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

1.1. Product identifier

Product name : POLYGEL W
Contains synthetic polymer microplastics (SPM) (Reg. EC 1907/2006 REACH)
This substance/mixture contains nanoforms (Reg. EC 1907/2006 REACH)
Product code: refer to sales department

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

Clarifying Agents
Sectors of use:
Manufacture of food products[SU4]
Product category:
Process aid for enological use

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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SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

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

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Pictograms:
None

Hazard Class and Category Code(s):
Non hazardous

Hazard statement Code(s):
Non hazardous

2.2. Label elements

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

Pictogram, Signal Word Code(s):
None

Hazard statement Code(s):
Non hazardous

Supplemental Hazard statement Code(s):
not applicable

Precautionary statements:
None in particular.

Contains:

PVPP (polyvinylpolypyrrolidone), silica gel 30%.
Food use, oenological use. Not intended for the final consumer. In accordance with current regulations on the specific matter.

2.3. Other hazards

Based on available data, there are no PBT or vPvB substances according to Regulation (EC) 1907/2006, Annex XIII, in concentration >0.1% w/w.
Based on available data, there are no substances that disrupt the endocrine system according to Regulations (EU) 2017/2100 and 2018/605 in concentration >0.1% w/w.

May form an explosive dust-air mixture if dispersed.

Use according to good working practices, avoiding dispersal of the product into the environment.

SECTION 3. Composition/information on ingredients

3.1 Substances

Irrilevant

3.2 Mixtures

Synthetic hydrated amorphous silica CAS No. 112926-00-8: substance containing nanoforms (Reg EC 1907/2006), information on particles: section 9 (experimental data)

Substance	Concentration[w/w]	Classification	Index	CAS	EINECS	REACh
Synthetic amorphous silica hydrated (Silica gel) substance for which there are Community workplace exposure limits	>= 25 < 30%				231-545-4	
2-pyrrolidone	>= 0,1 < 1%	Repr. 1B, H360 Limits: Repr. 1B, H360 %C >3;		616-45-5	210-483-1	

SECTION 4. First aid measures

4.1. Description of first aid measures

Inhalation:
Ventilate the area. Move immediately the contaminated patient from the area and keep him at rest in a well ventilated area. If you feel unwell seek medical advice.

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

Direct contact with eyes (of the pure product).:
Wash immediately and thorougly with running water for at least 10 minutes.

Ingestion:
Not dangerous. In case of malaise consult a doctor.

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

Contact with eyes may cause redness and tearing due to mechanical effect

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

If you feel unwell, go to a doctor or emergency room with this document. Symptomatic treatment.

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.
Hazardous combustion products: CO2, carbon monoxide, nitrogen oxides (NOx).

5.3. Advice for firefighters

Special protective equipment for firefighters: In case of fire, wear self-contained breathing apparatus, a safety helmet, and full protective clothing. Self-contained breathing apparatus is also recommended, especially when working in confined, poorly ventilated areas. Specific extinguishing methods: Standard procedure for chemical fires. Further information: Use extinguishing methods appropriate to local circumstances and the surrounding environment.

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel:
Move away from the area surrounding the spill or release. Do not smoke. Wear gloves and protective clothing.

6.1.2 For emergency responders:
Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the

danger area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spills. Dispose of residue in accordance with current regulations.
Prevent the product from entering drains, surface water or groundwater; if the product has flowed into a watercourse, sewer system or has contaminated the soil or vegetation, notify the relevant authorities.

6.3. Methods and material for containment and cleaning up

The product is immiscible with water and will settle in water systems.

Large spills:
Stop the flow of material if this can be done without risk. Contain the spilled material where possible. Vacuum up. After recovering the product, rinse the area with water.

Small spills:
Vacuum up the spill and collect in a suitable container for disposal. Clean the surface thoroughly to remove any residual contamination. Never return spills to the original containers for reuse.

For waste disposal, see section 13 of the SDS.

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 with eyes and skin. Handle the product after consulting all other sections of this safety data sheet. Ensure adequate ventilation, avoid the formation of airborne dust.

The products supplied are intended for industrial use only. Observe good industrial hygiene practices.

During handling, avoid spillage as it is harmful to the environment. The product must not be released into the environment – it must not be discharged into drains, waterways or the soil. Wash thoroughly after use. Please refer to the regulations in force.

Measures in case of accidental release

In case of accidental release, prevent the product from entering drains, waterways or water supplies.

Personal precautions

Keep unnecessary personnel away. Keep people away and upwind of the spill/leak.
Wear appropriate protective equipment and clothing during clean-up.
Notify local authorities if significant spills cannot be contained.

Environmental precautions

Avoid discharge into drains, waterways or the ground.
Containment methods. Stop the spill if it is safe to do so.

Clean-up methods

Ventilate the contaminated area. Wear appropriate protective equipment and clothing during clean-up.
Stop the spill if it is safe to do so. Collect with suction equipment and place in suitable containers for disposal.
Never return spilled material to original containers for reuse.
After recovering the product, wash the area with water.
Have the material disposed of by authorised companies.

We recommend consulting AEB's sales department and any technical documents.

In particular, we highlight the following useful and necessary information:

- The importance of packaging

- Minimising on-site storage before use/shelf life

- Correct storage conditions

- Thorough testing of the initial quality of the product

AEB spa guarantees that the product, if transported and stored correctly on site and used according to the instructions provided, complies with regulations regarding contact with foodstuffs.

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 a cool and dry place, away from heat sources and direct exposure to sunlight.

7.3. Specific end use(s)

Manufacture of food products:
Food industry: Handle with care. As this is a hygroscopic product, store in a clean, dry, and ventilated area, away from heat and direct sunlight, in the tightly closed original container.
Batch number (BN) and best before (EXP): See barcode.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

==========
Related to contained substances:
Synthetic amorphous silica hydrated (Silica gel):
Silica, amorphous

Limit value - Eight hours TWA
(ppm)/(mg/m³)

Australia: -/2 (1)
Austria: -/4 (1) inhalable aerosol
Belgium: -/10
Canada – Ontario: -/10
Canada - Québec: -/6(1)(2)
Denmark: 0-/ 2 inhalable aerosol
Finland: -/5
Germany (AGS): -/1 (1)

Germany (DFG): -/0,02 (1)
Ireland: (1) -/6 (1)
Latvia: -/1
New Zealand: -/1
People's Republic of China: -/2(1)
Poland: -/10(1)
Singapore: -/10
South Africa minining: -/6 (1)
South Korea: -/10
Switzerland: -/4 (1)
USA - NIOSH: -/6
USA - OSHA: 20 (1)(2)
United Kingdom: :-/6 (1)

Limit value - Short term STEL
(ppm)/(mg/m³)

Australia: -/-
Austria: -/-
Belgium: -/-
Canada – Ontario: -/-
Canada - Québec: -/-
Denmark: 0-/-
Finland: -/-
Germany (AGS): -/8 (1)(2)
Germany (DFG): -/0.16 (1)
Ireland: (1) -/-
Latvia: -/-
New Zealand: -/-
People's Republic of China: -/-
Poland: -/-
Singapore: -/-
South Africa minining: -/-
South Korea: -/-
Switzerland: -/-
USA - NIOSH: -/-
USA - OSHA: -/-
United Kingdom: :-/-

Remarks:

Australia (1) This value is for inhalable dust containing no asbestos and < 1% crystalline silica.
Austria (1) Inhalable fraction
Canada - Québec (1) Respirable fraction (2) The standard corresponds to dust containing no asbestos and the percentage in crystalline silica is less than 1%.
Germany (AGS): Colloidal amorphous silica including fumed silica and wet-process silica (precipitated silica, silica gel) (1) Inhalable fraction (2) 15 minutes average value
Ireland: (1) Inhalable fraction
New Zeland: (1) Inhalable fraction
Norway: (1) Respirable fraction
People's Republic of China: (1) Inhalable fraction
Poland: (1) Inhalable fraction
South Africa Mining: (1) Inhalable fraction
Switzerland: (1) inhalable aerosol
USA (OSHA) : (1) mppcf (2) mppcf × 35.3 = million particles per cubic meter = particles per c.c.
UK: (1) Inhalable fraction

- Substance: Synthetic amorphous silica hydrated (Silica gel)
DNEL

Local effects Long term Workers inhalation = 4 (mg/m3)

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 necessary for normal use, unless otherwise specified by the employer and/or by assessments of environmental hygiene

(b) Skin protection

(i) Hand protection
Not necessary for normal use, unless otherwise specified by the employer and/or by assessments of environmental hygiene

(ii) Other
Wear normal work clothing.

(c) Respiratory protection
Not necessary for normal use, unless otherwise specified by the employer and/or by assessments of environmental hygiene

(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	Very fine powder	
Colour	White	
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	

Physical and chemical properties	Value	Determination method
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	7.0 ± 0.5 (20 ° C; sol. 5%)	
Kinematic viscosity	not determined as considered not relevant for the characterization of the product	
Solubility	not determined as considered not relevant for the characterization of the product	
Water solubility	insoluble	
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	0.35 ± 0.05 (20 ° C)	
Relative vapour density	not determined as considered not relevant for the characterization of the product	
Particle characteristics	This substance-mixture contains nanoforms and microparticles of synthetic polymers (SPM)	

9.2. Other information

Particle characteristics: micron-sized aggregates and agglomerates with internal structure in the range 1-100 nm

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

No reactivity hazards

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

Organic dusts at sufficient concentrations can form explosive mixtures in air

10.4. Conditions to avoid

Protect from frost, heat, sunlight and moisture. Avoid dust formation.

10.5. Incompatible materials

Oxidizing agents, aluminum, copper, mild steel

10.6. Hazardous decomposition products

Does not decompose if used for intended purposes. Combustion products: Carbon monoxide Carbon dioxide (CO2) Nitrogen oxides (NOx)

SECTION 11. Toxicological information

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

(a) acute toxicity: Synthetic amorphous silica hydrated (Silica gel): Ingestion - LD50 rat (mg/kg/24h bw): >5000
Skin contact - LC50 rat/rabbit (mg/kg/24h bw): >2000
Inhalation - LD50 rat (mg/l/4h): nd
2-pyrrolidone: Ingestion - LD50 rat (mg/kg/24h bw): >2000
Skin contact - LD50 rabbit (mg/kg/24h bw): >2000
Inhalation - LD50 rat (mg/l/4h): nd
(b) skincorrosion/irritation: Synthetic amorphous silica hydrated (Silica gel): Non-corrosive
2-pyrrolidone: Non-corrosive
Synthetic amorphous silica hydrated (Silica gel): Non-irritating
2-pyrrolidone: Non-irritating (OECD Test Guideline 404)
(c) serious eye damage/irritation: Synthetic amorphous silica hydrated (Silica gel): Non-corrosive
2-pyrrolidone: Non-corrosive
Synthetic amorphous silica hydrated (Silica gel): Non-irritating
2-pyrrolidone: Irritating to eyes (OECD Test Guideline 405)
(d) respiratoryorskinsensitisation: Synthetic amorphous silica hydrated (Silica gel): Non-sensitizing
2-pyrrolidone: Non-sensitizing (LLNA test on mice, OECD Guideline 429)
(e) germ cell mutagenicity: Synthetic amorphous silica hydrated (Silica gel): Non-mutagenic
2-pyrrolidone: Not mutagenic (Ames test on mice, OECD guideline 474)
(f) carcinogenicity: Synthetic amorphous silica hydrated (Silica gel): Not cacerogeno
2-pyrrolidone: Non-carcinogenic
(g) eproductivetoxicity: Synthetic amorphous silica hydrated (Silica gel): Non-toxic for reproduction
2-pyrrolidone: Reproductive toxicity within the reported limits: clear evidence of adverse effects on sexual function and

fertility, and/or development, based on animal experiments.
(h) specific target organ toxicity (STOT) single exposure: Synthetic amorphous silica hydrated (Silica gel): Not classified. Oral NOAEL (rat): > 1000 mg/kg body weight/day
2-pyrrolidone: Unclassified
(i) specific target organ toxicity (STOT) repeated exposureSynthetic amorphous silica hydrated (Silica gel): Not available
2-pyrrolidone: Non-toxic
(j) aspiration hazard: Synthetic amorphous silica hydrated (Silica gel): Not available

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 and Regulation (EU) 2018/605.

SECTION 12. Ecological information

12.1. Toxicity

==========
Related to contained substances:
Synthetic amorphous silica hydrated (Silica gel):
Acute toxicity-fish LL50 (mg/l/96H): > 10000
Acute toxicity-crustaceans EL50 (mg/l/24H): > 10000
Acute algae toxicity ErC50 (mg/l/72-96H): n.a.

2-pyrrolidone:
Acute toxicity - fish LC50 (mg/l/96h): 4600-10000 (Brachydanio rerio)
Acute toxicity - crustaceans EC50 (mg/l/48h): >500 (Daphnia magna)
Acute toxicity - algae ErC50 (mg/l/72-96h): >500 (Desmodesmus subspicatus)
Chronic toxicity - fish NOEC (mg/l): nd
Chronic toxicity - crustaceans NOEC (mg/l): 160.2 (Daphnia magna)
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

==========
Related to contained substances:
Synthetic amorphous silica hydrated (Silica gel):
not applicable to inorganic substances

2-pyrrolidone:
Zahn-Wellens test: rapidly biodegradable: 98% (9d)

12.3. Bioaccumulative potential

==========
Related to contained substances:
Synthetic amorphous silica hydrated (Silica gel):
Not bioaccumulative

2-pyrrolidone:
Partition coefficient n-octanol/water: log Pow: -0.71 (20°C)

12.4. Mobility in soil

==========
Related to contained substances:
Synthetic amorphous silica hydrated (Silica gel):
Minimally soluble. Migration into soil is not expected.

2-pyrrolidone:
No data available

12.5. Results of PBT and vPvB assessment

This substance/mixture does not contain any components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at concentrations > 0.1%.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that disrupt the endocrine system according to Regulation (EU) 2017/2100 and Regulation (EU) 2018/605 at concentrations > 0.1%.

12.7. Other adverse effects

Contains SPM: Synthetic polymer microparticles for use at industrial sites - Annex XVII, entry 78 - derogation 4a

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Unused product residues must be considered non-hazardous special waste. Disposal must be carried out by a company authorised to manage waste, in accordance with national and local regulations. Solid residues may be suitable for disposal in authorised landfills.

Contaminated packaging
Contaminated packaging must be disposed of in accordance with national waste management regulations.
Prevent spilled material from entering sewer systems, waterways or water supplies. Both product residues and uncleaned empty packaging must be labelled, sealed and sent for disposal by incineration, landfill or recycling in accordance with local, regional and national regulations. For disposal within the EU, it is the user's responsibility to assign the appropriate waste code in accordance with the European Waste List (EWL, formerly EWC), based on the application for which the product was used.

Uncontaminated packaging
Empty, clean containers can be taken to an authorised waste treatment site for recycling or disposal.

Special precautions
Both products and packaging must be disposed of safely and in accordance with relevant local and national regulations. Empty containers or linings may retain product residues: prevent spilled material from entering sewer systems, waterways or water supplies.

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 it contains (Annex XVII of EC Regulation 1907/2006):
- list no. 78: the synthetic polymer microparticles supplied are subject to the conditions set out in Annex XVII, item 78, by way of derogation from Paragraph 4a of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council (Reg. (EU) 2023/2055). Polyvinylpolypyrrolidone (Synthetic polymer microparticle (SPM)) in concentration 44-46% w/w

HS Code:3905 Polymers of vinyl acetate or of other vinyl esters; other vinyl polymers.

Substances in the Candidate List (art. 59 of EC Regulation 1907/2006): the product does not contain SVHC in a percentage >= 0.1%.
Regulation (EU) No. 649/2012 of the European Parliament and of the Council concerning the export and import of dangerous chemicals: not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances: not applicable.

Regulation (EU) 1169/2011: see point 2.2
Regulation (EU) 1308/2013; see point 2.2

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: 1.1. Product identifier 2.3. Other hazards, 3.2 Mixtures 4.1. Description of first aid measures, 4.3. Indication of any immediate medical attention and special treatment needed, 5.2. Special hazards arising from the substance or mixture, 5.3. Advice for firefighters, 6.1. Personal precautions, protective equipment and emergency procedures, 6.2. Environmental precautions, 6.3. Methods and material for containment and cleaning up, 6.4. Reference to other sections, 7.1. Precautions for safe handling, 7.3. Specific end use(s), 8.2. Exposure controls, 9.2. Other information, 10.3. Possibility of hazardous reactions, 10.4. Conditions to avoid, 10.5. Incompatible materials, 10.6. Hazardous decomposition products, 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008, 11.2. Information on other hazards, 12.5. Results of PBT and vPvB assessment, 12.6. Endocrine disrupting properties, 12.7. Other adverse effects, 13.1. Waste treatment methods, 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixturee

Description of hazard statements set out in paragraph 3
H360 = May damage fertility or the unborn child May damage fertility or the unborn child <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazar

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

No hazard to report. 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 europèen relative au transport International des merchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
ATE: Acute Toxicity Estimat
BFC: BioconCentration Factor
BOD: Biochemical Oxigen 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 concernent le transport International ferroviaire des merchandises 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

This msds was made in good faith by technical Office on the basis of the information available at the date of the last revision. The person in charge must regularly inform the employees about the specific risks they encounter when using this substance/product. The information contained here relate only to the substance/the preparation indicated and may not apply if the product is used improperly or in combination with others. Nothing contained herein shall be construed as a guarantee, either express or implied. It is the responsibility of the user to ensure the opportunities and completeness of the information contained herein for their own particular use.

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

Changes to the previous edition: drawn up in accordance with the information provided for in Regulation 2023/2055.