S Number: 8853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
Ge	enotoxicity in vitro	:	Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
			Test Type: Chrom Result: negative	osome aberration test in vitro
			Test Type: in vitro Result: negative	micronucleus test
Ge	Genotoxicity in vivo		Test Type: Mamm cytogenetic assay Species: Rat Application Route Result: negative	
			Test Type: Mamm tion test (in vivo) Species: Hamster Result: negative	nalian spermatogonial chromosome aberra-
	erm cell mutagenicity - sessment	:	Weight of evidenc cell mutagen.	e does not support classification as a germ
Ge	entamicin:			
Ge	enotoxicity in vitro	:	Test Type: In vitro Result: negative	mammalian cell gene mutation test
			Test Type: Chrom Result: equivocal	osome aberration test in vitro
Ge	enotoxicity in vivo	:	Test Type: Mamm cytogenetic assay Species: Mouse	nalian erythrocyte micronucleus test (in vivo)
			Application Route Result: negative	: Intravenous injection
Be	etamethasone:			
Ge	enotoxicity in vitro	:	Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
			Test Type: In vitro Result: negative	mammalian cell gene mutation test
			Test Type: Chrom Result: positive	osome aberration test in vitro
Ge	enotoxicity in vivo	:	Test Type: Mamm cytogenetic assay Species: Mouse Application Route Result: equivocal	



	Revision Date: 04/12/2018		umber:Date of last issue: 10/10/20173-00009Date of first issue: 07/22/2016
Germ o Assess	cell mutagenicity - sment		eight of evidence does not support classification as a germ I mutagen.
	ogenicity ssified based on avai	lable info	rmation.
<u>Compo</u>	onents:		
White	mineral oil (petroleu	ım):	
Specie	S	: Ra	t
	ation Route		estion
Exposu Result	ure time		Months gative
Clotrin	nazole:		
Specie		: Ra	
	ation Route	: Or	al weeks
Result	ure time	-	gative
Gentar			
Carcino ment	ogenicity - Assess-	: Nc	data available
IARC			product present at levels greater than or equal to 0.1% is , possible or confirmed human carcinogen by IARC.
OSHA			product present at levels greater than or equal to 0.1% is ulated carcinogens.
NTP			product present at levels greater than or equal to 0.1% is or anticipated carcinogen by NTP.
•	ductive toxicity		
Mav da	amage the unborn chi	ld. Suspe	cted of damaging fertility.
	onents:		
•			
Compo	mineral oil (petroleu	ım):	
<u>Compo</u> White	mineral oil (petroleu on fertility	: Te Sp Ap	st Type: One-generation reproduction toxicity study ecies: Rat plication Route: Skin contact sult: negative
Compo White Effects		: Te Sp Ap Re t : Te Sp Ap	ecies: Rat plication Route: Skin contact
Compo White Effects	on fertility	: Te Sp Ap Re t : Te Sp Ap	ecies: Rat plication Route: Skin contact sult: negative st Type: Embryo-fetal development ecies: Rat plication Route: Ingestion



Versio 3.1	on	Revision Date: 04/12/2018		9S Number: 8853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
				Species: Rat Application Route Fertility: LOAEL: 5 Result: Effects on	50 mg/kg body weight
E	Effects on fetal development		:	Species: Rat Application Route Developmental To	ro-fetal development : Oral oxicity: LOAEL: 100 mg/kg body weight otal toxicity., No teratogenic effects.
				Species: Rat Application Route Developmental To	ro-fetal development : Oral oxicity: NOAEL: 50 mg/kg body weight etal toxicity., No teratogenic effects.
				Species: Mouse Application Route Developmental To	ro-fetal development : Oral oxicity: NOAEL: 200 mg/kg body weight o on fetal development.
				Species: Rabbit Application Route Developmental To	ro-fetal development : Oral oxicity: NOAEL: 180 mg/kg body weight o on fetal development.
	Reproductive toxicity - As- sessment		:	fertility, based on	f adverse effects on sexual function and animal experiments., Some evidence of n development, based on animal
c	Gentan	nicin:			
		on fertility	:	Species: Rat Fertility: NOAEL: 2	eneration reproduction toxicity study 20 mg/kg body weight cant adverse effects were reported
E	Effects	on fetal development	:	Species: Rabbit	ro-fetal development oxicity: NOAEL: 3.6 mg/kg body weight o-fetal toxicity.
				Species: Rat Application Route	oxicity: LOAEL: 75 mg/kg body weight
				Test Type: Embry Species: Mouse	ro-fetal development



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Versior 3.1	Revision Date: 04/12/2018		DS Number: 8853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
				e: Intraperitoneal oxicity: LOAEL: 10 mg/kg body weight tality., No malformations were observed.
			Species: Rat Application Route Developmental To	vo-fetal development e: Intraperitoneal oxicity: LOAEL: 50 mg/kg body weight tality., No malformations were observed.
	productive toxicity - As- ssment	:	Positive evidence human epidemiol	of adverse effects on development from ogical studies.
	tamethasone: ects on fetal development	:	Species: Rabbit	
LI		•	Application Route	e: Intramuscular oxicity: LOAEL: 0.05 mg/kg body weight ty., Malformations were observed.
				e: Subcutaneous oxicity: LOAEL: 0.42 mg/kg body weight tions were observed.
				e: Intramuscular oxicity: LOAEL: 1 mg/kg body weight tions were observed.
	productive toxicity - As- ssment	:	Clear evidence of animal experimer	f adverse effects on development, based on nts.
ет	OT-single expessive			

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Pituitary gland, Immune system, muscle, thymus, Blood, Adrenal gland) through prolonged or repeated exposure. May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated ex-

posure if swallowed.

Components:

Clotrimazole:

Target Organs Assessment	:	Liver, Kidney, Adrenal gland May cause damage to organs through prolonged or repeated exposure.
Gentamicin: Target Organs Assessment	:	Kidney, inner ear Causes damage to organs through prolonged or repeated exposure.



Version 3.1	Revision Date: 04/12/2018	SDS Number: 808853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
Targe	methasone: et Organs ssment	renal gland	Immune system, muscle, thymus, Blood, Ad- ge to organs through prolonged or repeated
Repe	ated dose toxicity		
<u>Com</u>	ponents:		
White	e mineral oil (petrole	um):	
		: Rat : 160 mg/kg : Ingestion : 90 Days	
	EL cation Route sure time	: Rat : >= 1 mg/l : inhalation (dus : 4 Weeks : OECD Test Gu	,
Clotri	imazole:		
Expos	EL cation Route sure time et Organs	: Rabbit : 5 - 40 mg/kg : Skin contact : 3 Weeks : Skin : Edema, Fissur	ing, Necrosis, Redness
Expos		: Rat : 10 mg/kg : Oral : 18 Months : Liver, Kidney, <i>i</i>	Adrenal gland
Expos	EL cation Route sure time et Organs	: Dog : 25 mg/kg : Oral : 6 - 12 Months : Adrenal gland : Salivation, Lac	hrymation, Vomiting
Genta	amicin:		
Speci LOAE Applic Expos	ies EL cation Route sure time et Organs	: Dog : 3 mg/kg : Intramuscular : 12 Months : Kidney : Vomiting, Saliv	ation



Version 3.1	Revision Date: 04/12/2018		DS Number: 8853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
Expos		: : : : : : : : : : : : : : : : : : : :	Monkey 50 mg/kg Subcutaneous 3 Weeks Kidney, inner ear	
Expos			Monkey 6 mg/kg Intramuscular 3 Weeks Blood, Kidney, inr	ner ear, Liver
Expos	E		Rat 5 mg/kg 10 mg/kg Intramuscular 52 Weeks Kidney, Blood	
Expos	E		Rat 12.5 mg/kg 50 mg/kg Intramuscular 13 Weeks Kidney	
Specie LOAE Applic Expos		: : :	Rabbit 0.05 % Skin contact 10 - 30 d Pituitary gland, Im	nmune system, muscle
Expos			Rat 0.05 % Skin contact 8 Weeks thymus	
Expos		: : :	Mouse 0.1 % Skin contact 8 Weeks thymus	
Expos			Dog 0.05 mg/kg Oral 28 d Blood, thymus, Ad	drenal gland



Version 3.1	Revision Date: 04/12/2018		DS Number: 08853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016		
Not	Aspiration toxicity Not classified based on available information. Experience with human exposure					
Com	ponents:					
	rimazole: contact	:	Symptoms: Rash	, Itching, Blistering, Edema, Redness		
Inge	stion	:	Symptoms: Abdo	minal pain, Nausea, Vomiting, Diarrhea		
Gen	tamicin:					
Inge	stion	:	Target Organs: K	idney		
			Target Organs: in Symptoms: Dizzir deafness	ner ear ness, Vertigo, hearing loss, tinnitus, fetal		
Beta	methasone:					
Inha	lation	:	Target Organs: A	drenal gland		
Skin	contact	:	Symptoms: Redn	ess, pruritis, Irritation		

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

White mineral oil (petroleum)	:	
Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic tox- icity)	:	NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l Exposure time: 28 d
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)	:	NOEC (Daphnia magna (Water flea)): 1,000 mg/l Exposure time: 21 d



Version 3.1	Revision Date: 04/12/2018		98 Number: 8853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
Clotri	mazole:			
	ty to fish	:	LC50 (Brachydan Exposure time: 96 Method: OECD Te	
	ty to daphnia and other c invertebrates	:	EC50 (Daphnia m Exposure time: 48	hagna (Water flea)): 0.02 mg/l 3 h
Toxici	ty to algae	:	EC50 (Desmodes Exposure time: 72	mus subspicatus (green algae)): 0.268 mg/l 2 h
			NOEC (Desmode Exposure time: 72	smus subspicatus (green algae)): 0.017 mg 2 h
Toxici icity)	ty to fish (Chronic tox-	:	NOEC (Oncorhyn Exposure time: 32 Method: OECD Te	
	ty to daphnia and other c invertebrates (Chron- city)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD T	
Toxici	ty to microorganisms	:	EC50: > 10,000 n Exposure time: 3 Test Type: Respir Method: OECD Te	h ration inhibition
Genta	micin:			
	ty to daphnia and other c invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD T	
			LC50 (Americamy Exposure time: 96 Method: US-EPA	
Toxici	ty to algae	:	EC50 (Pseudokiro Exposure time: 72 Method: OECD Te	
			NOEC (Pseudokin µg/l Exposure time: 72 Method: OECD T	
			EC50 (Anabaena Exposure time: 72 Method: OECD T	
			NOEC (Anabaena Exposure time: 72 Method: OECD T	



ersion 1	Revision Date: 04/12/2018		98 Number: 8853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
Toxicit	y to microorganisms	:	EC50: 288.7 mg/l Exposure time: 3 Test Type: Respir Method: OECD Te	ation inhibition
Betam	ethasone:			
	y to daphnia and other c invertebrates	:	EC50 (Americamy Exposure time: 96	
Toxicit	y to algae	:	mg/l Exposure time: 72 Method: OECD Te	
			mg/l Exposure time: 72 Method: OECD Te	
Toxicity	y to fish (Chronic tox-	:	NOEC (Pimephale Exposure time: 32 Method: OECD Te	
			NOEC (Oryzias la Exposure time: 21 Method: OECD Te	
	y to daphnia and other c invertebrates (Chron- ity)	:	NOEC (Daphnia n Exposure time: 21 Method: OECD Te	
Persis	tence and degradabili	itv		
	onents:	-		
White	mineral oil (petroleum Iradability	ו): י	Result: Not readily Biodegradation: 3 Exposure time: 28	31 %
Clotrin	nazole:			
	y in water	:	Hydrolysis: 50 %(242 d)
Genta Biodeg	micin: Jradability	:	Result: rapidly deg Biodegradation: 1 Exposure time: 28 Method: OECD Te	100 % 3 d



Version 3.1	Revision Date: 04/12/2018	SDS Number: 808853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
Bic	accumulative potential		
Co	mponents:		
Par	ntamicin: rtition coefficient: n- anol/water	: log Pow: < -2	
Par	tamethasone: rition coefficient: n- anol/water	: log Pow: 2.11	
	bility in soil data available		
•	ner adverse effects data available		
SECTIO	N 13. DISPOSAL CONSI	DERATIONS	
Dis	posal methods		

Waste from residues	: 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

UNRTDG		
UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Clotrimazole, Gentamicin)
Class	:	9
Packing group	:	
Labels	:	9
IATA-DGR		
UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Clotrimazole, Gentamicin)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	964
Packing instruction (passen- ger aircraft)	:	964



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Vers 3.1	sion	Revision Date: 04/12/2018		DS Number: 8853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
	Enviror	mentally hazardous	:	yes	
	Class Packing Labels EmS C Marine Transp Not app	nber shipping name g group ode pollutant port in bulk according plicable for product as stic regulation	-	N.O.S. (Clotrimazole, Ge 9 III 9 F-A, S-F yes Annex II of MARP	ALLY HAZARDOUS SUBSTANCE, LIQUID, ntamicin) OL 73/78 and the IBC Code
		NA number shipping name	:	UN 3082 Environmentally h (Clotrimazole, Ge	nazardous substance, liquid, n.o.s. entamicin)
	Labels ERG C	pollutant	:	liters., Shipment b however it may be	Gentamicin) ly to containers over 119 gallons or 450 by ground under DOT is non-regulated; e shipped per the applicable hazard icilitate multi-modal transport involving ICAO

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

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards :

Reproductive toxicity Specific target organ toxicity (single or repeated exposure)



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 3.1	Revision Date: 04/12/2018	SDS Number: 808853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
SA	RA 313	known CAS nur	bes not contain any chemical components with mbers that exceed the threshold (De Minimis) established by SARA Title III, Section 313.
US	State Regulations		
Per	n nsylvania Right To Kno White mineral oil (p		8042-47-5
WA to t		ause birth defects or o	icals including Gentamicin, which is/are known other reproductive harm. For more information
Cal	ifornia List of Hazardous		
	White mineral oil (p	,	8042-47-5
Cal	l ifornia Permissible Expo White mineral oil (p		emical Contaminants 8042-47-5
The	e ingredients of this proc	luct are reported in	the following inventories:
AIC	S	: not determined	
DS	L	: not determined	
IEC	SC	: not determined	

SECTION 16. OTHER INFORMATION





HMIS® IV:

HEALTH	*	3
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

:

:

ACGIH NIOSH REL USA. ACGIH Threshold Limit Values (TLV)

USA. NIOSH Recommended Exposure Limits



Version 3.1	Revision Date: 04/12/2018	SDS Number: 808853-00009	Date of last issue: 10/10/2017 Date of first issue: 07/22/2016
OSH/	A Z-1	: USA. Occup its for Air Co	ational Exposure Limits (OSHA) - Table Z-1 Lim- ntaminants
ACGIH / TWA NIOSH REL / TWA		: Time-weight	weighted average ed average concentration for up to a 10-hour ng a 40-hour workweek
NIOS	H REL / ST	: STEL - 15-m	inute TWA exposure that should not be exceeded luring a workday
OSHA	A Z-1 / TWA		veighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity: SADT - Self-Accelerating Decomposition Temperature: SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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

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

Revision Date

: 04/12/2018

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



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/10/2017
3.1	04/12/2018	808853-00009	Date of first issue: 07/22/2016

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.

US / Z8



Version 4.5	Revision Date: 08/27/2021		3 Number: 853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016	
SECTION	1. IDENTIFICATION				
Product name			Clotrimazole / Ge tion	entamicin / Betamethasone (0.1%) Formula-	
Man	ufacturer or supplier's	detai	ls		
Company name of supplier Address		:	Merck & Co., Inc 126 E. Lincoln A Rahway, New Je		
Tele	Telephone		: 908-740-4000		
	rgency telephone		1-908-423-6000		
E-ma	ail address	:	EHSDATASTEW	/ARD@merck.com	
Reco	ommended use of the o	chemi	cal and restrict	ions on use	

Recommended use

: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)						
Reproductive toxicity	:	Category 1A				
Specific target organ toxicity - repeated exposure	:	Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)				
Specific target organ toxicity - repeated exposure (Oral)	:	Category 2 (Liver, Kidney, Adrenal gland)				
GHS label elements						
Hazard pictograms	:					
Signal Word	:	Danger				
Hazard Statements	:	 H360Df May damage the unborn child. Suspected of damaging fertility. H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure. H373 May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed. 				
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 mist or vapors. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. 				



Revision Date: 08/27/2021	SDS Number: 808853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
	P280 Wear pro and face prote	otective gloves, protective clothing, eye protection ction.
	Response: P308 + P313 I	F exposed or concerned: Get medical attention.
	Storage: P405 Store loc	ked up.
	Disposal: P501 Dispose disposal plant.	of contents and container to an approved waste
hazards		
	08/27/2021	08/27/2021 808853-00015 P280 Wear pro and face prote Response: P308 + P313 I Storage: P405 Store loo Disposal: P501 Dispose disposal plant.

Substance / Mixture : Mixture

Components

••••••						
Chemical name	CAS-No.	Concentration (% w/w)				
White mineral oil (petroleum)	8042-47-5	>= 90 - <= 100				
clotrimazole	23593-75-1	>= 1 - < 5				
Gentamicin	1403-66-3	>= 0.1 - < 1				
Betamethasone	378-44-9	>= 0.1 - < 1				

Actual concentration 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	:	First Aid responders should pay attention to self-protection,



Version 4.5	Revision Date: 08/27/2021		DS Number: 8853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
Notes	s to physician	:	when the potentia	mmended personal protective equipment al for exposure exists (see section 8). cally and supportively.
SECTION	5. FIRE-FIGHTING ME	ASL	JRES	
Suita	Suitable extinguishing media		Water spray Alcohol-resistant Carbon dioxide (0 Dry chemical	
	Unsuitable extinguishing media		None known.	
	Specific hazards during fire fighting		Exposure to com	bustion products may be a hazard to health.
	Hazardous combustion prod-		Carbon oxides	
Spec ods	Specific extinguishing meth- ods		cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do
	Special protective equipment for fire-fighters			e, wear self-contained breathing apparatus. tective equipment.

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment 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 or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. 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 determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 4.5	Revision Date: 08/27/2021	SDS Number: 808853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016				
SECTION	7. HANDLING AND ST	ORAGE					
Tech	nical measures	5	: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.				
Loca	I/Total ventilation		itilation is unavailable, use with local exhaust				
Advid	e on safe handling	Do not breathe Do not swallow Avoid contact Wash skin tho Handle in acco practice, based assessment Keep containe Do not eat, drii					
Conc	litions for safe storage	Store locked u Keep tightly clo	•				
Materials to avoid			ith the following product types: g agents				

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
White mineral oil (petroleum)	8042-47-5	TWA (Mist)	5 mg/m³	OSHA Z-1
		TWA (Inhal- able particu- late matter)	5 mg/m³	ACGIH
		TWA (Mist)	5 mg/m³	NIOSH REL
		ST (Mist)	10 mg/m ³	NIOSH REL
clotrimazole	23593-75-1	TWA	0.2 mg/m3 (OEB 2)	Internal
Gentamicin	1403-66-3	TWA	0.1 mg/m3 (OEB 2)	Internal
Betamethasone	378-44-9	TWA	1 µg/m3 (OEB 4)	Internal
	Further inform	ation: Skin		
		Wipe limit	10 µg/100 cm ²	Internal

Engineering measures

: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 4.5	Revision Date: 08/27/2021	SDS Nur 808853-(Date of last issue: 10/10/2020 Date of first issue: 07/22/2016	
		Use o If har cabin poter	closed proce ndled in a lab net, fume hoc ntial exists fo	en handling permitted. ssing systems or containment technologies. oratory, use a properly designed biosafety od, or other containment device if the r aerosolization. If this potential does not lined trays or benchtops.	
Perso	onal protective equip	ment			
Respiratory protection		main conce unkn Follo use N by air haza supp relea circu	General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Wh concentrations are above recommended limits or are unknown, appropriate respiratory protection should be wor Follow OSHA respirator regulations (29 CFR 1910.134) ar use NIOSH/MSHA approved respirators. Protection provid by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provi adequate protection.		
Hand	protection		·		
M	aterial	: Chen	nical-resistar	at gloves	
	emarks protection	: Wear If the mists Wear	work enviror or aerosols, r a faceshield ntial for direct	gloving. ses with side shields or goggles. Inment or activity involves dusty conditions, wear the appropriate goggles. If or other full face protection if there is a t contact to the face with dusts, mists, or	
Skin a	and body protection	: Work Addit task l dispo Use a	a uniform or la tional body ga being perforr psable suits)	aboratory coat. arments should be used based upon the ned (e.g., sleevelets, apron, gauntlets, to avoid exposed skin surfaces. legowning techniques to remove potentially hing.	
Hygie	ene measures	: If exp eye f worki When Wash The e engin appro indus	oosure to che lushing syste ing place. n using do no n contaminat effective ope neering contro opriate degov	emical is likely during typical use, provide ems and safety showers close to the ot eat, drink or smoke. ed clothing before re-use. ration of a facility should include review of ols, proper personal protective equipment, whing and decontamination procedures, monitoring, medical surveillance and the	

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color

iiquiu

: No data available



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Vers 4.5	sion	Revision Date: 08/27/2021		S Number: 853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
	Odor		:	No data available	
	Odor Th	nreshold	:	No data available	
	рН		:	No data available	
	Melting	point/freezing point	:	No data available	
	Initial bo range	oiling point and boiling	:	No data available	
	Flash p	oint	:	No data available	
	Evapora	ation rate	:	No data available	
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	
		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 Wate	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	
	Viscosit Visc	ty osity, kinematic	:	No data available	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance or	mixture is not classified as oxidizing.
	Particle	size	:	Not applicable	

SECTION 10. STABILITY AND REACTIVITY



Version 4.5	Revision Date: 08/27/2021		0S Number: 8853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
Cher	ctivity nical stability ibility of hazardous reac-	:	Stable under no	a reactivity hazard. rmal conditions. trong oxidizing agents.
Incor	ditions to avoid npatible materials ardous decomposition ucts	:	None known. Oxidizing agents No hazardous d	s ecomposition products are known.
	I 11. TOXICOLOGICAL I			
Inhal Skin Inges	mation on likely routes ation contact stion contact	ot	exposure	
	e toxicity classified based on availa	ble	information.	
Prod	luct:			
Acute	e oral toxicity	:	Acute toxicity est Method: Calculat	imate: > 5,000 mg/kg ion method
Acute	e inhalation toxicity	:	Acute toxicity est Exposure time: 4 Test atmosphere Method: Calculat	h : dust/mist
Acute	e dermal toxicity	:	Acute toxicity est Method: Calculat	imate: > 5,000 mg/kg ion method
Com	ponents:			
Whit	e mineral oil (petroleun	n):		
Acute	e oral toxicity	:	LD50 (Rat): > 5,0	000 mg/kg
Acute	e inhalation toxicity	:	LC50 (Rat): > 5 r Exposure time: 4 Test atmosphere Assessment: The tion toxicity	ĥ
Acute	e dermal toxicity	:	LD50 (Rabbit): > Assessment: The toxicity	2,000 mg/kg e substance or mixture has no acute dermal
clotr	imazole:			
	e oral toxicity	:	LD50 (Rat): 708	mg/kg
			LD50 (Mouse): 7	61 mg/kg



ersion 5	Revision Date: 08/27/2021		9S Number: 8853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
			LD50 (Rabbit): > 2	1,000 mg/kg
Acute	e inhalation toxicity	:	LC50 (Rat): > 0.73 Exposure time: 4 Test atmosphere:	h
Acute	e dermal toxicity	:	LD50 (Mouse): 92	23 mg/kg
Gent	amicin:			
Acute	e oral toxicity	:	LD50 (Rat): 8,000) - 10,000 mg/kg
			LD50 (Mouse): 10),000 mg/kg
Acute	e inhalation toxicity	:	LC50 (Rat): > 0.2 Exposure time: 4 Test atmosphere: Remarks: No mor	h
	e toxicity (other routes of nistration)	:	LD50 (Rat): 67 - 9 Application Route	
			LD50 (Rat): 371 - Application Route	
			LDLo (Monkey): 3 Application Route	
Beta	methasone:			
Acute	e oral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
			LD50 (Mouse): > 4	4,500 mg/kg
Acute	e inhalation toxicity	:	LC50 (Rat): 0.4 m Exposure time: 4	
Not c	corrosion/irritation lassified based on availa ponents:	ble	information.	
	e mineral oil (petroleum	ı):		
Spec	ies	:	Rabbit	
Resu	lt	:	No skin irritation	
clotri	imazole:			
Spec Resu		:	Rabbit No skin irritation	
	amicin:			
Spec	ies	:	Rabbit	
			8/23	



Vers 4.5	sion	Revision Date: 08/27/2021	-	9S Number: 8853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
	Result		:	Mild skin irritation	
	Betam	ethasone:			
	Species		:	Rabbit	
	Result	-	:	Mild skin irritation	
	Seriou	s eye damage/eye i	rritati	on	
	Not clas	ssified based on avai	ilable	information.	
	<u>Compo</u>	onents:			
	White r	nineral oil (petroleu	ım):		
	Species	6	:	Rabbit	
	Result		:	No eye irritation	
	clotrim	azole:			
	Species	3	:	Rabbit	
	Result		:	Mild eye irritation	
	Gentar	nicin:			
	Species	6	:	Rabbit	
	Result		:	Mild eye irritation	
	Betam	ethasone:			
	Species	6	:	Rabbit	
	Result		:	No eye irritation	
	Respira	atory or skin sensit	izatio	n	
	Skin se	ensitization			
	Not clas	ssified based on avai	ilable	information.	
	Respira	atory sensitization			
	Not clas	ssified based on avai	ilable	information.	
	Compo	onents:			
	White r	nineral oil (petroleu	ım):		
	Test Ty	pe	:	Buehler Test	
		of exposure	:	Skin contact	
	Species Result	5	:	Guinea pig negative	
	_				
	Gentar	-			
	Remark	<s< td=""><td>:</td><td>No data available</td><td></td></s<>	:	No data available	
	Betame	ethasone:			
	Routes	of exposure	:	Dermal	
	Species		:	Guinea pig	
				9 / 23	



Vers 4.5	sion	Revision Date: 08/27/2021		0S Number: 8853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
	Result		:	Weak sensitizer	
	Not cla	cell mutagenicity ssified based on avail: onents:	able	information.	
		mineral oil (petroleur exicity in vitro	n): :	Test Type: In vitro Result: negative	o mammalian cell gene mutation test
	Genoto	oxicity in vivo	:	cytogenetic assay Species: Mouse Application Route Method: OECD T Result: negative	: Intraperitoneal injection
	clotrim	nazole:			
	Genoto	oxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)
				Test Type: Chron Result: negative	nosome aberration test in vitro
				Test Type: in vitro Result: negative	o micronucleus test
	Genoto	oxicity in vivo	:	Test Type: Mamn cytogenetic assay Species: Rat Application Route Result: negative	, ,
				Test Type: Mamn tion test (in vivo) Species: Hamster Result: negative	nalian spermatogonial chromosome aberra-
	Germ o Assess	cell mutagenicity -	:	Weight of evidend cell mutagen.	ce does not support classification as a germ
	Gentar	nicin:			
		oxicity in vitro	:	Test Type: In vitro Result: negative	o mammalian cell gene mutation test
				Test Type: Chron Result: equivocal	nosome aberration test in vitro
	Genoto	oxicity in vivo	:	Test Type: Mamn cytogenetic assay	nalian erythrocyte micronucleus test (in vivo /)



	Revision Date: 08/27/2021	SDS Number: 808853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
		Species: Mo Application Result: neg	Route: Intravenous injection
Betar	nethasone:		
Geno	toxicity in vitro	: Test Type: Result: neg	Bacterial reverse mutation assay (AMES) ative
		Test Type: Result: neg	In vitro mammalian cell gene mutation test ative
		Test Type: Result: pos	Chromosome aberration test in vitro itive
Geno	toxicity in vivo	cytogenetic Species: Me	ouse Route: Oral
	cell mutagenicity -	: Weight of e cell mutage	vidence does not support classification as a germ n.
Carci		allable information	
Not cl <u>Com</u> p	lassified based on av <u>conents:</u> e mineral oil (petrole		
Not cl <u>Comp</u> White Speci	lassified based on av ponents: e mineral oil (petrole es	eum): : Rat	
Not cl Comp White Speci Applic	lassified based on av <u>conents:</u> e mineral oil (petrole es cation Route	eum): : Rat : Ingestion	
Not cl Comp White Speci Applic	lassified based on av <u>conents:</u> e mineral oil (petrole es cation Route sure time	eum): : Rat	
Not cl Comp White Speci Applic Expos Resul	lassified based on av <u>conents:</u> e mineral oil (petrole es cation Route sure time	eum): : Rat : Ingestion : 24 Months	
Not cl <u>Comp</u> White Speci Applic Expos Resul clotri Speci	assified based on av <u>conents:</u> e mineral oil (petrole es cation Route sure time t mazole: es	eum): : Rat : Ingestion : 24 Months : negative : Rat	
Not cl Comp White Speci Applic Expos Resul Clotri Speci Applic	lassified based on av <u>conents:</u> <u>e mineral oil (petrole</u> es cation Route sure time t <u>mazole:</u> es cation Route	Eum): : Rat : Ingestion : 24 Months : negative : Rat : Oral	
Not cl Comp White Speci Applic Expos Resul Clotri Speci Applic	assified based on av <u>conents:</u> <u>e mineral oil (petrole</u> es cation Route sure time t mazole: es cation Route sure time	eum): : Rat : Ingestion : 24 Months : negative : Rat	
Not cl <u>Comp</u> White Speci Applic Expos Resul Clotri Speci Applic Expos Resul	assified based on av <u>conents:</u> <u>e mineral oil (petrole</u> es cation Route sure time t mazole: es cation Route sure time	Eum): : Rat : Ingestion : 24 Months : negative : Rat : Oral : 78 weeks	
Not cl Comp White Speci Applic Expos Resul Clotri Speci Applic Expos Resul Genta Carcin	assified based on av <u>conents:</u> mineral oil (petrole es cation Route sure time t mazole: es cation Route sure time t	Eum): : Rat : Ingestion : 24 Months : negative : Rat : Oral : 78 weeks	ailable
Not cl Comp Speci Applic Expos Resul Clotri Speci Applic Expos Resul Genta	assified based on av <u>conents:</u> <u>e mineral oil (petrole</u> es cation Route sure time t mazole: es cation Route sure time t maicin: nogenicity - Assess- No ingredi	eum): : Rat : Ingestion : 24 Months : negative : Rat : Oral : 78 weeks : negative : No data ava ent of this product p	ailable present at levels greater than or equal to 0.1% is e or confirmed human carcinogen by IARC.
Not cl Comp White Speci Applic Expos Resul Clotri Speci Applic Expos Resul Clotri Carcia ment	assified based on av <u>conents:</u> e mineral oil (petrole es cation Route sure time t mazole: es cation Route sure time t amicin: nogenicity - Assess- No ingredi identified a No compo	Eum): : Rat : Ingestion : 24 Months : negative : Rat : Oral : 78 weeks : negative : No data ava ent of this product p as probable, possible	present at levels greater than or equal to 0.1% is e or confirmed human carcinogen by IARC. present at levels greater than or equal to 0.1% is


Version	Revision Date:	SDS Number:	Date of last issue: 10/10/2020
4.5	08/27/2021	808853-00015	Date of first issue: 07/22/2016

Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

Components:

White mineral oil (petroleum)):	
Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Skin contact Result: negative
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative
clotrimazole:		
Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Oral Fertility: LOAEL: 50 mg/kg body weight Result: Effects on fertility.
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 100 mg/kg body weight Result: Embryo-fetal toxicity., No teratogenic effects.
		Test Type: Embryo-fetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 50 mg/kg body weight Result: Embryo-fetal toxicity., No teratogenic effects.
		Test Type: Embryo-fetal development Species: Mouse Application Route: Oral Developmental Toxicity: NOAEL: 200 mg/kg body weight Result: No effects on fetal development.
		Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 180 mg/kg body weight Result: No effects on fetal development.
Reproductive toxicity - As- sessment	:	Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.



Vers 4.5	sion	Revision Date: 08/27/2021		DS Number: 8853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
	Genta	nicin:			
	Effects on fertility		:	Test Type: Two-generation reproduction toxicity study Species: Rat Fertility: NOAEL: 20 mg/kg body weight Result: No significant adverse effects were reported	
	Effects on fetal development		:	Species: Rabbit	ro-fetal development oxicity: NOAEL: 3.6 mg/kg body weight o-fetal toxicity.
				Species: Rat Application Route	oxicity: LOAEL: 75 mg/kg body weight
				Species: Mouse Application Route Developmental To	ro-fetal development : Intraperitoneal oxicity: LOAEL: 10 mg/kg body weight tality., No malformations were observed.
				Species: Rat Application Route Developmental To	ro-fetal development : Intraperitoneal oxicity: LOAEL: 50 mg/kg body weight tality., No malformations were observed.
	Reproc sessme	luctive toxicity - As- ent	:	Positive evidence human epidemiol	of adverse effects on development from ogical studies.
	Betam	ethasone:			
	Effects	on fetal development	:		: Intramuscular oxicity: LOAEL: 0.05 mg/kg body weight ty., Malformations were observed.
					: Subcutaneous oxicity: LOAEL: 0.42 mg/kg body weight ions were observed.
				-	: Intramuscular oxicity: LOAEL: 1 mg/kg body weight ions were observed.
	Reproc sessme	luctive toxicity - As- ent	:	Clear evidence of animal experimen	adverse effects on development, based on ts.



Version	Revision Date:	SDS Number:	Date of last issue: 10/10/2020
4.5	08/27/2021	808853-00015	Date of first issue: 07/22/2016

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed.

Components:

alotrimazolo	
clotrimazole	

Target Organs Assessment	 Liver, Kidney, Adrenal gland May cause damage to organs through prolonged or repeated exposure.
Gentamicin: Target Organs Assessment	 Kidney, inner ear Causes damage to organs through prolonged or repeated exposure.
Betamethasone:	

Target Organs	:	Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Exposure time

Target Organs

Symptoms

White mineral oil (petroleum):

Species LOAEL Application Route Exposure time	: : :	Rat 160 mg/kg Ingestion 90 Days
Species LOAEL Application Route Exposure time Method	: : : : : : : : : : : : : : : : : : : :	Rat >= 1 mg/l inhalation (dust/mist/fume) 4 Weeks OECD Test Guideline 412
clotrimazole: Species LOAEL Application Route	:	Rabbit 5 - 40 mg/kg Skin contact



Version 4.5	Revision Date: 08/27/2021	SDS Number: 808853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
Expo		: Rat : 10 mg/kg : Oral : 18 Months : Liver, Kidney, A	Adrenal gland
Expo Targe		: Dog : 25 mg/kg : Oral : 6 - 12 Months : Adrenal gland : Salivation, Lac	hrymation, Vomiting
Spec LOAE Appli Expo Targe		: Dog : 3 mg/kg : Intramuscular : 12 Months : Kidney : Vomiting, Saliv	ation
Expo		: Monkey : 50 mg/kg : Subcutaneous : 3 Weeks : Kidney, inner e	ar
Expo		: Monkey : 6 mg/kg : Intramuscular : 3 Weeks : Blood, Kidney,	inner ear, Liver
Expo	EL	: Rat : 5 mg/kg : 10 mg/kg : Intramuscular : 52 Weeks : Kidney, Blood	
Expo	EL	: Rat : 12.5 mg/kg : 50 mg/kg : Intramuscular : 13 Weeks : Kidney	
Spec LOAE Applie		: Rabbit : 0.05 % : Skin contact : 10 - 30 d	



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 4.5	Revision Date: 08/27/2021		DS Number: 8853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
Targe	Target Organs		Pituitary gland, li	mmune system, muscle
Expo			Rat 0.05 % Skin contact 8 Weeks thymus gland	
Expo			Mouse 0.1 % Skin contact 8 Weeks thymus gland	
Expo			Dog 0.05 mg/kg Oral 28 d Blood, thymus gl	land, Adrenal gland
Aspi	ration toxicity			

Not classified based on available information.

Experience with human exposure

Components:

clotrimazole: Skin contact Ingestion Gentamicin:	:	Symptoms: Rash, Itching, Blistering, Edema, Redness Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea
Ingestion	:	Target Organs: Kidney Target Organs: inner ear Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness
Betamethasone:		
Inhalation Skin contact	:	Target Organs: Adrenal gland Symptoms: Redness, pruritis, Irritation

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

White mineral of	oil (petroleum):
------------------	------------------

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h



Version 4.5	Revision Date: 08/27/2021		0S Number: 8853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
			Method: OECD Te	est Guideline 202
Toxic plant	city to algae/aquatic ts	:	NOEC (Pseudokir mg/l Exposure time: 72 Method: OECD Te	
Toxic icity)	city to fish (Chronic tox-	:	NOEC (Oncorhyn Exposure time: 28	chus mykiss (rainbow trout)): 1,000 mg/l 3 d
aqua	city to daphnia and other atic invertebrates (Chron- kicity)	:	NOEC (Daphnia r Exposure time: 21	nagna (Water flea)): 1,000 mg/l I d
clotr	imazole:			
Τοχία	city to fish	:	LC50 (Brachydan Exposure time: 96 Method: OECD Te	
	city to daphnia and other atic invertebrates	:	EC50 (Daphnia m Exposure time: 48	agna (Water flea)): 0.02 mg/l 3 h
Toxic plant	city to algae/aquatic ts	:	EC50 (Desmodes Exposure time: 72	mus subspicatus (green algae)): 0.268 mg/l ? h
			NOEC (Desmode Exposure time: 72	smus subspicatus (green algae)): 0.017 mg/l 2 h
Toxic icity)	city to fish (Chronic tox-	:	NOEC (Oncorhyn Exposure time: 32 Method: OECD Te	
aqua	city to daphnia and other atic invertebrates (Chron- kicity)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD Te	
Toxic	city to microorganisms	:	EC50: > 10,000 m Exposure time: 3 Test Type: Respir Method: OECD Te	h ation inhibition
Gent	tamicin:			
	city to daphnia and other tic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	agna (Water flea)): 86 mg/l 3 h est Guideline 202
			LC50 (Americamy Exposure time: 96 Method: US-EPA	
Toxic plant	city to algae/aquatic ts	:	EC50 (Pseudokiro Exposure time: 72 Method: OECD To	



/ersion 4.5	Revision Date: 08/27/2021	-	0S Number: 8853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
			NOEC (Pseudoki µg/l Exposure time: 72 Method: OECD T	
			EC50 (Anabaena Exposure time: 7: Method: OECD T	
			NOEC (Anabaena Exposure time: 72 Method: OECD T	
Toxic	ity to microorganisms	:	Exposure time: 3 Test Type: Respi	h
Beta	nethasone:			
	ity to daphnia and other tic invertebrates	:	EC50 (Americam Exposure time: 90	
Toxic plants	ity to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD T	
			mg/l Exposure time: 72 Method: OECD T	
Toxic icity)	ity to fish (Chronic tox-	:	Exposure time: 32	es promelas (fathead minnow)): 0.052 mg/l 2 d est Guideline 210
			Exposure time: 2	atipes (Japanese medaka)): 0.07 μg/l 19 d est Guideline 229
	ity to daphnia and other tic invertebrates (Chron- icity)	:	NOEC (Daphnia i Exposure time: 2 Method: OECD T	
Persi	stence and degradabil	ity		
Com	ponents:			
	e mineral oil (petroleun egradability	n): :	Result: Not readil	y biodegradable.



ersion .5	Revision Date: 08/27/2021	SDS Number: 808853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
		Biodegradatic Exposure time	
clotri	mazole:		
Stabil	lity in water	: Hydrolysis: 50	0 %(242 d)
Genta	amicin:		
Biode	gradability	: Result: rapidl Biodegradatic Exposure time Method: OEC	on: 100 %
Bioad	ccumulative potentia	I	
Com	ponents:		
Genta	amicin:		
	ion coefficient: n- ol/water	: log Pow: < -2	
Betar	nethasone:		
	ion coefficient: n- ol/water	: log Pow: 2.11	
Mobi	lity in soil		
No da	ata available		
	r adverse effects ata available		

Dis	posal meth	nods	

Waste from residues Contaminated packaging	Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.
	il not otherwise specified. Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International	Regulations
---------------	-------------

UNRTDG		
UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
		(clotrimazole, Gentamicin)
Class	:	9
Packing group	:	III
Labels	:	9
IATA-DGR		



Version 4.5	-	Revision Date: 08/27/2021)S Number: 8853-00015	Date of last issue: 10/10/2020 Date of first issue: 07/22/2016
	UN/ID No. Proper shipping name		:		nazardous substance, liquid, n.o.s.
	Class Packing group		:	(clotrimazole, Ge 9 III	ntamicin)
Pa	Labels Packing instruction (cargo aircraft)		:	Miscellaneous 964	
Pa ge	Packing instruction (passen- ger aircraft)		:	964	
	DG-C	mentally hazardous	÷	yes	
	l num oper s	iber shipping name	:	UN 3082 ENVIRONMENTA N.O.S. (clotrimazole, Gen	ALLY HAZARDOUS SUBSTANCE, LIQUID,
Pa La Em	bels nS Co	group ode pollutant	:	9 III 9 F-A, S-F yes	
Tra	anspo			Annex II of MARP	OL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

49 CFR

UN/ID/NA number	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (clotrimazole, Gentamicin)
Class	:	9
Packing group	:	III
Labels	:	CLASS 9
ERG Code	:	171
Marine pollutant	:	yes(clotrimazole, Gentamicin)
Remarks	:	Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.



Version	Revision Date:	SDS Number:	Date of last issue: 10/10/2020
4.5	08/27/2021	808853-00015	Date of first issue: 07/22/2016

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards	:	Reproductive toxicity Specific target organ toxicity (single or repeated exposure)
SARA 313	:	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

-							
Pennsylvania Right To Know							
White mineral oil (p	bleum)	8042-47-5					
California Prop. 65							
WARNING: This product can expose you to chemicals including Gentamicin, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.							
California List of Hazardous Substances							
White mineral oil (petroleum)			8042-47-5				
California Permissible Exposure Limits for Chemical Contaminants							
White mineral oil (petroleum)			8042-47-5				
The ingredients of this product are reported in the following inventories:							
AICS	:	not determined					
DSL	:	not determined					
IECSC	:	not determined					

SECTION 16. OTHER INFORMATION

Further information





Full text of other abbreviations

ACGIH NIOSH REL OSHA Z-1	:	USA. ACGIH Threshold Limit Values (TLV) USA. NIOSH Recommended Exposure Limits USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim- its for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST	:	STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials: bw - Body weight: CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/10/2020
4.5	08/27/2021	808853-00015	Date of first issue: 07/22/2016

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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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

: 08/27/2021

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.

US / Z8