

| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024  |
|---------|----------------|-------------|---------------------------------|
| 4.3     | 28.09.2024     | 59344-00026 | Date of first issue: 16.02.2015 |

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

| 1.1 | Product identifier<br>Trade name  | :   | Letermovir Solid Formulation                 |
|-----|-----------------------------------|-----|--|
| 1.2 | Relevant identified uses of th    | e s | ubstance or mixture and uses advised against |
|     | Use of the Sub-<br>stance/Mixture |     | Pharmaceutical                               |
|     | Recommended restrictions on use   | :   | Not applicable                               |
| 1.3 | Details of the supplier of the    | saf | ety data sheet                               |
|     | Company                           | :   | MSD<br>Kilsheelan<br>Clonmel Tipperary, IE   |
|     | Telephone                         | :   | 353-51-601000                                |
|     | E-mail address of person          | :   | EHSDATASTEWARD@msd.com                       |

### **1.4 Emergency telephone number**

responsible for the SDS

+1-908-423-6000

# **SECTION 2: Hazards identification**

### 2.1 Classification of the substance or mixture

### Classification (REGULATION (EC) No 1272/2008)

| Reproductive toxicity, Category 2         |
|---|
| Specific target organ toxicity - repeated |
| exposure, Category 2                      |

H361d: Suspected of damaging the unborn child. H373: May cause damage to organs through prolonged or repeated exposure.

#### 2.2 Label elements

## Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

| Signal word       | : | Warning   |
|-------------------|---|---|
| Hazard statements | : | H361d Suspected of damaging the unborn child.<br>H373 May cause damage to organs through prolonged or<br>repeated exposure. |

:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Precautionary statements

#### **Prevention:**

P201 Obtain special instructions before use.
P260 Do not breathe dust.
P280 Wear protective gloves/ protective clothing/ eye protection/ 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: Letermovir

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# 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.

Ecological information: 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.

Toxicological information: 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.

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.<br>EC-No.<br>Index-No.<br>Registration number | Classification   | Concentration<br>(% w/w) |
|---------------|---|--|--------------------------|
| Letermovir    | 917389-32-3   | Repr. 2; H361d<br>STOT RE 2; H373<br>(Liver, spleen,<br>Blood) | >= 30 - < 50             |

For explanation of abbreviations see section 16.



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### **SECTION 4: First aid measures**

| 4.1 Description of first aid meas | sures | 3  |
|-----------------------------------|-------|--|
| General advice                    | :     | In the case of accident or if you feel unwell, seek medical ad-<br>vice immediately.<br>When symptoms persist or in all cases of doubt seek medical<br>advice.   |
| Protection of first-aiders        | :     | First Aid responders should pay attention to self-protection,<br>and use the recommended personal protective equipment<br>when the potential for exposure exists (see section 8).  |
| If inhaled                        | :     | If inhaled, remove to fresh air.<br>Get medical attention.   |
| In case of skin contact           | :     | In case of contact, immediately flush skin with soap and plenty<br>of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact            | :     | If in eyes, rinse well with water.<br>Get medical attention if irritation develops and persists.   |
| If swallowed                      | :     | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.  |
| 4.2 Most important symptoms a     | and e | ffects, both acute and delayed   |
| Risks                             | :     | Suspected of damaging the unborn child.<br>May cause damage to organs through prolonged or repeated<br>exposure.   |
|                                   |       | Contact with dust can cause mechanical irritation or drying of the skin.<br>Dust contact with the eyes can lead to mechanical irritation.  |
| 4.3 Indication of any immediate   | med   | lical attention and special treatment needed   |
| Treatment                         | :     | Treat symptomatically and supportively.  |
| SECTION 5: Firefighting mea       | asure | 9S   |
| E 4 Entinemain him or months      |       |  |

# 5.1 Extinguishing media

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



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|---------------|------------------------------------|------------------------------|-----|--|--|
|               | Unsuita<br>media                   | ble extinguishing            | :   | None known.  |  |
| 5.2 S         | pecial                             | hazards arising from         | the | substance or mi                                    | xture  |
|               | Specific<br>fighting               | hazards during fire-         | :   | concentrations, a potential dust exp               | dust; fine dust dispersed in air in sufficient<br>nd in the presence of an ignition source is a<br>plosion hazard.<br>pustion products may be a hazard to health.  |
|               | Hazardous combustion prod-<br>ucts |                              | :   | Carbon oxides<br>Metal oxides<br>Nitrogen oxides ( | NOx)   |
| 5.3 A         | dvice                              | or firefighters              |     |  |  |
|               | Special<br>for firefi              | protective equipment ghters  | :   |  | e, wear self-contained breathing apparatus. tective equipment.   |
|               | Specific<br>ods                    | extinguishing meth-          | :   | cumstances and<br>Use water spray                  | g measures that are appropriate to local cir-<br>the surrounding environment.<br>to cool unopened containers.<br>ged containers from fire area if it is safe to do |

# **SECTION 6: Accidental release measures**

# 6.1 Personal precautions, protective equipment and emergency procedures

| Personal precautions        | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal pro-<br>tective equipment recommendations (see section 8). |
|-----------------------------|---|---|
| 2 Environmental precautions |   |   |

# 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

| Avoid dispersal of dust in the air (i.e., clearing dust surfaces<br>with compressed air).<br>Dust deposits should not be allowed to accumulate on surfaces<br>es, as these may form an explosive mixture if they are re-<br>leased into the atmosphere in sufficient concentration.<br>Local or national regulations may apply to releases and dis- | suitable con-  | ethods for cleaning up |  |  |
|---|--|------------------------|--|--|
| es, as these may form an explosive mixture if they are re-<br>leased into the atmosphere in sufficient concentration.   | t in the air (i.e., clearing dust surfaces                 |                        |  |  |
| posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter  | they are re-<br>ntration.<br>ases and dis-<br>Is and items |                        |  |  |



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|---|--|--|---|--|--|--|--|--|--|--|
|   |  | Sections 13 a  | gulations are applicable.<br>nd 15 of this SDS provide information regarding<br>r national requirements.  |  |  |  |  |  |  |  |
| 6.4 Reference to other sections<br>See sections: 7, 8, 11, 12 and 13. |  |  |   |  |  |  |  |  |  |  |
| SECTION 7: Handling and storage                                       |  |  |   |  |  |  |  |  |  |  |
| 7.1 Preca   | utions for safe handlin                  | g  |   |  |  |  |  |  |  |  |
|   | nical measures                           | causing an ex<br>Provide adequ<br>and bonding,   | uate precautions, such as electrical grounding or inert atmospheres.  |  |  |  |  |  |  |  |
|   | /Total ventilation<br>e on safe handling | : Do not breath<br>Do not swallor<br>Avoid contact<br>Avoid prolong<br>Handle in acc<br>practice, base<br>sessment<br>Minimize dust<br>Keep containe<br>Keep away fro<br>Take precauti     | w.<br>with eyes.<br>ed or repeated contact with skin.<br>ordance with good industrial hygiene and safety<br>ed on the results of the workplace exposure as-<br>generation and accumulation.<br>er closed when not in use.<br>om heat and sources of ignition.<br>onary measures against static discharges.  |  |  |  |  |  |  |  |
| Hygiene measures  |  | <ul> <li>environment.</li> <li>If exposure to<br/>flushing syste<br/>place. When unated clothing<br/>The effective of<br/>engineering co<br/>appropriate de<br/>industrial hygi</li> </ul> | chemical is likely during typical use, provide eye<br>ms and safety showers close to the working<br>using do not eat, drink or smoke. Wash contami-<br>before re-use.<br>operation of a facility should include review of<br>ontrols, proper personal protective equipment,<br>egowning and decontamination procedures,<br>ene monitoring, medical surveillance and the<br>strative controls. |  |  |  |  |  |  |  |
| 7.2 Conditions for safe storage, including any incompatibilities      |  |  |   |  |  |  |  |  |  |  |
| Requ  | irements for storage<br>and containers   | : Keep in properly labelled containers. Store locked up. accordance with the particular national regulations.  |   |  |  |  |  |  |  |  |
| Advic   | e on common storage                      | : Do not store v<br>Strong oxidizi   | vith the following product types:<br>ng agents  |  |  |  |  |  |  |  |
| 7.3 Specif  | fic end use(s)                           |  |   |  |  |  |  |  |  |  |
| -   | ific use(s)                              | : No data availa   | able  |  |  |  |  |  |  |  |



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### **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

### **Occupational Exposure Limits**

Dust

5 mg/m3 Value type (Form of exposure): TWA (respirable dust) Basis: FOR-2011-12-06-1358

10 mg/m3 Value type (Form of exposure): TWA (total dust) Basis: FOR-2011-12-06-1358

| Components      | CAS-No.         | Value type (Form of exposure) | Control parameters    | Basis                   |
|-----------------|-----------------|-------------------------------|-----------------------|-------------------------|
| Letermovir      | 917389-32-<br>3 | TWA                           | 0.4 mg/m3 (OEB 2)     | Internal                |
| Silicon dioxide | 7631-86-9       | TWA (respirable dust)         | 1,5 mg/m3<br>(Silica) | FOR-2011-<br>12-06-1358 |

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

| Substance name  | End Use | Exposure routes | Potential health ef-<br>fects | Value   |
|-----------------|---------|-----------------|-------------------------------|---------|
| Silicon dioxide | Workers | Inhalation      | Long-term systemic<br>effects | 4 mg/m3 |

#### 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.<br>If the work environment or activity involves dusty conditions,<br>mists or aerosols, wear the appropriate goggles.<br>Wear a faceshield or other full face protection if there is a<br>potential for direct contact to the face with dusts, mists, or<br>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 expo-<br>sure assessment demonstrates exposures outside the rec-<br>ommended guidelines, use respiratory protection.<br>Equipment should conform to NS EN 143   |
| Filter type              | : | Particulates type (P)   |



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# **SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

| Physical state                                   | : | powder   |
|--|---|--|
| Colour   | : | No data available  |
| Odour  | : | No data available  |
| Odour Threshold                                  | : | No data available  |
| Melting point/freezing point                     | : | No data available  |
| Initial boiling point and boiling range          | : | No data available  |
| Flammability (solid, gas)                        | : | May form explosive dust-air mixture during processing, han-<br>dling or other means. |
| Flammability (liquids)                           | : | No data available  |
| Upper explosion limit / Upper flammability limit | : | No data available  |
| Lower explosion limit / Lower flammability limit | : | No data available  |
| Flash point                                      | : | Not applicable   |
| Auto-ignition temperature                        | : | No data available  |
| Decomposition temperature                        | : | No data available  |
| рН   | : | No data available  |
| Viscosity<br>Viscosity, kinematic                | : | Not applicable   |
| Solubility(ies)<br>Water solubility              | : | No data available  |
| Partition coefficient: n-<br>octanol/water       | : | Not applicable   |
| Vapour pressure                                  | : | Not applicable   |
| Relative density                                 | : | No data available  |
| Density  | : | No data available  |



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|--|---------|---------------------------|---------------|-------------------------|---|
| I                                      | Relativ | e vapour density          | :             | Not applicable          |   |
| Particle characterist<br>Particle size |         |                           | :             | No data availabl        | e   |
| 9.2 Other information<br>Explosives    |         | :                         | Not explosive |                         |   |
|  | •       | ng properties             | :             |                         | or mixture is not classified as oxidizing.                        |
| Evaporation rate                       |         |                           | :             | 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         | : | May form explosive dust-air mixture during processing, han-<br>dling or other means.<br>Can react with strong oxidizing agents. |
|-----------------------------|---|---|
| 10.4 Conditions to avoid    |   |   |
| Conditions to avoid         | : | Heat, flames and sparks.<br>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 hazard classes as defined in Regulation (EC) No 1272/2008

Eye contact

| Information on likely routes of | : | Inhalation   |
|---------------------------------|---|--------------|
| exposure                        |   | Skin contact |
|                                 |   | Indestion    |

# Acute toxicity

Not classified based on available information.

### **Components:**

#### Letermovir:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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|----------------|--|--|------|---------------------------------------|--|
| Ac             | Acute oral toxicity  |  | :    | LD50 (Rat): > 2.00                    | 00 mg/kg   |
|                |  |  |      | LD50 (Mouse): > 2                     | 2.000 mg/kg  |
|                |  | <b>sion/irritation</b><br>ed based on availa   | ble  | information.                          |  |
| <u>Cc</u>      | omponer  | <u>nts:</u>                                    |      |                                       |  |
|                | e <b>termovi</b> i<br>emarks   | :  | :    | No data available                     |  |
|                | -  | <b>e damage/eye irri</b><br>ed based on availa |      |                                       |  |
| <u>Cc</u>      | omponer  | <u>nts:</u>                                    |      |                                       |  |
|                | <b>Letermovir:</b><br>Remarks  |  |      | No data available                     |  |
| Re             | espirator  | y or skin sensitis                             | atio | n                                     |  |
| No<br>Re       | espirator  | ed based on availa<br>y sensitisation          |      |                                       |  |
|                |  | ed based on availa                             | ble  | information.                          |  |
|                | Components:  |  |      |                                       |  |
|                | Letermovir:<br>Remarks   |  |      | No data available                     |  |
|                | Germ cell mutagenicity<br>Not classified based on available information. |  |      |                                       |  |
| <u>Co</u>      | Components:  |  |      |                                       |  |
|                | etermovii  |  |      |                                       |  |
| Ge             | enotoxicit   | y in vitro                                     | :    | Test Type: Bacter<br>Result: negative | ial reverse mutation assay (AMES)  |
|                |  |  |      | Test Type: Chrom<br>Result: negative  | nosome aberration test in vitro  |
| Ge             | enotoxicit   | y in vivo                                      | :    | cytogenetic assay<br>Species: Mouse   | nalian erythrocyte micronucleus test (in vivo<br>/)<br>: Intraperitoneal injection |
| Ge             | erm cell n   | nutagenicity- As-                              | :    | Weight of evidenc                     | e does not support classification as a germ  |

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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|----------------|--|---|---|--|--|--|--|
| ses            | sment  | cell mutager  | cell mutagen.   |  |  |  |  |
|                | <b>cinogenicity</b><br>classified based on avail | able information.   |   |  |  |  |  |
| -              | productive toxicity<br>pected of damaging the u  | unborn child.   |   |  |  |  |  |
| <u>Cor</u>     | nponents:  |   |   |  |  |  |  |
|                | ermovir:<br>octs on fertility                    | Species: Rat<br>Application F<br>Fertility: NO                  |   |  |  |  |  |
|                |  | Species: Rat<br>Application F<br>Fertility: LOA<br>Result: No e |   |  |  |  |  |
|                |  | Species: Mo<br>Application F<br>Fertility: NO                   |   |  |  |  |  |
| Effe<br>mer    | ects on foetal develop-<br>nt                    | Species: Rat<br>Developmen<br>Result: Emb                       | imbryo-foetal development<br>t<br>tal Toxicity: LOAEL: 250 mg/kg body weight<br>ryo-foetal toxicity<br>aternal toxicity observed.                                   |  |  |  |  |
|                |  | Species: Ral<br>Developmen<br>Result: Emb<br>Abortion           | imbryo-foetal development<br>bbit<br>tal Toxicity: LOAEL: 225 mg/kg body weight<br>ryo-foetal toxicity, Malformations were observed.,<br>aternal toxicity observed. |  |  |  |  |
| •              | productive toxicity - As-<br>sment               | : Some evider<br>animal expe                                    | nce of adverse effects on development, based on riments.  |  |  |  |  |

# STOT - single exposure

Not classified based on available information.

# STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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|----------------|------------------------------|----------------------------|---|
| <u>Com</u>     | ponents:                     |                            |   |
| Leter          | movir:                       |                            |   |
| Expo           | sure routes                  | : Ingestion                |   |
|                | et Organs                    | : Liver, spleen,           | Blood   |
| Asse           | ssment                       | : May cause da exposure.   | amage to organs through prolonged or repeated                     |
| Repe           | ated dose toxicity           |                            |   |
| Com            | ponents:                     |                            |   |
| Leter          | movir:                       |                            |   |
| Spec           | ies                          | : Mouse                    |   |
| NOA            | EL                           | : 40 mg/kg                 |   |
| LOAE           |                              | : 100 mg/kg                |   |
|                | cation Route                 | : Oral                     |   |
|                | sure time                    | : 13 Weeks                 |   |
| Targe          | et Organs                    | : Liver, spleen            |   |
| Spec           |                              | : Rat                      |   |
| NOA            |                              | : 150 mg/kg                |   |
|                | cation Route                 | : Oral                     |   |
| Expo<br>Rema   | sure time                    | : 26 Weeks                 | t advarsa offacts ware reported                                   |
| Rema           |                              | . No significan            | t adverse effects were reported                                   |
| Spec           | ies                          | : Monkey                   |   |
| NOA            |                              | : 100 mg/kg                |   |
| LOAE           |                              | : 200 - 250 mg             | /kg   |
|                | cation Route<br>sure time    | : Oral<br>: 39 Weeks       |   |
|                | et Organs                    | : Kidney                   |   |
| raige          | or organo                    | . Rianoy                   |   |
| Spec           |                              | : Rat                      |   |
| NOA            |                              | : 60 mg/kg                 |   |
| LOAE           |                              | : 180 mg/kg                |   |
|                | sure time<br>et Organs       | : 13 Weeks                 | , Liver, spleen, Immune system                                    |
| raige          | organs                       | . 16303, 01000             | , Liver, spieeri, ininune system                                  |
| Spec           |                              | : Monkey                   |   |
| NOA            |                              | : 30 mg/kg                 |   |
| LOAE           |                              | : 100 mg/kg                |   |
|                | cation Route                 | : Oral                     |   |
|                | sure time                    | : 4 Weeks<br>: Blood       |   |
| rarge          | et Organs                    | . DIUUU                    |   |

### Aspiration toxicity

Not classified based on available information.



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### 11.2 Information on other hazards

### **Endocrine disrupting properties**

### Product:

Assessment

: 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.

### Experience with human exposure

### **Components:**

### Letermovir:

| Ingestion | : | Symptoms: Diarrhoea, Nausea, Vomiting, Headache, Dizzi- |
|-----------|---|---|
|           |   | ness, Fatigue, Back pain, Oedema, Rash, muscle pain     |

# **SECTION 12: Ecological information**

### 12.1 Toxicity

| Components:   |   |  |
|---|---|--|
| Letermovir:   |   |  |
| Toxicity to fish                                    | : | LC50 (Menidia beryllina (Silverside)): > 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203  |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Americamysis): 16 mg/l<br>Exposure time: 96 h  |
|   |   | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202  |
| Toxicity to algae/aquatic plants                    | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 8,8<br>mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility |
|   |   | NOEC (Pseudokirchneriella subcapitata (green algae)): 8,8<br>mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility   |
| Toxicity to microorganisms                          | : | EC50 : > 972 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209  |

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Letermovir Solid Formulation

| Version<br>4.3                           | Revision Date:<br>28.09.2024   |     | OS Number:<br>344-00026   | Date of last issue: 06.04.2024<br>Date of first issue: 16.02.2015                             |
|--|--|-----|---|---|
|  |  |     | NOEC : 29,6 mg/<br>Exposure time: 3<br>Test Type: Respi<br>Method: OECD T | h   |
| Toxicity to fish (Chronic tox-<br>icity) |  | :   | Method: OECD T  | 2 d<br>ales promelas (fathead minnow)<br>est Guideline 210<br>city at the limit of solubility |
| aqua                                     | Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) |     |   | 1 d<br>a magna (Water flea)<br>est Guideline 211  |
| 12.2 Pers                                | istence and degradabil   | ity |   |   |
| Com                                      | ponents:   |     |   |   |
|  | rmovir:<br>egradability  | :   | Result: rapidly de<br>Biodegradation:<br>Exposure time: 6                 | 50 %  |
| 12.3 Bioa                                | ccumulative potential  |     |   |   |
| Com                                      | ponents:   |     |   |   |
| Parti                                    | rmovir:<br>tion coefficient: n-<br>nol/water                           | :   | log Pow: 2,29   |   |
| 12.4 Mob                                 | ility in soil  |     |   |   |
| <u>Com</u>                               | ponents:   |     |   |   |
| Distr                                    | r <b>movir:</b><br>bution among environ-<br>al compartments            | :   | log Koc: 3,46   |   |

### 12.5 Results of PBT and vPvB assessment

| Product:   |   |
|------------|---|
| Assessment | : This substance/mixture contains no components considered<br>to be either persistent, bioaccumulative and toxic (PBT), or<br>very persistent and very bioaccumulative (vPvB) at levels of<br>0.1% or higher. |

Commission Regulation (EU) 2020/878



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### **12.6 Endocrine disrupting properties**

### Product:

Assessment

: 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.

### 12.7 Other adverse effects

No data available

# **SECTION 13: Disposal considerations**

| 13.1 Waste treatment methods |  |
|------------------------------|--|
| Product                      | <ul> <li>Dispose of in accordance with local regulations.</li> <li>According to the European Waste Catalogue, Waste Codes<br/>are not product specific, but application specific.</li> <li>Waste codes should be assigned by the user, preferably in<br/>discussion with the waste disposal authorities.</li> <li>Do not dispose of waste into sewer.</li> </ul> |
| Contaminated packaging       | <ul> <li>Empty containers should be taken to an approved waste han-<br/>dling site for recycling or disposal.</li> <li>If not otherwise specified: Dispose of as unused product.</li> </ul>  |

### **SECTION 14: Transport information**

### 14.1 UN number or ID 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 |
| ΙΑΤΑ                            | : | 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 |
| ΙΑΤΑ                            | : | 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 |



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|--|---------------------------|---|-----------------------------------|---|--|--|--|
|  |                           |   |                                   |   |  |  |  |
| RID  |                           | : | Not regulated as                  | a dangerous good  |  |  |  |
| IMDG   |                           | : | Not regulated as a dangerous good |   |  |  |  |
| ΙΑΤΑ   |                           | : | Not regulated as a dangerous good |   |  |  |  |
| 14.4 Packi   | ing 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  |  |  |  |
| ΙΑΤΑ   | (Cargo)                   | : | Not regulated as                  | a dangerous good  |  |  |  |
| ΙΑΤΑ   | (Passenger)               | : | Not regulated as                  | a dangerous good  |  |  |  |
| 14.5 Environmental hazards                                 |                           |   |                                   |   |  |  |  |
| Not regulated as a dangerous good                          |                           |   |                                   |   |  |  |  |
| <b>14.6 Special precautions for user</b><br>Not applicable |                           |   |                                   |   |  |  |  |
|  |                           |   |                                   |   |  |  |  |

# 14.7 Maritime transport in bulk according to IMO instruments

| emarks |
|--------|
| emarks |

: Not applicable for product as supplied.

# **SECTION 15: Regulatory information**

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

| REACH - Restrictions on the manufacture, placing on<br>the market and use of certain dangerous substances,<br>mixtures and articles (Annex XVII) | : | Not applicable |  |  |  |
|--|---|----------------|--|--|--|
| REACH - Candidate List of Substances of Very High<br>Concern for Authorisation (Article 59).   | : | Not applicable |  |  |  |
| REACH - List of substances subject to authorisation (Annex XIV)  | : | Not applicable |  |  |  |
| Regulation (EC) on substances that deplete the ozone layer   | : | Not applicable |  |  |  |
| Regulation (EU) 2019/1021 on persistent organic pollu-<br>tants (recast)   | : | Not applicable |  |  |  |
| Regulation (EU) No 649/2012 of the European Parlia-<br>ment and the Council concerning the export and import<br>of dangerous chemicals           | : | Not applicable |  |  |  |
| Seveso III: Directive 2012/18/EU of the European Parliament and of the Council   |   |                |  |  |  |

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

# Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of



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|--|----------------------------------|----------------------------|---|--|--|--|--|
| child  | children and young people.       |                            |   |  |  |  |  |
| The components of this product are reported in the following inventories:  |                                  |                            |   |  |  |  |  |
| AICS   |                                  | : not determined           | ł   |  |  |  |  |
| DSL  |                                  | : not determined           | t   |  |  |  |  |
| IECS   | C                                | : not determined           | t   |  |  |  |  |
| 15.2 Chemical safety assessment<br>A Chemical Safety Assessment has not been carried out.<br>SECTION 16: Other information |                                  |                            |   |  |  |  |  |
|  | r information                    | : Items where c            | <ul> <li>Items where changes have been made to the previous version<br/>are highlighted in the body of this document by two vertical</li> </ul> |  |  |  |  |
| Full text of H-Statements  |                                  |                            |   |  |  |  |  |
| H361<br>H373   | -                                |                            | damaging the unborn child.<br>mage to organs through prolonged or repeated<br>allowed.  |  |  |  |  |
| Full   | Full text of other abbreviations |                            |   |  |  |  |  |
|  |                                  |                            | organ toxicity - repeated exposure pational Exposure limits   |  |  |  |  |

FOR-2011-12-06-1358 / : Long term exposure limit

FOR-2011-12 TWA

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 sub-



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stance; 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<br>compile the Safety Data<br>Sheet | :   | Internal technical data, data from raw material SDSs, OECD<br>eChem Portal search results and European Chemicals Agen-<br>cy, http://echa.europa.eu/ |                           |  |
|---|-----|--|---------------------------|--|
| Classification of the mixtur                                    | e:  |  | Classification procedure: |  |
| Repr. 2   | H3( | 61d  | Calculation method        |  |
| STOT RE 2   | H3  | 73   | Calculation method        |  |

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.

NO / EN