

| Version | Revision Date: | SDS Number:   | Date of last issue: 06.04.2024  |
|---------|----------------|---------------|---------------------------------|
| 3.3     | 28.09.2024     | 3784229-00017 | Date of first issue: 19.11.2018 |

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

| 1.1 Product identifier<br>Trade name  | :          | Febantel / Pyrantel Pamoate / Praziquantel Formulation           |
|---|------------|--|
| <b>1.2 Relevant identified uses of</b><br>Use of the Sub-<br>stance/Mixture | the s<br>: | substance or mixture and uses advised against Veterinary product |
| Recommended restrictions on use   | :          | Not applicable   |
| 1.3 Details of the supplier of the  | e saf      | ety data sheet   |
| Company   | :          | MSD<br>Kilsheelan<br>Clonmel Tipperary, IE                       |
| Telephone   | :          | 353-51-601000  |
| E-mail address of person responsible for the SDS                            | :          | EHSDATASTEWARD@msd.com   |
| 1.4 Emergency telephone numl<br>+1-908-423-6000                             | oer        |  |

# **SECTION 2: Hazards identification**

### 2.1 Classification of the substance or mixture

| Classification (REGULATION (EC) No 1272/2008)       |   |  |  |  |  |
|---|---|--|--|--|--|
| Long-term (chronic) aquatic hazard, Cat-<br>egory 1 | H410: Very toxic to aquatic life with long lasting effects. |  |  |  |  |

#### 2.2 Label elements

Signal word

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

Hazard pictograms

| ¥2      |
|---------|
| Warning |
|         |

| Hazard statements | : | H410 | Very toxic to aquatic life with long lasting effects. |
|-------------------|---|------|---|
|-------------------|---|------|---|



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|----------------|---------------------------|--------------------|-------------|---|
| Preca          | utionary statements       | Preve              |             | ase to the environment.   |
|                |                           | Respo              | onse:       |   |
|                |                           | P391               | Collect spi | illage.   |
|                |                           |                    |             |   |

### Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 21,82 %

### 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) |
|---------------|---|---|--------------------------|
| Febantel      | 58306-30-2<br>261-205-0                               | Acute Tox. 4; H302<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 1;<br>H410<br>M-Factor (Acute<br>aquatic toxicity): 1<br>M-Factor (Chronic<br>aquatic toxicity): 10<br>Acute toxicity esti-<br>mate | >= 20 - < 25             |



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|----------------|--|-----------------|-------------------------|---|---------------|
| naph           | nethylenebis[3-hydrox<br>thoic] acid, compound     | with (E)-       | 22204-24-6<br>244-837-1 | <br>Acute oral toxicity:<br>1.250 mg/kg               | >= 20 - < 30  |
|                | ,6-tetrahydro-1-methyl<br>yl)vinyl]pyrimidine (1:1 |                 |                         |   |               |
|                | quantel  |                 | 55268-74-1<br>259-559-6 | Aquatic Chronic 3;<br>H412                            | >= 2,5 - < 10 |

For explanation of abbreviations see section 16.

# **SECTION 4: First aid measures**

# 4.1 Description of first aid measures

| General advice                  | :     | In the case of accident or if you feel unwell, seek medical 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 if symptoms occur.  |
| In case of skin contact         | :     | Wash with water and soap.<br>Get medical attention if symptoms occur.   |
| 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 if symptoms occur.<br>Rinse mouth thoroughly with water.   |
| 4.2 Most important symptoms a   | ind e | effects, both acute and delayed   |
| Risks                           | :     | 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 | me    | dical attention and special treatment needed  |

: Treat symptomatically and supportively.



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# **SECTION 5: Firefighting measures**

| 5.1 Extinguishing media                       |     |   |
|---|-----|---|
| Suitable extinguishing media                  | :   | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical   |
| Unsuitable extinguishing media                | :   | None known.   |
| 5.2 Special hazards arising from              | the | e substance or mixture  |
| Specific hazards during fire-<br>fighting     | :   | Avoid generating dust; fine dust dispersed in air in sufficient<br>concentrations, and in the presence of an ignition source is a<br>potential dust explosion hazard.<br>Exposure to combustion products may be a hazard to health.                     |
| Hazardous combustion prod-<br>ucts            | :   | Carbon oxides<br>Nitrogen oxides (NOx)<br>Sulphur oxides  |
| 5.3 Advice for firefighters                   |     |   |
| Special protective equipment for firefighters | :   | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |
| Specific extinguishing meth-<br>ods           | :   | Use extinguishing measures that are appropriate to local cir-<br>cumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do<br>so.<br>Evacuate area. |

# **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).  |
|--|---|--|
| 6.2 Environmental precautions<br>Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages<br>cannot be contained. |



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### 6.3 Methods and material for containment and cleaning up

|  | Methods for cleaning up | : | <ul> <li>Sweep up or vacuum up spillage and collect in suitable container for disposal.</li> <li>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).</li> <li>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.</li> <li>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.</li> <li>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.</li> </ul> |
|--|-------------------------|---|--|
|--|-------------------------|---|--|

# 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

# SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

| Technical measures                    | : Static electricity may accumulate and ignite suspended dust causing an explosion.           |   |
|---------------------------------------|---|---|
|                                       | Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |   |
| Local/Total ventilation               | : Use only with adequate ventilation.   |   |
| Advice on safe handling               | : Do not breathe dust.  |   |
| · · · · · · · · · · · · · · · · · · · | Do not swallow.   |   |
|                                       | Avoid contact with eyes.  |   |
|                                       | Avoid prolonged or repeated contact with skin.  |   |
|                                       | Handle in accordance with good industrial hygiene and safety                                  | / |
|                                       | practice, based on the results of the workplace exposure as-<br>sessment                      |   |
|                                       | Minimize dust generation and accumulation.  |   |
|                                       | Keep container closed when not in use.  |   |
|                                       | Keep away from heat and sources of ignition.  |   |
|                                       | Take precautionary measures against static discharges.  |   |
|                                       | Take care to prevent spills, waste and minimize release to the environment.                   | е |
| Hygiene measures                      | : If exposure to chemical is likely during typical use, provide ey                            |   |
| riygiche measures                     | flushing systems and safety showers close to the working                                      |   |
|                                       | place. When using do not eat, drink or smoke. Wash contami<br>nated 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.   |   |
|                                       |   |   |



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|----------------|---|-----|---------------------------------------|---|
| 7.2 Cond       | itions for safe storage,                  | inc | luding any incom                      | patibilities  |
| •              | uirements for storage<br>s and containers | :   |                                       | labelled containers. Store in accordance with ional regulations.  |
| Advi           | ce on common storage                      | :   | Do not store with<br>Strong oxidizing | the following product types:<br>agents                            |
| •              | i <b>fic end use(s)</b><br>cific use(s)   | :   | No data available                     |   |

### **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    |
|---|------------|-------------------------------|--------------------|----------|
| 4,4'-<br>methylenebis[3-<br>hydroxy-2-<br>naphthoic] acid,<br>compound with<br>(E)-1,4,5,6-<br>tetrahydro-1-<br>methyl-2-[2-(2-<br>thienyl)vinyl]pyrimi<br>dine (1:1) | 22204-24-6 | TWA                           | 250 μg/m3 (OEB 2)  | Internal |
| praziquantel  | 55268-74-1 | TWA                           | 0.5 mg/m3 (OEB 2)  | Internal |

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

| Substance name | Environmental Compartment | Value     |
|----------------|---------------------------|-----------|
| praziquantel   | Water                     | 0,03 mg/l |

#### 8.2 Exposure controls

### Engineering measures

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



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|----------------|-------------------------------|------|---|---|
| and t<br>vices | to prevent migration of       |      |   | mpounds are required to control at source rolled areas (e.g., open-face containment de-   |
| Pers           | onal protective equip         | ment |   |   |
| Eye/           | face protection               | :    | If the work enviro<br>mists or aerosols<br>Wear a faceshiel | ses with side shields or goggles.<br>Inment or activity involves dusty conditions,<br>I, wear the appropriate goggles.<br>I or other full face protection if there is a<br>et contact to the face with dusts, mists, or |
| Hand           | d protection                  |      |   |   |
| М              | laterial                      | :    | Chemical-resistar   | nt gloves   |
|                | emarks<br>and body protection | :    | being performed<br>suits) to avoid exp                      | aboratory coat.<br>arments should be used based upon the task<br>(e.g., sleevelets, apron, gauntlets, disposable<br>posed skin surfaces.<br>degowning techniques to remove potentially                                  |
| Resp           | piratory protection           | :    | If adequate local sure assessment ommended guide            | exhaust ventilation is not available or expo-<br>demonstrates exposures outside the rec-<br>lines, use respiratory protection.<br>d conform to NS EN 143  |
| Fi             | ilter type                    | :    | Particulates type   |   |

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

# 9.1 Information on basic physical and chemical properties

| Physical state                          | : | powder   |
|---|---|--|
| Colour                                  | : | yellow   |
| 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)                  | : | Not applicable   |
| Upper explosion limit / Upper           | : | No data available  |
|   |   |  |

Commission Regulation (EU) 2020/878



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|------------|-------------------|---|---|--------------------------|---|
|            | flamma            | bility limit                            |   |                          |   |
|            |                   | explosion limit / Lower<br>bility limit | : | No data available        | 9   |
|            | Flash p           | oint                                    | : | Not applicable           |   |
|            | Auto-ig           | nition temperature                      | : | No data available        | 9   |
|            | Decom             | position temperature                    | : | No data available        | 9   |
|            | рН                |   | : | No data available        | 9   |
|            | Viscosi<br>Visc   | ty<br>cosity, kinematic                 | : | Not applicable           |   |
|            | Solubili<br>Wat   | ty(ies)<br>er solubility                | : | No data available        | 9   |
|            | Partition octanol | n coefficient: n-<br>/water             | : | Not applicable           |   |
|            | Vapour            | pressure                                | : | Not applicable           |   |
|            | Relative          | e density                               | : | No data available        | 9   |
|            | Density           | ,                                       | : | No data available        | 9   |
|            | Relative          | e vapour density                        | : | Not applicable           |   |
|            |                   | e characteristics<br>icle size          | : | No data available        | 9   |
| 9.2        |                   | formation                               |   |                          |   |
|            | Explosi           |   | : | Not explosive            |   |
|            |                   | ng properties                           | : |                          | r mixture is not classified as oxidizing.                         |
|            | Evapor            | ation rate                              | : | Not applicable           |   |
|            | Molecu            | lar weight                              | : | No data available        | 9   |

# **SECTION 10: Stability and reactivity**

# 10.1 Reactivity

Not classified as a reactivity hazard.



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|----------------|---|------------------------|---|---|
| 10.2 Che       | emical stability  |                        |   |   |
| Stal           | ole under normal conditior                                      | ns.                    |   |   |
| 10.3 Pos       | sibility of hazardous rea                                       | actions                |   |   |
| Haz            | ardous reactions  | dlin                   | g or other me   | ve dust-air mixture during processing, han-<br>ans.<br>rong oxidizing agents. |
| 10.4 Co        | nditions to avoid   |                        |   |   |
| Cor            | ditions to avoid  |                        | at, flames and<br>bid dust forma                        |   |
| 10.5 Inc       | ompatible materials   |                        |   |   |
|                | erials to avoid   | : Oxi                  | dizing agents   |   |
|                |   |                        |   |   |
|                | ardous decomposition  |                        |   |   |
| No             | hazardous decomposition   | products               | are known.  |   |
| SECTIC         | N 11: Toxicological in  | ofrmati                | on  |   |
|                |   |                        |   |   |
| Info           | rmation on hazard class<br>rmation on likely routes of<br>osure | : Inha<br>Skin<br>Inge | etined in Reg<br>lation<br>contact<br>estion<br>contact | ulation (EC) No 1272/2008   |
| Αςι            | ite toxicity  | -                      |   |   |
|                | classified based on availa                                      | able inforr            | nation.   |   |
| Pro            | duct:   |                        |   |   |
| Acu            | te oral toxicity  |                        | te toxicity estin<br>nod: Calculatio                    | mate: > 2.000 mg/kg<br>on method  |
| Cor            | nponents:   |                        |   |   |
| Feb            | antel:  |                        |   |   |
|                | te oral toxicity  | : LD5                  | 0 (Rabbit): 1.2   | 250 mg/kg   |
| Acu            | te dermal toxicity  | : LD5                  | 0 (Rabbit): > 2   | 2.000 mg/kg   |
|                | -methylenebis[3-hydrox<br>hyl-2-[2-(2-thienyl)vinyl]            |                        |   | ompound with (E)-1,4,5,6-tetrahydro-1-  |
| Acu            | te oral toxicity  | : LD5                  | 0 (Rat): > 24.0   | 000 mg/kg   |
|                |   | LD5                    | 0 (Mouse): > 2  | 24.000 mg/kg  |
|                |   | LD5                    | 0 (Dog): 2.000  | ) mg/kg   |
|                |   |                        |   |   |



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|---------------|--|--------------|--|---|
| prazi         | quantel:                                       |              |  |   |
| Acute         | e oral toxicity                                | : L[         | 050 (Rat): 2.48                        | 30 mg/kg  |
|               |  | L            | 050 (Mouse): 2                         | 2.454 mg/kg   |
|               |  | L            | 050 (Dog): > 2                         | 00 mg/kg  |
|               |  | L            | 050 (Rabbit): 1                        | 1.050 mg/kg   |
|               | corrosion/irritation<br>lassified based on ava | ailable info | ormation.                              |   |
|               | ponents:                                       |              |  |   |
| Feba          | ntel:  |              |  |   |
| Speci         |  |              | abbit                                  |   |
| Resu          | lt   | : N          | o skin irritation                      |   |
| prazi         | quantel:                                       |              |  |   |
| Speci         |  |              | abbit                                  |   |
| Metho<br>Rema |  |              | aize Test<br>ght irritation            |   |
| Not c         | ies  | ailable info | ormation.<br>abbit<br>o eye irritation |   |
| prazi         | quantel:                                       |              |  |   |
| Speci         |  |              | abbit                                  |   |
| Metho<br>Resu |  |              | aize Test<br>ild eye irritatio         | n   |
| Resp          | iratory or skin sensi                          | tisation     |  |   |
|               | sensitisation<br>lassified based on ava        | ailable info | ormation.                              |   |
| Resp          | iratory sensitisation                          |              |  |   |
| Not c         | lassified based on ava                         | ailable info | ormation.                              |   |
| <u>Com</u>    | ponents:                                       |              |  |   |
| prazi         | quantel:                                       |              |  |   |
|               |  |              |  |   |

: Maximisation Test

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



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|---|---|---------|--|--|
| Expos<br>Speci<br>Resul   |   | :       | Dermal<br>Guinea pig<br>Not a skin sensiti   | zer.   |
|   | <b>cell mutagenicity</b><br>lassified based on ava  | ailable | information.   |  |
| <u>Com</u>  | oonents:  |         |  |  |
| Feba  | ntel:   |         |  |  |
| Geno  | toxicity in vitro   | :       | Test Type: Bacte<br>Result: negative   | rial reverse mutation assay (AMES)   |
|   |   |         |  | damage and repair, unscheduled DNA syn<br>lian cells (in vitro)                |
| Geno  | toxicity in vivo  | :       | Test Type: Mamr<br>cytogenetic assa<br>Species: Mouse<br>Application Route<br>Result: negative   |  |
| meth  | nethylenebis[3-hydro<br>yl-2-[2-(2-thienyl)vin  |         | midine (1:1):  | compound with (E)-1,4,5,6-tetrahydro-1-  |
| Geno  | toxicity in vitro   | :       | Result: negative   | rial reverse mutation assay (AMES)   |
|   |   | :       |  | rial reverse mutation assay (AMES)   |
| prazie  | toxicity in vitro<br><b>quantel:</b><br>toxicity in vitro   | :       | Result: negative   | rial reverse mutation assay (AMES)<br>rial reverse mutation assay (AMES)       |
| prazie  | quantel:  | :       | Result: negative<br>Test Type: Bacte<br>Result: negative<br>Test Type: Chror   |  |
| <b>prazi</b> e<br>Geno  | quantel:  | :       | Result: negative<br>Test Type: Bacte<br>Result: negative<br>Test Type: Chror<br>Test system: Chi   | rial reverse mutation assay (AMES)<br>nosomal aberration<br>nese hamster cells |
| <b>prazi</b> e<br>Geno<br>Geno  | quantel:<br>toxicity in vitro<br>toxicity in vivo   | :       | Result: negative<br>Test Type: Bacte<br>Result: negative<br>Test Type: Chror<br>Test system: Chi<br>Result: negative<br>Test Type: Micro<br>Species: Rat<br>Result: negative                 | rial reverse mutation assay (AMES)<br>nosomal aberration<br>nese hamster cells |
| <b>prazi</b> e<br>Geno<br>Geno<br><b>Carci</b><br>Not cl                      | <b>quantel:</b><br>toxicity in vitro<br>toxicity in vivo<br><b>nogenicity</b><br>lassified based on ava   | :       | Result: negative<br>Test Type: Bacte<br>Result: negative<br>Test Type: Chror<br>Test system: Chi<br>Result: negative<br>Test Type: Micro<br>Species: Rat<br>Result: negative                 | rial reverse mutation assay (AMES)<br>nosomal aberration<br>nese hamster cells |
| prazie<br>Geno<br>Geno<br>Carci<br>Not cl<br><u>Com</u>                       | quantel:<br>toxicity in vitro<br>toxicity in vivo<br><b>nogenicity</b><br>lassified based on ava  | :       | Result: negative<br>Test Type: Bacte<br>Result: negative<br>Test Type: Chror<br>Test system: Chi<br>Result: negative<br>Test Type: Micro<br>Species: Rat<br>Result: negative                 | rial reverse mutation assay (AMES)<br>nosomal aberration<br>nese hamster cells |
| prazie<br>Geno<br>Geno<br>Carci<br>Not cl<br><u>Comp</u><br>Feba              | quantel:<br>toxicity in vitro<br>toxicity in vivo<br>nogenicity<br>lassified based on ava<br><u>ponents:</u><br>ntel:                                     | :       | Result: negative<br>Test Type: Bacte<br>Result: negative<br>Test Type: Chror<br>Test system: Chi<br>Result: negative<br>Test Type: Micro<br>Species: Rat<br>Result: negative<br>information. | rial reverse mutation assay (AMES)<br>nosomal aberration<br>nese hamster cells |
| prazio<br>Geno<br>Geno<br>Carci<br>Not cl<br><u>Comp</u><br>Febar<br>Speci    | quantel:<br>toxicity in vitro<br>toxicity in vivo<br>nogenicity<br>lassified based on ava<br><u>ponents:</u><br>ntel:                                     | :       | Result: negative<br>Test Type: Bacte<br>Result: negative<br>Test Type: Chror<br>Test system: Chi<br>Result: negative<br>Test Type: Micro<br>Species: Rat<br>Result: negative                 | rial reverse mutation assay (AMES)<br>nosomal aberration<br>nese hamster cells |
| prazie<br>Geno<br>Geno<br>Carci<br>Not cl<br>Comp<br>Febar<br>Speci<br>Applio | quantel:<br>toxicity in vitro<br>toxicity in vivo<br>nogenicity<br>lassified based on ava<br><u>conents:</u><br>ntel:<br>les<br>cation Route<br>sure time | :       | Result: negative<br>Test Type: Bacte<br>Result: negative<br>Test Type: Chror<br>Test system: Chi<br>Result: negative<br>Test Type: Micro<br>Species: Rat<br>Result: negative<br>information. | rial reverse mutation assay (AMES)<br>nosomal aberration<br>nese hamster cells |

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



# Febantel / Pyrantel Pamoate / Praziquantel Formulation

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# praziquantel:

| Species                                       | : Hamster                                      |
|---|--|
| Application Route                             | : Oral   |
| Exposure time                                 | : 80 weeks                                     |
| NÓAEL   | : 100 mg/kg body weight                        |
| Result  | : negative                                     |
| Remarks                                       | : No significant adverse effects were reported |
|   |  |
| Species                                       | : Rat  |
| Species<br>Application Route                  | : Rat<br>: Oral                                |
| Species<br>Application Route<br>Exposure time |  |
| Application Route                             | : Oral   |
| Application Route<br>Exposure time            | : Oral<br>: 104 weeks                          |

# Reproductive toxicity

Not classified based on available information.

# Components:

| Febantel:                          |   |  |
|------------------------------------|---|--|
| Effects on fertility               | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 416<br>Result: negative |
| Effects on foetal develop-<br>ment | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 416<br>Result: negative |

# 4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

| Effects on foetal develop-<br>ment | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 3.000 mg/kg body weight<br>Result: No effects on fertility and early embryonic develop-<br>ment were detected.    |
|------------------------------------|---|
|                                    | Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 1.000 mg/kg body weight<br>Result: No effects on fertility and early embryonic develop-<br>ment were detected. |



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|------------------------------------|---------------------------|---|---|--|--|--|
| praz                               | iquantel:                 |   |   |  |  |  |
| Effects on fertility               |                           | Species: Rat  | : Test Type: Fertility<br>Species: Rat<br>Remarks: No significant adverse effects were reported   |  |  |  |
|                                    |                           | Test Type: Ferti<br>Species: Mouse<br>Remarks: No sig |   |  |  |  |
| Effects on foetal develop-<br>ment |                           | Species: Rat  |   |  |  |  |
|                                    |                           | Species: Mouse  | Test Type: Development<br>Species: Mouse<br>Remarks: No significant adverse effects were reported |  |  |  |

# STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

#### **Repeated dose toxicity**

#### Components:

# 4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

| Species<br>NOAEL<br>LOAEL<br>Application Route<br>Exposure time<br>Remarks |   | Dog<br>10 mg/kg<br>30 mg/kg<br>Ingestion<br>3 d<br>No significant adverse effects were reported |
|--|---|---|
| Species<br>NOAEL<br>Application Route<br>Exposure time<br>Remarks          | : | Dog<br>600 mg/kg<br>Oral<br>19 d<br>No significant adverse effects were reported                |
| Species<br>NOAEL<br>Application Route<br>Exposure time<br>Remarks          |   | Dog<br>600 mg/kg<br>Oral<br>30 d<br>No significant adverse effects were reported                |
| Species<br>NOAEL<br>Application Route<br>Exposure time                     | : | Dog<br>600 mg/kg<br>Oral<br>90 d  |

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

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|--|---------------------------|---|--|---|
| Remarks  |                           | :                                       | No significant a   | dverse effects were reported                                      |
| praz   | iquantel:                 |   |  |   |
| Spec<br>NOA<br>Appl<br>Rem   | EL<br>ication Route       | :                                       | Rat<br>1.000 mg/kg<br>Oral<br>No significant a                               | dverse effects were reported                                      |
| Species<br>NOAEL<br>LOAEL<br>Application Route<br>Target Organs<br>Remarks |                           | : | Dog<br>60 mg/kg<br>180 mg/kg<br>Oral<br>Gastrointestinal<br>No significant a | tract<br>dverse effects were reported                             |

# Aspiration toxicity

Not classified based on available information.

# 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:**

| 4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-<br>methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1): |   |  |  |  |
|--|---|--|--|--|
| Ingestion  | : | Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea,<br>Headache, Dizziness, Fever                                 |  |  |
| praziquantel:  |   |  |  |  |
| Inhalation   | : | Symptoms: Headache, Tiredness, Dizziness, Gastrointestinal discomfort, decrease body temperature, Allergic reactions |  |  |
|  |   |  |  |  |

# **SECTION 12: Ecological information**

#### 12.1 Toxicity

### Components:

#### Febantel:

Toxicity to fish

: LC50 (Danio rerio (zebra fish)): > 100 mg/l



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|-------------|---|---|---|---|---|--|
|             |   |   |   | Exposure time: 96   | 3 h   |  |
|             |   | <i>t</i> to daphnia and other invertebrates             | : | EC50 (Daphnia magna (Water flea)): 0,2 mg/l<br>Exposure time: 48 h  |   |  |
|             | Toxicity to algae/aquatic plants                            |   | : | ErC50 (Desmodesmus subspicatus (green algae)): > 0,43<br>mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |   |  |
|             | M-Factor (Acute aquatic tox-<br>icity)                      |   | : | 1   |   |  |
|             |   | / to daphnia and other<br>invertebrates (Chron-<br>ity) | : | Method: OECD Te   | d<br>magna (Water flea)   |  |
|             | M-Factor (Chronic aquatic toxicity)                         |   | : | 10  |   |  |
|             | 4,4'-methylenebis[3-hydrox<br>methyl-2-[2-(2-thienyl)vinyl] |   |   |   | ompound with (E)-1,4,5,6-tetrahydro-1-                            |  |
|             | Ecotox  | cicology Assessment                                     |   |   |   |  |
|             |   | aquatic toxicity  | : | Toxic effects cann  | not be excluded   |  |
|             | Chronic aquatic toxicity                                    |   | : | Toxic effects cannot be excluded  |   |  |
|             | praziqu   | uantel:   |   |   |   |  |
|             | Toxicity  |   | : | LC50 (Carassius a<br>Exposure time: 96<br>Method: OECD Te   |   |  |
|             |   |   |   | LC50 (Danio rerio<br>Exposure time: 96<br>Method: OECD Te   |   |  |
|             |   | <i>r</i> to daphnia and other<br>invertebrates          | : | EC50 (Daphnia m<br>Exposure time: 48<br>Method: OECD Te   |   |  |
|             | Toxicity  | <i>i</i> to microorganisms                              | : | Exposure time: 3  | ation inhibition of activated sludge                              |  |

# 12.2 Persistence and degradability

No data available



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#### 12.3 Bioaccumulative potential

#### Components:

### Febantel:

| Partition coefficient: n- | : | log Pow: 1,95        |
|---------------------------|---|----------------------|
| octanol/water             |   | Remarks: Calculation |

#### praziquantel:

| Partition coefficient: n- | : | log Pow: 2,012 |
|---------------------------|---|----------------|
| octanol/water             |   | pH: 7          |

#### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

|--|

Assessment

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

### 12.6 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> </ul> |
|------------------------|---|
|                        | Do not dispose of waste into sewer.   |
| Contaminated packaging | : Empty containers should be taken to an approved waste han-<br>dling site for recycling or disposal.   |
|                        | If not otherwise specified: Dispose of as unused product.   |



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|---|---|-----|---|---|-----------|
| SECTION                                       | V 14: Transport infor   | mat | ion   |   |           |
|   |   |     |   |   |           |
| 14.1 UN n                                     | umber or ID number  |     |   |   |           |
| ADN   |   | :   | UN 3077   |   |           |
| ADR   |   | :   | UN 3077   |   |           |
| RID   |   | :   | UN 3077   |   |           |
| IMDG  | ì   | :   | UN 3077   |   |           |
| ΙΑΤΑ  |   | :   | UN 3077   |   |           |
| 14.2 UN p                                     | roper shipping name   |     |   |   |           |
| ADN   |   | :   | ENVIRONMENT<br>N.O.S.<br>(Febantel)                                 | LLY HAZARDOUS SUBSTANCE   | E, SOLID, |
| ADR   |   | :   | ENVIRONMENT<br>N.O.S.<br>(Febantel)                                 | LLY HAZARDOUS SUBSTANCE   | E, SOLID, |
| RID   |   | :   | ENVIRONMENT/<br>N.O.S.<br>(Febantel)                                | LY HAZARDOUS SUBSTANCE  | E, SOLID, |
| IMDG  | <b>)</b>  | :   | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,<br>N.O.S.<br>(Febantel) |   |           |
| ΙΑΤΑ  |   | :   |   |   |           |
| 14.3 Transport hazard class(es)               |   |     |   |   |           |
|   |   |     | Class   | Subsidiary risks  |           |
| ADN   |   | :   | 9   |   |           |
| ADR   |   | :   | 9   |   |           |
| RID   |   | :   | 9   |   |           |
| IMDG  | ì   | :   | 9   |   |           |
| ΙΑΤΑ  |   | :   | 9   |   |           |
| 14.4 Pack                                     | ing group   |     |   |   |           |
| Class<br>Haza<br>Label<br><b>ADR</b><br>Packi | ng group<br>ification Code<br>rd Identification Number<br>s<br>ng group<br>ification Code | :   | III<br>M7<br>90<br>9<br>1II<br>M7                                   |   |           |

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|-----------------------|--|---|---|
| La                    | zard Identification Number<br>bels<br>nnel restriction code  | : 90<br>: 9<br>: (-)                        |   |
| Cla<br>Ha             | <b>D</b><br>acking group<br>assification Code<br>azard Identification Number<br>bels                         | : III<br>: M7<br>: 90<br>: 9                |   |
| Pa<br>La              | <b>DG</b><br>cking group<br>bels<br>nS Code  | : III<br>: 9<br>: F-A, S-F                  |   |
| Pa<br>air<br>Pa<br>Pa | <b>TA (Cargo)</b><br>cking instruction (cargo<br>craft)<br>cking instruction (LQ)<br>cking group<br>bels     | : 956<br>: Y956<br>: III<br>: Miscellaneous |   |
| Pa<br>ge<br>Pa<br>Pa  | TA (Passenger)<br>cking instruction (passen-<br>r aircraft)<br>cking instruction (LQ)<br>cking group<br>bels | : 956<br>: Y956<br>: III<br>: Miscellaneous |   |
| 14.5 Er               | vironmental hazards  |   |   |
| <b>A</b> E<br>En      | <b>DN</b><br>vironmentally hazardous   | : yes                                       |   |
| AC<br>En              | <b>DR</b><br>vironmentally hazardous   | : yes                                       |   |
| <b>Ri</b> l<br>En     | <b>D</b><br>vironmentally hazardous  | : yes                                       |   |
|                       | <b>DG</b><br>arine pollutant   | : yes                                       |   |
|                       | <b>TA (Passenger)</b><br>vironmentally hazardous   | : yes                                       |   |
|                       | TA (Cargo)<br>vironmentally hazardous  | : yes                                       |   |
| 14.6 Sp               | pecial precautions for use   | er  |   |

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 Maritime transport in bulk according to IMO instruments

Remarks



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# **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 the market and use of certain dangerous substances, 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 Parliam   | nen | t and of the Counc | il on the control of |
| major-accident hazards involving dangerous substances.   |     |                    |                      |
|  |     | Ouontity 1         | Outoptity 2          |

|    |               | Quantity 1 | Quantity 2 |
|----|---------------|------------|------------|
| E1 | ENVIRONMENTAL | 100 t      | 200 t      |
|    | HAZARDS       |            |            |

#### 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. Full text of H-Statements Harmful if swallowed. H302 2 H400 Very toxic to aquatic life. 2 Very toxic to aquatic life with long lasting effects. H410 2 Harmful to aquatic life with long lasting effects. H412 : Full text of other abbreviations Acute Tox. : Acute toxicity



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| Aqua<br>FOR | atic Acute<br>atic Chronic<br>-2011-12-06-1358<br>-2011-12-06-1358 / | : Long-term (chr | ute) aquatic hazard<br>ronic) aquatic hazard<br>pational Exposure limits<br>osure limit |

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

#### Further information

| Sources of key data used to : | Internal technical data, data from raw material SDSs, OECD |
|-------------------------------|--|
| compile the Safety Data       | eChem Portal search results and European Chemicals Agen-   |
| Sheet                         | cy, http://echa.europa.eu/                                 |

#### **Classification of the mixture:**

Aquatic Chronic 1 H410

Classification procedure:

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



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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