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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

National Poison Control Center (UZEM): 114

Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848 and subsequent amendments

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 T.R. SEA No 28848 and subsequent amendments

Hazard pictograms

Signal word : Danger

Hazard statements : H360FD May damage fertility. May damage the unborn

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child.

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

None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. KKDIK Registra- tion No.	SEA 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	>= 0,1 - < 0,25
Interferon alfa-2b	98530-12-2	Skin Irrit. 2; H315 Repr. 1B; H360FD STOT RE 2; H373 (Blood, Bone marrow) ————————————————————————————————————	>= 0,001 - < 0,1

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STOT RE 2; H373 >= 0,001 %

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks : 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)

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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.

Hazardous combustion prod: :

ucts

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.

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

harriers)

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-

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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.

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

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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 cm ²	Internal

Derived No Effect Level (DNEL)

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
	Consumers	Ingestion	Acute systemic effects	0,74 mg/kg bw/day

Predicted No Effect Concentration (PNEC)

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.

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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

Appearance : liquid Colour : colourless

Odour : No data available Odour Threshold : No data available

pH : 6,5 - 8

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

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Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available Partition coefficient: n- : Not applicable

octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : Not applicable

Particle size : 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.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

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

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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

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.

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Components:

m-Cresol:

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

Remarks : Based on data from similar materials

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

Result : positive

Remarks : Based on data from similar materials

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

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

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.

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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 : OECD Test Guideline 408 Method

Interferon alfa-2b:

Species Monkey : 0,095 mg/kg NOAEL : Intramuscular : 1 Months : No significant Application Route Exposure time

Remarks : No significant adverse effects were reported

: Rat

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

: No significant adverse effects were reported Remarks

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

9 d

No significant adverse effects were reported Remarks

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

Target Organs Blood, Bone marrow

Remarks Significant toxicity observed in testing

Aspiration toxicity

Not classified based on available information.

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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

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia pulex (Water flea)): > 99,5 mg/l

Exposure time: 48 h

Toxicity to fish (Chronic tox- : NOEC: 1,35 mg/l

icity)

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:

Species: Leuciscus idus (Golden orfe) Bioaccumulation

Bioconcentration factor (BCF): 17 - 20

Partition coefficient: n-

octanol/water

: log Pow: 1,96

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12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 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

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

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IATA 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 **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 Transport in bulk according to Annex II of Marpol and the IBC Code

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17)

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 not.

Regulation on Persistent Organic Pollutants (Number 30595 and subsequent amendments published)

Not applicable

Regulation on prevention of major industrial accidents. Reg number 30702 Not applicable

Other regulations:

T.R. Regulation on Classification, Labeling and Packaging of Substances and Mixtures, dated December 11, 2013 and numbered 28848 from the Ministry of Environment and Urbanization and the subsequent amendments published.

Regulation on Import and Export of Certain Hazardous : Not applicable

Chemicals, No. 32087, 2023

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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.

The SDS has been prepared by: Name: Gökhan Ardıç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September

2025

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.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

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

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

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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

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

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