

03.04.2024 Kit Components

Product code	Description			
CSI087209	S. Paratyphi B antigen H - Tube Test			
Components:				
392504	Sospensione S. Paratyphi B antigen H			
392073	Tampone PBS pH 7.2			



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Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

Printing date 03.04.2024

Version number 1

Revision: 03.04.2024

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

- · 1.1 Diagnostic Reagent
- · Trade name: Sospensione S. Paratyphi B antigen H
- · Article number: 392504
- · CAS Number:

7732-18-5

· EC number:

231-791-2

- **UFI:** NP01-Q05F-C00M-R8YH
- · 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
- · 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

7732-18-5 water, distilled, conductivity or of similar purity

(Contd. on page 2)

Printing date 03.04.2024 Version number 1 Revision: 03.04.2024

Trade name: Sospensione S. Paratyphi B antigen H

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· Identification number(s)

• EC number: 231-791-2

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.
- · 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.
- · 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.

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Printing date 03.04.2024 Version number 1 Revision: 03.04.2024

Trade name: Sospensione S. Paratyphi B antigen H

(Contd. of page 2)

· 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:
 Not required.
- · 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.

· 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.

 \cdot Eye/face protection Goggles recommended during refilling

9 Physical and chemical properties

- \cdot 9.1 Information on basic physical and chemical properties
- · General Information

Physical state
Colour:
Odour:
Odourless
Odour threshold:
Not determined.

• Melting point/freezing point: 0 °C

· Boiling point or initial boiling

· Flammability Not applicable.

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Decomposition temperature: Not determined.
pH Not determined.

· Viscosity:

Kinematic viscosity
 Dynamic at 20 °C:
 Not determined.
 0.952 mPas

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Printing date 03.04.2024 Version number 1 Revision: 03.04.2024

Trade name: Sospensione S. Paratyphi B antigen H

(Contd. of page 3) · Solubility · water: Fully miscible. · Partition coefficient n-octanol/ water (log value) Not determined. · Vapour pressure at 20 °C: 23 hPa (7732-18-5 water, distilled, conductivity or of similar purity) · Density and/or relative density · Density at 20 °C: $1 g/cm^3$ · Relative density Not determined. · Vapour density Not determined. · 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: · Water: 98.9 % · VOC (EC) 0.00 % · Solids content: 0.9 % · Molecular weight 18.02 g/mol · 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 \cdot 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

10 Stability and reactivity

· Desensitised explosives

· 10.1 Reactivity No further relevant information available.

Void

Void

(Contd. on page 5)

Printing date 03.04.2024 Version number 1 Revision: 03.04.2024

Trade name: Sospensione S. Paratyphi B antigen H

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- · 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.
- · 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 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.

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Printing date 03.04.2024 Version number 1 Revision: 03.04.2024

Trade name: Sospensione S. Paratyphi B antigen H

(Contd. of page 5)

- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes: Not hazardous for water.

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	ΙD	number
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· ADR, IMDG, IATA not regulated

· 14.2 UN proper shipping name

· ADR, IMDG, IATA

· 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.

 \cdot 14.7 Maritime transport in bulk

according to IMO instruments
Not applicable.

· UN "Model Regulation": not regulated

15 Regulatory information

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

not regulated

- · 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.

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Printing date 03.04.2024 Version number 1 Revision: 03.04.2024

Trade name: Sospensione S. Paratyphi B antigen H

(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.

- · Department issuing SDS: Product safety department.
- · Contact:
- · Date of previous version: 02.04.2024
- 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

EINECS: European Inventory of Existing Commercial 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

Printing date 03.04.2024

Version number 1

Revision: 13.12.2023

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

· 1.1 Diagnostic Reagent

· Trade name: Tampone PBS pH 7.2

· Article number: 392073

· CAS Number:

7732-18-5

· EC number:

231-791-2

- **UFI:** U5W0-X0V5-T00A-M92V
- · 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
- · 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

7732-18-5 water, distilled, conductivity or of similar purity

(Contd. on page 2)

Printing date 03.04.2024 Version number 1 Revision: 13.12.2023

Trade name: Tampone PBS pH 7.2

(Contd. of page 1)

· Identification number(s)

• **EC** number: 231-791-2

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.
- · 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.
- · 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.

(Contd. on page 3)

Printing date 03.04.2024 Version number 1 Revision: 13.12.2023

Trade name: Tampone PBS pH 7.2

(Contd. of page 2)

· 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:
 Not required.
- · 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.

· 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.

 \cdot 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
Colour:
Odour:
Odourless
Odour threshold:
Not determined.

• Melting point/freezing point: 0 °C

· Boiling point or initial boiling

· Flammability Not applicable.

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Decomposition temperature: Not determined.
pH Not determined.

· Viscosity:

Kinematic viscosity
 Dynamic at 20 °C:
 Not determined.
 0.952 mPas

(Contd. on page 4)

Printing date 03.04.2024 Version number 1 Revision: 13.12.2023

Trade name: Tampone PBS pH 7.2

(Contd. of page 3) · Solubility · water: Fully miscible. · Partition coefficient n-octanol/ water (log value) Not determined. · Vapour pressure at 20 °C: 23 hPa (7732-18-5 water, distilled, conductivity or of similar purity) · Density and/or relative density · Density at 20 °C: $1 g/cm^3$ · Relative density Not determined. · Vapour density Not determined. · 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: · Water: 98.9 % · VOC (EC) 0.00 % · Solids content: 0.9 % · Molecular weight 18.02 g/mol · 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 \cdot 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 · Desensitised explosives Void

10 Stability and reactivity

· 10.1 Reactivity No further relevant information available.

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Printing date 03.04.2024 Version number 1 Revision: 13.12.2023

Trade name: Tampone PBS pH 7.2

(Contd. of page 4)

- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- \cdot 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.
- · 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 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.

(Contd. on page 6)

Printing date 03.04.2024 Version number 1 Revision: 13.12.2023

Trade name: Tampone PBS pH 7.2

(Contd. of page 5)

- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes: Not hazardous for water.

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 nun	mber or	ID	number	
	A DD	TMDC	$T \Lambda T \Lambda$			

· ADR, IMDG, IATA not regulated

· 14.2 UN proper shipping name

· ADR, IMDG, IATA

not regulated

not regulated

- · 14.3 Transport hazard class(es)
- · ADR, ADN, IMDG, IATA
- · Class not regulated
- · 14.4 Packing group
- · ADR, IMDG, IATA
- 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 applicable.

· UN "Model Regulation":

not regulated

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 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)

Printing date 03.04.2024 Version number 1 Revision: 13.12.2023

Trade name: Tampone PBS pH 7.2

(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.

- · Department issuing SDS: Product safety department.
- · Contact:
- 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

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