according to the OSHA Hazard Communication Standard



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SECTION 1. IDENTIFICATION

Product name	:	Interferon Alfa-2b Solid Formulation			
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					
D					

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200) Combustible dust			
Reproductive toxicity	:	Category 1B	
Specific target organ toxicity - repeated exposure	:	Category 2 (Blood, Bone marrow)	
GHS label elements Hazard pictograms	:		
Signal Word	:	Danger	
Hazard Statements	:	If small particles are generated during further processing, han- dling or by other means, may form combustible dust concentra- tions in air. H360FD May damage fertility. May damage the unborn child. H373 May cause damage to organs (Blood, Bone marrow) through prolonged or repeated exposure.	
Precautionary Statements	:	 Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe dust. P280 Wear protective gloves, protective clothing, eye protection and face protection. Response: 	

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P308 + P313 IF exposed or concerned: Get medical attention.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

Dust contact with the eyes can lead to mechanical irritation.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)		
Interferon alfa-2b	98530-12-2	>= 1 - < 5		
Actual concentration is withhold as a trade secret				

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 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	:	If in eyes, rinse well with water. 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	:	May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. 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).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media :

Water spray Alcohol-resistant foam Carbon dioxide (CO2)



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				Dry chemical	
	Unsuita media	able extinguishing	:	None known.	
	Specifi fighting	c hazards during fire I	:	concentrations, and potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. oustion products may be a hazard to health.
	Hazarc ucts	lous combustion prod-	:	Carbon oxides Nitrogen oxides (I Metal oxides Phosphorus comp Oxides of phosph Carbon dioxide (C	oounds orus
	Specifi ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
		l protective equipment fighters	:		e, wear self-contained breathing apparatus. rective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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. 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	:	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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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. 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. 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. Take care to prevent spills, waste and minimize release to the
Conditions for safe storage	environment. Keep in properly labeled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplac	e control parameters
inert or nuisance dust	50 Million particles per cubic foot Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	15 mg/m³ Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	5 mg/m³ Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3
	15 Million particles per cubic foot Value type (Form of exposure): TWA (respirable fraction)



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		Basis: OS	SHA Z-3					
	Dust, nuisance dust and par- ticulates		3 De (Form of exposu AL PEL	re): PEL (Total dust)				
			5 mg/m³ Value type (Form of exposure): PEL (respirable dust fraction) Basis: CAL PEL					
Com	ponents	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis			
Inter	feron alfa-2b	98530-12	2-2 TWA	0.2 µg/m3 (OEB 5)	Internal			
			Wipe limit	2 µg/100 cm ²	Internal			
	ineering 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. 						
	piratory protection		and local exhaust	ventilation is recomme	nded to			
		: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided 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 provide adequate protection.						
Han	d protection	·						
Ν	laterial	: Chemica	al-resistant gloves					
	Remarks 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 			ere is a			

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Skin a	and body protection	task being perfor disposable suits)	garments should be used based upon the med (e.g., sleevelets, apron, gauntlets, to avoid exposed skin surfaces. degowning techniques to remove potentially
Hygiene measures		: If exposure to ch eye flushing syst working place. When using do n Wash contamina The effective ope engineering cont appropriate dego	emical is likely during typical use, provide ems and safety showers close to the not eat, drink or smoke. ted clothing before re-use. eration of a facility should include review of rols, proper personal protective equipment, owning and decontamination procedures, e monitoring, medical surveillance and the

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	White to light yellow
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

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Relative density		:	No data available	9	
	Density	/	:	No data available	9
	Solubility(ies) Water solubility		:	No data available	e
	Partitio octano	n coefficient: n-	:	Not applicable	
		nition temperature	:	No data available	9
	Decomposition temperature		:	No data available	9
	Viscosi Visc	ity cosity, kinematic	:	Not applicable	
	Explos	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Particle Particle	e characteristics e size	:	No data available	9

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

Not classified based on available information.

Product:

Acute oral toxicity

: Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

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	Skin c	orrosion/irritation					
	Not classified based on available information.						
	<u>Comp</u>	<u>onents:</u>					
	Interfe	eron alfa-2b:					
	Specie Result		:	Rat Skin irritation			
		us eye damage/eye i assified based on ava					
	<u>Comp</u>	onents:					
	Interfe	eron alfa-2b:					
	Specie Remai		:	Rabbit slight irritation			
	Respi	ratory or skin sensit	izatio	n			
		ensitization assified based on ava	ilable	information.			
	-	ratory sensitization assified based on ava	ilable	information.			
		cell mutagenicity assified based on ava	ilable	information.			
	<u>Comp</u>	onents:					
	Interfe	eron alfa-2b:					
	Genot	oxicity in vitro	:	Test Type: Chron Result: negative	nosome aberration test in vitro		
				Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)		
	Genot	oxicity in vivo	:	Test Type: Micror	nucleus test		
				Species: Mouse Result: negative Remarks: Based	on data from similar materials		
	Carcir	nogenicity					
	Not cla	assified based on ava					
	IARC				t at levels greater than or equal to 0.1% is onfirmed human carcinogen by IARC.		
	OSHA			this product prese regulated carcinog	nt at levels greater than or equal to 0.1% is gens.		
	NTP				t at levels greater than or equal to 0.1% is carcinogen by NTP.		

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Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

Interferon alfa-2b:		
Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Monkey Fertility: LOAEL: 3.8 µg/kg Result: menstrual irregularities Remarks: Abortion
Effects on fetal development	:	Test Type: Fertility/early embryonic development Species: Monkey Developmental Toxicity: LOAEL: 3.8 µg/kg body weight Result: Embryolethal effects.
Reproductive toxicity - As- sessment	:	May damage fertility. May damage the unborn child.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Blood, Bone marrow) through prolonged or repeated exposure.

Components:

Interferon alfa-2b:

Target Organs Assessment	:	Blood, Bone marrow May cause damage to organs through prolonged or repeated
		exposure.

Repeated dose toxicity

Components:

Interferon alfa-2b:

NOAEL Application Route Exposure time	:	Monkey 0.095 mg/kg Intramuscular 1 Months No significant adverse effects were reported
Exposure time		Rat 0.38 mg/kg Subcutaneous 3 Months No significant adverse effects were reported
Species NOAEL Application Route	:	Mouse 0.076 mg/kg Intraperitoneal

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Expo Rem	sure time arks	: 9 d : No significan	t adverse effects were reported		
Expo	EL cation Route sure time et Organs	: 3 Months : Blood, Bone	: 0.38 mg/kg : Intramuscular		
Not o	ration toxicity classified based on ava				
-	erience with human ex ponents:	cposure			
	feron alfa-2b:				
Skin	contact		The most common side effects are:, flu-like symp- chills, Fatigue		
SECTION	12. ECOLOGICAL IN	FORMATION			
No d	oxicity ata available				

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal n	nethods
------------	---------

Waste from residues	:	Dispose of in accordance with local regulations.
		Do not dispose of waste into sewer.
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

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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

49 CFR

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Disodium hydrogenorthophos- phate	7558-79-4	5000	53022

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

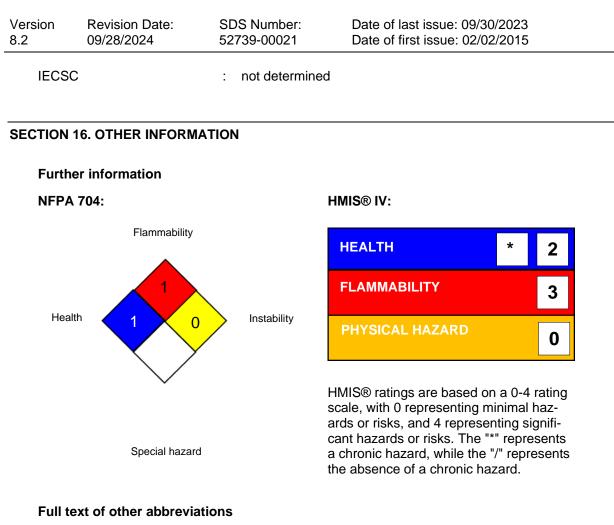
This material does not contain any components with a section 302 EHS TPQ.

			,	
SARA 31	1/312 Hazards	:	Combustible dust Reproductive toxicity Specific target organ toxicity (single or	repeated exposure)
SARA 31	3	:	This material does not contain any che known CAS numbers that exceed the t reporting levels established by SARA 1	hreshold (De Minimis)
US State Regulations				
Pennsylvania Right To Know				
	Glycine Disodium hydrogenorthophosphate Recombinant Human Albumin			56-40-6 7558-79-4 Not Assigned
California List of Hazardous Substances				
Disodium hydrogenorthophosphate 7558-79-4		7558-79-4		
The ingredients of this product are reported in the following inventories:				
AICS		:	not determined	
DSL		:	not determined	

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CAL PEL	:	California permissible exposure limits for chemical contami-
		nants (Title 8, Article 107)
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Min-
		eral Dusts
CAL PEL / PEL	:	Permissible exposure limit
OSHA Z-3 / 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 Pre-



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vention 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; 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	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
Data Sheet		cy, http://echa.europa.eu/

09/28/2024

Revision Date :

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