

24.06.2024	Kit Components	
Product code	Description	
391	Microalbuminuria / Microalbuminuria B78282271	
Components:		

282214	Tampone Plasma Proteine Bulk
19	Varius Antiserum to Human Proteins



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Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation *EU/2020/878*

Printing date 24.06.2024 Version number 1 Revision: 24.06.2024

	1.1 Diagnostic Reagent
2	Trade name: <u>Tampone Plasma Proteine Bulk</u>
בי א ג וו ע	Article number: 282214 1.2 Relevant identified uses of the substance or mixture and uses advised against Relevant Identified Uses: For laboratory use only Uses advised against: Uses other than those recommended Application of the substance / the mixture Diagnostic reagent
	1.3 Details of the supplier of the safety data sheet
	Manufacturer/Supplier: Sclavo Diagnostics International
	Via Po 26-28, Loc. Pian dei Mori
	CAP: 53018 - SOVICILLE - (SI)
-	ITALY
	Further information obtainable from: Product safety department. 1.4 Emergency telephone number: +39 0577 390 444 / 445
2 1	Hazards identification
2	2.1 Classification of the substance or mixture
	Classification according to Regulation (EC) No 1272/2008
	The product is not classified, according to the CLP regulation.
_	2.2 Label elements
	Labelling according to Regulation (EC) No 1272/2008 Void Hazard pictograms Void
	Signal word Void
	Hazard statements Void
ł	2.3 Other hazards
	Results of PBT and vPvB assessment
2	
2 1 1	PBT: Not applicable. vPvB: Not applicable.

- Description: Mixture of substances listed below with nonhazardous additions.
- · Dangerous components: Void

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• Additional information:

(Contd. of page 1)

For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- · 4.1 Description of first aid measures
- · General information: No special measures required.
- After inhalation:
- Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- After eye contact:
- Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- \cdot 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents:
- Use fire extinguishing methods suitable to surrounding conditions.
- \cdot 5.2 Special hazards arising from the substance or mixture
- No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Dilute with plenty of water. Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- 6.4 Reference to other sections
 See Section 7 for information on safe handling.
 See Section 8 for information on personal protection equipment.
 See Section 13 for disposal information.

7 Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
- Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.

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Trade name: Tampone Plasma Proteine Bulk

- (Contd. of page 2)
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

•	8.1 Control parameters
•	Ingredients with limit values that require monitoring at the workplace:
	The product does not contain any relevant quantities of materials with
	critical values that have to be monitored at the workplace.
•	Additional information:
	The lists valid during the making were used as basis.
	8.2 Exposure controls
	Appropriate engineering controls No further data; see section 7.
	Individual protection measures, such as personal protective equipment
•	General protective and hygienic measures:
	The usual precautionary measures are to be adhered to when handling
	chemicals.
	Respiratory protection: Not required.
•	Hand protection
	The glove material has to be impermeable and resistant to the product/
	the substance/ the preparation. Due to missing tests no recommendation to the glove material can be
	given for the product/ the preparation/ the chemical mixture.
	Selection of the glove material on consideration of the penetration
	times, rates of diffusion and the degradation
	Material of gloves
	The selection of the suitable gloves does not only depend on the
	material, but also on further marks of quality and varies from
	manufacturer to manufacturer. As the product is a preparation of
	several substances, the resistance of the glove material can not be
	calculated in advance and has therefore to be checked prior to the
	application.
•	Penetration time of glove material
	The exact break through time has to be found out by the manufacturer of
	the protective gloves and has to be observed.
•	Eye/face protection Goggles recommended during refilling
9	Physical and chemical properties
	9.1 Information on basic physical and chemical properties
	General Information
	Physical state Fluid
	Colour: Colourless
	Odour: Odourless
	Odour threshold: Not determined.
•	Melting point/freezing point: Undetermined.

- Melting point/freezing point:
- · Boiling point or initial boiling point and boiling range
- · Flammability
- · Lower and upper explosion limit
- · Lower:
- Upper:

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100 °C (7732-18-5 water, distilled, conductivity or of similar purity)

Not applicable.

Not determined.

Not determined.

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Trade name: Tampone Plasma Proteine Bulk

Decomposition temperature:Not determined.pH at 20 °C8Viscosity:Not determined.Kinematic viscosityNot determined.SolubilityNot determined.water:Fully miscible.Partition coefficient n-octanol/Not determined.Vapour pressure at 20 °C:23 hPa (732-18-5 water, distilled, conductivity or of similar purity)Density:Not determined.Relative densityNot determined.Vapour densityNot determined.Vapour densityNot determined.9.2 Other informationFluidAppearance:FluidForm:FluidImportant information onprotection of health andenvironment, and on safety.Product is not selfigniting.Ignition temperature:Product does not present an explosio hazard.Solvent content:0.00 %Solids content:0.9 %Change in conditionVoidExplosivesVoidPlanmable gasesVoidAerosolsVoidPlanmable gasesVoidProphoric liquidsVoidProphoric solidsVoidSelf-neacting substances andVoidProphoric liquidsVoidVoidSubstances and mixtures, whichemit flammable gases in contactVoidVoidVoidVoidVoidVoidVoidVoidVoidVoidVoid		(Contd. of page
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	-	Void
Corrosive to metals Void		Void
	Corrosive to metals	Void

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(Contd. of page 4)

Trade name: Tampone Plasma Proteine Bulk

· Desensitised explosives

10 Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- \cdot Thermal decomposition / conditions to be avoided:
- No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- \cdot 10.5 Incompatible materials: No further relevant information available.

Void

· 10.6 Hazardous decomposition products:

No dangerous decomposition products known.

11 Toxicological information

\cdot 11.1 Information on hazard classes as defined in Regulation (EC) No	
1272/2008	
· Acute toxicity	
Based on available data, the classification criteria are not met.	
· Skin corrosion/irritation	
Based on available data, the classification criteria are not met.	
· Serious eye damage/irritation	
Based on available data, the classification criteria are not met.	
· Respiratory or skin sensitisation	
Based on available data, the classification criteria are not met.	
· Germ cell mutagenicity	
Based on available data, the classification criteria are not met.	
· Carcinogenicity	
Based on available data, the classification criteria are not met.	
· Reproductive toxicity	
Based on available data, the classification criteria are not met.	
· STOT-single exposure	
Based on available data, the classification criteria are not met.	
· STOT-repeated exposure	
Based on available data, the classification criteria are not met.	
· Aspiration hazard	
Based on available data, the classification criteria are not met.	
 11.2 Information on other hazards 	
• Endocrine disrupting properties	
The product contains substances, which affect the thyroid system and	ł
other hormonal systems.	
None of the ingredients is listed.	

12 Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability
- No further relevant information available.
- · 12.3 Bioaccumulative potential
- No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.

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Trade name: Tampone Plasma Proteine Bulk

(Contd. of page 5)
12.5 Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.
12.6 Endocrine disrupting properties The product does not contain substances with endocrine disrupting properties.
12.7 Other adverse effects
Additional ecological information:
General notes: Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13 Disposal considerations

- · 13.1 Waste treatment methods
- Recommendation Smaller quantities can be disposed of with household waste.
- Uncleaned packaging:
- **Recommendation:** Disposal must be made according to official regulations.
- Recommended cleansing agents: Water, if necessary together with cleansing agents.

· 14.1 UN number or ID number · ADR, IMDG, IATA	not regulated
14.2 UN proper shipping name	
ADR, IMDG, IATA	not regulated
14.3 Transport hazard class(es)	
ADR, ADN, IMDG, IATA	
Class	not regulated
14.4 Packing group	
ADR, IMDG, IATA	not regulated
14.5 Environmental hazards:	Not applicable.
14.6 Special precautions for user	Not applicable.
14.7 Maritime transport in bulk	
according to IMO instruments	Not appliable

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Trade name: Tampone Plasma Proteine Bulk

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ΤE

15 Regulatory information

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

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

 DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II

- None of the ingredients is listed.
- · REGULATION (EU) 2019/1148
- Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

- Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors None of the ingredients is listed.
- · 15.2 Chemical safety assessment:
 - A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

- · Department issuing SDS: Product safety department.
- · Contact:
- · Date of previous version: 03.05.2023
- Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) VOC: Volatile Organic Compounds (USA, EU) PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative • *** Data compared to the previous version altered.**



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Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 24.06.2024

Version number 1

Revision: 24.06.2024

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

- · 1.1 Diagnostic Reagent
- Trade name: Varius Antiserum to Human Proteins
 1.2 Relevant identified uses of the substance or mixture and uses advised against Relevant Identified Uses: For laboratory use only Uses advised against: Uses other than those recommended
 Application of the substance / the mixture Diagnostic reagent
- 1.3 Details of the supplier of the safety data sheet
 Manufacturer/Supplier: Sclavo Diagnostics International Via Po 26-28, Loc. Pian dei Mori
 - CAP: 53018 SOVICILLE (SI) ITALY
- · Further information obtainable from: Product safety department.
- · 1.4 Emergency telephone number: +39 0577 390 444 / 445

2 Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008
- The substance is not classified, according to the CLP regulation.
- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- Signal word Void
- · Hazard statements Void
- \cdot 2.3 Other hazards
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · 3.1 Substances
- CAS No. Description Polyclonal goat antiserum

4 First aid measures

- · 4.1 Description of first aid measures
- · General information: No special measures required.

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Trade name: Varius Antiserum to Human Proteins

(Contd. of page 1)

- After inhalation:
- Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin. • After eye contact:

Rinse opened eye for several minutes under running water.

- · After swallowing: If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- \cdot 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

• 5.1 Extinguishing media

- Suitable extinguishing agents:
 - Use fire extinguishing methods suitable to surrounding conditions.
- · 5.2 Special hazards arising from the substance or mixture
- No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

- 6.3 Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- 6.4 Reference to other sections
 See Section 7 for information on safe handling.
 See Section 8 for information on personal protection equipment.
 See Section 13 for disposal information.

7 Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
- Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:
- No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

(Contd. on page 3)

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Trade name: Varius Antiserum to Human Proteins

(Contd. of page 2)

<i>8 Exposure controls/persona</i>	l protection
· 8.1 Control parameters	
-	that require monitoring at the workplace:
Not required.	
• Additional information:	· · · · · ·
The lists valid during the mak	ing were used as basis.
· 8.2 Exposure controls	
=	ls No further data; see section 7.
· Individual protection measures	, such as personal protective equipment
· General protective and hygieni	
The usual precautionary measur	es are to be adhered to when handling
chemicals.	2
 Respiratory protection: Not re 	quired.
• Hand protection	
The glove material has to be i	mpermeable and resistant to the product/
the substance/ the preparation	
Due to missing tests no recomm	endation to the glove material can be
given for the product/ the pre	paration/ the chemical mixture.
Selection of the glove materia	l on consideration of the penetration
times, rates of diffusion and	the degradation
• Material of gloves	
	gloves does not only depend on the
material, but also on further	marks of quality and varies from
manufacturer to manufacturer.	
\cdot Penetration time of glove mate	
	as to be found out by the manufacturer of
the protective gloves and has	
 Eye/face protection Goggles re 	commended during refilling
9 Physical and chemical pro	nortion
9 Physical and chemical pro	percies
• 9.1 Information on basic physi	cal and chemical properties
· General Information	
· Physical state	Fluid
· Colour:	Amber coloured
· Odour:	Nearly odourless
· Odour threshold:	Not determined.
• Melting point/freezing point:	Undetermined.
· Boiling point or initial boili	
point and boiling range	Undetermined.
· Flammability	Not applicable.
· Lower and upper explosion limi	
· Lower:	Not determined.
· Upper:	Not determined.
• Flash point:	Not applicable.
· Decomposition temperature:	Not determined.
· pH	
· Viscosity:	Not determined.
_	Not determined.
• Kinematic viscositv	
 Kinematic viscosity Dvnamic: 	Not determined.
· Dynamic:	
	Not determined.

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Trade name: Varius Antiserum to Human Proteins

	(Contd. of page 3
· Partition coefficient n-octanol.	
water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	not acterminea.
· Density at 20 °C:	1.846 g/cm³
· Relative density	Not determined.
· Vapour density	Not determined.
	Not acterminea.
• 9.2 Other information	
· Appearance:	
· Form:	Fluid
· Important information on	
protection of health and	
environment, and on safety.	
• Ignition temperature:	Not determined.
• Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· VOC (EC)	0.00 %
· Solids content:	0.0 %
• Change in condition	
· Evaporation rate	Not determined.
 Information with regard to physical hazard classes Explosives 	Void
· Flammable gases	Void
· Aerosols	Void
• Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and	
mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and	
mixtures	Void
· Substances and mixtures, which	
emit flammable gases in contact	
with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void

10 Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided:
- No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available. (Contd. on page 5)

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(Contd. of page 4)

Trade name: Varius Antiserum to Human Proteins

- 10.6 Hazardous decomposition products:
 - No dangerous decomposition products known.

11 Toxicological information

	11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
•	Acute toxicity
	Based on available data, the classification criteria are not met.
٠	Skin corrosion/irritation
	Based on available data, the classification criteria are not met.
•	Serious eye damage/irritation
	Based on available data, the classification criteria are not met.
•	Respiratory or skin sensitisation
	Based on available data, the classification criteria are not met.
•	Germ cell mutagenicity
	Based on available data, the classification criteria are not met.
•	Carcinogenicity
	Based on available data, the classification criteria are not met.
·	Reproductive toxicity
	Based on available data, the classification criteria are not met.
•	STOT-single exposure
	Based on available data, the classification criteria are not met.
•	STOT-repeated exposure
	Based on available data, the classification criteria are not met.
•	Aspiration hazard
	Based on available data, the classification criteria are not met.
	11.2 Information on other hazards
•	Endocrine disrupting properties
	The product contains substances, which affect the thyroid system and
	other hormonal systems.
	None of the ingredients is listed.

12 Ecological information

```
· 12.1 Toxicity
· Aquatic toxicity: No further relevant information available.

    12.2 Persistence and degradability

 No further relevant information available.
· 12.3 Bioaccumulative potential
 No further relevant information available.
· 12.4 Mobility in soil No further relevant information available.
· 12.5 Results of PBT and vPvB assessment
· PBT: Not applicable.
· vPvB: Not applicable.
· 12.6 Endocrine disrupting properties
 The product does not contain substances with endocrine disrupting
 properties.
· 12.7 Other adverse effects
· Additional ecological information:
· General notes:
 Water hazard class 1 (German Regulation) (Self-assessment): slightly
 hazardous for water
                                                            (Contd. on page 6)
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Trade name: Varius Antiserum to Human Proteins

(Contd. of page 5) Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13 Disposal considerations

- · 13.1 Waste treatment methods
- **Recommendation** Smaller quantities can be disposed of with household waste.
- Uncleaned packaging:
- · Recommendation:
- Disposal must be made according to official regulations.
- · Recommended cleansing agents:
- Water, if necessary together with cleansing agents.

14 Transport information

· 14.1 UN number or ID number	
· ADR, IMDG, IATA	not regulated
· 14.2 UN proper shipping name	
· ADR, IMDG, IATA	not regulated
\cdot 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	not regulated
· 14.4 Packing group	
· ADR, IMDG, IATA	not regulated
• 14.5 Environmental hazards:	Not applicable.
\cdot 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk	
according to IMO instruments	Not applicable.
· UN "Model Regulation":	not regulated

15 Regulatory information

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

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I Substance is not listed.

- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II
- None of the ingredients is listed.
- · REGULATION (EU) 2019/1148

 Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

(Contd. on page 7)

ΤE

Safety data sheet according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 24.06.2024 Version number 1

Revision: 24.06.2024

Trade name: Varius Antiserum to Human Proteins

(Contd. of page 6)

• Regulation (EC) No 273/2004 on drug precursors None of the ingredients is listed.

 Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878. · Department issuing SDS: Product safety department. · Contact: -· Date of previous version: 26.03.2024 · Abbreviations and acronyms: ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals CAS: Chemical Abstracts Service (division of the American Chemical Society) VOC: Volatile Organic Compounds (USA, EU) PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative \cdot * Data compared to the previous version altered.

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