

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
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Response:

P391 Collect spillage.

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.

Contact with dust can cause mechanical irritation or drying of the skin.

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)
Elbasvir	1370468-36-2	Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 10	>= 2,5 - < 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 advice 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 : Wash with water and soap.
Get medical attention if symptoms occur.
- 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.

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Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

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 : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Metal oxides
Chlorine compounds

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 methods : Use extinguishing measures that are appropriate to local circumstances 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 protective equipment recommendations (see section 8).

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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.

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 : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
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 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 contaminated 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,

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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 in accordance with the particular national regulations.

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

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
Cellulose	9004-34-6	OEL-RL	10 mg/m ³	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
Elbasvir	1370468-36-2	TWA	150 µg/m ³ (OEB 2)	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium chloride	Workers	Inhalation	Long-term systemic effects	2068,62 mg/m ³
	Workers	Inhalation	Acute systemic effects	2068,62 mg/m ³
	Workers	Skin contact	Long-term systemic effects	295,52 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	295,52 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	443,28 mg/m ³
	Consumers	Inhalation	Acute systemic effects	443,28 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	126,65 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	126,65 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	126,65 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	126,65 mg/kg bw/day

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

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Substance name	Environmental Compartment	Value
Sodium chloride	Fresh water	5 mg/l
	Sewage treatment plant	500 mg/l
	Soil	4,86 mg/kg dry weight (d.w.)

8.2 Exposure controls**Engineering measures**

Use feasible engineering controls to minimize exposure to compound.
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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
- Skin and body protection : Work uniform or laboratory coat.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

- Appearance : powder
- Colour : brown
- Odour : odourless
- Odour Threshold : No data available
- pH : 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.
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available

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Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids)	:	No data available
Particle size	:	No data available

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	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
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10.4 Conditions to avoid

Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
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10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
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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 exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:**Elbasvir:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
LD50 (Mouse): > 1.000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**Elbasvir:**

Species : reconstructed human epidermis (RhE)
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Elbasvir:**

Species : Bovine cornea
Result : No eye irritation

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Elbasvir:**

Test Type : Local lymph node assay (LLNA)
Exposure routes : Dermal
Species : Mouse
Result : negative

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Germ cell mutagenicity

Not classified based on available information.

Components:**Elbasvir:**

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
- Test Type: Chromosome aberration test in vitro
Result: negative
- Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Rat
Application Route: Oral
Result: negative
- Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:**Elbasvir:**

- Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat, male and female
Application Route: Oral
Fertility: NOAEL: 1.000 mg/kg body weight
Result: No effects on fertility
- Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 1.000 mg/kg body weight
Result: No effects on early embryonic development
- Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 1.000 mg/kg body weight
Result: No effects on early embryonic development

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

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Repeated dose toxicity**Components:****Elbasvir:**

Species : Rat
 NOAEL : 1.000 mg/kg
 Application Route : Oral
 Exposure time : 180 d
 Remarks : No significant adverse effects were reported

Species : Dog
 NOAEL : 1.000 mg/kg
 Application Route : Oral
 Exposure time : 270 d
 Remarks : No significant adverse effects were reported

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Elbasvir:**

Ingestion : Symptoms: Headache, Abdominal pain, constipation, Nausea, Fatigue, muscle pain, joint pain, Dizziness, Cough, Skin irritation, rhinitis, Drowsiness, nasal congestion

SECTION 12: Ecological information**12.1 Toxicity****Components:****Elbasvir:**

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 10 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 203
 Remarks: No toxicity at the limit of solubility

LC50 (Menidia beryllina (Silverside)): > 10 mg/l
 Exposure time: 96 h
 Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10 mg/l
 Exposure time: 48 h
 Method: OECD Test Guideline 202
 Remarks: No toxicity at the limit of solubility

LC50 (Americamysis): 7,7 mg/l
 Exposure time: 96 h
 Method: US-EPA OPPTS 850.1035
 Remarks: No toxicity at the limit of solubility

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Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (algae)): > 0,081 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 Remarks: No toxicity at the limit of solubility

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,081 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms : EC50 : > 1.000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209

NOEC : 271,9 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 0,0023 mg/l
 Exposure time: 32 d
 Species: Pimephales promelas (fathead minnow)
 Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,84 mg/l
 Exposure time: 21 d
 Species: Daphnia magna (Water flea)
 Method: OECD Test Guideline 211
 Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity) : 10

12.2 Persistence and degradability**Components:****Elbasvir:**

Biodegradability : Result: Not readily biodegradable.
 Biodegradation: 37 %
 Exposure time: 28 d

12.3 Bioaccumulative potential**Components:****Elbasvir:**

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
 Bioconcentration factor (BCF): 82
 Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 6,54

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12.4 Mobility in soil**Components:****Elbasvir:**

Distribution among environmental compartments : log Koc: 5,24

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 Other adverse effects**Product:**

Endocrine disrupting potential : 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 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 handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information**14.1 UN number**

ADN : UN 3077

ADR : UN 3077

RID : UN 3077

IMDG : UN 3077

IATA : UN 3077

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

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(Elbasvir)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Elbasvir)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Elbasvir)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Elbasvir)

IATA : Environmentally hazardous substance, solid, n.o.s.
(Elbasvir)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

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IATA (Passenger)

Packing instruction (passenger aircraft)	:	956
Packing instruction (LQ)	:	Y956
Packing group	:	III
Labels	:	Miscellaneous

14.5 Environmental hazards**ADN**

Environmentally hazardous	:	yes
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ADR

Environmentally hazardous	:	yes
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RID

Environmentally hazardous	:	yes
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IMDG

Marine pollutant	:	yes
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IATA (Passenger)

Environmentally hazardous	:	yes
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IATA (Cargo)

Environmentally hazardous	:	yes
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14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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

Remarks	:	Not applicable for product as supplied.
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SECTION 15: Regulatory information**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
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DSL	:	not determined
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IECSC	:	not determined
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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.
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Full text of H-Statements

H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard
 ZA OEL : South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
 ZA OEL / OEL-RL : Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; 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:

Aquatic Chronic 1 H410

Classification procedure:

Calculation method

SAFETY DATA SHEET



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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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