

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

1.1. Product identifier

Product Name: FSS Papain
Product Code: FSS16517SRL

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

Recommended Use: Topical cosmetic use.
Restrictions on Use: None.

1.3. Details of the supplier of the safety data sheet

Company name: Formulator Sample Shop® Srl
Company address: Via Petrolo Litta 9, 20008 - Bareggio (Milan) Italy
Telephone number: +39 (0)2 902 78 641
Fax number: +39 (0)2 903 60 718
E-mail address: info@formulatorsampleshop.eu

1.4. Emergency telephone number

Emergency telephone number: +39 (0)2 902 78 641 - Mon-Fri: 8:30AM-5:00PM

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance/mixture

Classification:

Classification made in accordance with the Regulation n° 1272/2008 (CLP):

Skin Irrit. 2	Skin irritation, Cat. 2, H315
Eye Irrit. 2	Eye irritation, Cat. 2, H319
Resp. Sens. 1	Respiratory sensitization, Cat. 1, H334
STOT SE 3	Specific target organ toxicity - single exposure, Cat. 3, H335

2.2. Labeling Elements

Regulation n° 1272/2008 (CLP):

Pictograph:





Hazard statements/Signal Word: H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335: May cause respiratory irritation
H319: Causes serious eye irritation
H315: Causes skin irritation

Precautionary Statements: P280: Wear protective gloves/protective clothing/eye protection/face protection.
P285: In case of inadequate ventilation wear respiratory protection.
P261: Avoid breathing dust/fume/gas/mist/vapours/spray
P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313: If eye irritation persists: Get medical advice/attention.
P304 + P341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P342 + P311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

2.3. Other hazards which do not result in classification:

US NFPA 704 (National Fire Protection Association) Hazard Rating System:

Health hazard: Rating 0; Normal Material
Flammability: Rating 0, Will Not Burn
Reactivity: Rating 0, Stable
Other Hazard Information: None

Results of PBT and vPvB assessment:

-PBT: Not applicable
-vPvB: Not applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Composition/information on ingredients

Common Chemical Name: Papain
Generic Name:
Chemical Family: Enzymes

Description: Mixture: consisting of the following components. This section describes all components of the mixture.

<u>Substance</u>	<u>CAS Numbers</u>	<u>EC Numbers</u>	<u>Percentage</u>
Papain	9001-73-4	232-627-2	100.00%

Formula: Not applicable



4. FIRST AID MEASURES

4.1. Description of first aid measures

General:	In all cases of doubt, or when symptoms persist, seek medical attention.
Direct contact with skin:	Rinse immediately with soap and water. Get medical advice if irritation develops.
Direct contact with eyes:	Immediately rinse with plenty of water for at least 15 minutes, while keeping the eyes wide open. Consult with a physician.
Inhalation:	Move to fresh air from exposure area. Get medical attention for any breathing difficulty.
Ingestion:	Consult with a physician.
Protection of first-aiders:	No special protection required.

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

Symptoms and effects: No data available

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

Indication: No data available

5. FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguishing Media: Use media appropriate for the surrounding fire.

5.2. Special hazards arising from the substance/mixture

Unusual Fire and Explosion Hazards: None known

5.3. Advice for firefighters

Special Fire Fighting Procedures: Wear self-contained breathing apparatus for firefighting if necessary.
Move container from fire area if it can be done without risk.
Avoid inhalation of material or combustion by-products.
Stay upwind and keep out of low area.

Protection for fire-fighters: Boots, gloves, goggles.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas.



6.2. Environmental precautions

Environmental Protection Measures: Prevent entry into sewers and waterways. Do not allow material to contaminate ground water system.
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3. Methods and material for containment and cleaning up

Recovery: Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations

6.4. Reference to other sections

References: Refer to paragraphs 8 and 13 for more information.

7. HANDLING AND STORAGE

7.1. Precaution for safe handling

Safe handling advice: Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.
Keep away from sources of ignition - No smoking.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures: Keep container closed.
Recommended Storage Conditions: Store in a dry place at temperatures not exceeding 32°C. Based on stability studies, the optimum storage temperature for maximization of shelf life is 23 - 25°C. However, it may be stored at temperatures between 16 and 32°C if such specific temperature control is not available. Do not freeze. Please refer to stability data for effects heat or cold may have on the specifications of the product.
Incompatible products: Avoid contact with strong oxidizers.
Refer to the detailed list of incompatible materials (Section 10 Stability/Reactivity).
Packaging: Product may be packaged in normal commercial packaging.
Packaging materials: Recommended - Polypropylene & High Density Polyethylene.

7.3. Specific and use(s)

Use(s): Cosmetic use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Precautionary statements: Ensure adequate ventilation.



8.1. Control parameters

Occupational exposure Limits:

France:	Not Determined
ACGIH:	Not Determined
Korea:	Not Determined
UK:	Not Determined

Surveillance procedures:	Not Determined
Engineering measures:	Not Determined

8.2. Exposure controls/ Personal Protective Equipment:

Respiratory protection:	In case of insufficient ventilation, wear suitable respiratory equipment.
Hand protection	Protective gloves made of rubber or neoprene.
Eye protection:	Safety glasses/face shield.
Collective emergency equipment:	Eye fountain.
Skin and Body Protection:	Suitable protective clothing, gloves and footwear.

Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

Measures related to the Environment: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance:	Off-White to white powder
Odor:	Characteristic
Loss on Drying:	7.0% Maximum
Activity:	70 MCU Minimum
pH (1 in 50 Solution):	4.0 – 6.2
Heavy Metals:	< 20 ppm
Lead:	< 10 ppm
Arsenic:	< 2 ppm
Cadmium:	< 1 ppm



Microbial Content:	< 100 CFU/g; No pathogens
Yeast & Mold:	< 100 CFU/g
Gram Negative Bacteria:	0 CFU/g
Specific Gravity:	Not determined
Vapor density:	Not applicable
Boiling Point:	Not applicable
Freezing Point:	Not applicable
Melting point:	Not determined
Flash point:	Not applicable
Oxidizing properties:	Non oxidizing material according to EC criteria.
Solubility:	
In water:	Soluble
In organic solvents:	Not determined
Log P:	Not determined

9.2. Other information

Information: N/A

10. STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity: None known

10.2. Chemical stability

Stability: Stable under ordinary conditions of use and storage up to one year then re-test to full product specifications to extend shelf life.

10.3. Possibility of hazardous reactions

Hazardous reaction: None known

10.4. Conditions to avoid

Conditions to avoid: No dangerous reactions known under use of normal conditions.
Avoid extreme heat.

10.5. Incompatible materials

Incompatibility: No dangerous reaction known with common products.

10.6. Hazardous decomposition products

Hazardous decomposition: None known

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11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

May cause sensitization by inhalation.

Once sensitized, an allergic reaction may occur when exposed to very low levels.

Repeated dose toxicity: No known effects

Subacute to chronic toxicity: Not Determined

Specific effects:

Carcinogenicity: No known effects

Mutagenicity: No known effects

Reproductive toxicity: No known effects

Neuro-toxicity: No known effects

For more information: Does not present any particular risk on handling under normal conditions of good occupational hygiene practice.

This product has not been tested for the following:

-Primary cutaneous and corrosive irritation

-Acute oral toxicity

-Mutagenicity/genotoxicity

12. ECOLOGICAL INFORMATION

12.1. Toxicity

Toxicity: Not determined

12.2. Persistence and degradability

Persistence and degradability: Readily Biodegradable (87.9% biodegradation after 28 days of testing)

12.3. Bioaccumulative potential

Bioaccumulative potential: Not determined

12.4. Mobility

Precipitation:

Expected behavior of the product: Ultimate destination of the product: Soil & sediment.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment: Not determined



12.6. Other adverse effects

Other adverse effects: None known

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Residues from product

Prohibition: Do not allow the product to be released into the Environment.
Destruction/Disposal: Dispose of in accordance with relevant local regulations.

Contaminated packaging

Decontamination/cleaning: Cleaning is not required prior to disposal.
Destruction/Disposal: Dispose of in accordance with relevant local regulations.

Note: Take all necessary precautions when disposing of this product according to local regulations.

14. TRANSPORT INFORMATION

14.1. UN number

Number: None

14.2. UN proper shipping name

Shipping name: None

14.3. Transport hazard class(es)

Hazard class: Not classified as dangerous for transport.

Land (rail/road): Material is not restrictive for land transport and is not regulated by ADR/RID
Sea: Material is not restrictive for sea transport and is not regulated by IMO/IMDG
Air: Material is not restrictive for land transport and is not regulated by ICA/IATA

Marine Pollutant: No

Transport/Additional Information: Not regulated for US DOT Transport in non-bulk containers.
This material is not dangerous or hazardous.

14.4. Picking group

Picking group: None

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14.5. Environmental hazards

Environmental hazards: None

14.6. Special precautions for user

Precautions: None known

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Transport in bulk: N/A

The above regulatory prescriptions are those valid on the date of publication of this sheet. However, given the possible evolution of transport regulations for hazardous materials and in the event of the MSDS in your possession dating back more than 12 months, it is advisable to check their validity with your sales office.

15. REGULATORY INFORMATION

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

This Safety Data Sheet complies with the requirements of Regulation (EC) No. 1272/2008

Further regulations

United Kingdom: Handle in accordance with relevant British regulation: control of substance Hazardous to Health Regulations Environmental Hygiene Guidance: EH40 Workplace Exposure Limits (revised annually)

Korea regulations: Industrial safety and hygiene regulation: No
Hazardous material control regulation: No
Fire prevention regulation: No

Germany: Regulations concerning the classification of hazards for water (WGK – Wassergefährdungsklasse:):
- WGK 1 – Low hazard to waters (VwVwS dd 27/07/2005, KBws)

Other regulations:

EINECS inventory status: Papain: 232-627-2
TSCA inventory status: Exempt
AICS inventory status: 9001-73-4
Canadian (CEPA DSL) inventory status: Listed as Papain (DSL)
Japan (MITI list): Papain
Korea: Papain
China inventory status: Papain
Philippines inventory status: Listed as Papain

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*Listed on 2010 INCI Standard Chinese Name Directory

15.2. Chemical safety assessment

Assessment: N/A

Note: The regulatory information given above only indicates the principal regulations specifically applicable to the products described in this sheet. The user's attention is drawn to the possible existence of additional provision which complete these regulations. Please refer to all applicable international, national and local regulations and provisions

16. OTHER INFORMATION

Prohibited uses: For specific uses, food industry, ask the manufacturer for more information.

Last Revision Date: N/A

Preparation Date: 18/01/2020

MSDS summary of changes: No deletion, addition or revision to date.

Further information: This document is in accordance with EC Directive 2001/58/EC and the Regulation (EC) 1907/2006 (REACH) Annex II.
The information given is based on our knowledge of this product, at the time of publication in good faith. The attention of the user is drawn to the possible risks incurred by using the product for any other purpose other than which it was intended. This is not in any way excuse the user from knowing and applying all the regulations governing their activity. It is sole responsibility of the user to take all precautions required in handling the product. The purpose of mandatory regulation mentioned is to help the user to fulfill his obligations regarding the use of products. This information is not exhaustive, this is not exonerated the user from ensuring that legal obligations other than those mentioned, relating to the use and storage.