

SECTION 1. Identification of the substance/mixture and of the company/enterprise

1.1. Product identifier

Product name : ENDOZYM Glucacel UHT
Product code: refer to sales department

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

Enzyme preparations
Sectors of use:
Manufacture of food products[SU4]
Product category:
Technological adjuvant

Not recommended uses
Do not use for purposes other than those listed

1.3. Details of the supplier of the safety data sheet

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1.4. Emergency telephone number

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SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

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

Pictograms:

GHS08

Hazard Class and Category Code(s):

Resp. Sens. 1

Hazard statement Code(s):

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

The product, if inhaled, can cause sensitization.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2. Label elements

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

Pictogram, Signal Word Code(s):

GHS08 - Danger

Hazard statement Code(s):

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Supplemental Hazard statement Code(s):

not applicable

Precautionary statements:



Prevention

- P261 - Avoid breathing vapours/spray.
- P284 - In case of inadequate ventilation wear respiratory protection.

Response

- P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or a doctor.

Contains:

betaglucanase (β 1-3, β 1-6), xylanase

Ingredients: glycerol, betaglucanase (β 1-3, β 1-6), potassium sorbate, sodium benzoate, xylanase, water qs to 100.

Food use, brewery use. Not intended for the final consumer. In accordance with current regulations on the specific matter. Only for industrial use.

2.3. Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

The use of this chemical agent implies the obligation of the "risk assessment" by the employer according to the provisions of Legislative Decree April 9, 2008 no. 81 and subsequent amendments. If the results of the risk assessment demonstrate that, in relation to the type, quantity, methods and frequency of exposure, there is only a low risk for the safety and irrelevant for the health of the workers and that the measures referred to in paragraph 1 of Legislative Decree April 9, 2008 no. 81 are sufficient to reduce the risk, the provisions of articles 225, 226, 229, 230 of the same Legislative Decree do not apply
Do not ingest. Keep out of reach of children.

SECTION 3. Composition/information on ingredients

3.1 Substances

Irrilevant

3.2 Mixtures

Substance	Concentration[w/w]	Classification	IUBnumber	CAS	EINECS	REACH
Glycerol substance for which there are Community workplace exposure limits	>= 25 < 50%			56-81-5	200-289-5	
Beta-glucanase (β 1-3, β 1-6)	>= 1 < 2,5%	Resp. Sens. 1, H334	3.2.1.6	62213-14-3	263-462-4	
Sodium benzoate substance for which there are	>= 0,1 < 1%	Eye Irrit. 2, H319		532-32-1	208-534-8	01-2119460 683-35

Substance	Concentration[w/w]	Classification	Index	CAS	EINECS	REACH
Community workplace exposure limits						

SECTION 4. First aid measures

4.1. Description of first aid measures

Inhalation: ventilate the environment. Immediately remove the patient from the contaminated environment and keep him at rest in a well-ventilated area. If he feels unwell, consult a doctor.

Direct contact with the skin (of the pure product): wash thoroughly with soap and water.

Direct contact with the eyes (of the pure product): rinse immediately with running water for 10-15 minutes, keeping the eyelid open. Remove contact lenses if they are worn and can be easily removed.

Ingestion: drink water in sips. Consult a doctor if you experience symptoms.

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

No data available.

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

If you experience respiratory symptoms, contact a POISON CENTER or doctor

SECTION 5. Firefighting measures

5.1. Extinguishing media

Suggested extinguishing media:

Water spray, CO2, foam, dry chemical, depending on the materials involved in the fire.

Extinguishing media to avoid:

Water jets. Use water jets only to cool the surfaces of the containers exposed to fire.

5.2. Special hazards arising from the substance or mixture

No data available.

5.3. Advice for firefighters

Use protection for the breathing apparatus

Safety helmet and full protective clothing.

The water spray can be used to protect the people involved in the extinction.

You may also use self-contained breathing apparatus, especially when working in confined and poorly ventilated areas.

Keep containers cool with water spray

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel:

Leave the area surrounding the spill or release. Do not smoke
Wear gloves and protective clothing

6.1.2 For emergency responders:

Eliminate all unguarded flames and possible sources of ignition. No smoking.
Provide a sufficient ventilation.
Evacuate the danger area and, in case, consult an expert.

6.2. Environmental precautions

Contain spills with earth or sand.
If the product has entered a watercourse, sewers or has contaminated soil or vegetation, notify the authorities.
Dispose of the waste material in compliance with the regulations

6.3. Methods and material for containment and cleaning up

6.3.1 Containment:

Rapidly recover the product, wear a mask and protective clothing (for specifications refer to section 8.2. SDS)
Recover the product for reuse, if possible, or for removal. Possibly absorb it with inert material or suck it.
Prevent it from entering the sewer system.

6.3.2 Cleaning up:

After wiping up, wash with water the area and materials involved

6.3.3 Other information:

None in particular.

6.4. Reference to other sections

Refer to paragraphs 8 and 13 for more information

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors
Handle the product after consulting all other sections of this safety data sheet.
At work do not eat or drink.
See also paragraph 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabelled containers.

Keep containers upright and safe by avoiding the possibility of falls or collisions.
Store in its original sealed packaging away from light in a cool dry place free of odors, at a temperature < 20°C. Do not freeze. Batch number (BN) and Best before date (EXP): See Barcode

7.3. Specific end use(s)

Manufacture of food products:
Store in its original sealed packaging, away from light, in a cool, dry place free from odors, at a temperature < 20°C. Do not freeze. Batch number (BN) and best before (EXP): See Barcode

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

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Related to contained substances:
Glycerol:

Limit value - Eight hours
Australia 10 (1) mg/m³
Belgium 10 mg/m³
Canada - Ontario 10 mg/m³
Canada - Quebec 10 mg/m³
Finland 20 mg/m³
France 10 mg/m³
Germany (AGS) 200 (1) mg/m³
Germany (DFG) 200 (1) mg/m³
Ireland 10 mg/m³
New Zealand 10 (1) mg/m³
Poland 10 mg/m³
Singapore 10 mg/m³
South Africa Mining 10 ppm
South Korea 10 mg/m³
Spain 10 mg/m³
Switzerland 50 inhalable aerosols mg/m³
USA - OSHA 15 (1) mg/m³
5 (2) mg/m³
United Kingdom 10 mg/m³

Limit value - Short-term
Germany (AGS) 400 (1)(2) mg/m³
Germany (DFG) 400 (1)(2) mg/m³
Switzerland 100 inhalable aerosols mg/m³

Remarks

Australia (1) This value refers to inhalable dust containing no asbestos and < 1% crystalline silica.
Germany (AGS) (1) Inhalable fraction (2) Average value 15 minutes
Germany (DFG) (1) Inhalable fraction (2) Average value 15 minutes
New Zealand (1) The value for inhalable dusts containing no asbestos and less than 1% free silica.
USA - OSHA (1) Inhalable fraction (2) Breathable fraction

Sodium benzoate:

Limit value - Eight hours
Germany (AGS) 10 mg/m³ (1)(2)mg/m³

Limit value - Short term
Germany (AGS) 20 mg/m³ (1)(2)(3)

Remarks

Germany (AGS) (1) Inhalable fraction (2) Skin (3) 15 minutes average value

- Substance: Glycerol

DNEL

Systemic effects Long term Workers inhalation = 56 (mg/m³) PNEC

Sweet water = 0,885 (mg/l)

sediment Sweet water = 3,3 (mg/kg/sediment)

Sea water = 0,088 (mg/l)

sediment Sea water = 0,33 (mg/kg/sediment)

ground = 0,141 (mg/kg ground)

- Substance: Beta-glucanase (β 1-3, β 1-6)

PNEC

Sweet water = 0,0052 (mg/l)

Sea water = 0,00052 (mg/l)

STP = 65 (mg/l)

ground = 0,001 (mg/kg ground)

- Substance: Sodium benzoate

DNEL

Systemic effects Long term Workers inhalation = 3 (mg/m³)

Systemic effects Long term Workers dermal = 62,5 (mg/kg bw/day)

Systemic effects Long term Consumers inhalation = 1,5 (mg/m³)

Systemic effects Long term Consumers oral = 16,6 (mg/kg bw/day)

Local effects Long term Workers inhalation = 0,1 (mg/m³)

Local effects Long term Consumers dermal = 31,25 (mg/kg bw/day)

PNEC

Sweet water = 0,13 (mg/l)

sediment Sweet water = 1,76 (mg/kg/sediment)

Sea water = 0,013 (mg/l)

sediment Sea water = 0,176 (mg/kg/sediment)

STP = 10 (mg/l)

ground = 0,265 (mg/kg ground)

8.2. Exposure controls

Appropriate engineering controls:

Manufacture of food products:

No specific monitoring foreseen (act according to good practice and specific rules for the type of risk associated)



8.2.2 Individual protection measures:

(a) Eye / face protection

Not needed for normal use, unless otherwise provided by the employer and / or by assessments of environmental hygiene investigations

(b) Skin protection

(i) Hand protection

Not needed for normal use, unless otherwise provided by the employer and / or by assessments of environmental hygiene investigations

(ii) Other

Wear normal work clothing.

(c) Respiratory protection

Use adequate protective respiratory equipment (EN 14387:2008)

(d) Thermal hazards

No hazard to report

Environmental exposure controls:

Use according to good working practices and avoid to disperse the product into the environment.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical and chemical properties	Value	Determination method
Physical state	Liquid	
Colour	Brown	
Odour	not determined as considered not relevant for the characterization of the product	
Odour threshold	not determined as considered not relevant for the characterization of the product	
Melting point/freezing point	not determined as considered not relevant for the characterization of the product	
Boiling point or initial boiling point and boiling range	not determined as considered not relevant for the characterization of the product	
Flammability	not determined as considered not relevant for the characterization of the product	
Lower and upper explosion limit	not determined as considered not relevant for the characterization of the product	
Flash point	not determined as considered not relevant for the characterization of the product	
Auto-ignition temperature	not determined as considered not relevant for the characterization of the product	
Decomposition temperature	not determined as considered not relevant for the characterization of the product	
pH	3.5-8.5	
Kinematic viscosity	not determined as considered not relevant for the characterization of the product	
Solubility	in water	
Water solubility	miscible in all proportions	
Partition coefficient n-octanol/water (log value)	not determined as considered not relevant for the characterization of the product	
Vapour pressure	not determined as considered not relevant for the characterization of the product	
Density and/or relative density	0.950-1.300	
Relative vapour density	not determined as considered not relevant for the characterization of the product	

Physical and chemical properties	Value	Determination method
Particle characteristics	not determined as considered not relevant for the characterization of the product	

9.2. Other information

9.2.1 Information with regard to physical hazard classes

Irrilevant

9.2.2 Other safety characteristics

Irrilevant

SECTION 10. Stability and reactivity

10.1. Reactivity

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Related to contained substances:

Glycerol:

Reacts with: Strong acids. Strong foundations

Beta-glucanase (β 1-3, β 1-6):

Not relevant.

Sodium benzoate:

When mixed with air and exposed to an ignition source, dust can ignite in open air or explode in a confined space.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions

10.4. Conditions to avoid

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Related to contained substances:

Glycerol:
Humidity

Beta-glucanase (β 1-3, β 1-6):
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

Sodium benzoate:
Heat and sunlight. Humidity. Sources of ignition.

10.5. Incompatible materials

None in particular

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION 11. Toxicological information

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

(a) acute toxicity: Glycerol: Ingestion - LD50 rat (mg / kg / 24h bw): not available

Skin contact - LC50 rat / rabbit (mg / kg / 24h bw): not available

Inhalation - LD50 rat (mg / l / 4h): not available

Beta-glucanase (β 1-3, β 1-6): Ingestion - LD50 rat (mg/kg/24h bw): > 2000

Skin contact - LC50 rabbit (mg/kg/24h bw): nd

Inhalation - LC50 rat (mg/l/4h): 2.42

Sodium benzoate: Ingestion - LD50 rat (mg / kg / 24h pc): 3140 mg / kg

Skin contact - LC50 rat / rabbit (mg / kg / 24h bw):> 2000 mg / kg

Inhalation - LD50 rat (mg / l / 4h): 12.2 mg / l / 4h

(b) skin corrosion/irritation: Glycerol: Not classified

Beta-glucanase (β 1-3, β 1-6): Unavailable

Sodium benzoate: Unavailable

Glycerol: Not classified

Beta-glucanase (β 1-3, β 1-6):Not classified

Sodium benzoate: Not classified - pure pH: 7 - 9

(c) serious eye damage/irritation: Glycerol: Not classified

Beta-glucanase (β 1-3, β 1-6): Unavailable

Sodium benzoate: Unavailable

Glycerol: Not classified

Beta-glucanase (β 1-3, β 1-6): Unavailable

Sodium benzoate: Causes severe eye irritation. Pure pH: 7 - 9

(d) respiratory or skin sensitisation: The product, if inhaled, can cause sensitization.

Glycerol: Not classified

Beta-glucanase (β 1-3, β 1-6): Once sensitized, a severe allergic reaction can occur upon subsequent exposure to very low levels.

Sodium benzoate: Not classified
(e) germ cell mutagenicity: Glycerol: Not classified
Beta-glucanase (β 1-3, β 1-6): Not classified
Sodium benzoate: Not classified
(f) carcinogenicity: Glycerol: Not classified
Beta-glucanase (β 1-3, β 1-6): Not classified
Sodium benzoate: Not classified
(g) eproductivetoxicity: Glycerol: Not classified - Does not affect fertility. Non-toxic for development.
Beta-glucanase (β 1-3, β 1-6): Unavailable
Sodium benzoate: Not classified
(h) specific target organ toxicity (STOT) single exposure: Glycerol: Not classified Ingestion may cause nausea, vomiting and avoidance.
Beta-glucanase (β 1-3, β 1-6): Unavailable
Sodium benzoate: Not classified
(i) specific target organ toxicity (STOT) repeated exposure: Glycerol: Not classified
Beta-glucanase (β 1-3, β 1-6): Not classified
Sodium benzoate: Not classified
(j) aspiration hazard: Glycerol: Inhalation: May cause irritation to the respiratory tract and other mucous membranes.
Beta-glucanase (β 1-3, β 1-6): May cause sensitization by inhalation
Sodium benzoate: Not classified

11.2. Information on other hazards

No data available.

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

SECTION 12. Ecological information

12.1. Toxicity

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Related to contained substances:

Glycerol:

Acute aquatic toxicity: Not classified

Chronic aquatic toxicity: Not classified

LC50-96 h - fish 54000 mg / l Oncorhynchus mykiss

EC50-48 h - Daphnia 1955 mg / l

EC50-72 h - algae 3200 mg / l Entosiphon sulcatum

Acute toxicity M-factor = 1

Chronic toxicity M-factor = 1

Beta-glucanase (β 1-3, β 1-6):

Acute toxicity - fish LC50 (mg / l / 96h): nd

Acute toxicity - crustaceans EC50 (mg / l / 48h): nd

Acute toxicity to algae ErC50 (mg / l / 72-96h): nd

Chronic toxicity - fish NOEC (mg / l): nd

Chronic toxicity - crustaceans NOEC (mg / l): nd

Chronic toxicity to algae NOEC (mg / l): nd

Acute toxicity M-factor = 1

Chronic toxicity M-factor = 1

Sodium benzoate:

Acute toxicity - fish LC50 (mg / l / 96h):> 100 mg / l
Acute toxicity - crustaceans EC50 (mg / l / 48h):> 100 mg / l Daphnia magna
Acute toxicity algae ErC50 (mg / l / 72-96h):> 100 mg / l
Chronic toxicity - Fish NOEC (mg / l): nd
Chronic toxicity - crustaceans NOEC (mg / l): nd
Chronic toxicity algae NOEC (mg / l): nd
Acute toxicity M-factor = 1
Chronic toxicity M-factor = 1

Use according to good working practices and avoid to disperse the product into the environment.

12.2. Persistence and degradability

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Related to contained substances:

Glycerol:

Persistence and degradability Readily biodegradable.

COD value 1.16 g O₂ / g substance

ThOD (gO₂ / g) 1.217 g O₂ / g substance

BOD (% of ThOD) 71% DTO

Beta-glucanase (β1-3, β1-6):

Easily biodegradable

Sodium benzoate:

Easily biodegradable.

12.3. Bioaccumulative potential

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Related to contained substances:

Glycerol:

Log P octanol / water at 20 ° C -1.76 - 2.6

Kow log -1.76 Bioaccumulative potential

Not expected to bioaccumulate.

Beta-glucanase (β1-3, β1-6):

No bioaccumulation potential

Sodium benzoate:

Log P octanol / water at 20 ° C: 1.88 Log P octanol / water at 20 ° C: -2.27 Bioaccumulation potential: Not expected to bioaccumulate.

12.4. Mobility in soil

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Related to contained substances:

Glycerol:

ground Product that penetrates easily into the ground.

Beta-glucanase (β 1-3, β 1-6):
Unavailable

Sodium benzoate:
Very high mobility potential in the ground

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with the regulations in force. Any remaining product should be disposed of according to applicable regulations by addressing to authorized companies.
Recover if possible. Operate according to local or national regulations

SECTION 14. Transport information

14.1. UN number or ID number

Not included in the field of application of regulations concerning the transport of dangerous goods: by road (ADR); by rail (RID); by air (ICAO / IATA); by sea (IMDG).

14.2. UN proper shipping name

None

14.3. Transport hazard class(es)

None

14.4. Packing group

None

14.5. Environmental hazards

None

14.6. Special precautions for user

No data available.

14.7. Maritime transport in bulk according to IMO instruments

Transport in bulk is not foreseen

SECTION 15. Regulatory information

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

Restrictions relating to the product or the substances contained (Annex XVII EC Reg. 1907/2006): not applicable
Substances in Candidate list (art. 59 EC Reg. 1907/2006): the product does not contain SVHC in percentage = a 0.1 %.

Regulation (EU) 1169/2011: see point 2.2

Regulation (EU) 1308/2013; see point 2.2

Regulation (EC) 1333/2008; see point 2.2

Regulation (EC) 1332/2008; see point 2.2

Regulation (EU) No 1357/2014 - waste:HP13 - Sensitising

15.2. Chemical safety assessment

No chemical safety assessment was carried out by the supplier

SECTION 16. Other information

16.1. Other information

Points modified compared to previous release: 2.2. Label elements, 2.3. Other hazards, 3.2 Mixtures, 4.1. Description of first aid measures, 7.2. Conditions for safe storage, including any incompatibilities, 7.3. Specific end use(s), 8.1. Control parameters, 8.2. Exposure controls, 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008, 11.2. Information on other hazards, 12.1. Toxicity, 12.2. Persistence and degradability, 12.3. Bioaccumulative potential, 12.4. Mobility in soil, 12.5. Results of PBT and vPvB assessment, 12.6. Endocrine disrupting properties, 12.7. Other adverse effects, 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Description of hazard statements set out in paragraph 3

H334 = May cause allergy or asthma symptoms or breathing difficulties if inhaled
H319 = Causes serious eye irritation.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled Classification procedure: Calculation method

Main normative references:

Reg. (CE) n. 1907 del 18/12/06 REACH (Registration, Evaluation and Authorisation of CHemicals) et seq.

Reg. (CE) 1272/2008 CLP (Classification Labelling and Packaging) et seq.

Directive 2012/18/EU (on the control of major-accident hazards involving dangerous substances) et seq.

Training required: This document must be submitted to the employer to determine the possible need for appropriate training for workers to ensure protection of human health and the environment.

n.a.: not applicable

n.d.: not available

ADR: Accord européen relative au transport International des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

ATE: Acute Toxicity Estimati

BFC: BioconCentration Factor

BOD: Biochemical Oxygen Demand

CAS: Chemical Abstract Service number

CAP: Centre AntiPoison

CE/EC number EINECS (European Inventory of existing Commercial Substances) e ELINCS (European List of notified Chemical Substances)

CL50/LC50: Lethal Concentration 50

DL50/LD50: Lethal Dose 50

COD: Chemical Oxygen Demand

DNEL: Derived No Effect Level

EC50: half maximal Effective Concentration

ERC: Enviroment Release Classes

EU/UE: European Union

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

IMDG: International Maritime Dangerous Goods code

Kow: Octanol water partition coefficient

NOEC: No Observed Effect Concentration

OEL: Occupational Exposure Limit

PBT: Persistent Bioaccumulative and Toxic

PC: Product Categories

PNEC: Predicted No Effect Concentration

PROC: Process Categories

RID: Règlement concernant le transport International ferroviaire des marchandises dangereuses (Regulations concerning International rail transport of dangerous goods)

STOT: Target Organ Systemic Toxicity

STOT (RE): Repeated Exposure

STOT (SE): Single Exposure

STP: Sewage Treatment Plants

SU: Sector of Use

SVCH: Substance of Very High Concern

TLV: Threshold Limit Value

vPvB: Very Persistent Very Bioaccumulative

References and Sources:

- ECHA Registered Substances:

<https://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

- SDS raw material supplier
- GESTIS International Limit Value: <http://limitvalue.ifa.dguv.de>

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*** this tab annuls and replaces any previous edition. (IIXX)

Changes to the previous edition: raw material data change
