

MATERIAL SAFETY DATA SHEET

according to the Commission Regulation (EU) no. 830/2015

Product Name: Polyversum®
Issue date: 19.2.2016
Date of change: 28.03.2019 (replaces all previous issues)

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

1.1 Product identifier

Trade Name: Polyversum®

Chemical Name: The product does not have chemical name, it is microbiological plant protection product, active substance is *Pythium oligandrum* M1

1.2 Relevant identified uses:

Plant protection product - fungicide.

1.3 Identification supplier of the safety data sheet:

Name: Biopreparáty, spol. s r. o.

Address: Tylišovská 772/1, 160 00 Praha 6, Czech Republic

Identification number: 25607324

Telephone: +420 478 048 275

Responsible person: Martin Suchánek

1.4 Emergency telephone number:

Biopreparáty, spol. s r. o.: +420 478 048 275

Department of Occupational Medicine, 1st Faculty of Medicine, Charles University in Prague, Poison Center, tel.: +420 224 919 293

2. HAZARD IDENTIFICATION

2.1 Classification of the product:

The product does not meet the criteria for classification in accordance with Regulation (EC) No 1272/2008

2.2 Label elements:

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Labelling in accordance with Regulation (EC) No 1272/2008

Hazard pictograms(s): none

Signal word(s): none

H(azard) statement(s): none

P(recautionary) statements(s):

P101: If medical advice is needed, have product container or label at hand.

P102: Keep out of reach of children.

P233: Keep container tightly closed.

P270: Do not eat, drink or smoke when using this product.

P280: Wear suitable protective clothing and gloves.

Labelling requirements in compliance with Commission Regulation (EU) No 547/2011

For professional users.

SP1: Do not contaminate water with the product or its container [Do not clean application equipment near surface water / Avoid contamination via drains from farmyards and roads].

EUH401 To avoid risks to human health and the environment, comply with the instructions for use.

2.3 Other hazards:

Supplemental information in compliance with Commission Regulation (EU) No 283/2013 (Annex Part B, point 5.2.1) and EFSA Journal 2013; 11(1):3034)

Contains *Pythium oligandrum* M1. Microorganisms may have the potential to provoke sensitising reactions.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture

The product is formulated as a mixture of the inert carrier and the technical active substance which is a concentrate of propagules of the microorganism *Pythium oligandrum* M1 containing residues of culture medium.

Composition of main substance

Name: Technical grade of *Pythium oligandrum*, strain M1

CAS No.: N/A

Content in the product: 100-250 g/kg

Reg. No.: No. 202 of the annex Commission Implementing Regulation (EU) No 540/2011

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The mixture does not contain any substance meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008

4. FIRST AID MEASURES

4.1 Description of first aid measures:

Inhalation:

Remove person to fresh air and keep comfortable for breathing.

Skin:

Wash with plenty of water.

Eyes

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Ingestion:

Rinse mouth. Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

None known.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray, foam, CO₂, dry powder.

Adapt fire-extinguishing measures to surroundings

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture:

None known.

5.3 Advice for fire-fighters

Wear suitable protective clothing and eye/face protection.

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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment, and emergency procedures

6.1.1 For non-emergency personnel:

Use suitable protective clothing and equipment (ref section 8).

6.1.2 For emergency responders:

Use suitable protective clothing and equipment (ref section 8).

6.2 Environmental precautions

SP1: Do not contaminate water with the product or its container [Do not clean application equipment near surface water / Avoid contamination via drains from farmyards and roads].

6.3 Methods and material for containment and cleaning up:

The spills can be disposed on the site (agricultural soil) or in public landfill or incinerated in an official incinerator

6.4 Reference to other sections

For personal protection see section 8.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Read label before use.

The usual precautions for handling chemicals should be observed. For personal protection see section 8.

Fire and explosion prevention: No specific recommendations.

7.2. Conditions for safe storage, including any incompatibilities

Storage requirements:

Store in a dry place in accordance with relevant national regulations.

Keep out of the reach of children.

Keep away from food, drink and animal food.

Keep only in original container.

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Do not store above 40°C for prolonged time.

Active substance minimum shelf life: 2 years.

Transport: Transport only in firmly sealed original containers

7.3. Specific end use(s)

See label on the container.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

There is no national exposure limit for this product.

No chemical safety report is required for this kind of product.

8.2 Exposure controls:

8.2.1 Appropriate engineering controls

Apply the spray in windless condition or in light wind only, in wind direction from other people.

8.2.2. Individual protection measures, such as personal protective equipment

Respiratory system protection: not necessary

Hand protection: rubber or plastic gloves with chemical danger symbol.

Eye and face protection: not necessary

Body protection: overall protective clothing or other protective clothes with the symbol / graphic mark "protection against chemicals

Additional head protection: not necessary

Additional feet protection: protective boots (e.g. rubber or plastic boots with regard to work in agricultural environment)

If the worker is sufficiently protected in an enclosed driver's cabin no PPAs are necessary. However at least protective gloves have to be prepared in case of failure of the device

The treated land may be re-entered when completely dried.

Do not eat, drink or smoke during application as well as after finishing, until removal of protective clothes and PPAs and thorough washing.

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Unless disposable protective clothes are used wash (clean) the protective clothes and PPAs before reuse.

Do not use contact lenses during liquid preparation and application.

The product does not require specific measures in terms of protection of birds, terrestrial vertebrates, water organisms, bees, other non-target arthropods, soil macro organisms, soil microorganisms and non-target plants.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic chemical properties

Appearance (20 °C): Light whitish amorphous powder (Visual assessment)

Odour: Slight fungi-like odour (Olfactory assessment)

Odour threshold: Not determined.

pH value: 6,5 (1% w/w aqueous suspension, 20 °C) (CIPAC MT 75.2)

Melting point/freezing point: Not determined

Initial boiling point & boiling range: Not applicable

Flash point: Not applicable

Evaporation rate: Not applicable

Flammability: Not "highly flammable" (EEC A 10)

Upper/lower flammability or explosive limits:
Not determined

Vapour pressure: not applicable

Vapour density: not applicable

Relative density: not applicable

Bulk density: 260 g/l

Solubility in water: Suspends

Partition coefficient n-octanol/water:
Not applicable

Autoignition temperature: Not applicable

Decomposition temperature: Not applicable.

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Viscosity : Not applicable

Explosive properties: Not explosive (based on the characteristics of the active substance and ingredients)

Oxidising properties: Not oxidising (based on the characteristics of the active substance and ingredients)

10. STABILITY AND REACTIVITY

10.1 Reactivity

Stable under recommended storage and handling conditions (see also section 7).

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reaction known under conditions of normal use

10.4 Conditions to avoid

No specific hazards are known.

10.5 Non-compatible materials

None known.

10.6 Hazardous decomposition products:

None known.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Not classified, the product is not hazardous.

- (a) acute toxicity: Not classified, the product is not hazardous.
- (b) skin corrosion/irritation: Not classified, the product is not hazardous.
- (c) serious eye damage/irritation: Not classified, the product is not hazardous.
- (d) respiratory or skin sensitisation: Contains *Pythium oligandrum* M1. Microorganisms may have the potential to provoke sensitising reactions.

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- (e) germ cell mutagenicity: Not classified, the product is not hazardous.
(f) carcinogenicity: Not classified, the product is not hazardous.
(g) reproductive toxicity: Not classified, the product is not hazardous.
(h) STOT-single exposure: Not classified, the product is not hazardous.
(i) STOT-repeated exposure: Not classified, the product is not hazardous.
(j) aspiration hazard: Not classified, the product is not hazardous.

12. EKOLOGICAL INFORMATION

12.1 Ekotoxicity:

The following data are applicable to the ingredient(s) listed below:

Name: Active substance, *Pythium oligandrum* M1, technical grade

Fish: LC₅₀ 96 hrs., (*Poecilia reticulata*): > 100 mg.L⁻¹

Daphnia: EC₅₀ 48 hrs., (*Daphnia magna*): 530 mg.L⁻¹

Algae: IC₅₀ 72 hrs., (*Desmodesmus subspicatus*): 598 mg.L⁻¹

Predatory mites: LR₅₀ (*Typhlodromus pyri*): > 1340 g /ha
LD_{50/24 h} (*Typhlodromus pyri*): > 1.2 mg /mite

Parasitic wasps: LR₅₀ (*Aphidius colemani*): > 1340 g /ha
LD_{50/24 h} (*Aphidius colemani*): > 1.1 mg /adult

Bees: oral LD_{50/48h} (*Apis mellifera*): > 105 µg /bee
contact LD_{50/48h} (*Apis mellifera*): > 491 µg /bee
tarsal LD_{50/24 h} (*Apis mellifera*): > 1000 µg /bee

Earthworms: LC₅₀ (*Eisenia foetida*) > 1000 mg /kg soil

12.2 Persistence and degradability:

The active substance, microorganism *Pythium oligandrum* is naturally present in the environment and suffers to microbial decomposition.

12.3 Bioaccumulative potential:

Not applicable; the active microorganism is not pathogenic to non-target organisms and has not been seen to reproduce in non-target organisms.

12.4 Mobility in soil

The active substance, microorganism *Pythium oligandrum* is natural inhabitant of soil ecosystems.

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Adsorption K_{Foc} values: not applicable for microbial substances

Desorption $K_{Foc-des}$ values: not applicable for microbial substances

12.5 Results of PBT a vPvB assessment

Microorganism *Pythium oligandrum* does not belong to PBT a vPvB.

12.6 Other adverse effects:

Pythium oligandrum may parasite cultivated *Agaricus bisporus*.

13. DISPOSAL CONSIDERATIONS

13.1 Waste:

Substance and/or Mixture: According to local regulations.. The surplus water suspension may be applied on agricultural land. For further advice contact manufacturer

Contaminated packaging: According to local regulations.

14. TRANSPORT INFORMATION

Land transport ADR/RID, Sea transport IMO/IMDG, Air transport ICAO-TI/IATA-DGR:

14.1 UN number

Not assigned, the product is not hazardous according to ADR/RID, IMO/IMDG or ICAO-TI/IATA-DGR.

14.2 UN proper shipping name

Not assigned, the product is not hazardous according to ADR/RID, IMO/IMDG or ICAO-TI/IATA-DGR.

14.3 Class / Transport hazard class

Not restricted according to ADR/RID, IMO/IMDG or ICAO-TI/IATA-DGR.

14.4 Packing group

Not assigned, the product is not hazardous according to ADR/RID, IMO/IMDG or ICAO-TI/IATA-DGR.

14.5 Environmental hazards

Marine pollutant: No

14.6 Special precautions for user

EMS: not relevant

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No other special precaution required.

15. REGULATORY INFORMATION

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

REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

The active substance (= microorganism) was listed to the list of approved active substances of the Regulation (EU) 540/2011.

16. OTHER INFORMATION

Method for evaluating information referred to in Article 9 of Regulation (EC) No 1272/2008 used for the purpose of classification:

Classification based on tests and properties of the active substance.

Changes made to the previous version:

All sections were modified according to the changes required by Commission Regulation (EU) No 453/2010.

Full text of risk phrase(s) used in this document:

none

Full text of hazard statement(s) used in this document:

none

This information only concerns the above mentioned product and does not need to be valid if used with other product(s) or in any process. The information is to our best present knowledge correct and complete and is given in good faith but without warranty. It remains the user's own responsibility to make sure that the information is appropriate and complete for his special use of this product.