

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

1.1. Product identifier

Trade name or designation of the mixture	Protein S Activator Reagent
Registration number	-
Synonyms	None.
Product code	843L, 843L-HS, 843LACT
Issue date	25-February-2021
Version number	03
Revision date	25-February-2021
Supersedes date	01-December-2017

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

Identified uses	For In Vitro Diagnostic use.
Uses advised against	Use in accordance with supplier's recommendations.

1.3. Details of the supplier of the safety data sheet

Corporate Headquarters BioMedica Diagnostics Inc.
 94 Wentworth Road, PO Box 1030
 Windsor, Nova Scotia CANADA B0N 2T0

Contact person Corporate Phone: 1-902-798-5105
 Corporate Fax: 1-902-798-1025
 Email: info@biomedicadiagnostics.com
 Website: www.biomedicadiagnostics.com

1.4. Emergency telephone number US, Canada, Puerto Rico & Virgin Islands 1-800-255-3924
 International +1-813-248-0585
 Australia 1-300-954-583
 Brazil 0-800-591-6042
 China 400-120-0751
 India 000-800-100-4086
 Mexico 01-800-099-0731

Contract number MIS9591327

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

Hazard summary Dust may cause eye, skin and respiratory tract irritation.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Hazard pictograms	None.
Signal word	None.
Hazard statements	The mixture does not meet the criteria for classification.

Precautionary statements

Prevention	Observe good laboratory hygiene practices.
Response	Wash with plenty of water.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.

Supplemental label information None.

2.3. Other hazards Not a PBT or vPvB substance or mixture.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Sodium chloride	5 - 10	7647-14-5 231-598-3	01-2119485491-33-XXXX	-	
Classification:	-				

List of abbreviations and symbols that may be used above

CLP: Regulation No. 1272/2008.

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation Move to fresh air. If breathing is difficult, give oxygen. Get medical attention if any discomfort continues.

Skin contact For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.

Eye contact In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Ingestion Rinse mouth thoroughly if dust is ingested. Get medical advice/attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed Dust may cause eye, skin and respiratory tract irritation.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media Water spray, carbon dioxide, dry chemical or alcohol-resistant foam.

Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace. Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel No special precautions are necessary beyond normal good hygiene practices. See Section 8 of the SDS for additional personal protection advice when handling this product.

For emergency responders Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up Avoid dust formation. Sweep or scoop up and remove.

6.4. Reference to other sections For personal protection, see Section 8 of the SDS. For waste disposal, see Section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid prolonged exposure. Avoid contact with skin and eyes. Use personal protection as recommended in Section 8 of the SDS.
7.2. Conditions for safe storage, including any incompatibilities	Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.
7.3. Specific end use(s)	For In Vitro Diagnostic use only.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived no-effect level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

8.2. Exposure controls

Appropriate engineering controls	No special ventilation requirements.
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Individual protection measures, such as personal protective equipment

General information	Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eye/face protection	Wear dust-resistant safety goggles.
Skin protection	
- Hand protection	It is a good industrial hygiene practice to minimise skin contact. Chemical resistant gloves are recommended.
- Other	It is a good industrial hygiene practice to minimise skin contact.
Respiratory protection	In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practices.
Environmental exposure controls	Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	White powder.
Physical state	Solid.
Form	Powder.
Colour	White.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.

Relative density	Not available.
Solubility(ies)	Water soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidizing properties	Not oxidising.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	Stable at normal conditions.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Hazardous polymerisation will not occur.
10.4. Conditions to avoid	Keep away from heat.
10.5. Incompatible materials	Strong oxidising agents. Strong acids.
10.6. Hazardous decomposition products	Carbon oxides.

SECTION 11: Toxicological information

Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system.
Skin contact	Dust may irritate skin.
Eye contact	Dust in the eyes will cause irritation.
Ingestion	May cause discomfort if swallowed.

Symptoms Mechanical irritation of skin, eyes and respiratory system.

11.1. Information on toxicological effects

Acute toxicity May cause discomfort if swallowed.

Components	Species	Test results
Sodium chloride (CAS 7647-14-5)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 10000 mg/kg
<i>Oral</i>		
LD50	Rat	> 3980 mg/kg
<i>Other</i>		
LD50	Mouse	2602 mg/kg
Skin corrosion/irritation	Dust may irritate skin.	
Serious eye damage/eye irritation	Dust may irritate the eyes.	
Respiratory sensitisation	Not classified.	
Skin sensitisation	Not classified.	
Germ cell mutagenicity	Not classified.	
Carcinogenicity	Not classified.	
Reproductive toxicity	Not classified.	
Specific target organ toxicity - single exposure	Not classified.	
Specific target organ toxicity - repeated exposure	Not classified.	
Aspiration hazard	Not classified.	
Mixture versus substance information	Not available.	

Other information No other specific acute or chronic health impact noted.

SECTION 12: Ecological information

12.1. Toxicity

Components	Species	Test results
Sodium chloride (CAS 7647-14-5)		
Aquatic		
Crustacea	EC50 Water flea (Daphnia magna)	874 mg/l, 48 hours

12.2. Persistence and degradability No data available.

12.3. Bioaccumulative potential No data available.

Partition coefficient n-octanol/water (log Kow) Not available.

Bioconcentration factor (BCF) Not available.

12.4. Mobility in soil Not available.

Mobility in general The product is soluble in water.

12.5. Results of PBT and vPvB assessment Not a PBT or vPvB substance or mixture.

12.6. Other adverse effects The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste Dispose in accordance with all applicable regulations.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

ADN

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended
Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended
Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended
Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended
Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended
Not listed.
Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended
Not listed.
Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended
Not listed.
Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA
Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended
Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended
Not listed.
Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended
Not listed.
Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding, as amended
Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances
Not listed.
Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work
Not listed.
Directive 94/33/EC on the protection of young people at work
Not listed.

Other regulations

This product does not meet the criteria for classification according to Regulation (EC) 1272/2008 (CLP Regulation) and Directive 1999/45/EC and their amendments respectively. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006 as amended.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

CLP: Regulation No. 1272/2008.
DNEL: Derived No-Effect Level.
PNEC: Predicted No-Effect Concentration.

References

Not available.

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any H-statements not written out in full under Sections 2 to 15

None.

Training information

Follow training instructions when handling this material.

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

1.1. Product identifier

Name of the substance	Protein S Deficient Plasma
Identification number	-
Registration number	-
Synonyms	None.
Product code	843L, 843L-HS, 843LDP
Issue date	25-February-2021
Version number	03
Revision date	25-February-2021
Supersedes date	01-December-2017

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

Identified uses	Various.
Uses advised against	Use in accordance with supplier's recommendations.

1.3. Details of the supplier of the safety data sheet

Corporate Headquarters BioMedica Diagnostics Inc.
 94 Wentworth Road, PO Box 1030
 Windsor, Nova Scotia CANADA B0N 2T0

Contact person Corporate Phone: 1-902-798-5105
 Corporate Fax: 1-902-798-1025
 Email: info@biomedicadiagnostics.com
 Website: www.biomedicadiagnostics.com

1.4. Emergency telephone number US, Canada, Puerto Rico & Virgin Islands 1-800-255-3924
 International +1-813-248-0585
 Australia 1-300-954-583
 Brazil 0-800-591-6042
 China 400-120-0751
 India 000-800-100-4086
 Mexico 01-800-099-0731

Contract number MIS9591327

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The substance has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

This substance does not meet the criteria for classification according to Directive 67/548/EEC as amended.

Classification according to Regulation (EC) No 1272/2008 as amended

This substance does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

Hazard summary

Physical hazards	Not classified for physical hazards.
Health hazards	Not classified for health hazards.
Environmental hazards	Not classified for hazards to the environment.
Specific hazards	Dust may cause eye, skin and respiratory tract irritation.
Main symptoms	Mechanical irritation of skin, eyes and respiratory system.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Contains:	Human plasma
Hazard pictograms	None.
Signal word	None.
Hazard statements	None.

Precautionary statements

Prevention	Observe good laboratory hygiene practices.
Response	Wash with plenty of water.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.

Supplemental label information None.

2.3. Other hazards Not a PBT or vPvB substance or mixture.

SECTION 3: Composition/information on ingredients

3.1. Substances

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Human plasma	100	N/A	-	-	
Classification:	DSD: -				
	CLP: -				

List of abbreviations and symbols that may be used above

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation	Move to fresh air. If breathing is difficult, give oxygen. Get medical attention if any discomfort continues.
Skin contact	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
Eye contact	In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Ingestion	Rinse mouth thoroughly if dust is ingested. Get medical advice/attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed Dust may cause eye, skin and respiratory tract irritation.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards Will burn if involved in a fire.

5.1. Extinguishing media

Suitable extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	None known.

5.2. Special hazards arising from the substance or mixture Fire will generate toxic and irritating gases.

5.3. Advice for firefighters

Special protective equipment for firefighters	Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace. Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	No special precautions are necessary beyond normal good hygiene practices. See Section 8 of the SDS for additional personal protection advice when handling this product.
For emergency responders	Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up Avoid dust formation. Sweep or scoop up and remove.

6.4. Reference to other sections For personal protection, see Section 8 of the SDS. For waste disposal, see Section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Avoid prolonged exposure. Avoid contact with skin and eyes. The source material for this product is of human origin and has been found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus Type 1 and Type 2 (HIV-1, HIV-2) using registered methods. As no known test method can provide complete assurance that products derived from human specimens will not transmit HBsAg, HCV, HIV-1, HIV-2 or other blood-borne pathogens, this reagent should be handled as recommended for any potentially infectious human specimen. Observe good laboratory hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities Store at 2 - 8°C. Store in a closed container away from incompatible materials.

7.3. Specific end use(s) Various.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived no-effect level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

8.2. Exposure controls

Appropriate engineering controls No special ventilation requirements.

Individual protection measures, such as personal protective equipment

General information	Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eyeface protection	Wear dust-resistant safety goggles.
Skin protection	
- Hand protection	It is a good industrial hygiene practice to minimise skin contact. Chemical resistant gloves are recommended.
- Other	It is a good industrial hygiene practice to minimise skin contact.
Respiratory protection	In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practices.
Environmental exposure controls	Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Straw colored powder.
Physical state	Solid.
Form	Powder.
Colour	Straw colored.
Odour	None.
Odour threshold	Not applicable.

pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not relevant.
Flash point	Not relevant.
Evaporation rate	Not available.
Flammability (solid, gas)	Non flammable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not relevant.
Vapour density	Not relevant.
Relative density	Not available.
Solubility(ies)	Soluble in water.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not relevant.
Explosive properties	Not relevant.
Oxidizing properties	Not oxidizing.

9.2. Other information

Percent volatile	Not relevant.
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SECTION 10: Stability and reactivity

10.1. Reactivity	Stable at normal conditions.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Polymerization will not occur.
10.4. Conditions to avoid	Keep away from heat.
10.5. Incompatible materials	Strong oxidising agents. Strong reducing agents. Strong acids.
10.6. Hazardous decomposition products	Carbon oxides. Nitrogen oxides.

SECTION 11: Toxicological information

Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system.
Skin contact	Dust may irritate skin.
Eye contact	Dust in the eyes will cause irritation.
Ingestion	May cause discomfort if swallowed.

Symptoms	Mechanical irritation of skin, eyes and respiratory system.
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11.1. Information on toxicological effects

Acute toxicity	May cause discomfort if swallowed.
Skin corrosion/irritation	Dust may irritate skin.
Serious eye damage/eye irritation	Dust may irritate the eyes.
Respiratory sensitisation	Not classified.
Skin sensitisation	Not classified.
Germ cell mutagenicity	Not classified.
Carcinogenicity	Not classified.
Reproductive toxicity	Not classified.
Specific target organ toxicity - single exposure	Not classified.

Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Mixture versus substance information	Not available.
Other information	No other specific acute or chronic health impact noted.

SECTION 12: Ecological information

12.1. Toxicity	No toxicity data noted for the ingredient(s).
12.2. Persistence and degradability	No data available.
12.3. Bioaccumulative potential	No data available.
Partition coefficient n-octanol/water (log K_{ow})	Not available.
Bioconcentration factor (BCF)	Not available.
12.4. Mobility in soil	Not available.
Mobility in general	The product is soluble in water.
12.5. Results of PBT and vPvB assessment	Not a PBT or vPvB substance or mixture.
12.6. Other adverse effects	No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods	
Residual waste	Dispose in accordance with all applicable regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.

SECTION 14: Transport information

ADR	Not regulated as dangerous goods.
RID	Not regulated as dangerous goods.
ADN	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended
Not listed.
Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended
Not listed.
Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended
Not listed.
Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA
Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended
Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended
Not listed.
Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended
Not listed.
Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding, as amended
Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances
Not listed.
Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work
Not listed.
Directive 94/33/EC on the protection of young people at work
Not listed.

Other regulations

This product does not meet the criteria for classification according to Regulation (EC) 1272/2008 (CLP Regulation) and Directive 67/548/EEC and their amendments respectively. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006 as amended.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

DSD: Directive 67/548/EEC.
CLP: Regulation No. 1272/2008.
DNEL: Derived No-Effect Level.
PNEC: Predicted No-Effect Concentration.

References

Not available.

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

None.

Training information

Follow training instructions when handling this material.

Disclaimer

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall BioMedica Diagnostics be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if BioMedica Diagnostics has been advised of the possibility of such damages.

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

1.1. Product identifier

Trade name or designation of the mixture	Sample Dilution Buffer
Registration number	-
Synonyms	None.
Product code	843L, 843L-HS, 843LDB
Issue date	25-February-2021
Version number	03
Revision date	25-February-2021
Supersedes date	01-December-2017

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

Identified uses	Various.
Uses advised against	Use in accordance with supplier's recommendations.

1.3. Details of the supplier of the safety data sheet

Corporate Headquarters BioMedica Diagnostics Inc.
 94 Wentworth Road, PO Box 1030
 Windsor, Nova Scotia CANADA B0N 2T0

Contact person Corporate Phone: 1-902-798-5105
 Corporate Fax: 1-902-798-1025
 Email: info@biomedicadiagnostics.com
 Website: www.biomedicadiagnostics.com

1.4. Emergency telephone number US, Canada, Puerto Rico & Virgin Islands 1-800-255-3924
 International +1-813-248-0585
 Australia 1-300-954-583
 Brazil 0-800-591-6042
 China 400-120-0751
 India 000-800-100-4086
 Mexico 01-800-099-0731

Contract number MIS9591327

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

This preparation is not classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification according to Regulation (EC) No 1272/2008 as amended

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

Hazard summary

Physical hazards	Not classified for physical hazards.
Health hazards	Not classified for health hazards.
Environmental hazards	Not classified for hazards to the environment.
Specific hazards	Avoid contact with eyes and skin. Do not ingest or inhale.
Main symptoms	Ingestion may cause irritation and malaise.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Hazard pictograms	None.
Signal word	None.
Hazard statements	None.

Precautionary statements

Prevention	Observe good laboratory hygiene practices.
Response	Wash with plenty of water.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.

Supplemental label information None.

2.3. Other hazards Not a PBT or vPvB substance or mixture.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Sodium chloride	5 - 15	7647-14-5 231-598-3	01-2119485491-33-XXXX	-	
Classification:	DSD: - CLP: -				
Sodium hydroxide	0 - < 1	1310-73-2 215-185-5	-	011-002-00-6	
Classification:	DSD: C;R35 CLP: Skin Corr. 1A;H314				

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved.

4.1. Description of first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
Eye contact	In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Ingestion	If material is ingested, immediately contact a physician or poison control centre.

4.2. Most important symptoms and effects, both acute and delayed Ingestion may cause irritation and malaise.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards The product is not flammable.

5.1. Extinguishing media

Suitable extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	None known.

5.2. Special hazards arising from the substance or mixture None known.

5.3. Advice for firefighters

Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
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For emergency responders	Use personal protection as recommended in section 8 of the SDS.
6.2. Environmental precautions	Do not allow to enter drains, sewers or watercourses.
6.3. Methods and material for containment and cleaning up	Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.
6.4. Reference to other sections	For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.
7.2. Conditions for safe storage, including any incompatibilities	Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.
7.3. Specific end use(s)	Various.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Sodium hydroxide (CAS 1310-73-2)	STEL	2 mg/m3
Biological limit values	No biological exposure limits noted for the ingredient(s).	
Recommended monitoring procedures	Follow standard monitoring procedures.	
Derived no-effect level (DNEL)	Not available.	
Predicted no effect concentrations (PNECs)	Not available.	

8.2. Exposure controls

Appropriate engineering controls	Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of inhalation of vapours.
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Individual protection measures, such as personal protective equipment

General information	Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eyeface protection	Wear approved safety glasses or goggles.
Skin protection	
- Hand protection	Wear appropriate chemical resistant gloves.
- Other	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Respiratory protection	Under normal conditions, respirator is not normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practices.
Environmental exposure controls	Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Clear, colourless liquid.
Physical state	Liquid.
Form	Liquid.
Colour	Colourless, clear.
Odour	Not available.
Odour threshold	Not available.
pH	7.2
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.

Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	Water soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non reactive under normal conditions of storage and transport.
10.2. Chemical stability	Stable under normal storage and handling conditions.
10.3. Possibility of hazardous reactions	Hazardous polymerisation does not occur.
10.4. Conditions to avoid	None under normal conditions.
10.5. Incompatible materials	Strong oxidizers, strong acids, and strong bases.
10.6. Hazardous decomposition products	None expected under normal conditions of use.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
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Information on likely routes of exposure

Inhalation	Vapours may irritate throat and respiratory system and cause coughing.
Skin contact	Prolonged skin contact may cause redness, irritation and dry skin.
Eye contact	Splashes in the eyes may cause redness and irritation.
Ingestion	May cause discomfort if swallowed.

Symptoms	Ingestion may cause irritation and malaise.
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11.1. Information on toxicological effects

Acute toxicity	May cause discomfort if swallowed.
Skin corrosion/irritation	Prolonged skin contact may cause redness, irritation and dry skin.
Serious eye damage/eye irritation	May cause eye irritation.
Respiratory sensitisation	Not classified.
Skin sensitisation	No data available.
Germ cell mutagenicity	Not classified.
Carcinogenicity	Not classified.
Reproductive toxicity	Not classified.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Mixture versus substance information	Not available.
Other information	No other specific acute or chronic health impact noted.

SECTION 12: Ecological information

12.1. Toxicity

Components		Species	Test results
Sodium chloride (CAS 7647-14-5)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	874 mg/l, 48 hours
Sodium hydroxide (CAS 1310-73-2)			
Aquatic			
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	34.59 - 47.13 mg/l, 48 hours
Acute			
Fish	LC50	Bluegill (Lepomis macrochirus)	99 mg/l, 48 hours
		Mosquitofish (Gambusia affinis affinis)	125 mg/l, 96 hours

12.2. Persistence and degradability No data is available on the degradability of this product.

12.3. Bioaccumulative potential Not available.

Partition coefficient n-octanol/water (log Kow) Not available.

Bioconcentration factor (BCF) Not available.

12.4. Mobility in soil Not available.

Mobility in general The product is soluble in water.

12.5. Results of PBT and vPvB assessment Not a PBT or vPvB substance or mixture.

12.6. Other adverse effects The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	Dispose in accordance with all applicable regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code	Waste codes should be assigned by the user based on the application for which the product was used.
Disposal methods/information	Dispose in accordance with all applicable regulations. Contract with a licensed chemical disposal agency.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

ADN

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended
Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding, as amended

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Sodium hydroxide (CAS 1310-73-2)

Directive 94/33/EC on the protection of young people at work

Sodium hydroxide (CAS 1310-73-2)

Other regulations

This product does not meet the criteria for classification according to Regulation (EC) 1272/2008 (CLP Regulation) and Directive 67/548/EEC and their amendments respectively. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006 as amended.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

DSD: Directive 67/548/EEC.
CLP: Regulation No. 1272/2008.
DNEL: Derived No-Effect Level.
PNEC: Predicted No-Effect Concentration.

References

Not available.

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R35 Causes severe burns.
H314 Causes severe skin burns and eye damage.

Training information

Follow training instructions when handling this material.

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