

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier Trade name	:	Temozolomide Injection Formulation
1.2	Relevant identified uses of th	ne s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture	:	Pharmaceutical
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety data sheet
	Company	:	MSD Piercetown A86 HD21 Dunboyne, Ireland
	Telephone	:	908-740-4000
	E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 3	H301: Toxic if swallowed.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Germ cell mutagenicity, Category 2	H341: Suspected of causing genetic defects.
Carcinogenicity, Category 2	H351: Suspected of causing cancer.
Reproductive toxicity, Category 1B	H360FD: May damage fertility. May damage the
	unborn child.
Specific target organ toxicity - repeated	H373: May cause damage to organs through pro-
exposure, Category 2	longed or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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Haza	rd pictograms	-	
Signa	al word	: Dange	er en
Haza	rd statements	: H301 H319 H341 H351 H360F H373	 Toxic if swallowed. Causes serious eye irritation. Suspected of causing genetic defects. Suspected of causing cancer. TD May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.
Prec	autionary statements	P201 P260 P280 Resp 0 P301	+ P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/ doctor. Rinse mouth.
			 + P313 IF exposed or concerned: Get medical advice/ attention. + P313 If eye irritation persists: Get medical advice/ attention.

Hazardous components which must be listed on the label:

Temozolomide

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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



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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Concentration
(% w/w)
, , , , , , , , , , , , , , , , , , ,
319 >= 10 - < 20
1335
H300 >= 1 - < 10 60FD H372 v, thy- ymph h)
٩ ٧

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
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	:	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 swallowed, DO NOT induce vomiting.



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			Rinse mouth tho	or poison control centre immediately. roughly with water. hing by mouth to an unconscious person.
4.2 Most i	mportant symptoms a	nd ef	fects, both acut	e and delayed
Risks			Suspected of ca May damage fer	eye irritation. using genetic defects.
			Contact with dus the skin.	t can cause mechanical irritation or drying of
4.3 Indica	tion of any immediate	medi	cal attention an	nd special treatment needed
Treat	ment	:	Treat symptoma	tically and supportively.
-	u ishing media ble extinguishing media		Water spray Alcohol-resistant	t foam
Cana				
Unsui media	itable extinguishing		None known.	
5.2 Specia	al hazards arising from	the	substance or m	ixture
•	fic hazards during fire-	:	Avoid generating concentrations, a potential dust ex	g dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a
Haza ucts	rdous combustion prod-		Carbon oxides Nitrogen oxides Metal oxides Chlorine compou	
5.3 Advice	e for firefighters			
	al protective equipment efighters			re, wear self-contained breathing apparatus. otective equipment.
Speci ods	fic extinguishing meth-		cumstances and	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers.



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		Remove unda so. Evacuate are	amaged containers from fire area if it is safe to do a.	
SECTION	6: Accidental relea	ase measures		
6.1 Persor	al precautions, prote	ective equipment a	nd emergency procedures	
Personal precautions :		Follow safe h	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).	
6.2 Enviro	nmental precautions			
Enviro	onmental precautions	Prevent furthe Retain and di	to the environment. er leakage or spillage if safe to do so. spose of contaminated wash water. ies should be advised if significant spillages ntained.	
6.3 Metho	ds and material for co	ontainment and cle	eaning up	
Methods for cleaning up :		tainer for disp Avoid dispers with compres Dust deposits es, as these r leased into th Local or natio posal of this r employed in t mine which re Sections 13 a	 Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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. 	

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.

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according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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			Handle in accord practice, based of sessment Keep container to Minimize dust ge Keep container of Keep away from Take precautions Do not eat, drink	ughly after handling. Jance with good industrial hygiene and safety on the results of the workplace exposure as- ightly closed. meration and accumulation. closed when not in use. heat and sources of ignition. ary measures against static discharges. or smoke when using this product. vent spills, waste and minimize release to the		
Hygiene measures		:	 If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami- nated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. 			
7.2 Condi	tions for safe storage,	inc	luding any incom	patibilities		
	irements for storage and containers	:		labelled containers. Store locked up. Keep ore in accordance with the particular national		
Advic	e on common storage	:	Strong oxidizing	ostances and mixtures		
7.3 Specif	ic end use(s) fic use(s)	:	No data available	9		

Occupational Exposure Limits

Occupational Exposure Limits	6
dusts non-specific	4 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust) Basis: IE OEL
	10 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust) Basis: IE OEL



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Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Temozolomide	85622-93-1	TWA	0.1 ug/m3 (OEB 5)	Internal
		Wipe limit	1 μg/100 cm2	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Sodium chloride	Workers	Inhalation	Long-term systemic effects	2068.62 mg/m3
	Workers	Inhalation	Acute systemic ef- fects	2068.62 mg/m3
	Workers	Skin contact	Long-term systemic effects	295.52 mg/kg bw/day
	Workers	Skin contact	Acute systemic ef- fects	295.52 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	443.28 mg/m3
	Consumers	Inhalation	Acute systemic ef- fects	443.28 mg/m3
	Consumers	Skin contact	Long-term systemic effects	126.65 mg/kg bw/day
	Consumers	Skin contact	Acute systemic ef- fects	126.65 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	126.65 mg/kg bw/day
	Consumers	Ingestion	Acute systemic ef- fects	126.65 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Citric acid	Fresh water	0.44 mg/l
	Marine water	0.044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34.6 mg/kg dry weight (d.w.)
	Marine sediment	3.46 mg/kg dry weight (d.w.)
	Soil	33.1 mg/kg dry weight (d.w.)
Sodium chloride	Fresh water	5 mg/l
	Sewage treatment plant	500 mg/l
	Soil	4.86 mg/kg dry weight (d.w.)

8.2 Exposure controls

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.



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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.

Eye/face protection	: 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
Hand protection	aerosols.
Material	: Chemical-resistant gloves
Remarks	: Consider double gloving.
Skin and body protection	: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis- posable suits) to avoid exposed skin surfaces.
	Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	 If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143
Filter type	: Particulates type (P)

9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper	:	No data available



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	flamma	ability limit			
Lower explosion limit / Lower flammability limit		:	No data available	e	
	Flash p	point	:	Not applicable	
	Auto-ig	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	Э
	рН		:	No data available	e
	Viscosi Visc	ity cosity, kinematic	:	Not applicable	
	Solubil Wat	ity(ies) ter solubility	:	soluble	
	Partitio octano	n coefficient: n- I/water	:	Not applicable	
	Vapou	r pressure	:	Not applicable	
	Relativ	e density	:	No data available	e
	Density	ý	:	No data available	9
	Relativ	e vapour density	:	Not applicable	
		e characteristics ticle size	:	No data available	e e e e e e e e e e e e e e e e e e e
9.2		nformation			
	Explosi		:	Not explosive	
		ng properties			r mixture is not classified as oxidizing.
		ration rate	:	Not applicable	
	Molecular weight			No data available	9

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.



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10.2 Ch	emical stability			
Sta	ole under normal condition	ons.		
	sibility of hazardous r	eaction		
Haz	ardous reactions	:	dling or other r	osive dust-air mixture during processing, han- neans. strong oxidizing agents.
10.4 Co	nditions to avoid			
Cor	ditions to avoid	:	Heat, flames a Avoid dust forr	
10.5 Inc	ompatible materials			
	erials to avoid	:	Oxidizing ager	nts
	ardous decomposition	-		
	hazardous decompositio	n pro		
SECTIC	N 11: Toxicological	infor	mation	
11 1 Inf	rmation on bazard ala		aa dafinad in D	agulation (EC) No 1272/2009
	rmation on likely routes		Inhalation	egulation (EC) No 1272/2008
	osure		Skin contact Ingestion Eye contact	
Αςι	ite toxicity			
Тох	ic if swallowed.			
<u>Pro</u>	duct:			
Acu	te oral toxicity	:	Acute toxicity e Method: Calcul	stimate: 243.59 mg/kg ation method
Cor	nponents:			
Citr	ic acid:			
	te oral toxicity	:	LD50 (Mouse):	5,400 mg/kg
Δcu	te dermal toxicity		LD50 (Rat): > 2	
7.00			Method: OECD	Test Guideline 402 he substance or mixture has no acute dermal
Ten	nozolomide:			
Acu	te oral toxicity	:	LD50 (Dog): 19) mg/kg
			LD50 (Rat): 31	5 mg/kg
			LD50 (Mouse):	205 mg/kg

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Skin corrosion/irritation

Not classified based on available information.

Components:

Citric acid:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Citric acid:

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Temozolomide:

Test Type	:	Maximisation Test
Exposure routes	:	Dermal
Species	:	Guinea pig
Result	:	negative

Germ cell mutagenicity

Suspected of causing genetic defects.

Components:

Citric acid:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: in vitro micronucleus test Result: positive
		Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)



ersion 1	Revision Date: 28.09.2024		DS Number: 567-00027	Date of last issue: 06.04.2024 Date of first issue: 03.11.2014
			Species: Rat Application Ro Result: negativ	
Temo	zolomide:			
Geno	toxicity in vitro	:	Test Type: Ba Result: positiv	cterial reverse mutation assay (AMES) e
				romosome aberration test in vitro Human lymphocytes e
Germ sessn	cell mutagenicity- As- nent	:		s from in vitro mammalian mutagenicity assay cture activity relationship to known germ cell
	nogenicity ected of causing cancer	r.		
<u>Com</u>	oonents:			
Temo	zolomide:			
	es cation Route sure time	:	Rat Oral 6 Months	
Resul Targe	lt et Organs	:	4 mg/kg body positive Mammary glar	-
Carcii ment	nogenicity - Assess-	:	Limited evider	nce of carcinogenicity in animal studies
Repro	oductive toxicity			
-	damage fertility. May da	imag	e the unborn ch	nild.
	oonents:			
	e acid: is on foetal develop-	:	Test Type: On Species: Rat Application Ro Result: negativ	
Temo	zolomide:			
Effect	s on fertility	:	Species: Rat, Application Ro	oute: Oral EL: 8.5 mg/kg body weight
Effect ment	s on foetal develop-	:	Test Type: Err Species: Rat	nbryo-foetal development
			12/2	0



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		I		te: Oral oxicity: LOAEL: 13 mg/kg body weight Malformations were observed.
Repr	oductive toxicity - As- nent	i	ty, based on an	of adverse effects on sexual function and fertil- imal experiments., Clear evidence of adverse opment, based on animal experiments.
	Γ - single exposure lassified based on avai	lable in	formation.	
Com	ponents:			
Citric	c acid:			
Asse	ssment	: 1	May cause resp	iratory irritation.
STO	Г - repeated exposure	•		
May	cause damage to orgar	ns throu	ugh prolonged o	r repeated exposure.
Com	ponents:			
Temo	ozolomide:			
Targe	sure routes et Organs ssment	: E : (nymus gland, Lymph nodes, spleen e to organs through prolonged or repeated
-	eated dose toxicity ponents:			
Citric	c acid:			
	EL	: 4 : 8 : 1	Rat 4,000 mg/kg 3,000 mg/kg ngestion 10 Days	
Temo	ozolomide:			
Spec NOA LOAE Appli Expo	ies EL		Rat, female 4 mg/kg 21 mg/kg Oral 6 Months _ymph nodes, th organs	nymus gland, Bone marrow, Reproductive
Spec NOA LOAI Appli	EL	: 8	Rat, male 3.5 mg/kg 34 mg/kg Dral	

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	sure time t Organs		, thymus gland, Bone marrow, male reproductive rointestinal tract
Expos	E	 Dog 2.5 mg/kg 6.3 mg/kg Oral 6 Months Bone marrow tinal tract, thy 	, spleen, male reproductive organs, Gastrointes- mus gland

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Temozolomide:

Ingestion

: Symptoms: Blood disorders, Nausea, Vomiting, Diarrhoea, anorexia, Fatigue, hair loss

SECTION 12: Ecological information

12.1 Toxicity

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
Temozolomide:		
Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203



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		/ to daphnia and other invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202	
	Toxicity plants	/ to algae/aquatic	:	mg/l Exposure time: 7	chneriella subcapitata (green algae)): > 90 2 h rest Guideline 201
				mg/l Exposure time: 7	rchneriella subcapitata (green algae)): 40 2 h rest Guideline 201
-	Toxicity	/ to microorganisms	:	EC50 : > 100 mg Exposure time: 3 Test Type: Respi Method: OECD T	h
12.2	Persis	tence and degradabil	ity		
9	Compo	onents:			
	Citric a				
I	Biodeg	radability	:	Result: Readily b Biodegradation: Exposure time: 2 Method: OECD T	97 %
	Temoz	olomide:			
I	Biodeg	radability	:	Result: rapidly de Biodegradation: Exposure time: 3	83 %
:	Stabilit	y in water	:	Degradation half	life (DT50): < 1 d
12.3	Bioaco	cumulative potential			
<u>(</u>	Compo	onents:			
	Citric a Partitio octanol	n coefficient: n-	:	log Pow: -1.72	
		olomide: n coefficient: n- /water	:	log Pow: 1.35	
		t y in soil a available			



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12.5 Results of PBT and vPvB assessment

Product:

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment	 The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
	· · · · · · · · · · · · · · · · · · ·

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	 Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste are not product specific, but application specific. Waste codes should be assigned by the user, prefe discussion with the waste disposal authorities. Do not dispose of waste into sewer. 	
Contaminated packaging	Empty containers should be taken to an approved we dling site for recycling or disposal. If not otherwise specified: Dispose of as unused pro-	

SECTION 14: Transport information

14.1 UN number or ID number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.2 UN proper shipping name		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good

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IMDG		: Not regulated as a dangerous good				
ΙΑΤΑ	N	: Not regulated as a dangerous good				
14.3 Tran	14.3 Transport hazard class(es)					
ADN		: Not regulated as a dangerous good				
ADR		: Not regulated as a dangerous good				
RID		: Not regulated as a dangerous good				
IMDO	6	: Not regulated as a dangerous good				
ΙΑΤΑ	۱.	: Not regulated as a dangerous good				
14.4 Packing group						
ADN		: Not regulated as a dangerous good				
ADR		: Not regulated as a dangerous good				
RID		: Not regulated as a dangerous good				
IMDO	6	: Not regulated as a dangerous good				
ΙΑΤΑ	(Cargo)	: Not regulated as a dangerous good				
ΙΑΤΑ	(Passenger)	: Not regulated as a dangerous good				
14.5 Environmental hazards						
Not regulated as a dangerous good						
14.6 Special precautions for user Not applicable						
14.7 Maritime transport in bulk according to IMO instruments						
Rem	arks	: Not applicable for product as supplied.				

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is appli-



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				cable to the placing on the market or not.
	ACH - Candidate List of ncern for Authorisation (A	gh :	Not applicable	
Re	gulation (EC) on substan	one :	Not applicable	
lay Re	er gulation (EU) 2019/1021	ollu- :	Not applicable	
	ts (recast)			
me	gulation (EU) No 649/201 Int and the Council conce dangerous chemicals		Not applicable	
RE	ACH - List of substances	n :	Not applicable	
Se	,	•		nt and of the Council on the control of
	-			Quantity 1 Quantity 2

		Quantity 1	Quantity 2
H2	ACUTE TOXIC	50 t	200 t

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H300	:	Fatal if swallowed.
H319	:	Causes serious eye irritation.
H335	:	May cause respiratory 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 through prolonged or repeated
		exposure if swallowed.

Full text of other abbreviations



Temozolomide Injection Formulation

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Cai Eye Mu Rej STO STO	a Irrit. ta.		Specific target or Ireland. List of Ch	
IE OEL / OELV - 8 hrs (TWA)				osure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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: NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture:

Classification procedure:

Acute Tox. 3

Commission Regulation (EU) 2020/878



Temozolomide Injection Formulation

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Eye Irı	rit. 2	H319	Calculation method	
Muta. 2		H341	Calculation method	
Carc. 2		H351	Calculation method	
Repr. 1B		H360FD	Calculation method	
STOT RE 2		H373	Calculation method	

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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