

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

1.1. Product identifier

Product name: Amylo-X LC / Valcure
Product Type: Suspension concentrate [Code: SC]
Registered as a plant protection product according to Regulation (EC) 1107/2009

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

Identified uses: Biofungicide.

1.3. Details of the supplier of the safety data sheet

Name: Certis U.S.A., LLC
Address: 9145 Guilford Road, Suite 175
Columbia, Maryland 21046 U.S.A.

Phone Number: +1 (800) 250-5024
E-mail: sds@certisbio.com

National contact: [Please refer to the national SDS]

1.4. Emergency telephone number

Emergency number: +1 800 255-3924 (USA)

National Emergency Number: [Please refer to the national SDS]

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified as hazardous

2.2. Label elements

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

Hazard Pictogram(s): None

Signal Word: None

Hazard Statements: None

Supplemental Hazard information: EUH401: To avoid risks to human health and the environment, comply with the instructions for use.
Contains *Bacillus amyloliquefaciens* D747. Microorganisms may have the potential to provoke sensitizing reactions.

Precautionary Statements: P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P501: Dispose of contents/container according to local regulations.

Prevention: P102: Keep out of the reach of children.
[Please refer to the national SDS for additional statements]

2.3. Other hazards

The mixture does not contain PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties nor it is identified as having endocrine disturbing properties in accordance with the criteria set out Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1% by weight.

This mixture does not contain nanoforms.

SECTION 3: Composition/information on ingredients

3.1. Substances

No applicable. The product is a mixture.

3.2 Mixture

Name	Substance identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
<i>B. amyloliquefaciens</i> subspecies <i>plantarum</i> strain D747	Not applicable	5	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

- Generic measures** IF POISONING is suspected, immediately contact a physician, the nearest hospital, or the nearest poison control centre. Tell the person contacted the complete product name, and the type and amount of exposure. Describe any symptoms and follow any advice given. Have the product label with you when calling a poison control centre or doctor.
- Eye Contact:** IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control centre or doctor for further treatment advice.
- Skin Contact:** IF ON SKIN: Take off contaminated clothing and shoes. Rinse skin with plenty of water and soap. Consult a physician in case of skin irritation or rash.
- Inhalation:** IF INHALED: Move person to fresh air. If person is not breathing, call an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control centre or doctor for further treatment advice.
- Ingestion:** IF SWALLOWED: If victim is fully conscious, immediately give large amounts of water to drink and induce vomiting. Never give anything by mouth to an unconscious person.

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

May cause sensitization in some individuals.

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

Note to Physicians: No specific advice available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable Extinguishing Media:** Product is not flammable in itself. Treat for surrounding material.
- Unsuitable Extinguishing Media:** Not available.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products: No dangerous reactions known under normal conditions of use.

5.3. Advice for firefighters

Protection of Firefighters: Keep upwind of fire.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

For non-emergency personnel: Keep unauthorized people away from the concerned area. Use personal protections as indicated in Section 8. Evacuate the danger area and observe emergency procedures.

For emergency responders: Use personal protection recommended in Section 8. Isolate the hazard area and deny entry to unnecessary and unprotected personnel.

6.2. Environmental precautions

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

Methods for Containment: Contain spill. Reclaim material if possible.

Methods for Clean-Up: For small spills, contain or absorb with inert material and place in an approved chemical container. Wash the spill with water containing a strong detergent, absorb with pet litter or other absorbent material, sweep up and place in a chemical container. Seal the container and handle in an approved manner. Flush the area with water to remove any residues. Do not allow wash water to decontaminate water supplies.

Other Information: 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.

6.4. Reference to other sections

See Section 8 for occupational exposure limits and risk management measures. Refer to Section 13 for disposal considerations.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Store in a dry area inaccessible to children. Store in original containers only. Keep container closed when not in use.

7.3. Specific end use(s)

Amylo-X LC is used as biofungicide; to avoid risks to human health and the environment, comply with the instructions for use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No occupational exposure limits have been established for this substance. The standard protection measures for workers are adequately protecting their health in case material containing *B. amyloliquefaciens* D747 is released or spilled accidentally at the manufacturing facilities.

8.2. Exposure controls

Engineering Controls:	Ensure ventilation is adequate.
Personal Protective Equipment	
Eye/Face Protection:	Not required
Skin Protection	It is requested according to the below indications
Hand Protection:	Wear protective waterproof gloves.
Body Protection:	Long-sleeved shirt and long pants.
Respiratory Protection:	Wear appropriate respiratory protection.
Thermal Hazards:	Not applicable.
General Hygiene Considerations:	Handle according to established industrial hygiene and safety practices.
Environmental exposure controls:	Follow all applicable environmental protection legislation.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	Sand yellow
Odour:	Characteristic
Odour Threshold:	Not available.
pH:	4.39
Melting Point / Freezing Point:	Not applicable (since it is a mixture, only a range would be measured).
Initial Boiling Point:	Not available.
Boiling Range:	>100°C

Flash Point:	The test item has no flash point under atmospheric conditions (1013 hPA)
Evaporation Rate:	Not available.
Flammability (solid, gas):	Not highly flammable (test method according to European Commission Regulation (EC) 440/2008). Testing method: EEC A.10.
Lower & Upper Flammability Limits:	Not available.
Vapour Pressure:	Not available.
Vapour Density:	Not available.
Density:	1.06 g/mL
Solubility:	Not available.
Partition Coefficient (n-octanol/water):	Not available.
Auto-ignition Temperature:	540°C (test method according to European Commission Regulation (EC) 440/2008, Testing method EEC A.15)
Decomposition Temperature:	Not available.
Viscosity:	Not available.
Explosive Properties:	Not explosive (test method according to European Commission Regulation (EC) 440/2008). Testing method: EEC A.14
Oxidising Properties:	Not oxidising (test method according to European Commission Regulation (EC) 440/2008). Testing method: EEC A.17

9.2. Other information

Not available.

SECTION 10: Stability and reactivity

<u>10.1. Reactivity</u>	No known hazardous reactions when handled and stored according to stated provisions.
<u>10.2. Chemical stability</u>	Stable when handled and stored according to stated provisions.
<u>10.3. Possibility of hazardous reactions</u>	No known hazardous reactions.
<u>10.4. Conditions to avoid</u>	No known conditions to avoid when handled and stored according to stated provisions.
<u>10.5. Incompatible materials</u>	No known incompatible materials.
<u>10.6. Hazardous decomposition products</u>	No known hazardous decomposition products at temperatures above 250°C.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Routes of exposure: Ingestion, inhalation, skin and eye contacts

Symtoms:

Ingestion	Not known relevant nor critical effects due to the use of the product containing microorganism.
Eyes	Not known relevant nor critical effects due to the use of the product containing microorganism.
Skin	Not known relevant nor critical effects due to the use of the product containing microorganism.

May have the potential to provoke allergic reactions

Acute Toxicity

Toxicological information on the substance or mixture:

LD₅₀ (oral)	> 5000 mg/kg bw, rat, corresponding to > 2.5 10 ¹¹ CFU <i>B. amyloliquefaciens</i> D474/ kg bw, rat (study with WG product with higher concentration AI)
LD₅₀ (dermal)	> 5050 mg/kg bw, corresponding to > 2.53 x 10 ¹¹ CFU <i>B. amyloliquefaciens</i> D747/ kg bw (study with WG product with higher concentration AI)
LC₅₀ (inhalation)	> 2.18 mg/L 1.1 x 10 ⁸ CFU/L (maximum attainable concentration in air) no observed effect (study with WG product with higher concentration AI)
Skin corrosion / irritation:	Based on PII of 0.0, the test substance is rated non-irritating.
Serious eye damage/irritation:	No positive effects exhibited in any eyes after treatment, rated practically non-irritating
Respiratory or skin sensitization:	Contains <i>B. amyloliquefaciens</i> D747. Microorganisms may have the potential to provoke sensitizing reactions.
Mutagenicity:	No data available. No specific information is required for microorganism or plant protection product containing microorganism as active substance.
Germ Cell Mutagenicity:	No data available. No specific information is required for microorganism or plant protection product containing microorganism as active substance.
Carcinogenicity:	No data available.
Reproductive toxicity:	No data available.
Developmental toxicity:	No data available. No specific information is required for microorganism or plant protection product containing microorganism as active substance.
Fertility:	No data available. No specific information is required for microorganism or plant protection product containing microorganism as active substance.
Target Organs:	No data available.

- STOT-single exposure:** No data available.
- STOT-repeated exposure:** No data available.
- Aspiration hazard:** No data available.
- Repeated Dose Toxicity:** No data available. No specific information is required for microorganism or plant protection product containing microorganism as active substance.
- Narcosis:** No data available.
- Interactive Effects:** No data available.
- Chronic Effects:** No data available.

Other information on adverse health effects: No other information available.

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

SECTION 12: Ecological information

12.1. Toxicity

Low toxicity and non-pathogenic to tested aquatic species (fish, daphnia, algae), birds, bees and non-target arthropods.

Test species	Test method	Test substance	LC ₅₀
<i>Oncorhynchus mykiss</i>	30 days	<i>B. amyloliquefaciens</i> D747	LC ₅₀ > 8.1 x 10 ¹⁰ CFU/L NOEC = 1.44 x 10 ¹⁰ CFU/L
<i>Daphnia magna</i>	21 days	<i>B. amyloliquefaciens</i> D747	EC ₅₀ (mortality) > 2.3 x 10 ¹⁰ CFU/L NOEC = 2.84 x 10 ⁸ CFU/L
<i>Desmodemus subspicatus</i>	72 hours	Amylo-X WG	E _b C ₅₀ > 2.3 x 10 ¹⁰ CFU/L (144 mg/L)
<i>Apis mellifera</i> L	48-hour, dose-response test	Amylo-X WG	LD ₅₀ Oral /48 h > 446.63 µg/bee LD ₅₀ Contact /48 h > 320 µg/bee

12.2. Persistence and degradability

The active substance *B. amyloliquefaciens* D474 populations spreading to the environment during or after field application will rapidly decline to naturally occurring background levels. Survival of *B. amyloliquefaciens* is restricted by nutrient availability/competition, microbial attack (grazing/infection) and sunlight-mediated inactivation. The persistence of vegetative cells is very short while spores might persist for longer periods but will be finally degraded.

12.3. Bioaccumulative potential

The active substance *B. amyloliquefaciens* D474 does not multiply and accumulate in animal and humans.

12.4. Mobility in soil

The active substance *B. amyloliquefaciens* spores readily adsorb to the clay fractions in soils

and show no evidence of leaching. Therefore, the risk of groundwater contamination is considered negligible.

12.5. Results of PBT and vPvB assessment

Not available as chemical safety assessment not required/not conducted.

12.6. Endocrine disrupting properties

Not required for microorganisms

12.7. Other adverse effects

No data available.

12.8. Additional information

No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal Instructions:

Waste material must be disposed of in accordance with the directive on waste 2008/98/EC as well as other national and local regulations. No mixing with other waste. Handle uncleaned containers like the product itself. Waste should not be disposed of by release to sewers.

SECTION 14: Transportation information

14.1. UN number

Not regulated.

14.2. UN proper shipping name

Not regulated.

14.3. Transport hazard class(es)

Not regulated.

14.4. Packing group

Not regulated.

14.5. Environmental hazards

Not regulated.

14.6. Special precautions for user

Not regulated.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not regulated.

SECTION 15: Regulatory information

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

Regulation (EC) No. 1107/2009:

The active ingredient *B. amyloliquefaciens* D747 is approved in EU under Regulation (EC) No 1107/2009. Amylo-X LC is a biofungicide authorized in several EU Member States.

Registration number: *[add from corresponding Member State authorization database for plant protection products]*

Further information:

The active ingredient *B. amyloliquefaciens* D747 contained in this product is deposited in the ARS Culture Collection (NRRL). Peoria, Illinois, USA under the accession number B-50405.

15.2. Chemical safety assessment**Chemical Safety
Assessment:**

Not applicable for microorganism. No Chemical Safety Assessments have been carried out for this substance.

SECTION 16: Other information

Disclaimer:

The information in this Safety Data Sheet is based on the present state of knowledge and legislation. This SDS provides guidance on health, safety and environmental aspects of the product and should not be construed as any guarantee of technical performance. The product should not be used for any other purposes than those in Section 1. All material may present unknown health hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards which exist.

SDS Authoring Information:

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SDS Prepared by: Certis U.S.A., L.L.C.

Indication of changes:

Version 3.0: SDS EU format according to Commission Regulation (EU) 2020/878.
Version 3.1: minor text edits/corrections.

Label according to the PRAPeR Expert Meeting on micro-organisms in June 2009: “*Bacillus amyloliquefaciens* D747 may have the potential to provoke sensitizing reactions”.

Abbreviations and Acronyms:

ARS = Agricultural Research Service
CFU= Colony Forming Units
CIPAC = Collaborative International Pesticides Analytical Council
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
EEC = European Economic Community
EC = European Community
ECHA = European Chemicals Agency
EU = European Union
EUH statement = CLP-specific Hazard statement
LoW = List of Wastes (see <http://ec.europa.eu/environment/waste/framework/list.htm>)
IBC = IBC Code means the International Code for the Construction and Equipment of Ships carrying dangerous Chemicals in Bulk, as amended
IMO = International Maritime Organisation
LC50 = Lethal Concentration to 50 % of a test population
LD50= Lethal Dose to 50% of a test population (Median Lethal Dose)
NOEC = No Observed Effect Concentration
N/A = Not available
PBT = Persistent, Bioaccumulative and Toxic
PPE = Personal Protection Equipment
SDS = Safety Data Sheet
UN = United Nations
vPvB = Very Persistent and Very Bioaccumulative