



Temozolomide Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/20/2023
10.1	09/26/2023	27554-00024	Date of first issue: 11/03/2014

SECTION 1. IDENTIFICATION

Product name	:	Temozolomide Injection Formulation
Other means of identification	:	No data available

Manufacturer or supplier's details

Company name of supplier	:	Merck & Co., Inc
Address	:	126 E. Lincoln Avenue
		Rahway, New Jersey U.S.A. 07065
Telephone	:	908-740-4000
Emergency telephone	:	1-908-423-6000
E-mail address	:	EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use	: Pharma	ceutical
Restrictions on use	: Not app	licable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Acute toxicity (Oral)	:	Category 3
Eye irritation	:	Category 2A
Germ cell mutagenicity	:	Category 2
Carcinogenicity	:	Category 2
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Bone marrow, thymus gland, Lymph nodes, spleen)
GHS label elements Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H301 Toxic if swallowed. H319 Causes serious eye irritation. H341 Suspected of causing genetic defects.

H301 Toxic if swallowed.
H319 Causes serious eye irritation.
H341 Suspected of causing genetic defects.
H351 Suspected of causing cancer.
H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs (Bone marrow, thymus gland, Lymph nodes, spleen) through prolonged or repeated exposure if swallowed.

according to the Hazardous Products Regulations



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Preca	utionary Statements	P202 Do not h and understoo P260 Do not b P264 Wash sk P270 Do not e	reathe dust. in thoroughly after handling. at, drink or smoke when using this product. otective gloves, protective clothing, eye protection	
		POISON CEN P305 + P351 - for several mir to do. Continue P308 + P313 I	 P330 IF SWALLOWED: Immediately call a TER. Rinse mouth. P338 IF IN EYES: Rinse cautiously with water nutes. Remove contact lenses, if present and easy e rinsing. F exposed or concerned: Get medical attention. f eye irritation persists: Get medical attention. 	
		Storage: P405 Store locked up.		
		Disposal: P501 Dispose disposal plant.	of contents and container to an approved waste	

Other hazards

Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Citric acid	2- hydroxypro- pane-1,2,3- tricarboxylic acid	77-92-9	>= 10 - < 30 *
Temozolomide	No data availa- ble	85622-93-1	>= 5 - < 10 *

^{*} 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.





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If inhaled			: If inhaled, remove to fresh air. Get medical attention.				
In case of skin contact		of v Rei Ge ^s Wa	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 cas	In case of eye contact		In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.				
If swallowed		: If s Cal Rin	wallowed, DO I a physician c se mouth thor	NOT induce vomiting. or poison control center immediately. oughly with water. ing by mouth to an unconscious person.			
	mportant symptoms ffects, both acute and ed	: Toy Cau Sus Sus Ma Cau exp Cou	Toxic if swallowed. Causes serious eye irritation. Suspected of causing genetic defects. Suspected of causing cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeat exposure if swallowed. Contact with dust can cause mechanical irritation or dry the skin.				
Protec	ction of first-aiders	and	use the reco	ers should pay attention to self-protection, mmended personal protective equipment al for exposure exists (see section 8).			
Notes	to physician			cally and supportively.			

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides Nitrogen oxides (NOx) Metal oxides Chlorine compounds
Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so.

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	Special for fire-	protective equipment fighters	:	Evacuate area. In the event of fire Use personal prot	, wear self-contained breathing apparatus. ective equipment.
SEC	CTION 6	ACCIDENTAL RELE	ASE	EMEASURES	
	Personal precautions, protec- tive equipment and emer- gency procedures		:		ective equipment. ng advice (see section 7) and personal ent recommendations (see section 8).
	Enviror	mental precautions	:	Retain and dispos	akage or spillage if safe to do so. e of contaminated wash water. hould be advised if significant spillages
	Methods and materials for containment and cleaning up		:	container for dispo Avoid dispersal of with compressed a Dust deposits sho surfaces, as these released into the a Local or national r disposal of this ma employed in the cl determine which r Sections 13 and 1	dust in the air (i.e., clearing dust surfaces

SECTION 7. HANDLING AND STORAGE

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in 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. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the

according to the Hazardous Products Regulations



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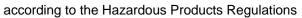
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Conditions for safe storage		environment. : Keep in properly labeled containers. Store locked up. Keep tightly closed.				
Materials to avoid		: Do not store with Strong oxidizing	ostances and mixtures			

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
Temozolomide	85622-93-1	TWA	0.1 ug/m3 (OEB 5)	Internal
		Wipe limit	1 µg/100 cm2	Internal

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





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Hygier	ne measures	task being perf disposable suit Use appropriat contaminated of : If exposure to of eye flushing sy working place. When using do Wash contamin The effective o engineering co appropriate de industrial hygie	y garments should be used based upon the ormed (e.g., sleevelets, apron, gauntlets, ss) to avoid exposed skin surfaces. e degowning techniques to remove potentially clothing. chemical is likely during typical use, provide stems and safety showers close to the o not eat, drink or smoke. hated clothing before re-use. peration of a facility should include review of ntrols, proper personal protective equipment, gowning and decontamination procedures, ene monitoring, medical surveillance and the trative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	white
Odor	:	No data 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	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
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	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available

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Density	: No c	data available	
Solubility(ies) Water solubilit	ty : solu	ble	
Partition coefficie	nt: n- : Not	applicable	
octanol/water Autoignition temp	erature : No c	data available	9
Decomposition te	emperature : No c	data available)
Viscosity Viscosity, kine	ematic : Not	applicable	
Explosive propert	ties : Not	explosive	
Oxidizing properti Molecular weight		substance or data available	r mixture is not classified as oxidizing.
-			
Particle size	: No c	data available	

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions		Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
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

Toxic if swallowed.

Product:

Acute oral toxicity

: Acute toxicity estimate: 241.75 mg/kg Method: Calculation method

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<u>Com</u>	ponents:			
Citric	acid:			
Acute	e oral toxicity	:	LD50 (Mouse)	: 5,400 mg/kg
Acute	e dermal toxicity	:		2,000 mg/kg D Test Guideline 402 Fhe substance or mixture has no acute derma
Temo	ozolomide:			
Acute	e oral toxicity	:	LD50 (Dog): 1	9 mg/kg
			LD50 (Rat): 31	15 mg/kg
			LD50 (Mouse)	: 205 mg/kg
Citric Speci Metho Resu	od	:	Rabbit OECD Test Go No skin irritatio	
Serio Caus	ous eye damage/eye ir es serious eye irritation ponents:			
	acid:			
Speci Resu Metho	ies It	::	Rabbit Irritation to eye OECD Test Ge	es, reversing within 21 days uideline 405
Resp	iratory or skin sensiti	zatic	'n	
	sensitization lassified based on avai	lable	information.	
	iratory sensitization			

Not classified based on available information.

Components:

Temozolomide:

Test Type	:	Maximization Test
Routes of exposure	:	Dermal
Species	:	Guinea pig
Result	:	negative

according to the Hazardous Products Regulations



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	cell mutagenicity ected of causing genetic	def	ects.	
Comp	oonents:			
Citric	acid:			
Genot	toxicity in vitro	:	Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
			Test Type: in vitro Result: positive	o micronucleus test
			Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
Genot	toxicity in vivo	:		enicity (in vivo mammalian bone-marrow chromosomal analysis) :: Ingestion
Temo	zolomide:			
Genot	toxicity in vitro	:	Test Type: Bacter Result: positive	ial reverse mutation assay (AMES)
			Test Type: Chrom Test system: Hum Result: positive	nosome aberration test in vitro nan lymphocytes
	cell mutagenicity - sment	:		om in vitro mammalian mutagenicity assays a activity relationship to known germ cell
	nogenicity acted of causing cancer.			
Comp	oonents:			
Temo	zolomide:			
	es ation Route sure time	: : : :	Rat Oral 6 Months 4 mg/kg body wei	aht
Resul Targe	t t Organs	:	positive Mammary gland	J
Carcir ment	nogenicity - Assess-	:	Limited evidence	of carcinogenicity in animal studies
Repro	oductive toxicity			

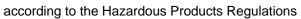
May damage fertility. May damage the unborn child.





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	Compo	onents:			
	Citric a Effects	acid: on fetal development	:	Test Type: One-g Species: Rat Application Route Result: negative	eneration reproduction toxicity study : Ingestion
	Temoz	olomide:			
		on fertility	:	Species: Rat, mal Application Route	
	Effects	on fetal development	:	Species: Rat Application Route Embryo-fetal toxic	ro-fetal development : Oral city.: LOAEL: 13 mg/kg body weight //alformations were observed.
	Reproc sessme	luctive toxicity - As- ent	:	fertility, based on	adverse effects on sexual function and animal experiments., Clear evidence of n development, based on animal
	STOT-	single exposure			
	Not cla	ssified based on availa	ble	information.	
	<u>Compo</u>	onents:			
	Citric a Assess		:	May cause respire	atory irritation.
	Causes	repeated exposure s damage to organs (Be or repeated exposure			and, Lymph nodes, spleen) through pro-
	Compo	onents:			
	Routes	olomide: of exposure Organs ment	:		mus gland, Lymph nodes, spleen o organs through prolonged or repeated
	Repeat	ted dose toxicity			
	Compo	onents:			
	Citric a	acid:			
	Specie	S	:	Rat	

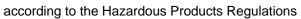




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		 4,000 mg/kg 8,000 mg/kg Ingestion 10 Days
Temo	zolomide:	
Expos	EL	 Rat, female 4 mg/kg 21 mg/kg Oral 6 Months Lymph nodes, thymus gland, Bone marrow, Reproductive organs
Expos	EL	 Rat, male 8.5 mg/kg 34 mg/kg Oral 6 Months Lymph nodes, thymus gland, Bone marrow, male reproductive organs, Gastrointestinal tract
Expos	EL	 Dog 2.5 mg/kg 6.3 mg/kg Oral 6 Months Bone marrow, spleen, male reproductive organs, Gastrointes- tinal tract, thymus gland
-	ration toxicity lassified based on ava	able information.
Expe	rience with human e	oosure
Com	oonents:	
Temo Inges	zolomide: tion	: Symptoms: Blood disorders, Nausea, Vomiting, Diarrhea, anorexia, Fatigue, hair loss
SECTION	12. ECOLOGICAL IN	ORMATION

Ecotoxicity		
Components:		
Citric acid: Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1,535 mg/l Exposure time: 24 h





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Tomo	zolomido:				
Temozolomide: 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		r :	Exposure time	ia magna (Water flea)): > 100 mg/l e: 48 h D Test Guideline 202	
Toxicity to algae/aquatic plants		:	mg/l Exposure time	okirchneriella subcapitata (green algae)): > 90 e: 72 h D Test Guideline 201	
			mg/l Exposure time	dokirchneriella subcapitata (green algae)): 40 e: 72 h D Test Guideline 201	
Toxici	Toxicity to microorganisms		EC50: > 100 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209		
Persis	stence and degradab	ility			
Comp	onents:				
	Citric acid: Biodegradability		Biodegradatio Exposure time		
Temo	zolomide:				
Biode	Biodegradability		Result: rapidly Biodegradatio Exposure time	n: 83 %	
Stabili	ty in water	:	Degradation h	nalf life (DT50): < 1 d	
Bioac	cumulative potential				
<u>Comp</u>	onents:				
Citric Partiti	acid: on coefficient: n-	:	log Pow: -1.72	2	
octanol/water		•	log i ow1.72	-	
Temo	zolomide:				

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octan	ol/water					
	lity in soil					
No data available						
Other adverse effects No data available						
SECTION 13. DISPOSAL CONSIDERATIONS						
Dispo	osal 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

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Domestic regulation

TDG Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

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

according to the Hazardous Products Regulations



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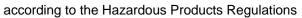
SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median 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	:	09/26/2023 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.





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