

Version 5.1	Revision Date: 30.09.2023	SDS N 52740-		Date of last issue: 04.04.2023 Date of first issue: 02.02.2015
SECTION	N 1: Identification of	the sub	stance/mixt	ure and of the company/undertaking
	ıct identifier			
Irade	e name	: Inte	erferon Alfa-2b	Solid Formulation
				ure and uses advised against
	of the Sub- ce/Mixture	: Pha	armaceutical	
Reco on us	mmended restrictions	: Not	applicable	
1.3 Detail	s of the supplier of the	e safety c	lata sheet	
Com	pany		16th Road	use, Midrand, South Africa
Telep	bhone	: +27	' 11 655 3000	
	il address of person onsible for the SDS	: EH	SDATASTEW	ARD@msd.com
	gency telephone numk 08-423-6000	ber		
	N 2: Hazards identifie		_	

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B

Specific target organ toxicity - repeated exposure, Category 2

H360FD: May damage fertility. May damage the unborn child. H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H360FD May damage fertility. May damage the unborn child.H373 May cause damage to organs through prolonged or repeated exposure.



Version 5.1	Revision Date: 30.09.2023	SDS Number: 52740-00019	Date of last issue: 04.04.2023 Date of first issue: 02.02.2015
Preca	autionary statements	P260 Do not	special instructions before use. breathe dust. rotective gloves/ protective clothing/ eye protec- ction.
		Response: P308 + P313 attention.	IF exposed or concerned: Get medical advice/
		Storage:	

P405 Store locked up.

Hazardous components which must be listed on the label: Interferon alfa-2b

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.

Dust contact with the eyes can lead to mechanical irritation.

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Interferon alfa-2b	98530-12-2	Skin Irrit. 2; H315 Repr. 1B; H360FD STOT RE 2; H373 (Blood, Bone mar- row)	>= 1 - < 10

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).



Version 5.1	Revision Date: 30.09.2023	-	0S Number: 740-00019	Date of last issue: 04.04.2023 Date of first issue: 02.02.2015
lf inha	aled	:	If inhaled, remove Get medical atter	
In case of skin contact		:	In case of contact, immediately flush skin with plenty of water Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.	
In cas	se of eye contact	:	If in eyes, rinse w Get medical atter	ell with water. htion if irritation develops and persists.
If swallowed		:	Get medical atter	NOT induce vomiting. htion. oughly with water.
4.2 Most i	mportant symptoms a	nd e	effects, both acute	e and delayed
Risks		•		ility. May damage the unborn child. ge to organs through prolonged or repeated
			Dust contact with	the eyes can lead to mechanical irritation.
	(*************************************			
4.3 Indica Treati	-	meo		d special treatment needed ically and supportively.
5.1 Exting	I 5: Firefighting meas juishing media ple extinguishing media	suro :	Water spray Alcohol-resistant Carbon dioxide (0	
			Dry chemical	
Unsui media	itable extinguishing a	:	None known.	
5.2 Specia	al hazards arising from	the	substance or mi	xture
-	fic hazards during fire-	:	Avoid generating concentrations, a potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a
Hazaı ucts	rdous combustion prod-	:	Carbon oxides Nitrogen oxides (



Version 5.1	Revision Date: 30.09.2023		OS Number: 740-00019	Date of last issue: 04.04.2023 Date of first issue: 02.02.2015	
5.3 Advi	ce for firefighters				
Special protective equipment for firefighters		:	: In the event of fire, wear self-contained breathing apparatus Use personal protective equipment.		
Specific extinguishing meth- ods		:	cumstances and t Use water spray t	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	

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions		Avoid release to the environment.
		Prevent further leakage or spillage if safe to do so.
		Retain and dispose of contaminated wash water.
		Local authorities should be advised if significant spillages
		cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up	 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.
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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

SAFETY DATA SHEET



Interferon Alfa-2b Solid Formulation

Version 5.1	Revision Date: 30.09.2023	SDS Number: 52740-00019	Date of last issue: 04.04.2023 Date of first issue: 02.02.2015			
Advice on safe handling Hygiene measures		Do not breath Do not swalld Avoid contac Handle in acc practice, bas sessment Keep contain Keep contain Keep away fr Take precaut Take care to environment. If exposure to flushing syste place. When nated clothin The effective engineering of appropriate of industrial hyg	ow. t with eyes. cordance with good industrial hygiene and safety ed on the results of the workplace exposure as- er tightly closed. t generation and accumulation. er closed when not in use. om heat and sources of ignition. ionary measures against static discharges. prevent spills, waste and minimize release to the			
7.2 Conc	litions for safe storage	e, including any incompatibilities				
	uirements for storage is and containers		erly labelled containers. Store locked up. Keep . Store in accordance with the particular national			
Adv	ice on common storage	Strong oxidiz	substances and mixtures			

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Interferon alfa-2b	98530-12-2	TWA	0.2 μg/m3 (OEB 5)	Internal
		Wipe limit	2 µg/100 cm²	Internal

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

Explosives Gases



Ver 5.1	sion Revision Date: 30.09.2023	SDS Numl 52740-000		of last issue: 04.04.2023 of first issue: 02.02.2015	
	Substance name	End Use	Exposure routes	s Potential health ef- fects	Value
	Disodium hy- drogenorthophos- phate	Workers	Inhalation	Long-term systemic effects	4,07 mg/m3
		Consumers	Inhalation	Long-term systemic effects	3,04 mg/m3

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

Substance name	Environmental Compartment	Value
Disodium hydrogenorthophos-	Fresh water	0,05 mg/l
phate		
	Marine water	0,005 mg/l
	Intermittent use/release	0,5 mg/l
	Sewage treatment plant	50 mg/l

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.

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 equipment

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 aerosols.
Hand protection		
Material	:	Chemical-resistant gloves
Remarks Skin and body protection	:	Consider double gloving. 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
Respiratory protection Filter type	:	contaminated clothing. If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

: powder



Versior 5.1	n Revision Date: 30.09.2023		S Number: 740-00019	Date of last issue: 04.04.2023 Date of first issue: 02.02.2015
Oc	blour dour dour Threshold	:	White to light yell No data available No data available	9
p⊦	1	:	No data available	9
Me	elting point/freezing point	:	No data available	9
	itial boiling point and boiling nge	:	No data available	9
	ash point	:	Not applicable	
Ev	vaporation rate	:	Not applicable	
Fla	ammability (solid, gas)	:	May form explosi dling or other me	ive dust-air mixture during processing, han- ans.
	oper explosion limit / Upper mmability limit	:	No data available	9
	wer explosion limit / Lower mmability limit	:	No data available	9
Va	apour pressure	:	Not applicable	
Re	elative vapour density	:	Not applicable	
Re	elative density	:	No data available	9
De	ensity	:	No data available	9
Pa oc	blubility(ies) Water solubility artition coefficient: n- stanol/water	:	No data available Not applicable	
	uto-ignition temperature	•	No data available	
	ecomposition temperature	-	No data available	Ż
Vi	scosity Viscosity, kinematic	:	Not applicable	
Ex	plosive properties	:	Not explosive	
O	kidizing properties	:	The substance o	r mixture is not classified as oxidizing.
9.2 Otł	ner information			
Fla	ammability (liquids)	:	No data available	9
Pa	article size	:	No data available)



Version 5.1	Revision Date: 30.09.2023	SDS Number: 52740-00019	Date of last issue: 04.04.2023 Date of first issue: 02.02.2015
SECTIO	N 10: Stability and rea	activity	
10.1 Read Not c	ctivity classified as a reactivity h	nazard.	
10.2 Chei	mical stability		
10.3 Poss	sibility of hazardous rea	actions	
	rdous reactions	: May form exp dling or other	losive dust-air mixture during processing, han- means. n strong oxidizing agents.
10.4 Con	ditions to avoid		
Conc	litions to avoid	: Heat, flames a Avoid dust for	
10.5 Inco	mpatible materials		
Mate	rials to avoid	: Oxidizing age	nts
No h	ardous decomposition azardous decomposition N 11: Toxicological ir	products are knowr	۱.
No hi SECTIOI 11.1 Infor	azardous decomposition N 11: Toxicological ir mation on toxicologica mation on likely routes of	nformation al effects f : Inhalation Skin contact Ingestion	۱.
No h SECTIOI 11.1 Infor Infor expo	azardous decomposition N 11: Toxicological ir mation on toxicologica mation on likely routes of sure	al effects f : Inhalation Skin contact	η.
No hi SECTIOI 11.1 Infor Infor expo Acut	azardous decomposition N 11: Toxicological ir mation on toxicologica mation on likely routes of	al effects f : Inhalation Skin contact Ingestion Eye contact	λ.
No h SECTIOI 11.1 Infor Inforr expo Acut Not c Skin	azardous decomposition N 11: Toxicological ir mation on toxicologica mation on likely routes of sure e toxicity	al effects f : Inhalation Skin contact Ingestion Eye contact	λ.
No hi SECTIOI 11.1 Infor Infor expo Acut Not c Skin Not c	azardous decomposition N 11: Toxicological ir mation on toxicologica mation on likely routes of sure e toxicity classified based on availa corrosion/irritation	al effects f : Inhalation Skin contact Ingestion Eye contact	λ.
No hi SECTIOI 11.1 Infor Infor expo Acut Not c Skin Not c Com	Azardous decomposition N 11: Toxicological ir mation on toxicological mation on likely routes of sure e toxicity classified based on availa corrosion/irritation classified based on availa	al effects f : Inhalation Skin contact Ingestion Eye contact	λ.
No hi SECTIOI 11.1 Infor Infor expo Acut Not c Skin Not c <u>Com</u>	azardous decomposition N 11: Toxicological ir mation on toxicologica mation on likely routes of sure e toxicity classified based on availa corrosion/irritation classified based on availa ponents: feron alfa-2b: cies	a products are known nformation al effects f : Inhalation Skin contact Ingestion Eye contact able information.	λ.
No hi SECTIOI 11.1 Infor Infor expo Acut Not c Skin Not c Com Inter Spec Resu	azardous decomposition N 11: Toxicological ir mation on toxicologica mation on likely routes of sure e toxicity classified based on availa corrosion/irritation classified based on availa ponents: feron alfa-2b: cies	nformation al effects f : Inhalation Skin contact Ingestion Eye contact able information. able information. : Rat : Skin irritation	λ.
No hi SECTIOI 11.1 Infor Infor expo Acut Not o Skin Not o Com Inter Spec Resu Serio Not o	azardous decomposition N 11: Toxicological ir mation on toxicologica mation on likely routes of sure e toxicity classified based on availa corrosion/irritation classified based on availa ponents: feron alfa-2b: cies lt	nformation al effects f : Inhalation Skin contact Ingestion Eye contact able information. able information. : Rat : Skin irritation	λ.
No hi SECTIOI 11.1 Infor Infor expo Acut Not c Skin Not c Com Inter Spec Resu Seric Not c Com	azardous decomposition N 11: Toxicological ir mation on toxicological mation on likely routes of sure e toxicity classified based on availa corrosion/irritation classified based on availa ponents: feron alfa-2b: cies lit	nformation al effects f : Inhalation Skin contact Ingestion Eye contact able information. able information. : Rat : Skin irritation	λ.



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assay (AMES)
naterials
velopment
velopment g/kg body weigł
unborn child.

May cause damage to organs through prolonged or repeated exposure.



sion	Revision Date: 30.09.2023	SDS Number: 52740-00019	Date of last issue: 04.04.2023 Date of first issue: 02.02.2015
<u>Com</u>	oonents:		
Interf	eron alfa-2b:		
Targe	et Organs	: Blood, Bone	marrow
	ssment		lamage to organs through prolonged or repeate
Repe	ated dose toxicity		
<u>Com</u>	oonents:		
Interf	eron alfa-2b:		
Speci		: Monkey	
NOAE		: 0,095 mg/kg	
	cation Route	: Intramuscula	ar
	sure time	: 1 Months	te de serve effecte e serve e de d
Rema	arks	: No significar	nt adverse effects were reported
Speci		: Rat	
NOAE		: 0,38 mg/kg	
	cation Route	: Subcutaneo	JS
	sure time	: 3 Months	t advarage offects were reported
Rema	arks	: No significar	t adverse effects were reported
Speci	es	: Mouse	
NOAE		: 0,076 mg/kg	
	cation Route	: Intraperitone	al
	sure time	: 9 d	te de serve effecte e serve e de d
Rema	arks	: No significar	t adverse effects were reported
Speci		: Monkey	
LOAE		: 0,38 mg/kg	
	cation Route	: Intramuscula	ar
	sure time	: 3 Months	
Rema	et Organs	: Blood, Bone	marrow exicity observed in testing
	arks	. Signincant id	Sicily observed in lesting
-	lassified based on av	nilable information	
Expe	rience with human e	exposure	
<u>Com</u>	ponents:		
Interf	eron alfa-2b:		
Skin o	contact		The most common side effects are:, flu-like syn chills, Fatigue

12.1 Toxicity

No data available



Version 5.1	Revision Date: 30.09.2023		DS Number: 740-00019	Date of last issue: 04.04.2023 Date of first issue: 02.02.2015
	stence and degradabi	lity		
No da	ata available			
	ccumulative potential ata available			
12.4 Mobi No da	lity in soil ata available			
12.5 Resu	lts of PBT and vPvB a	sse	ssment	
Produ	uct:			
	ssment	:	to be either persis	hixture contains no components considered stent, bioaccumulative and toxic (PBT), or not very bioaccumulative (vPvB) at levels of
12.6 Othe	r adverse effects			
Produ	uct:			
Endoo tial	crine disrupting poten-	:	ered to have end REACH Article 5	ixture does not contain components consid- ocrine disrupting properties according to 7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at higher.

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

SECTION 14: Transport information

14.1 UN 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



Version 5.1	Revision Date: 30.09.2023	SDS Number:Date of last issue: 04.04.202352740-00019Date of first issue: 02.02.2015	
ADR		: Not regulated as a dangerous good	
RID			
		: Not regulated as a dangerous good	
		: Not regulated as a dangerous good	
		: Not regulated as a dangerous good	
14.3 Iran	sport hazard class(e	,	
ADN		: Not regulated as a dangerous good	
ADR		: Not regulated as a dangerous good	
RID		: Not regulated as a dangerous good	
IMDO	3	: Not regulated as a dangerous good	
ΙΑΤΑ		: Not regulated as a dangerous good	
14.4 Pack	ing 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	
-	r onmental hazards egulated as a dangero	s good	
-	ial precautions for u pplicable	er	
14.7 Tran	sport in bulk accordi	g to Annex II of Marpol and the IBC Code	
Rema	arks	Not applicable for product as supplied.	

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

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



Version 5.1	Revision Date: 30.09.2023	SDS Number: 52740-00019	Date of last issue: 04.04.2023 Date of first issue: 02.02.2015	
Othe	r information		Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.	
Full 1 H315 H360 H373)FD	: May damage	Causes skin irritation. May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated	
Full	text of other abbreviat	exposure.		
Repr Skin		: Reproductive : Skin irritation	toxicity et organ toxicity - repeated exposure	
of the Euro asso cy Se socia borat Tran rying tiona IMDC - Ind KEC tion; tiona NO(/ fect Cher of Ch stanc tative Parlia	e German Institute for a pean Chemicals Agenci- ciated with x% respons chedule; ENCS - Existin- ated with x% growth ra- tory Practice; IARC - In- sport Association; IBC - Dangerous Chemicals I Civil Aviation Organiz G - International Maritim ustrial Safety and Heal I - Korea Existing Chem LD50 - Lethal Dose to I Convention for the P A)EC - No Observed (A Level; NOELR - No O nicals; OECD - Organiz nemical Safety and Pol ce; PICCS - Philippines e) Structure Activity Rel ament and of the Cou	Standardisation; DS cy; EC-Number - Eu e; ELx - Loading rai ng and New Chemic te response; GHS nternational Agency - International Code in Bulk; IC50 - Half cation; IECSC - Invente th Law (Japan); ISC nicals Inventory; LCS 50% of a test population dverse) Effect Cond bservable Effect Loc zation for Economic llution Prevention; F Inventory of Chemic lationship; REACH ncil concerning the	utagen or Reproductive Toxicant; DIN - Standar SL - Domestic Substances List (Canada); ECHA ropean Community number; ECx - Concentratio te associated with x% response; EmS - Emerger cal Substances (Japan); ErCx - Concentration as - Globally Harmonized System; GLP - Good La for Research on Cancer; IATA - International A for the Construction and Equipment of Ships can maximal inhibitory concentration; ICAO - Interna- entory of Existing Chemical Substances in China s; IMO - International Maritime Organization; ISH D - International Organisation for Standardization 60 - Lethal Concentration to 50 % of a test popula- lation (Median Lethal Dose); MARPOL - Interna- con from Ships; n.o.s Not Otherwise Specified contration; NO(A)EL - No Observed (Adverse) E- bading Rate; NZIOC - New Zealand Inventory of Co-operation and Development; OPPTS - Offic PBT - Persistent, Bioaccumulative and Toxic sub- cals and Chemical Substances; (Q)SAR - (Quant - Regulation (EC) No 1907/2006 of the Europea Registration, Evaluation, Authorisation and Re- cerning the International Carriage of Dangerou	

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

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:



Version 5.1	Revision Date: 30.09.2023	SDS Number: 52740-00019	Date of last issue: 04.04.2023 Date of first issue: 02.02.2015
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.

ZA / EN