SECTION 1. IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND THE COMPANY

1.1 Product identifier

Product name	**ROTSTOP® (SC)**
EC No. / Cas No.	Not applicable
REACH registration number	Exempted from Registration according to the provisions of Annex V of REACH related to micro-organisms.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Biological fungicide (plant protection product) for professional use only.
Uses advised against	Any uses except relevant identified uses described above and as listed on the product label.

1.3 Details of the supplier of the safety data sheet

Supplier	Danstar Ferment AG / LALLEMAND PLANT CARE Poststrasse 30. CH-6300 Zug, Switzerland Phone: +41 41 727 20 30 email: plantcare@lallemand.com

1.4 Emergency telephone number

Phone (EU Emergency number)	112
Phone (National Poison Center)	+358(0) 800 147 111 (24h/7)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]:
This product does not meet the criteria for classification in a hazard class according to Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures.

Hazard identification (according to Regulations for plant protection products):

None

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard Pictogram: –
Signal Word: –
Hazard Statements: –

Precautionary Statements:

P102	Keep out of reach of children.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P262	Do not get in eyes, on skin, or on clothing.
P280	Wear protective gloves/protective clothing/face protection.

Additional label elements:

EUH401	To avoid risks to human health and the environment, comply with the instructions for use.
EUH208	Contains *Phlebiopsis gigantea* strain VRA 1835. Micro-organisms may have the potential to provoke sensitizing reactions.

Labelling according to the Regulation to (EU) 547/2011 and other guidance's related to plant protection products:

–

General labelling requirements for micro-organisms (in plant protection products):

Contains *Phlebiopsis gigantea* strain VRA 1835. Micro-organisms may have the potential to provoke sensitizing reactions.

General provisions / National label elements:
Leftovers and unusable plant protection product is taken to hazardous waste collection point and empty, rinsed sales packages to the appropriate waste point.

2.3 Other hazards

Information on PBT and vPvB:

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) and does not fall under Annex XIII of Regulation (EC) 1907/2006.

Information on endocrine disrupting properties:

This substance/mixture does not contain any components considered to have endocrine disrupting properties according to REACH Article 57(f), Commission Delegated regulation (EU) 2017/2100 or to Commission Regulation (EU) 2018/605.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

Product is a mixture.

3.2 Mixtures

Ingredient (active):	***Phlebiopsis gigantea* strain VRA 1835**
CAS No. / EC No.	Not applicable
REACH Registration No.	Not applicable
Content	> 2.0 x 10^6 CFU/g
Classification according to Reg (EC) No 1272/2008 [CLP]	Not classified
SCL, M-factor, ATE	–
Other ingredients:	Mixture does not contain any other ingredients that are classified as dangerous according to Reg (EC) No. 1272/2008 [CLP].

SECTION 4. FIRST AID MEASURES

4.1 Description of First Aid Measures

Generic measures	If medical advice is needed, have the product package / container or label at hand. In the event of poisoning, consult a doctor or local poison center for treatment advice.
Eye Contact	Remove contact lenses. Hold eye open and rinse slowly and gently for 15-20 minutes with plenty of water.
Skin Contact	Take off contaminated clothing. Wash exposed skin with plenty of water and consult a doctor if skin irritation occurs.
Inhalation	Move person to fresh air. Keep the victim resting in a semi-seated position. If person is not breathing, call 112 or an ambulance, then give artificial respiration. Depending on symptoms or if severe exposure occurs, seek medical attention.
Ingestion	Rinse mouth with water. Consult a doctor if symptoms develop. Have the product container or label with you when calling a poison center or when calling / visiting a doctor or a treatment center.

4.2 Most important symptoms and effects, both acute and delayed

Micro-organisms may have the potential to provoke sensitizing reactions.

4.3 Indication of any immediate medical attention and special treatment needed

No specific treatment requirements or recommendations for medical attention exists for this product. Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media:	Water, foam, carbon dioxide, dry powder.
Unsuitable Extinguishing Media:	None known.

5.2 Special hazard arising from the substance or mixture

Hazardous combustion products: None known.

Do not inhale explosion and combustion gases. Burning may produce heavy smoke.

5.3 Advice for firefighters

Protection of firefighters: None specified.

Wear a self-contained breathing apparatus (SCBA) when exposed to confined or enclosed fires as product powder could be in the air. Collect contaminated fire extinguishing water separately. Contaminated fire extinguishing water must not be discharged into drains. Move undamaged containers from immediate hazard area, if it can be done safely.

SECTION 6. ACCIDENTIAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Avoid contact with the eyes, skin and clothing (see Section 8). Use personal protections as indicated in Section 8. Keep unauthorized people away from the concerned area. Evacuate the danger area and observe emergency procedures.

For emergency responders: Use personal protection recommended in Section 8.

6.2 Environmental precautions

Avoid release to the environment.
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 Method and materials for clean up

Small accidental spillage or leak: Avoid the formation of dust or spray. Mop up with appropriate material. Place in an appropriate container. Clean the area affected with plenty of water. Do not allow wash water to contaminate water supplies. Dispose of in accordance with local and national regulations for disposal of plant protection product waste.

Large accidental spillage or leak: Prevent spillage into the drains, subsoil or confined areas. Contain if necessary. Mop up the product spilled with inert material (e.g. dry sand or dry earth) and place in a chemical waste container. Recycle if possible. Dispose of in accordance with local and national regulations for disposal of plant protection product waste.

6.4 References to other sections

See Section 8 for personal protective equipment, occupational exposure limits and risk management measures. Refer to Section 13 for waste disposal recommendations.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Preventive measures:	Keep out of the reach of children and unauthorized persons.
Handling:	Avoid breathing dust/spray. Avoid contact with skin or eyes. Use localized ventilation system.
Occupational hygiene:	Wash hands thoroughly after handling. Do not eat, drink or smoke while working. Store work clothing separately. See also section 8 for recommended equipment.

7.2 Conditions for safe storage, including any incompatibilities

Place of storage:	Store in dry and well-ventilated place in its tightly closed original packaging, at +4°C. Keep away from food, drink and animal feeding stuffs.

7.3 Specific end use

Product is a biological fungicide used in plant protection. See detailed end uses and instructions for use on product label. For professional use only.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

National occupational exposure limit values:	None.
Other limit values:	None.
DNEL:	None.
PNEC:	None.

8.2 Exposure controls

Appropriate engineering controls:	Ensure good ventilation. This can be achieved by local exhaust ventilation or general exhaust ventilation. Avoid exposure. No exposure to the product is to be expected during normal handling.
Personal Protective Equipment:	Applicators and other handlers.
Eye / face protection:	Not needed during normal handling.

Skin protection :	Avoid contact with skin. Wear suitable protective clothing.
Hand protection:	Not needed during normal handling, but it is recommended to wear protective gloves.
Respiratory protection:	Avoid breathing spray / dust. Respiratory protection not needed during normal handling. In case of insufficient ventilation, effective dust mask (with PPF2 or PPF3 filter).
Thermal hazards:	None.
Other information:	None.

Environmental exposure controls: Active microbe is a natural and generally occurring fungus. No environmental exposure limits or controls.

Do not apply directly to water, or to areas where surface water is present. Do not contaminate water when cleaning equipment or disposing of equipment wash waters or rinsate. Do not reuse product containers. Dispose of product containers, waste containers, and residues according to local and national health and environmental regulations.

SECTION 9. PHYSICAL & CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Dark beige viscous suspension concentrate.
Odour:	Weak fungus like odour.
pH:	Approx. 7 (10% aqueous suspension)
Melting point/Freezing point:	Not relevant
Initial boiling point and boiling range:	Not relevant
Flash point:	Not relevant
Evaporation rate:	Not relevant
Flammability (solid, gas):	Not relevant
Upper/lower flammability or explosive limits:	Not relevant
Vapour pressure:	Not relevant
Vapour density:	Not relevant
Relative density:	1.15 g/mL at +20°C
Solubility in water:	Partially soluble
Partition coefficient (n-octanol/water):	Not relevant
Auto-ignition temperature:	Not relevant
Decomposition temperature:	Not relevant
Viscosity:	Not relevant
Explosive properties:	Not relevant
Oxidising properties:	Not relevant

9.2 Other information

Not available.

SECTION 10. STABILITY AND REACTIVITY

Stable under recommended conditions of storage, use and transportation.

10.1 Reactivity

Not reactive. No hazardous reactions when transported, stored, and handled according to prescribed instructions.

10.2 Chemical stability

Product is stable under normal conditions of use, storage, and transportation.

10.3 Possibility of hazardous reactions

Product is stable and hazardous reactions do not occur under recommended conditions of use, storage, and transportation.

10.4 Conditions to avoid

No specific data.

10.5 Incompatible materials

Acids, bases, concentrated fertilizer liquids, chemical pesticides, food, drink and animal feeding stuffs.

10.6 Hazardous decomposition products

Under recommended storage and use conditions, no hazardous decomposition products should appear. In case of fire, see section 5.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on toxicological data assessed:

Toxicological data originates from experimental data (testing results) made with the substance (*Phlebiopsis gigantea* strain VRA 1835) and/or the product. This data applies to the substance as well as to the product (mixture) as a whole, as no other components / ingredients with toxicological hazard properties are included in the substance or the product.

Acute toxicity:	**No toxicity, infectivity or pathogenicity.**
Oral:	LD_{50} (rat) > $4.26x10^7$ CFU/kg of body weight.
Dermal:	LD_{50} (rat) > 2 g/kg of body weight.
Inhalation:	Not toxic, pathogenic or infective to rat (LC_{50} > $1.12x10^6$ CFU/kg body weight).
Intraperitoneal:	Not toxic, pathogenic or infective to rat (NOEC > $1.27x10^5$ CFU/per animal).
Skin corrosion/irritation:	Not irritating (rabbit). Not classified.
Serious eye damage/irritation:	Mild eye irritation (rabbit). Not classified.
Respiratory / Skin sensitization:	Micro-organisms may have the potential to provoke sensitizing reactions. Not a skin sensitizer (guinea pig).
Germ cell mutagenicity:	No data available. Not required for microbial based product.
Carcinogenicity:	No data available. Not required for microbial based product.
Reproductive toxicity:	No data available. Not required for microbial based product.
STOT-single exposure:	No data available. Not required for microbial based product.
STOT-repeated exposure:	No data available. Not required for microbial based product.
Aspiration hazard:	No data available. Not required for microbial based product.
Other information:	No further information. No classification required based on toxicological information.

According to the Regulation (EC) No. 1272/2008, ROTSTOP® (SC) is not classified.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

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.

11.2.2. Other information

No other known hazards.

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Information on ecotoxicological data assessed:
Toxicological data originates from experimental data (testing results) made with the substance (*Phlebiopsis gigantea* strain VRA 1835) and/or the product. This data applies to the substance as well as to the product (mixture) as a whole, as no other components / ingredients with ecotoxicological hazard properties are included in the substance or the product.

Mammals:	Not toxic or pathogenic (LD_{50} oral (rat) > $4.26x10^7$ CFU/kg of body weight).
Birds:	No data. No toxic or pathogenic effects expected.
Fish:	No data. No toxic or pathogenic effects expected.
Daphnia magna:	No data. No toxic or pathogenic effects expected.
Algae:	No data. No toxic or pathogenic effects expected.
Aquatic macrophytes:	No data. No toxic or pathogenic effects expected.
Honeybees:	Not toxic or pathogenic (48 h LD_{50} > 100 µg product / bee (oral, contact) (*Apis mellifera*).
Bumblebees:	No data. No toxic or pathogenic effects expected.
Arthropods (other than bees):	No data. No toxic or pathogenic effects expected.
Earthworms:	No data. No toxic or pathogenic effects expected.
Soil micro-organisms:	No data. No toxic or pathogenic effects expected.

12.2 Persistence and degradability

Degradability expected to be easy, as for other naturally occurring soil microbes.

12. 3 Bioaccumulative potential

No expected bio accumulative potential.

12.4 Mobility in soil

Phlebiopsis gigantea strain VRA 1835 is not mobile in soil.

12.5 Results of PBT and vPvB assessment

This substance / mixture does not contain any substances that are assessed or considered to be PBT or vPvB.

12.6 Endocrine disrupting properties

This substance / mixture does not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in Section B of Regulation (EU) No 2017/2100.

12.7 Other adverse effects

No other known adverse effects on non-target organisms.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Disposal instructions: Dispose of contents and container in accordance with local and national regulations.
Do not throw the product or packaging / containers into waters, ponds, rivers or ditches.

Product disposal: To avoid wastes, use all material in this package / container by application according to label instructions. If wastes cannot be avoided, offer remaining product to an appropriate waste collection point according to national and local pesticide disposal requirements and instructions.

Sewage disposal: Waste should not be disposed of by release to sewers.

Packaging disposal: Rinse empty packaging / container with water to reduce any potential product residue in the packaging / container to insignificant amounts. Empty, rinsed packages / containers are disposed to appropriate waste collection point according to national and local requirements and instructions. Do not reuse or refill the packages / containers for other purposes.

SECTION 14. TRANSPORT INFORMATION

General: Product is not classified as dangerous goods according to international transportation regulations in force ADR, RID, ADN, OACI/IATA and OMI/IMDG.

14.1. UN number or ID number: Not applicable, not regulated.

	Road/rail transport (ADR/RID)	Sea transport (IMDG code)	Air transport (IATA)
14.2. UN proper shipping name	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)	Not applicable	Not applicable	Not applicable
14.4. Packing group	Not applicable	Not applicable	Not applicable

14.5. Environmental hazards	None	None	None

14.6. Special precautions for user: None.

14.7. Maritime transport in bulk according to IMO instruments: Product is not intended for bulk transport.

SECTION 15. REGULATORY INFORMATION

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

Safety Data Sheet and Classification in accordance with following **EU Regulations**:

COMMISSION **REGULATION (EU) 2020/878** of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

CLP Regulation (EC) 1272/2008 on classification, labelling, and packaging of substances and mixtures, amending and repealing Directives 67/548/EC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Regulation (EU) 453/2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (**REACH**).

Regulation (EU) 453/2010 ANNEX II: Requirements for the compilation of safety data sheets.

Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

Directive 1999/45/EC concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

Regulation (EU) 547/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products.

Directive 2003/82/EC regarding standard phrases for special risk and safety precautions for plant protection products.

Directive 2001/36/EC concerning the placing of plant protection products on the market.

Authorizations

Active substance authorization:

Commission Implementing Regulation (EU) 2020/1003 of 9 July 2020 renewing the approval of the active substances *Phlebiopsis gigantea* strain VRA 1835, VRA 1984 and FOC PG 410.3 as a low-risk active substances in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Product (mixture) authorization(s):

Product authorizations have been granted in EU Member States by national Competent Authorities and national specific authorization / registration numbers are assigned for the product.

15.2 Chemical safety assessment

Chemical safety assessment	No Chemical Safety Assessment has been carried out for this substance/mixture under Regulation (EC) 1907/2006 (REACH).
Other safety assessment	Active substance and formulated end product/mixture regulated, assessed, and approved as plant protection product under Regulation (EC) 1107/2009, (EU) 540/2011 and Directive 91/414/EEC.

SECTION 16. OTHER INFORMATION

Indication of changes: Revision of Section 1 to 16.

Abbreviations and acronyms:

ADR	Accord European Relatif au International Transport des Marchandises Dangereuses par Route (= European Agreement concerning the International Carriage of Dangerous Goods by Road)
CFU	Colony forming units
CLP	Classification, Labeling and Packaging (REGULATION (EC) No. 1272/2008 on classification, labeling and packaging of substances and mixtures)
EC_{50}	Average effective concentration
ECHA	European Chemicals Agency
EC	European Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances

EN	European standards
EU	European Union
IATA	International Air Transport Association (= International Air Transport Association)
IMDG Code	International Maritime Code for Dangerous Goods
LC_{50}	Lethal Concentration to 50% of a test population
LD_{50}	Lethal Dose to 50% of a test population (Median Lethal Dose) (= lethal dose for 50% of a test population (median lethal dose))
n.a.	not applicable
NOEC	No observed effect concentration
NOAEC	No observed adverse effect concentration
PBT	persistent, bioaccumulative and toxic
vPvB	very persistent and very bioaccumulative

Key literature and sources of data:

CLP Regulation (EC) 1272/2008, Regulation (EU) 453/2010 and Directive 1999/45/EC with amendments. Guidelines and Instructions for the creation of safety data sheets in the current version (ECHA). Guidelines on labelling and packaging in accordance with Regulation (EC) No. 1272/2008 (CLP) as amended (ECHA). Regulations for the transport of dangerous goods by road, rail, sea and air transport (ADR, RID, IMDG, IATA) in the currently valid version

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Classification: Not classified.

Procedure: On basis of test data made with active substance and/or product. Data evaluated by authorities and experts according to Uniform Principles.
Active substance and formulated end product/mixture regulated, assessed, and approved as plant protection product under Regulation (EC) 1107/2009, (EU) 540/2011 and Directive 91/414/EEC.
The product has been validated, assessed and classified according to Regulation (EC) 1272/2008 [CLP] with amendments, Directive 1999/45/EC, Regulation (EC) No 1107/2009, Regulation (EU) 547/2011 and Directive 2003/82/EC.

Relevant H-statements (number and full text): No H-statements.

Training advice for workers: No specific recommendations.

VERSIONS

Version No.	Date	Modification	Author
1	2024 04 22	Creation of national SDS according to Reg (EC) No. 2020/878	MB

DISCLAIMER

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