

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

1.1. Product identifier

Product form	: Mixture
Trade name	: SpecPure® PPN20
EC-No.	: 232-627-2, 200-075-1
CAS-No.	: 9001-73-4, 50-99-7
REACH registration No.	: <i>This substance is exempted from Registration as< 1t/a for each composition.</i>
UFI No.	: 4W2F-A38U-1G1N-1N2E
Product code	: 16000402

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Cosmetic ingredient

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufactured By	: Spec-Chem Industry Inc. No.10 Wanshou Road (ShiLin Industrial Park) Nanjing 211800, P.R. of China
Phone Number	: 86-25-84523390, 84523391
Fax Number	: 86-25-84520790, 84520791
Email.	: sc@specchemind.com
Only representative	: SpecChem GmbH Prinzenallee 1, 40549 Düsseldorf, Germany
Phone Number	: +4917673592556

1.4. Emergency telephone number

Emergency number : 112 / 116117 (EU emergency numbers);
1-800-424-9300/ +1 703-527-3887 (North America, CCN 1010066)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Respiratory sensitisation, Category 1	H334
Specific target organ toxicity – Single exposure, Category 3,	H335
Respiratory tract irritation	

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause respiratory irritation. Causes skin irritation. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

GHS08

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Signal word (CLP)	: Danger
Contains	: Papain
Hazard statements (CLP)	: 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.
Precautionary statements (CLP)	: P261 - Avoid breathing dust/fume/gas/mist/vapours/spray. P264 - Wash hands, forearms and face thoroughly after handling. P271 - Use only outdoors or in a well-ventilated area. P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P284 - Wear respiratory protection. P302+P352 - IF ON SKIN: Wash with plenty of water.

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ 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, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Glucose	CAS-No.: 50-99-7 EC-No.: 200-075-1	85 – 90	Not classified
Papain	CAS-No.: 9001-73-4 EC-No.: 232-627-2	10 – 15	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1, H334 STOT SE 3, H335

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Call a poison center or a doctor if you feel unwell.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a poison center or a doctor if you feel unwell.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after inhalation	: May cause respiratory irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Symptoms/effects after skin contact	: Irritation.
Symptoms/effects after eye contact	: Eye irritation.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam.
Unsuitable extinguishing media : high volume water jet.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Mechanically recover the product.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Use only outdoors or in a well-ventilated area. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes. Wear personal protective equipment.
Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : During the shelf life of the product, the activity remains stable at 0-35°C, but the storage conditions at 2-8°C are better. Protect from sunlight and high temperature.

7.3. Specific end use(s)

No additional information available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

[In case of inadequate ventilation] wear respiratory protection.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: White to off-white.
Appearance	: Powder.
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not applicable
Boiling point	: Not available
Flammability	: Non flammable.
Lower explosion limit	: Not applicable

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Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

Papain (9001-73-4)

LD50 oral rat	> 4000 mg/kg Source: Corporate Solution From Thomson Micromedex
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Glucose (50-99-7)

LD50 oral rat	25800 mg/kg Source: HSDB, Animal: rat
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Skin corrosion/irritation	: Causes skin irritation.
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Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: May cause respiratory irritation.

Papain (9001-73-4)

STOT-single exposure	May cause respiratory irritation.
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STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

Not rapidly degradable

Glucose (50-99-7)

LC50 - Fish [1]	11300000 mg/l Source: Ecological Structure Activity Relationships
LC50 - Fish [2]	2148.58 mg/l Source: Danish QSAR
EC50 - Crustacea [1]	31559.13 mg/l Source: Danish QSAR
EC50 96h - Algae [1]	3880000 mg/l Source: Ecological Structure Activity Relationships
EC50 96h - Algae [2]	17667.12 mg/l Source: Danish QSAR

12.2. Persistence and degradability

Glucose (50-99-7)

Readily biodegradable (Various screening studies have found D(+)-glucose to be readily biodegradable.)

12.3. Bioaccumulative potential

Glucose (50-99-7)

Bioconcentration factor (BCF REACH) 3 Not bioaccumulative

Partition coefficient n-octanol/water (Log Pow) -3 Source: HSDB

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

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12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
HP Code : HP13 - "Sensitising:" waste which contains one or more substances known to cause sensitising effects to the skin or the respiratory organs.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated for transport				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

- Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG).
Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
- Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).
- Storage class (LGK, TRGS 510) : LGK 13 - Non-combustible solids.
- Joint storage table :
- | | | | | |
|----------|---------|----------|----------|-----------|
| LGK 1 | LGK 2A | LGK 2B | LGK 3 | LGK 4.1A |
| LGK 4.1B | LGK 4.2 | LGK 4.3 | LGK 5.1A | LGK 5.1B |
| LGK 5.1C | LGK 5.2 | LGK 6.1A | LGK 6.1B | LGK 6.1C |
| LGK 6.1D | LGK 6.2 | LGK 7 | LGK 8A | LGK 8B |
| LGK 10 | LGK 11 | LGK 12 | LGK 13 | LGK 10-13 |
- Joint storage not permitted for : LGK 1, LGK 6.2, LGK 7.
- Joint storage with restrictions permitted for : LGK 4.1A, LGK 5.1C.
- Joint storage permitted for : LGK 2A, LGK 2B, LGK 3, LGK 4.1B, LGK 4.2, LGK 4.3, LGK 5.1A, LGK 5.1B, LGK 5.2, LGK 6.1A, LGK 6.1B, LGK 6.1C, LGK 6.1D, LGK 8A, LGK 8B, LGK 10, LGK 11, LGK 12, LGK 13, LGK 10-13.
- Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

- ABM category : B(4) - low hazard for aquatic organisms
- SZW-lijst van kankerverwekkende stoffen : Papain is listed
- SZW-lijst van mutagene stoffen : Papain is listed
- SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed
- SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : None of the components are listed
- SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

Denmark

- Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

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Switzerland

Storage class (LK) : LK 6.1 - Toxic materials

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Version information:

Version 2.0: Update in accordance with Regulation (EC) No.1907/2006 as amended by Regulation (EU) 2020/878, (EC) No.1272/2008.

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit

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Abbreviations and acronyms:

VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
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.
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.