



SAFETY DATA SHEET FORMEA PRIME

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

1.1. Product identifier

Product name FORMEA PRIME

Product number 61903

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

Identified uses Biocatalyst Food industry Industrial application

1.3. Details of the supplier of the safety data sheet

Supplier Univar Solutions UK Ltd
Aquarius House
6 Mid Point Business Park
Bradford
BD3 7AY
+44 1274 267300
+44 1274 267306
SDS.EMEA@univarsolutions.com

1.4. Emergency telephone number

Emergency telephone SGS - +32 (0)3 575 55 55 (24h)

Sds No. 61903

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards Not Classified

Health hazards Resp. Sens. 1 - H334

Environmental hazards Not Classified

2.2. Label elements

Hazard pictograms



Signal word Danger

Hazard statements H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements P261 Avoid breathing vapour/ spray.
P284 [In case of inadequate ventilation] wear respiratory protection.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.
P501 Dispose of contents/ container in accordance with national regulations.

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Contains TRYPSIN

2.3. Other hazards

This product does not contain any substances classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

TRYPSIN	2.5 - < 5%
CAS number: 9002-07-7	EC number: 232-650-8
Classification Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 Resp. Sens. 1 - H334 STOT SE 3 - H335	

The full text for all hazard statements is displayed in Section 16.

Composition comments The data shown are in accordance with the latest EC Directives.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information	Show this Safety Data Sheet to the medical personnel.
Inhalation	Remove person to fresh air and keep comfortable for breathing. Get medical attention if any discomfort continues.
Ingestion	Immediately rinse mouth and drink plenty of water (200-300 ml). Get medical attention if any discomfort continues.
Skin contact	Take off immediately all contaminated clothing and wash it before reuse. Rinse immediately with plenty of water. Get medical attention if any discomfort continues.
Eye contact	Rinse immediately with plenty of water. Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.

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

Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Coughing. Shortness of breath. Wheezing/breathing difficulties. Effects may be delayed.
Ingestion	May cause irritation.
Skin contact	May be slightly irritating to skin.
Eye contact	May be slightly irritating to eyes.

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

Notes for the doctor Treat symptomatically. Effects may be delayed.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water fog.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.

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5.2. Special hazards arising from the substance or mixture

Specific hazards May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Hazardous combustion products When heated, vapours/gases hazardous to health may be formed.

5.3. Advice for firefighters

Protective actions during firefighting Contain and collect extinguishing water.

Special protective equipment for firefighters Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Wear protective clothing as described in Section 8 of this safety data sheet. Provide adequate ventilation. Avoid handling which leads to dust formation. Avoid the formation of mists. Do not allow to dry out.

6.2. Environmental precautions

Environmental precautions Spillages or uncontrolled discharges into watercourses must be reported immediately to the Environmental Agency or other appropriate regulatory body.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Remove spillage with vacuum cleaner or collect with a shovel and broom, or similar. Collect and place in suitable waste disposal containers and seal securely. Do not allow to dry out. Flush contaminated area with plenty of water. Clean contaminated objects and areas thoroughly, observing environmental regulations.

6.4. Reference to other sections

Reference to other sections For personal protection, see Section 8. For waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions Provide adequate ventilation. Wear protective clothing as described in Section 8 of this safety data sheet. Avoid handling which leads to dust formation. Avoid the formation of mists. Avoid breathing vapour/spray. Do not allow to dry out.

Advice on general occupational hygiene When using do not eat, drink or smoke. Take off immediately all contaminated clothing and wash it before reuse. Wash after use and before eating, smoking and using the toilet. Remove contaminated clothing and protective equipment before entering eating areas.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Store in tightly-closed, original container in a dry, cool and well-ventilated place. Store at temperatures between 0°C and 10°C.

7.3. Specific end use(s)

Specific end use(s) The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure controls/Personal protection

8.1. Control parameters

TRYPSIN (CAS: 9002-07-7)

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DMEL

Workers - Inhalation; Long term local effects: 60 ng/m³

8.2. Exposure controls

Protective equipment



Appropriate engineering controls

Provide adequate ventilation. Observe any occupational exposure limits for the product or ingredients.

Eye/face protection

Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. Unless the assessment indicates a higher degree of protection is required, the following protection should be worn: Tight-fitting safety glasses. Personal protective equipment for eye and face protection should comply with European Standard EN166.

Hand protection

Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible. The most suitable glove should be chosen in consultation with the glove supplier/manufacturer, who can provide information about the breakthrough time of the glove material. To protect hands from chemicals, gloves should comply with European Standard EN374.

Other skin and body protection

Wear suitable protective clothing as protection against splashing or contamination.

Hygiene measures

Wash after use and before eating, smoking and using the toilet. When using do not eat, drink or smoke. Remove contaminated clothing and protective equipment before entering eating areas. Take off immediately all contaminated clothing and wash it before reuse.

Respiratory protection

If ventilation is inadequate, suitable respiratory protection must be worn. Use respiratory equipment with particle filter, type P3. Ensure all respiratory protective equipment is suitable for its intended use and is 'CE'-marked.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid.
Colour	Black.
Odour	Slight.
Odour threshold	No information available.
pH	No information available.
Melting point	No information available.
Initial boiling point and range	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Evaporation factor	No information available.
Flammability (solid, gas)	No information available.
Upper/lower flammability or explosive limits	No information available.
Other flammability	No information available.

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Vapour pressure	No information available.
Vapour density	No information available.
Relative density	1.14
Bulk density	No information available.
Solubility(ies)	Immiscible with water.
Partition coefficient	No information available.
Auto-ignition temperature	No information available.
Decomposition Temperature	No information available.
Viscosity	No information available.
Explosive properties	No information available.
Explosive under the influence of a flame	No information available.
Oxidising properties	No information available.

9.2. Other information

Other information	Not available.
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SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	No information available.
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10.2. Chemical stability

Stability	Stable under the prescribed storage conditions.
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10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	Under normal conditions of storage and use, no hazardous reactions will occur.
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10.4. Conditions to avoid

Conditions to avoid	Avoid the formation of mists. Do not allow to dry out.
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10.5. Incompatible materials

Materials to avoid	None known.
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10.6. Hazardous decomposition products

Hazardous decomposition products	Does not decompose when used and stored as recommended. When heated, vapours/gases hazardous to health may be formed.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological effects	No information available.
<u>Skin corrosion/irritation</u>	
Skin corrosion/irritation	May be slightly irritating to skin.
<u>Serious eye damage/irritation</u>	
Serious eye damage/irritation	May be slightly irritating to eyes.

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Respiratory sensitisation

Respiratory sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation

Skin sensitisation No information available.

Germ cell mutagenicity

Genotoxicity - in vitro No information available.

Carcinogenicity

Carcinogenicity No information available.

Reproductive toxicity

Reproductive toxicity - fertility No information available.

Specific target organ toxicity - single exposure

STOT - single exposure No information available.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure No information available.

Aspiration hazard

Aspiration hazard No information available.

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Shortness of breath. Wheezing/breathing difficulties. Coughing. Effects may be delayed.

Ingestion May cause irritation.

Skin contact May be slightly irritating to skin.

Eye contact May be slightly irritating to eyes.

Acute and chronic health hazards May cause respiratory allergy.

Toxicological information on ingredients.

TRYPSIN

Acute toxicity - oral

Notes (oral LD₅₀) LD₅₀ >2000 mg/kg, Oral, OECD 401

Skin corrosion/irritation

Animal data Irritating.

Serious eye damage/irritation

Serious eye damage/irritation Irritating.

Skin sensitisation

Skin sensitisation Sensitising.

Germ cell mutagenicity

Genotoxicity - in vitro Based on available data the classification criteria are not met.

Specific target organ toxicity - single exposure

STOT - single exposure May cause respiratory irritation.

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SECTION 12: Ecological information

Ecotoxicity The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

12.1. Toxicity

Toxicity No information available.

Ecological information on ingredients.

TRYPSIN

Acute aquatic toxicity

Acute toxicity - fish	LC ₅₀ , 96 hours: >18.4 mg/l, Fish OECD 203
Acute toxicity - aquatic invertebrates	EC ₅₀ , 48 hours: 3.24 mg/l, Daphnia magna OECD 202
Acute toxicity - aquatic plants	EC ₅₀ , 72 hours: 0.518 mg/l, Algae OECD 201

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulative potential No information available.

Partition coefficient No information available.

12.4. Mobility in soil

Mobility No information available.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment This product does not contain any substances classified as PBT or vPvB.

12.6. Other adverse effects

Other adverse effects No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

General information	Waste is classified as hazardous waste.
Disposal methods	Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.
Waste class	Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

SECTION 14: Transport information

General The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

Not applicable.

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14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

No transport warning sign required.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant

No.

14.6. Special precautions for user

Not applicable.

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

Transport in bulk according to Not applicable.

Annex II of MARPOL 73/78

and the IBC Code

SECTION 15: Regulatory information

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

EU legislation

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as amended).
Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended).
Commission Regulation (EU) No 2015/830 of 28 May 2015.

Restrictions (Annex XVII Regulation 1907/2006)

This product is/contains a substance that is included in REGULATION (EC) No 1907/2006 (REACH) ANNEX XVII - RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES. Entry number: 3

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

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Abbreviations and acronyms used in the safety data sheet

ATE: Acute Toxicity Estimate.
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
 ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
 CAS: Chemical Abstracts Service.
 DNEL: Derived No Effect Level.
 IATA: International Air Transport Association.
 IMDG: International Maritime Dangerous Goods.
 Kow: Octanol-water partition coefficient.
 LC₅₀: Lethal Concentration to 50 % of a test population.
 LD₅₀: Lethal Dose to 50% of a test population (Median Lethal Dose).
 PBT: Persistent, Bioaccumulative and Toxic substance.
 PNEC: Predicted No Effect Concentration.
 REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.
 RID: European Agreement concerning the International Carriage of Dangerous Goods by Rail.
 vPvB: Very Persistent and Very Bioaccumulative.
 IARC: International Agency for Research on Cancer.
 MARPOL 73/78: International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978.
 cATpE: Converted Acute Toxicity Point Estimate.
 BCF: Bioconcentration Factor.
 BOD: Biochemical Oxygen Demand.
 EC₅₀: 50% of maximal Effective Concentration.
 LOAEC: Lowest Observed Adverse Effect Concentration.
 LOAEL: Lowest Observed Adverse Effect Level.
 NOAEC: No Observed Adverse Effect Concentration.
 NOAEL: No Observed Adverse Effect Level.
 NOEC: No Observed Effect Concentration.
 LOEC: Lowest Observed Effect Concentration.
 DMEL: Derived Minimal Effect Level.
 EL50: Exposure Limit 50
 hPa: Hectopascal
 LL50: Lethal Loading fifty
 OECD: Organisation for Economic Co-operation and Development
 POW: Octanol-water partition coefficient
 SCBA: self-contained breathing apparatus
 STP: Sewage Treatment Plant
 VOC: Volatile Organic Compounds

Classification abbreviations and acronyms

Acute Tox. = Acute toxicity
 Aquatic Acute = Hazardous to the aquatic environment (acute)
 Aquatic Chronic = Hazardous to the aquatic environment (chronic)

Key literature references and sources for data

Supplier's information.

Classification procedures according to Regulation (EC) 1272/2008

Resp. Sens. 1 - H334: Calculation method.

Revision comments

This is the first issue.

Revision date

24/02/2021

FORMEA PRIME

Version number	1.000
SDS number	61903
SDS status	Approved.
Hazard statements in full	H315 Causes skin irritation. H319 Causes serious eye irritation. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335 May cause respiratory irritation.
Signature	J Spenceley

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