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

#### 1.1. Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>EVRYSDI® (Risdiplam) 0.75 mg/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>CSE-3277</td>
</tr>
</tbody>
</table>

**Synonyms**
- SMN2 (3) RO7034067
- aqueous solution containing 0.75 mg/ml Risdiplam and excipients
- SIP - SMN2 RG7916
- Risdiplam 0.75 mg/ml

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

<table>
<thead>
<tr>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>pharmaceutical active substance</td>
</tr>
<tr>
<td>in clinical trials</td>
</tr>
</tbody>
</table>

#### 1.3. Details of the supplier of the safety data sheet

**Company information**

<table>
<thead>
<tr>
<th>Enquiries:  Genentech, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>South San Francisco</td>
</tr>
<tr>
<td>USA-CA 94080</td>
</tr>
<tr>
<td>United States of America</td>
</tr>
</tbody>
</table>

**Local representation:**

<table>
<thead>
<tr>
<th>Phone</th>
<th>001-(650) 225-1000</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-Mail</td>
<td><a href="mailto:info.sds@roche.com">info.sds@roche.com</a></td>
</tr>
<tr>
<td>US Chemtrec phone:</td>
<td>(800)-424-9300</td>
</tr>
</tbody>
</table>

**1** referring to: Risdiplam

#### 1.4. Emergency telephone number

| Emergency telephone number | US Chemtrec phone: (800)-424-9300 |

### SECTION 2: Hazards identification

#### Classification of the substance or mixture / Label elements

**GHS Classification**

no classification and labelling according to GHS

#### Other hazards

**Note**

- no information available
SECTION 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Characterization</th>
<th>Risdiplam and other inactive ingredients</th>
</tr>
</thead>
</table>

**Ingredients**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risdiplam 1825352-65-5</td>
<td>0.075 %</td>
<td>- Acute toxicity (Category 3), H301</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Germ cell mutagenicity (Category 2), H341</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Reproductive toxicity (Category 1B), H360FD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Specific target organ toxicity - Repeated exposure (Category 2), H373</td>
</tr>
<tr>
<td>Strawberry Flavour</td>
<td>0.19 %</td>
<td>- Skin corrosion/irritation (Category 2), H315</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Serious eye damage/eye irritation (Category 2A), H319</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Skin sensitization (Category 1A), H317</td>
</tr>
</tbody>
</table>

For the full text of the ‘Hazard statements’ mentioned in this Section, see Section 16.

*1 referring to: Risdiplam

SECTION 4: First aid measures

4.1. Description of first aid measures

**Eye contact**
- rinse immediately with tap water for at least 20 minutes - open eyelids forcibly
- consult a physician if irritation persists

**Skin contact**
- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents

**Inhalation**
- remove the casualty to fresh air
- in the event of symptoms get medical treatment

4.2. Most important symptoms and effects, both acute and delayed

**Note**
- no information available

4.3. Indication of any immediate medical attention and special treatment needed

**Note to physician**
- treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

**Suitable extinguishing media**
- water spray jet, dry powder, foam, carbon dioxide
- adapt extinguishing media to surrounding fire conditions
Flash point (liquid) not applicable

5.2. Special hazards arising from the substance or mixture
Specific hazards - formation of toxic and corrosive combustion gases (nitrogen oxides (NOx)) possible

5.3. Advice for firefighters
Protection of fire-fighters - precipitate gases/vapours/mists with water spray
Special method of fire-fighting - if possible precipitate fire gases with a water jet

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Personal precautions - avoid exposure

6.2. Environmental precautions
Environmental protection - no special environmental precautions required

6.3. Methods and material for containment and cleaning up
Methods for cleaning up - collect spilled solutions with inert adsorbent and hand over to waste removal
- flush afterwards with plenty of water

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Technical measures - avoid formation of aerosols
- no special measures necessary if stored and handled as prescribed
Suitable materials - dark glass, stainless steel

7.2. Conditions for safe storage, including any incompatibilities
Storage conditions - protected from heat and light
Packaging materials - amber glass ampoules
- glass vials, brown
SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air
- IOEL (Internal Occupational Exposure Limit): 2 µg/m³ *1
- PNEC 0.73 µg/l, surface freshwaters, based on acute data *1

8.2. Exposure controls

Respiratory protection
- Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
- breathing apparatus in case of aerosol mist formation

Hand protection
- protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection
- safety glasses

*1 referring to: Risdiplam

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color
- greenish-yellow to yellow

Form
- clear solution

Solubility
- 0.406 mg/l, water (20 °C, pH 7.7, OECD No. 105) *1

Partition coefficient
- log P_{ow} 0.58 (octanol/water°C pH 7 (HPLC Method, OECD No. 117) *1

9.2. Other information

Note
- no information available

*1 referring to: Risdiplam

SECTION 10: Stability and reactivity

10.1. Reactivity

Note
- no information available

10.2. Chemical stability

Stability
- stable under the conditions mentioned in chapter 7
EVRYSDI® (Risdiplam) 0.75 mg/ml

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - warming
                     - light

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity
- MTD > 10 mg/kg (oral, mouse)  '1
- NOEL 10 mg/kg (oral, rat)  '1

Subacute toxicity
- NOEL 2.5 mg/kg/d (oral, rat, 14 d)  '1
- NOAEL 7.5 mg/kg/d (oral, rat, 14 d)  '1
- MTD 20 mg/kg/d (oral, mouse, 7 d)  '1

Local effects
- skin: non-irritant
- may penetrate the skin (based on animal data)  '1
- eye: functional effects (in vitro)
- not phototoxic (In Vitro; 3T3 fibroblast Neutral Red uptake assay (in vitro))  '1

Sensitization
- not skin sensitizing (mouse)
  (OECD No. 429, LLNA (Local Lymph Node Assay))  '1

Mutagenicity
- negative (Ames test; OECD No. 471 (Salmonella typhimurium))  '1
- positive (OECD No. 487 (In vitro Mammalian Cell Micronucleus Test))  '1
- genotoxic (clastogen); no direct DNA reactivity  '1
- positive (test system in vivo; OECD No. 474 (Micronucleus Test))  '1

Carcinogenicity
- not classified as carcinogenic  '1

Reproductive toxicity
- based on its mechanism of action, effects on embryofetal development can be assumed  '1
- NOAEL (maternal toxicity and embryo-fetal development) (4 mg/kg/d, rabbit, female, 14 d)  '1
- embryo-fetal lethality evidenced by increased number of late resorptions and fetal malformation (12 mg/kg/d, rabbit, female, 14 d)  '1
- NOAEL = 3 mg/kg/d (rat, female, 12 d)  '1
- retarded fetal development (7.5 mg/kg/d, rat, female, 12 d) *1

STOT-single exposure - no information available

STOT-repeated exposure - may cause damage to organs (gastrointestinal system, skin, eye, testes) through prolonged or repeated exposure *1

Aspiration hazard - no information available

Potential Health Effects - Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Carcinogenicity: not listed by NTP, IARC or OSHA

*1 referring to: Risdiplam

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity - highly toxic for planktonic crustaceans (Daphnia magna)
EC\textsubscript{50} (48 h) 0.732 mg/l
NOEC (48 h) 0.28 mg/l
(OECD No. 202, semistatic) *1
- no adverse influence on substrate biodegradation (activated sludge)
concentration (14 d) 35.0 mg/l
(Manometric Respirometry Test, OECD No. 301 F) *1

12.2. Persistence and degradability

Ready biodegradability - not readily biodegradable
0 %, 28 d
(Manometric Respirometry Test, OECD No. 301 F) *1

Abiotic degradation - not abiotically degradable (Manometric respirometry test, OECD no. 301 F, abiotic control) *1

12.3. Bioaccumulative potential

Note - no information available

12.4. Mobility in soil

Note - no information available

12.5. Results of PBT and vPvB assessment

Note - no information available
12.6. Other adverse effects

Note - no information available

*1 referring to: Risdiplam

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal
- incinerate in qualified installation with flue gas scrubbing

SECTION 14: Transport information

Note - not classified as Dangerous Good according to the Dangerous Goods Regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases, which are likely to endanger the public health, harm the environment or cause a complaint, to the NJDEPE Hotline and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Full text of H-Statements referred to under section 3

<table>
<thead>
<tr>
<th>H</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H301</td>
<td>Toxic if swallowed.</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation.</td>
</tr>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation.</td>
</tr>
<tr>
<td>H341</td>
<td>Suspected of causing genetic defects.</td>
</tr>
<tr>
<td>H360FD</td>
<td>May damage fertility. May damage the unborn child.</td>
</tr>
<tr>
<td>H373</td>
<td>May cause damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

Edition documentation - changes from previous version in sections 9

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.