

## Praziquantel Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2025/02/19  |
| 2.0     | 2025/04/14     | 11511880-00002 | Date of first issue: 2025/02/19 |

## 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Praziquantel Formulation

Product code : Hadaclean 5%, Hadaclean A

**Supplier's company name, address and phone number**

Company name of supplier : MSD

Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : 1-908-423-6000

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product

Restrictions on use : Not applicable

## 2. HAZARDS IDENTIFICATION

**GHS classification of chemical product**

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

**GHS label elements**

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

**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, handling or other means.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No.   | Concentration (% w/w) | ENCS No. |
|---------------|-----------|-----------------------|----------|
| Starch        | 9005-25-8 | >= 50 - < 60          | 8-98     |

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|                             |            |                         |               |
|-----------------------------|------------|-------------------------|---------------|
| praziquantel                | 55268-74-1 | $\geq 2.5 - < 10$       | -             |
| 3,7-Dimethyl 2,6-octadienal | 5392-40-5  | $\geq 0.1 - < 1$        | 2-515         |
| Dimethyl octadienol         | 78-70-6    | $\geq 0.1 - < 1$        | 2-258, 2-249  |
| 2,6-Di-tert-butyl-p-cresol  | 128-37-0   | $\geq 0.0025 - < 0.025$ | 3-540, 9-1805 |

## 4. FIRST AID MEASURES

|                                                             |                                                                                                                                                                                                                         |
|-------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| General advice                                              | : In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.                                                                |
| If inhaled                                                  | : If inhaled, remove to fresh air.<br>Get medical attention if symptoms occur.                                                                                                                                          |
| In case of skin contact                                     | : In case of contact, immediately flush skin with soap and plenty 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 if symptoms occur.<br>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.<br>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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical |
| Unsuitable extinguishing media        | : None known.                                                                                |
| Specific hazards during fire-fighting | : Exposure to combustion products may be a hazard to health.                                 |
| Hazardous combustion products         | : Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )                                        |

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- 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 get on skin or clothing.  
Avoid breathing dust, fume, gas, mist, vapours or spray.  
Do not swallow.  
Avoid contact with eyes.
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Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment

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.

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.

Contaminated work clothing should not be allowed out of the workplace.

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**

| Components                  | CAS-No.    | Value type<br>(Form of exposure)   | Control parameters / Concentration standard / Permissible concentration | Basis                |
|-----------------------------|------------|------------------------------------|-------------------------------------------------------------------------|----------------------|
| Starch                      | 9005-25-8  | TWA                                | 10 mg/m <sup>3</sup>                                                    | ACGIH                |
| praziquantel                | 55268-74-1 | TWA                                | 0.5 mg/m <sup>3</sup> (OEB 2)                                           | Internal             |
| 3,7-Dimethyl 2,6-octadienal | 5392-40-5  | TWA (Inhalable fraction and vapor) | 5 ppm                                                                   | ACGIH                |
| 2,6-Di-tert-butyl-p-cresol  | 128-37-0   | 8h-OEL-M                           | 10 mg/m <sup>3</sup>                                                    | JP ISHL OEL 577-2(2) |
|                             |            | TWA (Inhalable fraction and vapor) | 2 mg/m <sup>3</sup>                                                     | ACGIH                |

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**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 recommended guidelines, use respiratory protection.

Filter type : Particulates type

**Hand protection**

Material : 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.

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Physical state** : Crystalline solid

**Colour** : No data available

**Odour** : No data available

**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)** : Not applicable

**Lower explosion limit and upper explosion limit / flammability limit**

Upper explosion limit / Up- : No data available  
per flammability limit

Lower explosion limit / : No data available  
Lower flammability limit

**Flash point** : Not applicable

**Decomposition temperature** : No data available

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|                                        |   |                                                          |
|----------------------------------------|---|----------------------------------------------------------|
| 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                                        |
| Partition coefficient: n-octanol/water | : | Not applicable                                           |
| Vapour pressure                        | : | Not applicable                                           |
| Density and / or relative density      | : |                                                          |
| Relative density                       | : | No data available                                        |
| Density                                | : | No data available                                        |
| Relative vapour density                | : | Not applicable                                           |
| Explosive properties                   | : | Not explosive                                            |
| Oxidizing properties                   | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight                       | : | No data available                                        |
| Particle characteristics               | : |                                                          |
| Particle size                          | : | No data available                                        |

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**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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | Heat, flames and sparks.<br>Avoid dust formation.                                                                          |
| Incompatible materials             | : | Oxidizing agents                                                                                                           |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.                                                                             |

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**11. TOXICOLOGICAL INFORMATION**

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

**Acute toxicity**

Not classified based on available information.

**Components:****Starch:**

|                       |                                |
|-----------------------|--------------------------------|
| Acute oral toxicity   | : LD50 (Rat): > 5,000 mg/kg    |
| Acute dermal toxicity | : LD50 (Rabbit): > 2,000 mg/kg |

**praziquantel:**

|                     |                            |
|---------------------|----------------------------|
| Acute oral toxicity | : LD50 (Rat): 2,480 mg/kg  |
|                     | LD50 (Mouse): 2,454 mg/kg  |
|                     | LD50 (Dog): > 200 mg/kg    |
|                     | LD50 (Rabbit): 1,050 mg/kg |

**3,7-Dimethyl 2,6-octadienal:**

|                           |                                                                            |
|---------------------------|----------------------------------------------------------------------------|
| Acute oral toxicity       | : LD50 (Rat, female): 4,895 mg/kg                                          |
| Acute inhalation toxicity | : LC50 (Rat): > 0.68 mg/l<br>Exposure time: 7 h<br>Test atmosphere: vapour |
| Acute dermal toxicity     | : LD50 (Rabbit): 2,250 mg/kg                                               |

**Dimethyl octadienol:**

|                           |                                                                                                                                       |
|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity       | : LD50 (Rat): 2,790 mg/kg<br>Method: OECD Test Guideline 401<br>Remarks: The test was conducted equivalent or similar to guideline    |
| Acute inhalation toxicity | : LC50 (Mouse): > 3.2 mg/l<br>Exposure time: 90 min<br>Test atmosphere: vapour<br>Remarks: No test guideline followed                 |
| Acute dermal toxicity     | : LD50 (Rabbit): 5,610 mg/kg<br>Method: OECD Test Guideline 402<br>Remarks: The test was conducted equivalent or similar to guideline |

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**2,6-Di-tert-butyl-p-cresol:**

|                       |   |                                                                                                                                   |
|-----------------------|---|-----------------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity   | : | LD50 (Rat): > 6,000 mg/kg<br>Method: OECD Test Guideline 401                                                                      |
| Acute dermal toxicity | : | LD50 (Rat): > 2,000 mg/kg<br>Method: OECD Test Guideline 402<br>Assessment: The substance or mixture has no acute dermal toxicity |

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****praziquantel:**

|         |   |                   |
|---------|---|-------------------|
| Species | : | Rabbit            |
| Method  | : | Draize Test       |
| Remarks | : | slight irritation |

**3,7-Dimethyl 2,6-octadienal:**

|         |   |                 |
|---------|---|-----------------|
| Species | : | Rabbit          |
| Result  | : | Skin irritation |

**Dimethyl octadienol:**

|         |   |                                               |
|---------|---|-----------------------------------------------|
| Species | : | Rabbit                                        |
| Method  | : | OECD Test Guideline 404                       |
| Result  | : | Skin irritation                               |
| Remarks | : | The test was conducted according to guideline |

**2,6-Di-tert-butyl-p-cresol:**

|         |   |                                      |
|---------|---|--------------------------------------|
| 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:****Starch:**

|         |   |                   |
|---------|---|-------------------|
| Species | : | Rabbit            |
| Result  | : | No eye irritation |

**praziquantel:**

|         |   |                     |
|---------|---|---------------------|
| Species | : | Rabbit              |
| Result  | : | Mild eye irritation |
| Method  | : | Draize Test         |



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**3,7-Dimethyl 2,6-octadienal:**

|         |                                                |
|---------|------------------------------------------------|
| Species | : Rabbit                                       |
| Result  | : Irritation to eyes, reversing within 21 days |

**Dimethyl octadienol:**

|         |                                                             |
|---------|-------------------------------------------------------------|
| Species | : Rabbit                                                    |
| Result  | : Irritation to eyes, reversing within 21 days              |
| Method  | : OECD Test Guideline 405                                   |
| Remarks | : The test was conducted equivalent or similar to guideline |

**2,6-Di-tert-butyl-p-cresol:**

|         |                                        |
|---------|----------------------------------------|
| 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:****Starch:**

|                 |                     |
|-----------------|---------------------|
| Test Type       | : Maximisation Test |
| Exposure routes | : Skin contact      |
| Species         | : Guinea pig        |
| Result          | : negative          |

**praziquantel:**

|                 |                          |
|-----------------|--------------------------|
| Test Type       | : Maximisation Test      |
| Exposure routes | : Dermal                 |
| Species         | : Guinea pig             |
| Result          | : Not a skin sensitizer. |

**3,7-Dimethyl 2,6-octadienal:**

|                 |                                          |
|-----------------|------------------------------------------|
| Test Type       | : Human repeat insult patch test (HRIPT) |
| Exposure routes | : Skin contact                           |
| Result          | : positive                               |

|            |                                                           |
|------------|-----------------------------------------------------------|
| Assessment | : Probability or evidence of skin sensitisation in humans |
|------------|-----------------------------------------------------------|

**Dimethyl octadienol:**

|           |                                 |
|-----------|---------------------------------|
| Test Type | : Local lymph node assay (LLNA) |
|-----------|---------------------------------|

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|                 |                                                 |
|-----------------|-------------------------------------------------|
| Exposure routes | : Skin contact                                  |
| Species         | : Mouse                                         |
| Method          | : OECD Test Guideline 429                       |
| Result          | : positive                                      |
| Remarks         | : The test was conducted according to guideline |

|            |                                                                                |
|------------|--------------------------------------------------------------------------------|
| Assessment | : Probability or evidence of low to moderate skin sensitisation rate in humans |
|------------|--------------------------------------------------------------------------------|

**2,6-Di-tert-butyl-p-cresol:**

|                 |                                          |
|-----------------|------------------------------------------|
| Test Type       | : Human repeat insult patch test (HRIPT) |
| Exposure routes | : Skin contact                           |
| Species         | : Humans                                 |
| Result          | : negative                               |

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Starch:**

|                       |                                                                          |
|-----------------------|--------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
|-----------------------|--------------------------------------------------------------------------|

**praziquantel:**

|                       |                                                                          |
|-----------------------|--------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
|-----------------------|--------------------------------------------------------------------------|

Test Type: Chromosomal aberration  
Test system: Chinese hamster cells  
Result: negative

|                      |                                                                    |
|----------------------|--------------------------------------------------------------------|
| Genotoxicity in vivo | : Test Type: Micronucleus test<br>Species: Rat<br>Result: negative |
|----------------------|--------------------------------------------------------------------|

**3,7-Dimethyl 2,6-octadienal:**

|                       |                                                                          |
|-----------------------|--------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
|-----------------------|--------------------------------------------------------------------------|

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Test Type: In vitro sister chromatid exchange assay in mammalian cells  
Result: positive

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

**Dimethyl octadienol:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: The test was conducted equivalent or similar to guideline

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: The test was conducted equivalent or similar to guideline

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: The test was conducted equivalent or similar to guideline

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: The test was conducted according to guideline

**2,6-Di-tert-butyl-p-cresol:**

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

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative

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**Carcinogenicity**

Not classified based on available information.

**Components:****praziquantel:**

|                   |                                                |
|-------------------|------------------------------------------------|
| Species           | : Hamster                                      |
| Application Route | : Oral                                         |
| Exposure time     | : 80 weeks                                     |
| NOAEL             | : 100 mg/kg body weight                        |
| Result            | : negative                                     |
| Remarks           | : No significant adverse effects were reported |

|                   |                                                |
|-------------------|------------------------------------------------|
| Species           | : Rat                                          |
| Application Route | : Oral                                         |
| Exposure time     | : 104 weeks                                    |
| NOAEL             | : 250 mg/kg body weight                        |
| Result            | : negative                                     |
| Remarks           | : No significant adverse effects were reported |

**3,7-Dimethyl 2,6-octadienal:**

|                   |                   |
|-------------------|-------------------|
| Species           | : Mouse           |
| Application Route | : Ingestion       |
| Exposure time     | : 104 - 105 weeks |
| Result            | : negative        |

**2,6-Di-tert-butyl-p-cresol:**

|                   |             |
|-------------------|-------------|
| Species           | : Rat       |
| Application Route | : Ingestion |
| Exposure time     | : 22 Months |
| Result            | : negative  |

**Reproductive toxicity**

Not classified based on available information.

**Components:****praziquantel:**

|                               |                                                       |
|-------------------------------|-------------------------------------------------------|
| Effects on fertility          | : Test Type: Fertility                                |
|                               | Species: Rat                                          |
|                               | Remarks: No significant adverse effects were reported |
|                               | Test Type: Fertility                                  |
|                               | Species: Mouse                                        |
|                               | Remarks: No significant adverse effects were reported |
| Effects on foetal development | : Test Type: Development                              |
|                               | Species: Rat                                          |
|                               | Remarks: No significant adverse effects were reported |
|                               | Test Type: Development                                |

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Species: Mouse  
Remarks: No significant adverse effects were reported

**3,7-Dimethyl 2,6-octadienal:**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 443  
Result: negative

Effects on foetal development : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 443  
Result: negative

**Dimethyl octadienol:**

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: No test guideline followed

**2,6-Di-tert-butyl-p-cresol:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Components:****2,6-Di-tert-butyl-p-cresol:**

Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

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**Repeated dose toxicity****Components:****Starch:**

|                   |                           |
|-------------------|---------------------------|
| Species           | : Rat                     |
| NOAEL             | : $\geq 2,000$ mg/kg      |
| Application Route | : Skin contact            |
| Exposure time     | : 28 Days                 |
| Method            | : OECD Test Guideline 410 |

**praziquantel:**

|                   |                                                |
|-------------------|------------------------------------------------|
| Species           | : Rat                                          |
| NOAEL             | : 1,000 mg/kg                                  |
| Application Route | : Oral                                         |
| Remarks           | : No significant adverse effects were reported |

|                   |                                                |
|-------------------|------------------------------------------------|
| Species           | : Dog                                          |
| NOAEL             | : 60 mg/kg                                     |
| LOAEL             | : 180 mg/kg                                    |
| Application Route | : Oral                                         |
| Target Organs     | : Gastrointestinal tract                       |
| Remarks           | : No significant adverse effects were reported |

**3,7-Dimethyl 2,6-octadienal:**

|                   |               |
|-------------------|---------------|
| Species           | : Rat, female |
| LOAEL             | : 335 mg/kg   |
| Application Route | : Ingestion   |
| Exposure time     | : 14 Weeks    |

**Dimethyl octadienol:**

|                   |                                                 |
|-------------------|-------------------------------------------------|
| Species           | : Rat, male                                     |
| NOAEL             | : $\geq 497.9$ mg/kg                            |
| Application Route | : Ingestion                                     |
| Exposure time     | : 96 Days                                       |
| Method            | : OECD Test Guideline 408                       |
| Remarks           | : The test was conducted according to guideline |

|                   |                                                             |
|-------------------|-------------------------------------------------------------|
| Species           | : Rat                                                       |
| NOAEL             | : 250 mg/kg                                                 |
| Application Route | : Skin contact                                              |
| Exposure time     | : 91 Days                                                   |
| Method            | : OECD Test Guideline 411                                   |
| Remarks           | : The test was conducted equivalent or similar to guideline |

**2,6-Di-tert-butyl-p-cresol:**

|                   |             |
|-------------------|-------------|
| Species           | : Rat       |
| NOAEL             | : 25 mg/kg  |
| Application Route | : Ingestion |

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Exposure time : 22 Months

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****praziquantel:**

Inhalation : Symptoms: Headache, Tiredness, Dizziness, Gastrointestinal discomfort, decrease body temperature, Allergic reactions

**12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****praziquantel:**

Toxicity to fish : LC50 (Carassius auratus (goldfish)): 29.2 mg/l  
Exposure time: 96 hrs  
Method: OECD Test Guideline 203

LC50 (Danio rerio (zebra fish)): 31.6 mg/l  
Exposure time: 96 hrs  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 35 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition of activated sludge  
Method: OECD Test Guideline 209

**3,7-Dimethyl 2,6-octadienal:**

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 6.78 mg/l  
Exposure time: 96 h  
Method: DIN 38412

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 6.8 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 103.8 mg/l  
Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 3 mg/l  
Exposure time: 72 h

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Toxicity to microorganisms : EC50 (activated sludge): 160 mg/l  
Exposure time: 30 min  
Method: OECD Test Guideline 209

**Dimethyl octadienol:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 27.8 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: The test was conducted according to guideline

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 59 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: The test was conducted according to guideline

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 156.7 mg/l  
Exposure time: 96 h  
  
EC10 (Desmodesmus subspicatus (green algae)): 54.3 mg/l  
Exposure time: 96 h

Toxicity to microorganisms : EC10 (activated sludge): > 100 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: The test was conducted according to guideline

**2,6-Di-tert-butyl-p-cresol:**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 0.57 mg/l  
Exposure time: 96 h  
Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.48 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
  
NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l  
Exposure time: 30 d  
Method: OECD Test Guideline 210



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|                                                                        |   |                                                                              |
|------------------------------------------------------------------------|---|------------------------------------------------------------------------------|
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0.316 mg/l<br>Exposure time: 21 d         |
| M-Factor (Chronic aquatic toxicity)                                    | : | 1                                                                            |
| Toxicity to microorganisms                                             | : | EC50: > 10,000 mg/l<br>Exposure time: 3 h<br>Method: OECD Test Guideline 209 |

**Persistence and degradability****Components:****3,7-Dimethyl 2,6-octadienal:**

|                  |   |                                                                                                                                 |
|------------------|---|---------------------------------------------------------------------------------------------------------------------------------|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: > 90 %<br>Exposure time: 28 d<br>Method: Directive 67/548/EEC Annex V, C.4.D. |
|------------------|---|---------------------------------------------------------------------------------------------------------------------------------|

**Dimethyl octadienol:**

|                  |   |                                                                                                                                                                               |
|------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 64.2 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301D<br>Remarks: The test was conducted according to guideline |
|------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**2,6-Di-tert-butyl-p-cresol:**

|                  |   |                                                                                                                        |
|------------------|---|------------------------------------------------------------------------------------------------------------------------|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 4.5 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301C |
|------------------|---|------------------------------------------------------------------------------------------------------------------------|

**Bioaccumulative potential****Components:****praziquantel:**

|                                        |   |                         |
|----------------------------------------|---|-------------------------|
| Partition coefficient: n-octanol/water | : | log Pow: 2.012<br>pH: 7 |
|----------------------------------------|---|-------------------------|

**3,7-Dimethyl 2,6-octadienal:**

|                                        |   |               |
|----------------------------------------|---|---------------|
| Partition coefficient: n-octanol/water | : | log Pow: 2.76 |
|----------------------------------------|---|---------------|

**Dimethyl octadienol:**

|                                        |   |                                                                                                                        |
|----------------------------------------|---|------------------------------------------------------------------------------------------------------------------------|
| Partition coefficient: n-octanol/water | : | log Pow: 2.84<br>Method: OECD Test Guideline 107<br>Remarks: The test was conducted equivalent or similar to guideline |
|----------------------------------------|---|------------------------------------------------------------------------------------------------------------------------|

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**2,6-Di-tert-butyl-p-cresol:**

Bioaccumulation : Species: Cyprinus carpio (Carp)  
Bioconcentration factor (BCF): 330 - 1,800

Partition coefficient: n-octanol/water : log Pow: 5.1

**Mobility in soil**

No data available

**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.  
Do not dispose of waste into sewer.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

**14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

**IATA-DGR**

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

**IMDG-Code**

UN number : Not applicable

## Praziquantel Formulation

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|                      |                  |
|----------------------|------------------|
| Proper shipping name | : Not applicable |
| Class                | : Not applicable |
| Subsidiary risk      | : Not applicable |
| Packing group        | : Not applicable |
| Labels               | : Not applicable |
| EmS Code             | : Not applicable |
| Marine pollutant     | : Not applicable |

**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**

Not applicable

**15. REGULATORY INFORMATION****Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

Priority Assessment Chemical Substance

| Chemical name                    | Number |
|----------------------------------|--------|
| 2,6-Di-tert-butyl-4-methylphenol | 64     |

**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**

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

| Chemical name                  | Concentration (%)  | Remarks              |
|--------------------------------|--------------------|----------------------|
| 3,7-Dimethyl-1,6-octadien-3-ol | $\geq 0.1$ - $< 1$ | From April 1st, 2025 |
| citral                         | $\geq 0.1$ - $< 1$ | From April 1st, 2025 |

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**Substances Subject to be Indicated Names**

Not applicable

**Skin and Eye Damage Substances (ISHL MO Art. 594-2)**

Not applicable

**Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

**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**

Not regulated as a dangerous good

**Aviation Law**

Not regulated as a dangerous good

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not 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

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**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**

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

**Further information**

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

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

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
JP ISHL OEL 577-2(2) : Concentration standard (Value set by the Minister of Health, Labour and Welfare stipulated under the Ministerial Ordinance Article 577-2(2))

ACGIH / TWA : 8-hour, time-weighted average  
JP ISHL OEL 577-2(2) / 8h-OEL-M : 8-hour Occupational Exposure Limit-Mean

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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;

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n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECL - 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; WHMIS - Workplace Hazardous Materials Information System

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