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

1.1 Product identifier
   Trade name : Vorinostat Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   117 16th Road
   07033 Halfway house, Midrand, South Africa
   Telephone : +27 11 655 3000
   Telefax : 908-735-1496
   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)**
- Germ cell mutagenicity, Category 2
- Reproductive toxicity, Category 1B
- Specific target organ toxicity - repeated exposure, Category 1
- Short-term (acute) aquatic hazard, Category 1
- Long-term (chronic) aquatic hazard, Category 1

**Hazard statements**
- H341: Suspected of causing genetic defects.
- H360FD: May damage fertility. May damage the unborn child.
- H372: Causes damage to organs through prolonged or repeated exposure.
- H400: Very toxic to aquatic life.
- H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008)**
- Hazard pictograms :
- Signal word : Danger
- Hazard statements : H341 Suspected of causing genetic defects. H360FD May damage fertility. May damage the unborn
child.
H372  Causes damage to organs through prolonged or re-
peated exposure.
H410  Very toxic to aquatic life with long lasting effects.

Precautionary statements:

**Prevention:**
P201  Obtain special instructions before use.
P260  Do not breathe dust.
P273  Avoid release to the environment.
P280  Wear protective gloves/ protective clothing/ eye protec-
tion/ face protection.

**Response:**
P308 + P313  IF exposed or concerned: Get medical advice/
attention.
P391  Collect spillage.

Hazardous components which must be listed on the label:

**Vorinostat**

2.3 Other hazards

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**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
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</table>
| Vorinostat    | 149647-78-9 |        |           |                    | Mut. 2; H341  Repr. 1B; H360FD STOT RE 1; H372 (Blood, thymus gland, Bone mar-
row, spleen, Gastrointestinal tract) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1 | >= 50 - < 70 |

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: 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: 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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Suspected of causing genetic defects. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

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: None known.
5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: 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

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).

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: 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.
- Wash skin thoroughly after handling.
- 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.
- Do not eat, drink or smoke when using this product.
- 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.

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
  - 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
**Vorinostat Formulation**

### 8.2 Exposure controls

#### Engineering measures

Minimize workplace exposure concentrations.

Apply measures to prevent dust explosions.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

If sufficient ventilation is unavailable, use with local exhaust ventilation.

#### Personal protective equipment

**Eye protection**

Wear the following personal protective equipment:
- Safety goggles

**Hand protection**

Material: Chemical-resistant gloves

Remarks:

Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

**Skin and body protection**

Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.

Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

**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**: No data available
- **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**: No data available
- **Evaporation rate**: No data available
- **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
- **Vapour pressure**: No data available
- **Relative vapour density**: No data available
- **Density**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
  - **Partition coefficient: n-octanol/water**: No data available
  - **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**
  - **Viscosity, dynamic**: No data available
  - **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 : 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.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks. Avoid dust formation.

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 toxicological effects
Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

Vorinostat:
Acute oral toxicity : LD50 (Mouse): > 2.000 mg/kg
LD50 (Rat): > 750 mg/kg

Acute toxicity (other routes of administration) : LDLo (Mouse): 1.250 mg/kg
Application Route: Intravenous
Exposure time: 4 h

Skin corrosion/irritation
Not classified based on available information.
Components:

Vorinostat:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Vorinostat:
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:

Vorinostat:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: Not a skin sensitizer.

Germ cell mutagenicity
Suspected of causing genetic defects.

Components:

Vorinostat:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: positive
Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Result: positive
Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Oral
Result: positive

Germ cell mutagenicity: Positive result(s) from in vivo mammalian somatic cell muta-
Carcinogenicity
Not classified based on available information.

Reproductive toxicity
May damage fertility. May damage the unborn child.

Components:

Vorinostat:

Effects on fertility:

- Test Type: Fertility/early embryonic development
  Species: Rat, female
  Application Route: Oral
  Fertility: LOAEL: 15 mg/kg body weight
  Result: Preimplantation loss, Increased resorptions.

- Test Type: Fertility/early embryonic development
  Species: Rat, male
  Application Route: Oral
  Fertility: NOAEL: 150 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: LOAEL: 50 mg/kg body weight
  Result: positive

- Test Type: Embryo-foetal development
  Species: Rat
  Application Route: Oral
  Developmental Toxicity: NOAEL: 15 mg/kg body weight
  Result: positive

- Test Type: Embryo-foetal development
  Species: Rabbit
  Application Route: Oral
  Developmental Toxicity: LOAEL: 150 mg/kg body weight
  Result: Embryotoxic effects.

- Test Type: Embryo-foetal development
  Species: Rabbit
  Application Route: Oral
  Developmental Toxicity: NOAEL: 50 mg/kg body weight
  Result: Embryotoxic effects.

- Test Type: Embryo-foetal development
  Species: Rabbit
  Application Route: Oral
  Developmental Toxicity: LOAEL: 15 mg/kg body weight
  Result: Malformations were observed.

Reproductive toxicity - Assessment:
Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.
Clear evidence of adverse
effects on development, based on animal experiments.

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Causes damage to organs through prolonged or repeated exposure.

**Components:**

**Vorinostat:**
- Exposure routes: Ingestion
- Target Organs: Blood, thymus gland, Bone marrow, spleen, Gastrointestinal tract
- Assessment: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Vorinostat:**
- Species: Rat
  - LOAEL: 20 mg/kg
  - Application Route: Oral
  - Exposure time: 6 Months
  - Target Organs: Blood, thymus gland, Bone marrow, spleen
- Species: Dog
  - NOAEL: 60 mg/kg
  - LOAEL: 160 mg/kg
  - Application Route: Oral
  - Exposure time: 6 Months
  - Target Organs: Gastrointestinal tract
- Species: Dog
  - NOAEL: 40 mg/kg
  - LOAEL: 100 mg/kg
  - Application Route: Oral
  - Exposure time: 4 Weeks
  - Target Organs: Blood

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Vorinostat:**
- Ingestion: Symptoms: Diarrhoea, Fatigue, Nausea, anorexia
12.1 Toxicity

Components:

Vorinostat:

Toxicity to fish:
- LC50 (Pimephales promelas (fathead minnow)): > 10 mg/l
  Exposure time: 96 h
- LC50 (Cyprinodon variegatus (sheepshad minnow)): > 10 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): > 10 mg/l
  Exposure time: 48 h
- EC50 (Americamysis): 7.4 mg/l
  Exposure time: 96 h

Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): 0.183 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 0.011 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity):
- 1

Toxicity to microorganisms:
- EC50: > 1,000 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition

Toxicity to fish (Chronic toxicity):
- NOEC: 1.5 mg/l
  Exposure time: 33 d
  Species: Pimephales promelas (fathead minnow)
  Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 0.15 mg/l
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)
  Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity):
- 1

12.2 Persistence and degradability

Components:

Vorinostat:
Biodegradability

Result: Not readily biodegradable.
Biodegradation: 39.5 %
Exposure time: 28 d
Method: OECD Test Guideline 314

12.3 Bioaccumulative potential

**Components:**

**Vorinostat:**
Partition coefficient: n-octanol/water

log Pow: 1.42

12.4 Mobility in soil

**Components:**

**Vorinostat:**
Distribution among environmental compartments

log Koc: 3.37

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.

**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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<th>Subsection</th>
<th>Code</th>
<th>Description</th>
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<tr>
<td><strong>IATA</strong></td>
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<td>Environmentally hazardous substance, solid, n.o.s. (Vorinostat)</td>
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### 14.3 Transport hazard class(es)

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### 14.4 Packing group

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<td>III</td>
<td>Miscellaneous</td>
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</tbody>
</table>
14.5 Environmental hazards

ADN
Environmentally hazardous: yes

ADR
Environmentally hazardous: yes

RID
Environmentally hazardous: yes

IMDG
Marine pollutant: yes

IATA (Passenger)
Environmentally hazardous: yes

IATA (Cargo)
Environmentally hazardous: yes

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.

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

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.
SAFETY DATA SHEET

Vorinostat Formulation

Version 3.4 Revision Date: 16.10.2020 SDS Number: 42863-00015 Date of last issue: 23.03.2020
Date of first issue: 06.01.2015

Full text of H-statements

H341: Suspected of causing genetic defects.
H360FD: May damage fertility. May damage the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure if swallowed.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Acute: Short-term (acute) aquatic hazard
Aquatic Chronic: Long-term (chronic) aquatic hazard
Muta.: Germ cell mutagenicity
Repr. : Reproductive toxicity
STOT RE: Specific target organ toxicity - repeated exposure
ZA OEL: South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL: Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL: Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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; 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 Bio-accumulative

Further information

Sources of key data used to compile the Safety Data: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
SAFETY DATA SHEET

Vorinostat Formulation

<table>
<thead>
<tr>
<th>Classification of the mixture:</th>
<th>Classification procedure:</th>
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<tbody>
<tr>
<td>Muta. 2</td>
<td>H341</td>
</tr>
<tr>
<td>Repr. 1B</td>
<td>H360FD</td>
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<td>H372</td>
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<td>Aquatic Chronic 1</td>
<td>H410</td>
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</table>

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

ZA / EN