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



# Interferon Alfa-2b Liquid Formulation

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 SDS Number:
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 3.11
 28.09.2024
 45284-00021
 Date of first issue: 07.01.2015

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Interferon Alfa-2b Liquid Formulation

1.2 Relevant identified uses of the substance 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 safety data sheet

Company : MSD

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

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)

Reproductive toxicity, Category 1B H360FD: May damage fertility. May damage the

unborn child.

Specific target organ toxicity - repeated

exposure, Category 2

H373: May cause damage to organs through pro-

longed 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.

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H373 May cause damage to organs through prolonged or

repeated exposure.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

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.

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.

## **SECTION 3: Composition/information on ingredients**

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
m-Cresol	108-39-4 203-577-9 604-004-00-9	Acute Tox. 3; H301 Acute Tox. 3; H311 Skin Corr. 1B; H314 Eye Dam. 1; H318 Aquatic Chronic 3; H412 EUH071  Acute toxicity esti-	>= 0,1 - < 0,25

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		mate  Acute oral toxicity: 121 mg/kg Acute dermal toxicity: 301 mg/kg	
Interferon alfa-2b	98530-12-2	Skin Irrit. 2; H315 Repr. 1B; H360FD STOT RE 2; H373 (Blood, Bone marrow) ————————————————————————————————————	>= 0,001 - < 0,1

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 : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

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4.2 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.

4.3 Indication of any immediate medical attention and special treatment needed

**Treatment** : Treat symptomatically and supportively.

**SECTION 5: Firefighting measures** 

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

ucts

Hazardous combustion prod- : No hazardous combustion products are known

5.3 Advice 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

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.

Evacuate area.

**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.

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Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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 deter-

mine 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 : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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 mist or vapours.

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 as-

sessment

Keep container tightly closed.

Take care to prevent spills, waste and minimize release to the

environment.

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.

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## 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

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	Control parameters	Basis
		of exposure)		
m-Cresol	108-39-4	TWA	20 mg/m3	FOR-2011-
			_	12-06-1358
	Further information: Chemicals that can be absorbed through the skin.			
Interferon alfa-2b	98530-12-2	TWA	0.2 μg/m3 (OEB 5)	Internal
		Wipe limit	2 μg/100 cm <sup>2</sup>	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
m-Cresol	Workers	Inhalation	Long-term systemic effects	3,5 mg/m3
	Workers	Inhalation	Acute systemic effects	343 mg/m3
	Workers	Skin contact	Long-term systemic effects	0,5 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	1,47 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0,75 mg/m3
	Consumers	Inhalation	Acute systemic effects	222 mg/m3
	Consumers	Skin contact	Long-term systemic effects	0,25 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	0,74 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,25 mg/kg bw/day

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Consumers Ingestion Acute systemic ef- 0,74 mg/kg fects bw/day

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

Substance name	Environmental Compartment	Value
m-Cresol	Fresh water	0,1 mg/l
	Marine water	0,01 mg/l
	Intermittent use/release	0,076 mg/l
	Sewage treatment plant	1,14 mg/l
	Fresh water sediment	0,71 mg/kg
	Marine sediment	0,071 mg/kg
	Soil	0,0831 mg/kg

### 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 : 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, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Respiratory protection : No personal respiratory protective equipment normally re-

quired.

### **SECTION 9: Physical and chemical properties**

# 9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : colourless

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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) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 6,5 - 8

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : Not applicable

## **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

## 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

## 10.4 Conditions to avoid

Conditions to avoid : None known.

# 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## **SECTION 11: Toxicological information**

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

exposure Skin contact Ingestion

Eye contact

#### **Acute toxicity**

Not classified based on available information.

### **Product:**

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg

Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg

Method: Calculation method

#### **Components:**

m-Cresol:

Acute oral toxicity : LD50 (Rat): 121 mg/kg

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Remarks: Based on data from similar materials

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

Acute dermal toxicity : LD50 (Rabbit): 301 mg/kg

Remarks: Based on data from similar materials

#### Skin corrosion/irritation

Not classified based on available information.

### **Components:**

m-Cresol:

Species : Rabbit

Result : Corrosive after 3 minutes to 1 hour of exposure

Interferon alfa-2b:

Species : Rat

Result : Skin irritation

## Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

m-Cresol:

Species : Rabbit

Result : Irreversible effects on the eye

Interferon alfa-2b:

Species : Rabbit

Remarks : slight irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

### Respiratory sensitisation

Not classified based on available information.

### Germ cell mutagenicity

Not classified based on available information.

### **Components:**

m-Cresol:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: positive

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Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Genotoxicity in vivo Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Mouse

Application Route: Ingestion Method: OECD Test Guideline 475

Result: negative

Interferon alfa-2b:

Genotoxicity in vitro Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo Test Type: Micronucleus test

> Species: Mouse Result: negative

Remarks: Based on data from similar materials

## Carcinogenicity

Not classified based on available information.

## Components:

m-Cresol:

**Species** Mouse, males Application Route Ingestion Exposure time 105 weeks Result equivocal

Based on data from similar materials Remarks

Species Mouse, female Application Route Inaestion Exposure time 106 - 107 weeks

Result positive

Remarks Based on data from similar materials

Carcinogenicity - Assess-

Weight of evidence does not support classification as a carment cinogen

# Reproductive toxicity

May damage fertility. May damage the unborn child.

#### Components:

m-Cresol:

Effects on fertility Test Type: Two-generation reproduction toxicity study

Species: Rat

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Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Prenatal development toxicity study (teratogenicity)

Species: Rat

Application Route: Ingestion

Result: negative

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 foetal develop-

ment

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 through prolonged or repeated exposure.

#### **Components:**

#### Interferon alfa-2b:

Target Organs : Blood, Bone marrow

Assessment : May cause damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

### **Components:**

#### m-Cresol:

Species : Rat
NOAEL : 150 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Method : OECD Test Guideline 408

#### Interferon alfa-2b:

Species : Monkey
NOAEL : 0,095 mg/kg
Application Route : Intramuscular
Exposure time : 1 Months

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Remarks : No significant adverse effects were reported

Species : Rat

NOAEL : 0,38 mg/kg
Application Route : Subcutaneous
Exposure time : 3 Months

Remarks : No significant adverse effects were reported

Species : Mouse
NOAEL : 0,076 mg/kg
Application Route : Intraperitoneal

Exposure time : 9 d

Remarks : No significant adverse effects were reported

Species : Monkey
LOAEL : 0,38 mg/kg
Application Route : Intramuscular
Exposure time : 3 Months

Target Organs : Blood, Bone marrow

Remarks : Significant toxicity observed in testing

#### **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 consid-

ered 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:**

Interferon alfa-2b:

Skin contact : Symptoms: The most common side effects are:, flu-like symp-

toms, Fever, chills, Fatigue

# **SECTION 12: Ecological information**

### 12.1 Toxicity

#### **Components:**

m-Cresol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 8,6 mg/l

Exposure time: 96 h

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Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia pulex (Water flea)): > 99,5 mg/l

Exposure time: 48 h

Toxicity to fish (Chronic tox-

icity)

NOEC: 1,35 mg/l Exposure time: 32 d

Species: Pimephales promelas (fathead minnow) Remarks: Based on data from similar materials

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 1 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

Remarks: Based on data from similar materials

# 12.2 Persistence and degradability

#### **Components:**

m-Cresol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 90 % Exposure time: 28 d

Method: OECD Test Guideline 301D

#### 12.3 Bioaccumulative potential

#### **Components:**

m-Cresol:

Bioaccumulation : Species: Leuciscus idus (Golden orfe)

Bioconcentration factor (BCF): 17 - 20

Partition coefficient: n-

octanol/water

: log Pow: 1,96

#### 12.4 Mobility in soil

No data available

## 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 consid-

ered 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

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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 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 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
IATA : 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
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

#### 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
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

#### 14.4 Packing group

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**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 IATA (Cargo) Not regulated as a dangerous good IATA (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

Remarks 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 3

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 applicable to the placing on the market or

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation

(Annex XIV)

Regulation (EC) on substances that deplete the ozone

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia-

of dangerous chemicals

ment and the Council concerning the export and import

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

not.

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



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### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

#### 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**

H301 : Toxic if swallowed.

H311 : Toxic in contact with skin.

H314 : Causes severe skin burns and eye damage.

H315 : Causes skin irritation.

H318 : Causes serious eye damage.

H360FD : May damage fertility. May damage the unborn child.

H373 : May cause damage to organs through prolonged or repeated

exposure.

H412 : Harmful to aquatic life with long lasting effects.

EUH071 : Corrosive to the respiratory tract.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Dam. : Serious eye damage Repr. : Reproductive toxicity

Skin Corr. : Skin corrosion Skin Irrit. : Skin irritation

STOT RE : Specific target organ toxicity - repeated exposure

FOR-2011-12-06-1358 : Norway. Occupational Exposure limits

FOR-2011-12-06-1358 / : Long term exposure limit

TWA

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

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



# **Interferon Alfa-2b Liquid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.11 28.09.2024 45284-00021 Date of first issue: 07.01.2015

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; 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 Agen-

cy, http://echa.europa.eu/

#### Classification of the mixture:

Classification procedure:

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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