Trade name: LEPINOX PLUS

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

1.1. Product identifier

Substance/Mixture name: **LEPINOX PLUS.**

Product form: mixture.

Product code: LSI001.

IUPAC name: -

Other means of identification

Classification according to Annex VI of Reg. 1272/2008: -

CAS No.: -

EC No.: -

REACH registration No.: -

CIPAC No.: -

Unique formula identifier (UFI): -

Other: -

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

Relevant identified uses

Plant protection product for professional use. Insecticide for agriculture.

Uses advised against

All the uses not reported on the label.

Reason why uses advised against

Intended for agricultural usage only, it is dangerous for other purposes.

1.3. Details of the supplier of the safety data sheet

Supplier:	**CBC** (Europe) S.r.l.
Street address/P.O. Box:	Via Zanica 25
Country ID/Postcode/Place:	24050 Grassobbio (BG), Italy
Telephone number:	+39-035-335313
Fax:	+39-035-335334
e-mail address of competent person responsible for SDS:	infobiogard@cbceurope.it
National contact:	infobiogard@cbceurope.it

1.4. Emergency telephone number

Emergency telephone number: **(+44) 111** National Health Service (NHS).

Opening hours: 24h/7d.

Other comments (e.g. language of the phone service): English.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP):

Product is not classified.

Classification information:
Classification and labelling are based on toxicological studies on the active substance (substance) and the product (mixture).
Classification and labelling with regards to water pollution risks are based on ecotoxicological studies performed on the active substance (substance) and the product (mixture).
This product is assessed and classified using the methods and criteria below referred to in Article 9 of Regulation (EC) 1272/2008 (CLP):
Physical hazards: determined though assessment data based on the methods or standards referred to in Part 2 of Annex I to CLP.
Health hazards and environmental hazards: determined though toxicological and ecotoxicological assessment data based on the methods or standards referred to in Part 3, 4 and 5 of Annex I to CLP.

For full text of Hazard-, Precautionary- and EU Hazard-statements: see section 16.

2.2. Label elements

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

Hazard pictograms: -

Signal word: -

Hazardous component(s) to be indicated on the label: -

Hazard statements: -

Precautionary statements:

P102: Keep out of reach of children.

P262: Do not get in eyes, on skin, or on clothing.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P501: Dispose of contents/container to a licensed hazardous waste disposal contractor or collection site except for triple rinsed empty containers which can be disposed of as non-hazardous waste.

Supplemental hazard information:

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

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

2.3. Other hazards

The product should be handled according to the label and SDS instructions.

PBT assessment: the components of this product are not considered to be PBT.

vPvB assessment: the components of this product are not considered to be vPvB.

Do not use by people who are highly immunocompromised or under immunosuppressive therapy.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable, the product is not a substance or nanoform.

3.2. Mixtures

Type of formulation:

Solid plant protection formulation, wettable powder [WP].

Active ingredient: *Bacillus thuringiensis*, subspecies *kurstaki*, strain EG 2348.

IRAC Mode of Action (MoA) classification: 11A.

Substance name	Index no.	EC no.	CAS no.	REACH registration no.	% [weight]	Classification Reg. 1272/2008	SCL, M-Factor, ETA
Bacillus thuringiensis, subsp. *kurstaki* strain EG 2348	-	614-245-1	68038-71-1	Not subject to registration	37.5% (32.000 I.U./mg *T.ni* of formulated product)	Not classified. Micro-organisms may have the potential to provoke sensitizing reactions.	-

For full text of Hazard-, Precautionary- and EU Hazard-statements: see section 16.

Not applicable, the product does not contain a nanoform.

Name of (set of) nanoform(s)		-	
		value	Unit
Number based particle size distribution	d10	-	
	d50	-	
	d90	-	
Shape and aspect ratio of particles		-	
Crystallinity		-	
Surface functionalisation/-treatment	Agent(s)	-	
	Process	-	
Specific surface area		-	
Additional information		-	

SECTION 4: First aid measures

4.1. Description of first aid measures

General notes:

In the event of any complaints or symptoms, avoid further exposure. Avoid contact with skin and eyes.
The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the safety data sheet and/or label of this product.
The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.
In case of animal poisoning, contact your veterinarian.

Route of exposure	First aid	Second aid	Manoeuvres to avoid
Inhalation	Move exposed person from the area to fresh air. Keep the affected person warm and at rest.	If person is not breathing, call an ambulance, then give artificial respiration. Call a poison control centre or physician for further treatment advice.	Avoid mouth-to-mouth contact by using a barrier device.
Skin contact	Take off contaminated clothing or jewellery that have been in contact with the chemical. Rinse skin with plenty of water for 15-20 minutes. Make sure the water is cool.	In case of irritation or rash, call a poison control centre or physician for further treatment advice.	Do not brush away chemicals with your bare hands.
Eye contact	Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Make sure the water is cool. Remove immediately contact lenses, if present.	Call a poison control centre or a physician (ophthalmologist) for further treatment advice.	Do not attempt to manually remove anything from the eyes.
Ingestion	If victim is fully conscious, immediately give plenty of water to drink and rinse the mouth. If vomiting occurs naturally, lie the exposed person on his side, in the recovery position.	Call a poison control centre or physician for further treatment advice.	Do not induce vomiting without medical advice and never give anything by mouth to an unconscious person.

Note: see section 8.2 for the PPE.

Self-protection of the first aider:

Wear suitable PPE (see section 8.2) to protect yourself from exposure to the chemical. Pay attention to self-protection.

4.2. Most important symptoms and effects, both acute and delayed

Acute effects:

Skin: redness, burning, tearing, itching.

Nose: no data available.

Eyes: redness, burning, tearing, itching.

Lung: no data available.

Delayed effects:

Skin: no data available.

Brain: no data available.

4.3. Indication of any immediate medical attention and special treatment needed

See section 4.1.

May cause allergic reactions. Therapy: symptomatic.

Bacillus thuringiensis, subsp. *kurstaki* (Btk), strain EG 2348 has been shown to be sensitive to a broad range of antibiotics commonly used in human and veterinary medicine. The strain Btk EG 2348 has intrinsic resistant to Ampicillin and Penicillin G and is susceptible to Chloramphenicol, Clindamycin, Erythromycin, Gentamicin, Kanamycin, Streptomycin, Tetracyclin and Vancomycin. The strain is not multiresistant.

SECTION 5: Firefighting measures

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies.
Fire extinguishers and wall hydrants (small hose stations) are needed in an adequate number and they must be available and easy to access in all areas.
Eliminate any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation or explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium; all the materials used for the firefighting must be disposed in a proper manner.

5.1. Extinguishing media

Suitable extinguishing media:

Water spray, carbon dioxide (CO_2), dry chemical powder, alcohol resistant foam.

Unsuitable extinguishing media:

IT IS NOT RECOMMENDED to use tap water as an extinguishing agent.

5.2. Special hazards arising from the substance or mixture

Combustion or thermal decomposition may generate toxic vapours: nitrogen oxides, carbon monoxide, hydrocarbons.

5.3. Advice for firefighters

Firefighting instructions:

Exercise caution when fighting any chemical fire.
Fight fire from safe distance and protected location.
Do not breathe fumes.
Cool closed containers exposed to fire with water spray.
If possible, take the containers out of dangerous zone.
Contain fire-fighting water with dikes or absorbents to prevent migration and entry into sewers, streams or groundwaters. All the materials used for the firefighting must be disposed in a proper manner.

Protection during firefighting:

Wear suitable protective clothing, gloves, eye/face protection and respiratory protection. Wear a self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:

The following information shall be addressed to suitably trained personnel working in the installation units where the mixture is normally used and shall be designed to ensure, where possible without risk, preliminary security operations prior to departure and pending emergency response.
Wear appropriate personal protection equipment: protective clothing, gloves, goggles, mouth/face masks. Avoid direct skin or eye contact with the product.
Persons not involved in emergency response shall be removed from the area affected by the spillage.
Contain and/or stop the leak if the operation is safe. Eliminate all possible sources of ignition.
If possible, operate over wind.

For emergency responders:

The following information shall be addressed to experienced personnel such as emergency team personnel and, for that purpose, trained personnel.
Wear appropriate personal protection equipment: protective clothing, gloves, goggles, mouth/face masks and in case self-contained breathing apparatus. Avoid direct skin or eye contact with the product.
Persons not involved in emergency response shall be removed from the area affected by the spillage.
Contain and/or stop the leak if the operation is safe. Eliminate all possible sources of ignition.
If possible, operate over wind.
All equipment used during the operation must be grounded. It can also be effective to dilute the spree with water. Avoid formation of dust formation.

Emergency procedure:

Evacuate area.
Contain and/or stop any spills with dikes or absorbents to prevent migration and entry into sewers, streams or groundwater.
Ensure adequate ventilation.
Contact the authorities.
Dispose spill control material and, depending on the product spilled, decontaminate all tools, machines and the area.
Avoid direct contact with the mixture.

6.2. Environmental precautions

In case of an uncontrolled or an incidental spill, regional or national environmental agencies must be immediately notified. Avoid any dispersion of spilled material in soil, waterways, sewage drains.
Do not reuse product containers. Dispose of product containers, waste containers, and residues according to local and national health and environmental regulations.

6.3. Methods and material for containment and cleaning up

For containment:

Stop the spill source sealing leaky barrel(s) or container(s).
Use appropriate equipment to block drains, sewer grates or water outlets.
Use absorbent materials (sand, diatomaceous earth, universal binders, sawdust), or pads, or SOCs or mats to prevent the spill from spreading.

For cleaning up:

For small spills, after the spill absorption with pads or absorbent materials, clean up by sweeping with

shovels and put in an approved chemical container closed and properly labelled. Seal the container and handle in an approved manner. Try to keep dust to a minimum. Flush the area with water to remove any residues. Do not allow wash water to decontaminate water supplies.
Rinse application equipment thoroughly with water and spray over already treated area. Dispose of in accordance with local regulations for disposal of non-hazardous waste.

Other information:

Check for any local site procedures.

6.4. Reference to other sections

Information regarding safe handling, see section 7. Information regarding personal protective equipment, see section 8. Information regarding waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures:

Measures to prevent fire: store in a dry and cold area. Store in original containers and keep containers closed when not in use.

Measures to prevent aerosol and dust generation: store in original containers and keep containers closed when not in use.

Measures to protect the environment: store in original containers and keep containers closed when not in use.

Advice on general occupational hygiene:

Always wash your hands immediately after handling this product, and once again before leaving the workplace. Remove PPE immediately after handling this product and do not wear gloves into the hallways because it can lead to spreading contamination into the hallways. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Contaminated work clothing should not be allowed out of the workplace. Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Store in a dry area inaccessible to children. Store in original containers and keep containers closed when not in use. Keep away from heat and direct sunlight. Do not store the product in extreme heat or cold temperature. Keep out from freezing. Keep away from food, drink and animal feeding stuffs.

At room temperature (20 °C) product is stable for 3 years.

Packaging materials:

Use original packaging; reclose the package if partially used.

Requirements for storage rooms and vessels:

Store in dry, cool, well-ventilated area.

7.3. Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated. Always read the label and product information before use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The product does not contain significant quantities of substances whose limit values must be monitored in the working environment. In the case of small accidental spillage of material in production facilities, standard protection measures and PPE adequately protect workers and their health.

Substance name: -	EC number: -	CAS number: -
Eight-hour time weighted average (TWA): -		
Short-term limits/excursion limits (STEL): -		
Biological limit values/biological guidance values (BLV/BGV): -		

Derived No Effect Level(s) (DNELs)

Route of exposure	**Acute effect local**	**Acute effects systemic**	**Chronic effects local**	**Chronic effects**
Oral	Not required			
Inhalation	no hazard identified	no hazard identified	no hazard identified	no hazard identified
Dermal	no hazard identified	no hazard identified	no hazard identified	no hazard identified

Note: (i) hazard identified but no DNEL available, (ii) no exposure expected, (iii) no hazard identified.

Predicted No Effect Concentration(s) **(PNECs)**

Environmental protection target	**PNEC**
Fresh water	no hazard identified
Freshwater sediments	no hazard identified
Marine water	no hazard identified
Marine sediments	no hazard identified
Secondary poisoning *via* food chain	no hazard identified
Microorganisms in sewage treatment	no hazard identified
Soil (agricultural)	no hazard identified
Air	no hazard identified

Note: (i) hazard identified but no PNEC available, (ii) no exposure expected, (iii) no hazard identified.

8.2. Exposure controls

Appropriate engineering controls:

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure ventilation is adequate.

Individual protection measures, such as personal protective equipment:

Use personal protective equipment in accordance with the standards set by European and national

regulations.



Eye and face protection: Wear goggles (conforming to EN166, Field of Use= 5 or equivalent).

Skin protection: Wear protective gloves and protective clothing against biological and chemical agents at least type 6-B according to UNE EN14126:2004. Wash when contaminated and dispose of when contaminated inside, when perforated or when contamination on the outside cannot be removed. Wear standard coveralls and Category 3 Type 5 suit.

Respiratory protection: Wear disposable filtering facepiece respirator to at least EN149 FFP3 or equivalent.

Thermal hazards: -

Environmental exposure controls:

Keep away from foodstuffs, beverages and feed. Follow all applicable environmental protection legislation. Discharge into the environment must be avoided. Do not contaminate surface and groundwater.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Physical state: powder.

b) Colour: curry (RAL 1027).

c) Odour: characteristic.

d) Melting point/freezing point: no data available.

e) Boiling point or initial boiling point and boiling range: no data applicable.

f) Flammability (EEC A.10): not flammable.

g) Lower and upper explosion limit: no data available.

h) Flash point (EEC A.10): not flammable.

i) Auto-ignition temperature (EEC A.16): > 400 °C.

j) Decomposition temperature: no data available.

k) pH (CIPAC MT 75.3): 6.24, 1% solution in demineralised water at ambient temperature.

l) Viscosity: no data applicable.

m) Solubility: water soluble.

n) Partition coefficient n-octanol/water (log K_{ow}): not available.

o) Vapour pressure: no data applicable.

p) Density and/or relative density (CIPAC MT 186): 0.579 g/ml (tap density).

q) Relative vapour density (gas and liquids): no data applicable.

r) Particle characteristics (solids): by laser diffraction D(v, 0.1) = 3.66 µm, D(v, 0.5) = 16.45 µm, D(v, 0.9) = 49.11 µm (OECD 110).

9.2. Other information

Information with regard to physical hazard classes:

a) Explosives (EEC A.14): no explosive properties.
b) Flammable gases: no data applicable.
c) Aerosols: no data applicable.
d) Oxidising gases: no data applicable.
e) Gases under pressure: no data applicable.
f) Flammable liquids: no data applicable.
g) Flammable solids (EEC A.15): not flammable.
h) Self-reactive substances and mixtures: no data available.
i) Pyrophoric liquids: no data available.
j) Pyrophoric solids: no data applicable.
k) Self-heating substances and mixtures: no data available.
l) Substances and mixtures, which emit flammable gases in contact with water: no data available.
m) Oxidising liquids: no data applicable.
n) Oxidising solids (EEC A.21): no oxidising properties.
o) Organic peroxides: no data applicable.
p) Corrosive to metals: no data available.
q) Desensitised explosives: no data available.

Other safety characteristics:

a) Mechanical sensitivity: no data available.
b) Self-accelerating polymerisation temperature: no data available.
c) Formation of explosible dust/air mixtures: no data available.
d) Acid/alkaline reserve: no data applicable.
e) Evaporation rate: no data applicable.
f) Miscibility: no data applicable.
g) Conductivity: no data available.
h) Corrosiveness: no data applicable.
i) Gas group: no data applicable.
j) Redox potential: no data applicable.
k) Radical formation potential: no data applicable.
l) Photocatalytic properties: no data available.

SECTION 10: Stability and Reactivity

10.1. Reactivity

The product is stable at normal handling and storage conditions. No known hazardous reactions when handled and stored according to stated provisions.

10.2. Chemical stability

Stable under normal ambient conditions and under the anticipated conditions of use (see section 7).

10.3. Possibility of hazardous reactions

No special risks of hazardous reactions under normal conditions. Hazardous polymerization does not occur. It is not explosive and does not exhibit oxidant properties.

10.4. Conditions to avoid

Extreme heat or cold temperature. Keep out from freezing.
Avoid water with a pH greater than 8, otherwise use an acidifier agent.
Avoid sources of radiation, static electricity.

10.5. Incompatible materials

The product is not miscible with alkaline products such as Bordeaux mixture, calcium polysulphide etc.
Store only in the original container.

10.6. Hazardous decomposition products

Combustion or thermal decomposition may generate toxic vapours: nitrogen oxides, carbon oxides, hydrocarbons.

SECTION 11: Toxicological Information

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

a) Acute toxicity:

LD_{50} (oral, rat):

Mixture (study on a very similar mixture): > 5.9 and 7.9 x 10^8 CFU per kg bw for males and female rats, respectively. No mortalities, no toxicity, no infectivity.
Method: US EPA OPPTS 885.3050.

Mixture (study on a very similar mixture): > 5050 mg/kg bw. No mortalities, no toxicity, no infectivity.
Method: US EPA OPPTS 870.1100.

LD_{50} (dermal, rat):

Mixture (study on a very similar mixture): > 5050 mg/kg bw. No mortalities, no toxicity, no infectivity.
Method: US EPA OPPTS 870.1200.

LC_{50} (inhalation, rat):

Mixture (study on a very similar mixture): > 1.0 mg/L (3.4 x 10^7 CFU *Bacillus thuringiensis* per litre of air) for male and female rats. No mortalities, no toxicity, no infectivity.
Method: US EPA OPPTS 870.1300.

b) Skin corrosion/irritation (rabbit, very similar mixture, OECD 404): slightly irritating to the skin.

c) Serious eye damage/irritation (rabbit, very similar mixture, OECD 405): not irritating for eye.

d) Respiratory or skin sensitisation (guinea pig, mixture, OECD 406): not sensitising for skin.

e) Germ cell mutagenicity: no indications of genotoxicity are known for *Bacillus thuringiensis*, subspecies *kurstaki*.

f) Carcinogenicity: not required.

g) Reproductive toxicity: *Bacillus thuringiensis*, subspecies *kurstaki* is not an intracellular replicating microorganism, cell culture studies are not required.

h) Summary of evaluation of the CMR properties: no data available.

i) STOT-single exposure: no data available.

j) STOT-repeated exposure: no data available.

k) Aspiration hazard: no data available.

Conclusion: based on the available data, the classification criteria are not met.

11.2. Information on other hazards

Endocrine disrupting properties:

No data available.

Other information:

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Acute toxicity:

Birds (*Northern bobwhite*, 30 days, 5 days exposure):

Mixture (study on a very similar mixture): LD_{50} > 3333 mg a.i./kg bw equivalent to > 3.3×10^{10} CFU/kg bw/day. No pathogenicity observed in the study.
Method: FIFRA guideline No. 154-16.

Mammals (*ICR albino mice*):

Mixture (study on a very similar mixture): LD_{50} > 4.6×10^{11} CFU/kg bw. No mortality or significant toxic effects, clearance not investigated.
Method: US EPA OPPTS 870.1100.

Fish:

Rainbow trout (*Oncorhynchus mykiss*, 30 days, semi-static condition):
Mixture (study on a very similar mixture): LC_{50} > 10 mg a.i./L equivalent to > 1.0×10^{9} CFU/L.
Method: FIFRA guideline No. 154A-19.

Rainbow trout (*Oncorhynchus mykiss*, 30 days, semi-static condition):
Mixture (study on a very similar mixture): LC_{50} > 41.5 mg a.i./L equivalent to > 1.0×10^{6} CFU/L.
Method: FIFRA guideline No. 154A-19.

Sheepshead minnow (*Cyprinodon variegates*, 32 days, semi-static condition):
Mixture (study on a very similar mixture): LC_{50} > 100 mg a.i./L equivalent to > 1.05×10^{10} CFU/L.
Method: FIFRA guideline No. 154A-19.

Aquatic invertebrates:

Daphnia magna, 21 days, semi-static condition:

Substance: EC_{50} > 8.4×10^8 CFU/L.
Method: FIFRA Guideline 154A-19.

Daphnia magna, 48 h, static condition:

Mixture (study on a very similar mixture): EC_{50} > 41.5 mg a.i./l.
Method: OECD 202.

Algae/aquatic plants:

Selenastrum capricornutum, acute toxicity (72 h), static condition:

Mixture (study on a very similar mixture): EC_{50} > 1.0×10^9 CFU/L (> 42 mg Btk/L).
Method: OECD No. 201.

Selenastrum capricornutum, acute toxicity (96 h), static condition:

Mixture (study on a very similar mixture): EC_{50} > 1.47 mg/L
Method: FIFRA Guideline 154-22.

Bees (*Apis mellifera*, 48 h):

Substance: contact LD_{50} > 25 µg a.i./bee, oral LD_{50} > 100 µg a.i./bee.
Method: contact FIFRA guideline No. 154-24; oral OECD 213.

Non-target arthropods:

Brachymeria intermedia (48 hours, laboratory limit test, contact):

Substance: LR_{50} > 0.56 mg Btk/animal.

Green lacewing larvae (48 hours, laboratory limit test, contact):

Substance: LR_{50} > 0.56 mg Btk/animal.

Chrysopa carnea larvae (96 hours, Bell Jar dusting test, contact, residue & oral):

Substance: LR_{50} > 2.24 kg Btk/ha.

Ladybird beetles (48 hours, laboratory limit test, contact):

Substance: LR_{50} > 0.56 mg Btk/animal.

Aphidius rhopalosiphi (adult):

Substance: LR_{50} > 1968.8 g Btk/ha.

Typhlodromus pyri (adult):

Substance: LR_{50} > 1968.8 g Btk/ha.

Soil macroorganisms *(Eisenia fetida*, 14 day):

Substance: LC_{50} > 1000 mg a.i./kg artificial soil.
NOEC = 1000 mg a.i./kg artificial soil.
Method: OECD No. 207.

Soil microorganisms: no classification required.

12.2. Persistence and degradability

Abiotic degradation:

The mixture and its components are easily degradable. *Bacillus thuringiensis* shows a rapid loss of activity in

response to UV light; increasing humidity also contributes to this reduction. High values of pH (pH > 8) also decrease the insecticidal activity.

Physical- and photo-chemical elimination:

Rapid loss of activity in response to UV light.

Biodegradation:

No data available.

12.3. Bioaccumulative potential

The active substance *Bacillus thuringiensis* does not multiply and accumulate in animal and humans.

Partition coefficient n-octanol/water (log K_{ow}): see section 9.1.

No data available.

Bioconcentration factor (BCF):

No data available.

12.4. Mobility in soil

Known or predicted distribution to environmental compartments:

Bacillus thuringiensis has a high capacity to adsorb to the clay fractions in soils and shows no evidence of leaching. Therefore, the risk of groundwater contamination is considered negligible.

Surface tension:

No data available.

Adsorption/Desorption:

Bacillus thuringiensis has a strong binding to soil with a high clay content.

12.5. Results of PBT and vPvB assessment

PBT assessment: the components of this product are not considered to be a PBT.

vPvB assessment: the components of this product are not considered to be a vPvB.

12.6. Endocrine disrupting properties

No data available.

12.7. Other adverse effects

No additional information available.

SECTION 13: Disposal considerations

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations.

13.1. Waste treatment methods

In accordance with current Regulations and, if necessary, after consultation with the site operator and/or with the responsible Authority, the product may be taken to a waste disposal site or incineration plant. Advice may be obtained from the local waste regulation Authority.

Product / Packaging disposal:

Product: dispose of the product after assessing reuse in the same or another production cycle. Dispose of the product in a manner most compatible with the environment and in accordance with local or state laws, the product may be taken to a waste disposal site or incineration plant.

Disposal: Small containers (< 10 L or < 10 kg) should be rinsed thoroughly using an integrated pressure rinsing device, or, by manually rinsing three times. Add washings to sprayer at time of filling. Dispose of empty and cleaned packaging safely. Dispose of the clean containers in a manner most compatible with the environment and in accordance with local or state laws, reusing parts and recycling components and materials when possible. Do not rinse and re-use large containers (> 25 L or > 25 kg).

Waste codes / waste designations according to LoW: data not available.

Waste treatment-relevant information:

Dispose of the clean containers in a manner most compatible with the environment and in accordance with local or state laws.

Sewage disposal-relevant information:

Release to the environment or sewage system is strictly forbidden.

Other disposal recommendations:

No additional information.

SECTION 14: Transport information

Product is not classified as hazardous in accordance with the provisions of the current legislation governing the transport of dangerous goods by road (ADR), by Rail (RID), by sea (IMDG Code) and by air (IATA).

14.1. UN number or ID number

No dangerous good in sense of transport regulations.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

No additional information available.

14.6. Special precautions for user

No additional information available.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

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

EU regulations:

Regulation (EC) 1107/2009.

Regulation 1272/2008 (CLP).

Regulation 1907/2006 (REACH).

Directive 2012/18/UE.

Authorisations and/or restrictions on use:

Authorisations: MAPP n. 16269 of 29.08.2013

Restrictions on use: -

SVHC List: no component of the mixture is on the list of substances of very high concern.

Directive 2012/18/UE: -

Other EU regulations:

-

Other National regulations:

-

15.2. Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier according to article 14 of Regulation (EC) No. 1907/2006.

SECTION 16: Other information

Revision Date:

-

Indication of changes:

-

Key literature references and sources for data:

Regulation (EC) 1107/2009 of the European Parliament as amended in each case.

Regulation (EC) 1907/2006 of the European Parliament (REACH) as amended in each case.

Regulation (EC) 1272/2008 of the European Parliament (CLP) as amended in each case.

Directive 2012/18/UE of the European Parliament as amended in each case.

Regulations concerning the ADR, RID, IMDG and IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding section.

Abbreviations and acronyms:

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

ADN: Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.

ATE: Acute Toxicity Estimate.

BLV/BGV: Biological limit values/biological guidance values.

CAS: Chemical Abstract Service number.

CLP: Classification, Labelling Packaging Regulation.

DNEL: Derived No-effect level.

ECHA: European Chemicals Agency.

EC-Number: EINECS and ELINCS Number.

IATA: International Air Transport Association.

IMDG: International Maritime Dangerous Goods.

IUPAC: International Union for Pure Applied Chemistry.

LC_{50}: Lethal Concentration to 50 % of a test population.

LD_{50}: Lethal Dose to 50% of a test population (Median Lethal Dose).

LoW: List of Wastes.

PBT: Persistent, Bioaccumulative and Toxic substance.

PPE: Personal Protection Equipment.

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.

STEL: Short-term limits/excursion limits.

STOT: Specific Target Organ Toxicity.

(STOT) RE: Repeated Exposure.

(STOT) SE: Single Exposure.

vPvB: Very Persistent and Very Bioaccumulative.

SVHC: Substances of Very High Concern.

TWA: Eight-hour time weighted average.

Relevant H-statements (number and full text): -

Relevant P-statements (number and full text): see section 2.1.

P102: Keep out of reach of children.

P262: Do not get in eyes, on skin, or on clothing.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P501: Dispose of contents/container to a licensed hazardous waste disposal contractor or collection site except for triple rinsed empty containers which can be disposed of as non-hazardous waste.

Supplemental hazard information (number and full text): see section 2.1.

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

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

Training advice:

In addition to training programs on the environment, health and safety for their workers, companies must ensure that workers read, understand, and apply the requirements of this SDS.

Safety Data Sheet in according to Regulation (EC) 878/2020 and Regulation (EC) 1272/2008 (CLP).

The above information is intended to give general health and safety guidance on the storage and transport of the product. It is not intended to apply to the use of the product for which purposes the product label and any appropriate technical usage literature available should be consulted and any relevant licenses, consents or approvals complied with. The requirements or recommendations of any relevant site or working procedure, system or policy in force or arising from any risk assessment involving the substance or product should take precedence over any of the guidance contained in this safety data sheet where there is a difference in the information given. The information provided in this safety data sheet is accurate at the date of publication and will be updated as and when appropriate. No liability will be accepted for any injury, loss or damage resulting from any failure to take account of information or advice contained in this safety data sheet.