1. PRODUCT AND COMPANY IDENTIFICATION

- Chemical product name: Elbasvir Formulation
- Supplier's company name, address and phone number:
  - Company name of supplier: MSD
  - Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
  - Telephone: 048-588-8411
  - E-mail address: EHSDATASTEWARD@msd.com
  - Emergency telephone number: +1-908-423-6000

- Recommended use of the chemical and restrictions on use:
  - Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

- GHS classification of chemical product:
  - Long-term (chronic) aquatic hazard: Category 1

- GHS label elements:
  - Hazard pictograms: 
  - Signal word: Warning
  - Hazard statements: H410 Very toxic to aquatic life with long lasting effects.
  - Precautionary statements: 
    - Prevention: P273 Avoid release to the environment.
    - Response: P391 Collect spillage.
    - Disposal: P501 Dispose of contents/container to an approved waste disposal plant.

- Other hazards which do not result in classification:
  - Important symptoms and outlines of the emergency assumed:
    - 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, han-
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Elbasvir</td>
</tr>
<tr>
<td></td>
<td>Titanium dioxide</td>
</tr>
<tr>
<td></td>
<td>Silicon, amorphous</td>
</tr>
</tbody>
</table>

4. 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.

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

Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

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).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

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 prod- : Carbon oxides
SAFETY DATA SHEET

Elbasvir Formulation

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.

Special protective equipment for firefighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.

Methods and materials for containment and 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.

7. HANDLING AND STORAGE

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.
Avoidance of contact: Oxidizing agents
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, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Storage
Conditions for safe storage: Keep in properly labelled containers. Store in accordance with the particular national regulations.
Materials to avoid: Do not store with the following product types: Strong oxidizing agents
Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Elbasvir</td>
<td>1370468-36-2</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>OEL-M (Respirable dust)</td>
<td>1 mg/m³ (Titanium)</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OEL-M (Total dust)</td>
<td>4 mg/m³ (Titanium)</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³ (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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
Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the rec-
Filter type: Recommended guidelines, use respiratory protection.
   Particulates type
Hand protection:
   Chemical-resistant gloves
Eye 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.
Skin and body protection:
   Work uniform or laboratory coat.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: powder
Colour: brown
Odour: odourless
Odour Threshold: No data available
Melting point/freezing point: No data available
Boiling point, initial boiling point and boiling range: No data available
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids): No data available
Lower explosion limit and upper explosion limit / flammability limit
   Upper explosion limit / Upper flammability limit: No data available
   Lower explosion limit / Lower flammability limit: No data available
Flash point: Not applicable
Decomposition temperature: No data available
pH: No data available
Evaporation rate: Not applicable
Auto-ignition temperature: No data available
Viscosity
   Viscosity, kinematic: Not applicable
Solubility(ies)
   Water solubility: No data available
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks.
Avoid dust formation.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

Components:

Cellulose:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity:
LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
### SAFETY DATA SHEET

**Elbasvir Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0</td>
<td>2021/08/27</td>
<td>529964-00016</td>
<td>2021/04/09</td>
<td>2016/02/23</td>
</tr>
</tbody>
</table>

- **Acute dermal toxicity**: LD50 (Rabbit): > 2,000 mg/kg

**Elbasvir**:
- **Acute oral toxicity**: LD50 (Rat): > 2,000 mg/kg
  - LD50 (Mouse): > 1,000 mg/kg

**Titanium dioxide**:
- **Acute oral toxicity**: LD50 (Rat): > 5,000 mg/kg
- **Acute inhalation toxicity**: LC50 (Rat): > 6.82 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Assessment: The substance or mixture has no acute inhalation toxicity

**Silicon, amorphous**:
- **Acute oral toxicity**: LD50 (Rat): > 5,000 mg/kg
  - Method: OECD Test Guideline 401
  - Remarks: Based on data from similar materials
- **Acute inhalation toxicity**: LC50 (Rat): > 2.08 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Assessment: The substance or mixture has no acute inhalation toxicity
  - Remarks: Based on data from similar materials
- **Acute dermal toxicity**: LD50 (Rabbit): > 5,000 mg/kg
  - Remarks: Based on data from similar materials

**Skin corrosion/irritation**
Not classified based on available information.

### Components:

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

**Titanium dioxide**:
- **Species**: Rabbit
- **Result**: No skin irritation

**Silicon, amorphous**:
- **Species**: Rabbit
- **Method**: OECD Test Guideline 404
- **Result**: No skin irritation
- **Remarks**: Based on data from similar materials
Serious eye damage/eye irritation
Not classified based on available information.

**Components:**

**Elbasvir:**
- **Species**: Bovine cornea
- **Result**: No eye irritation

**Titanium dioxide:**
- **Species**: Rabbit
- **Result**: No eye irritation

**Silicon, amorphous:**
- **Species**: Rabbit
- **Result**: No eye irritation
- **Method**: OECD Test Guideline 405
- **Remarks**: Based on data from similar materials

**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

**Titanium dioxide:**
- **Test Type**: Local lymph node assay (LLNA)
- **Exposure routes**: Skin contact
- **Species**: Mouse
- **Result**: negative

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Cellulose:**
- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- **Test Type**: In vitro mammalian cell gene mutation test
  - Result: negative
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

**Elbasvir:**

Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo: Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vitro: 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.

**Titanium dioxide:**

Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo: Test Type: In vivo micronucleus test  
Species: Mouse  
Result: negative

**Silicon, amorphous:**

Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

**Carcinogenicity**

Not classified based on available information.

**Components:**

**Cellulose:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>72 weeks</td>
<td>negative</td>
</tr>
</tbody>
</table>
## Titanium dioxide:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 453</td>
</tr>
<tr>
<td>Result</td>
<td>Positive</td>
</tr>
<tr>
<td>Remarks</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

## Silicon, amorphous:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>103 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>Negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

## Reproductive toxicity

Not classified based on available information.

### Components:

#### Cellulose:

- **Effects on fertility**
  - Test Type: One-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Result: Negative

- **Effects on foetal development**
  - Test Type: Fertility/early embryonic development
  - Species: Rat
  - Application Route: Ingestion
  - Result: Negative

#### 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

- **Effects on foetal 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

Silicon, amorphous:
Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeted dose toxicity

Components:

Cellulose:
Species: Rat
NOAEL: >= 9,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

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

Titanium dioxide:
Species: Rat
NOAEL: 24,000 mg/kg
Application Route: Ingestion
Exposure time: 28 Days

Species: Rat
NOAEL: 10 mg/m3
Application Route: inhalation (dust/mist/fume)
Exposure time: 2 yr

Silicon, amorphous:
Species: Rat
NOAEL: 1.3 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 13 Weeks
Remarks: Based on data from similar materials

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

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

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

- **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 fish (Chronic toxicity)

- **NOEC (Pimephales promelas (fathead minnow))**: 0.0023 mg/l  
  - Exposure time: 32 d  
  - Method: OECD Test Guideline 210

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

- **NOEC (Daphnia magna (Water flea))**: 0.84 mg/l  
  - Exposure time: 21 d  
  - Method: OECD Test Guideline 211  
  - Remarks: No toxicity at the limit of solubility

### M-Factor (Chronic aquatic toxicity)

- **M-Factor**: 10

### 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

### Titanium dioxide

- **LC50 (Oncorhynchus mykiss (rainbow trout))**: > 100 mg/l  
  - Exposure time: 96 h  
  - Method: OECD Test Guideline 203

- **EC50 (Daphnia magna (Water flea))**: > 100 mg/l  
  - Exposure time: 48 h  
  - Method: OECD Test Guideline 211

- **EC50 (Skeletonema costatum (marine diatom))**: > 10,000 mg/l  
  - Exposure time: 72 h

### Toxicity to microorganisms

- **EC50**: > 1,000 mg/l  
  - Exposure time: 3 h  
  - Method: OECD Test Guideline 209

### Silicon, amorphous

- **LC50 (Danio rerio (zebra fish))**: > 10,000 mg/l  
  - Exposure time: 96 h  
  - Method: OECD Test Guideline 203  
  - Remarks: Based on data from similar materials

- **EC50 (Daphnia magna (Water flea))**: > 1,000 mg/l  
  - Exposure time: 24 h  
  - Method: OECD Test Guideline 202  
  - Remarks: Based on data from similar materials

- **EC50 (Desmodesmus subspicatus (green algae))**: > 10,000
**Persistence and degradability**

**Components:**

**Cellulose:**

| Biodegradability | Result: Readily biodegradable. |

**Elbasvir:**

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: Not readily biodegradable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation</td>
<td>: 37 %</td>
</tr>
<tr>
<td>Exposure time</td>
<td>: 28 d</td>
</tr>
</tbody>
</table>

**Bioaccumulative potential**

**Components:**

**Elbasvir:**

<table>
<thead>
<tr>
<th>Bioaccumulation</th>
<th>Species: Lepomis macrochirus (Bluegill sunfish)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bioconcentration factor (BCF):</td>
<td>82</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 305</td>
<td></td>
</tr>
</tbody>
</table>

| Partition coefficient: n-octanol/water | log Pow: 6.54 |

**Mobility in soil**

**Components:**

**Elbasvir:**

| Distribution among environmental compartments | : log Koc: 5.24 |

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

### 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

- **Waste from residues**: Dispose of in accordance with local regulations.
- **Contaminated packaging**: Empty containers should be taken to an approved waste han-
14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Elbasvir)

Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Elbasvir)

Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Elbasvir)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
Refer to section 15 for specific national regulation.

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.
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium(IV) oxide</td>
<td>191</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
<tr>
<td>Crystalline silica</td>
<td>165 2</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crystalline silica</td>
<td>165 2</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable
Poisonous and Deleterious Substances Control Law  
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof  
Not applicable

High Pressure Gas Safety Act  
Not applicable

Explosive Control Law  
Not applicable

Vessel Safety Law  
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law  
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

<table>
<thead>
<tr>
<th>Bulk transportation</th>
<th>Not classified as noxious liquid substance</th>
</tr>
</thead>
</table>

Marine Pollution and Sea Disaster Prevention etc Law  
Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act  
Narcotic or Psychotropic Raw Material (Export / Import Permission)  
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)  
Not applicable

Waste Disposal and Public Cleansing Law  
Industrial waste

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Further information

Sources of key data used to compile the Safety Data Sheet  

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

Date format  
yyyy/mm/dd
**SAFETY DATA SHEET**

**Elbasvir Formulation**

<table>
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<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
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<td>529964-00016</td>
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**Full text of other abbreviations**

<table>
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<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>JP OEL JSOH / OEL-M</td>
<td>Occupational Exposure Limit-Mean</td>
</tr>
</tbody>
</table>

### Glossary of Abbreviations

- **ACGIH**: USA. American Conference of Governmental Industrial Hygienists
- **ACGIH / TWA**: 8-hour, time-weighted average
- **JP OEL JSOH / OEL-M**: Occupational Exposure Limit-Mean

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.

**JP / EN**