Medicines & Healthcare products Regulatory Agency

NIBSC | Confidence in biological medicines

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 18-May-2024 **Revision Number** 1.02

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

1.1. Product identifier

Product Code(s) 16/164

Product Name Sabin bivalnet Polio vaccines types 1 and 3 (1st International Standard)

Form Not applicable

Pure substance/mixture Mixture

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

Recommended use Laboratory use

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Supplier

MHRA
Blanche Lane
South Mimms
Potters Bar
Hertfordshire
EN6 3QG
UK

For further information, please contact

E-mail address Standards@nibsc.org

1.4. Emergency telephone number

Emergency Telephone +44 (0) 1707 641467 - Mon to Fri (9.00 – 17.00 GMT) Excluding weekends and English public holiday
+44 (0) 1707 641200 - Any other time

Emergency Telephone - §45 - (EC)1272/2008	
Europe	**112**
Austria	No information available

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Bulgaria	
Croatia	
Cyprus	
Czech Republic	
Denmark	
France	
Hungary	
Ireland	
Italy	
Lithuania	
Luxembourg	
Netherlands	
Norway	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	
Sweden	
Switzerland	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to
Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation	Category 1 - (H317)

2.2. Label elements

Contains Sodium pyruvate



Signal word
Warning

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Hazard statements
H317 - May cause an allergic skin reaction

Precautionary Statements - EU (§28, 1272/2008)
P261 - Avoid breathing dust/fume/gas/mist/vapours/spray
P280 - Wear protective gloves
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash it before reuse
P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

Causes mild skin irritation.

This mixture contains no substance considered to be persistent, bioaccumulating or toxic (PBT). This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

Chemical name	EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation	EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances
Sodium chloride	-	-
Sodium bicarbonate	-	-
Potassium chloride	-	-
Calcium Chloride Dihydrate	-	-
L-leucine	-	-
L-Isoleucine	-	-
L-Valine	-	-
L-Threonine	-	-
L-Phenylalanine	-	-
Methionine	-	-
L-Glutamic acid	-	-
L-Aspartic Acid	-	-
Nicotinamide	-	-
L-Tryptophan	-	-
L-serine	-	-
L-Proline	-	-
L-Alanine	-	-
Glycine	-	-

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SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sodium chloride 7647-14-5	40 - 60	-	231-598-3	-			
Sodium bicarbonate 144-55-8	10 - 20	-	205-633-8	-			
Potassium chloride 7447-40-7	3 - <5	-	231-211-8	-			
Calcium Chloride Dihydrate 10035-04-8	1 - <3	-	640-414-4	Acute Tox. 4 (H302) Eye Irrit. 2 (H319)			
L-leucine 61-90-5	0.1 - 1	-	200-522-0	-			
L-Isoleucine 73-32-5	0.1 - 1	-	200-798-2	-			
L-Valine 72-18-4	0.1 - 1	-	200-773-6	-			
L-Threonine 72-19-5	0.1 - 1	-	200-774-1	-			
L-Phenylalanine 63-91-2	0.1 - 1	-	200-568-1	-			
Methionine 63-68-3	0.1 - 1	-	200-562-9	-			
L-Glutamic acid 56-86-0	0.1 - 1	-	200-293-7	-			
L-Aspartic Acid 56-84-8	0.1 - 1	-	200-291-6	-			
Nicotinamide 98-92-0	<0.1	-	202-713-4	Eye Irrit. 2 (H319)			
L-Tryptophan 73-22-3	<0.1	-	200-795-6	-			
L-serine	<0.1	-	200-274-3	-			

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56-45-1							
L-Proline 147-85-3	<0.1	-	205-702-2	-			
L-Alanine 56-41-7	<0.1	-	200-273-8	-			
Glycine 56-40-6	<0.1	-	200-272-2	-			

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Sodium chloride 7647-14-5	3550	10000	No data available	No data available	No data available
Sodium bicarbonate 144-55-8	4220	No data available	No data available	No data available	No data available
Potassium chloride 7447-40-7	2600	No data available	No data available	No data available	No data available
Calcium Chloride Dihydrate 10035-04-8	1000	5000	No data available	No data available	No data available
Methionine 63-68-3	36000	No data available	No data available	No data available	No data available
L-Glutamic acid 56-86-0	30000	2000	No data available	No data available	No data available
L-Aspartic Acid 56-84-8	9000	No data available	No data available	No data available	No data available
Nicotinamide 98-92-0	3500	2000	No data available	No data available	No data available
L-Tryptophan 73-22-3	16000	No data available	No data available	No data available	No data available
L-Proline 147-85-3	5110	No data available	No data available	No data available	No data available
Glycine 56-40-6	7930	No data available	No data available	No data available	No data available

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Additional information
BSL1.
This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.
Skin contact	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a doctor.
Ingestion	Rinse mouth.

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

Symptoms	Itching. Rashes. Hives. Prolonged contact may cause redness and irritation.

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

Note to doctors	May cause sensitisation in susceptible persons. Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.

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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Product is or contains a sensitiser. May cause sensitisation by skin contact.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse.

General hygiene considerations Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
Potassium chloride 7447-40-7	-	-	-	TWA: 5.0 mg/m³	-
L-Aspartic Acid 56-84-8	-	-	-	TWA: 10.0 mg/m³	-
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Sodium bicarbonate 144-55-8	-	TWA: 5 mg/m³ Ceiling: 10 mg/m³	-	-	-
Calcium Chloride Dihydrate 10035-04-8	-	TWA: 5 mg/m³ Ceiling: 4 mg/m³	-	-	-
Chemical name	Ireland	Italy MDLPS	Italy AIDII	Latvia	Lithuania
Sodium chloride 7647-14-5	-	-	-	TWA: 5 mg/m³	TWA: 5 mg/m³
Sodium bicarbonate	-	-	-	TWA: 5 mg/m³	-

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144-55-8					
Potassium chloride 7447-40-7	-	-	-	TWA: 5 mg/m³	TWA: 5 mg/m³
Calcium Chloride Dihydrate 10035-04-8	-	-	-	TWA: 2 mg/m³	-
L-leucine 61-90-5	-	-	-	TWA: 5 mg/m³	-
L-Isoleucine 73-32-5	-	-	-	TWA: 5 mg/m³	-
L-Valine 72-18-4	-	-	-	TWA: 5 mg/m³	-
L-Threonine 72-19-5	-	-	-	TWA: 2 mg/m³	-
L-Phenylalanine 63-91-2	-	-	-	TWA: 5 mg/m³	-
Methionine 63-68-3	-	-	-	TWA: 5 mg/m³	-
L-Glutamic acid 56-86-0	-	-	-	TWA: 10 mg/m³	-
L-Aspartic Acid 56-84-8	-	-	-	TWA: 10 mg/m³	-
Nicotinamide 98-92-0	-	-	-	TWA: 1 mg/m³	TWA: 1 mg/m³
L-Tryptophan 73-22-3	-	-	-	TWA: 2 mg/m³	-
L-serine 56-45-1	-	-	-	TWA: 5 mg/m³	-
L-Proline 147-85-3	-	-	-	TWA: 5 mg/m³	-
L-Alanine 56-41-7	-	-	-	TWA: 5 mg/m³	-
Glycine 56-40-6	-	-	-	TWA: 5 mg/m³	-

Biological occupational exposure limits
This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC)	No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection	Avoid contact with eyes. Wear safety glasses with side shields (or goggles).
Hand protection	Wear suitable gloves. The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear protective nitrile rubber gloves.
Skin and body protection	Wear suitable protective clothing.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.
Environmental exposure controls	Do not allow into any sewer, on the ground or into any body of water.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Liquid
Colour	colourless
Odour	No information available.
Odour threshold	No information available

Property	**Values**	**Remarks • Method**
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	

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limits		
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

9.2.1. Information with regards to physical hazard classes
Not applicable

9.2.2. Other safety characteristics
No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data
Sensitivity to mechanical impact None.
Sensitivity to static discharge None.

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10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact May cause sensitisation by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). Causes mild skin irritation.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Itching. Rashes. Hives. Prolonged contact may cause redness and irritation.

Numerical measures of toxicity

No information available

Acute toxicity

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The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	4,675.80 mg/kg
ATEmix (dermal)	99,999.00 mg/kg
ATEmix (inhalation-gas)	99,999.00 ppm
ATEmix (inhalation-dust/mist)	99,999.00 mg/l
ATEmix (inhalation-vapour)	99,999.00 mg/l

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium chloride	= 3550 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h
Sodium bicarbonate	= 4220 mg/kg (Rat)		
Potassium chloride	= 2600 mg/kg (Rat)		
Calcium Chloride Dihydrate	= 1000 mg/kg (Rat)	> 5000 mg/kg (Rabbit)	
L-leucine	> 2000 mg/kg (Rat)		
L-Isoleucine			> 5410 mg/m³ (Rat) 4 h
L-Valine			> 5260 mg/m³ (Rat) 4 h
L-Threonine			> 5.15 mg/L (Rat) 4 h
Methionine	= 36 g/kg (Rat)		> 5.25 mg/L (Rat)
L-Glutamic acid	> 30 g/kg (Rat)	> 2000 mg/kg (Rat)	
L-Aspartic Acid	= 9000 mg/kg (Rat)		
Nicotinamide	= 3500 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	
L-Tryptophan	> 16 g/kg (Rat)		> 5.75 mg/L (Rat) 4 h
L-Proline	> 5110 mg/kg (Rat)		
Glycine	= 7930 mg/kg (Rat)		

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation Classification based on data available for ingredients. Causes mild skin irritation.

Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitisation	May cause an allergic skin reaction.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties	No information available.

11.2.2. Other information

Other adverse effects	No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

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Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium chloride	-	LC50: 5560 - 6080mg/L (96h, Lepomis macrochirus) LC50: =12946mg/L (96h, Lepomis macrochirus) LC50: 6020 - 7070mg/L (96h, Pimephales promelas) LC50: =7050mg/L (96h, Pimephales promelas) LC50: 6420 - 6700mg/L (96h, Pimephales promelas) LC50: 4747 - 7824mg/L (96h, Oncorhynchus mykiss)	-	EC50: =1000mg/L (48h, Daphnia magna) EC50: 340.7 - 469.2mg/L (48h, Daphnia magna)
Sodium bicarbonate	-	LC50: 8250 - 9000mg/L (96h, Lepomis macrochirus)	-	EC50: =2350mg/L (48h, Daphnia magna)
Potassium chloride	EC50: =2500mg/L (72h, Desmodesmus subspicatus)	LC50: =1060mg/L (96h, Lepomis macrochirus) LC50: 750 - 1020mg/L (96h, Pimephales promelas)	-	EC50: =825mg/L (48h, Daphnia magna) EC50: =83mg/L (48h, Daphnia magna)
Calcium Chloride Dihydrate	-	LC50: =10650mg/L (96h, Lepomis macrochirus)	-	LC50: 2280000 - 3948000µg/L (48h, Daphnia magna)
L-Valine	-	LC50: >10g/L (96h, Danio rerio)	-	-
Methionine	-	> 3 200 mg/L(Fish, 96h)	-	324 mg/l (Daphnia,48h)
L-Glutamic acid	-	LC50: >100mg/L (96h, Cyprinus carpio)	-	-
Nicotinamide	-	LC50: >1000mg/L (96h, Poecilia reticulata)	-	EC50 > 1000 mg/l (Daphnia, 24h)
L-Proline	-	-	-	> 100 mg/L (Daphnia Magna, 48h)

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Glycine	-	LC50: >1000mg/L (96h, Oryzias latipes)	-	EC50: >220 mg/L (48h, daphnia)

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

Chemical name	Partition coefficient
L-leucine	-1.59
L-Isoleucine	-1.72
L-Valine	-2.26
L-Threonine	-2.94
L-Phenylalanine	-1.52
Methionine	-1.87
L-Glutamic acid	-4
L-Aspartic Acid	-3.89
Nicotinamide	-0.38
L-Tryptophan	-1.06
L-serine	-3.07
L-Proline	-2.54
L-Alanine	-2.74
Glycine	-3.21

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Sodium chloride	The substance is not PBT / vPvB
Sodium bicarbonate	The substance is not PBT / vPvB
Potassium chloride	The substance is not PBT / vPvB
L-leucine	The substance is not PBT / vPvB
L-Isoleucine	The substance is not PBT / vPvB
L-Valine	The substance is not PBT / vPvB

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L-Threonine	The substance is not PBT / vPvB
L-Phenylalanine	The substance is not PBT / vPvB
Methionine	The substance is not PBT / vPvB
L-Glutamic acid	The substance is not PBT / vPvB
L-Aspartic Acid	The substance is not PBT / vPvB
Nicotinamide	The substance is not PBT / vPvB
L-Tryptophan	The substance is not PBT / vPvB
L-serine	The substance is not PBT / vPvB
L-Proline	The substance is not PBT / vPvB
L-Alanine	The substance is not PBT / vPvB
Glycine	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

14.1 UN number or ID number Not regulated
14.2 UN proper shipping name Not regulated
14.3 Transport hazard class(es) Not regulated
14.4 Packing group Not regulated
14.5 Environmental hazards Not applicable
14.6 Special precautions for user
Special Provisions None

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IMDG

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Marine pollutant	Not applicable
14.6 Special precautions for user Special Provisions	None No information available
14.7 Maritime transport in bulk according to IMO instruments	No information available

RID

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user Special Provisions	None

ADR

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user Special Provisions	None

SECTION 15: Regulatory information

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

National regulations

France
Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
Sodium chloride 7647-14-5	RG 78	-
Potassium chloride	RG 67	-

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7447-40-7		

Water hazard class (WGK) slightly hazardous to water (WGK 1)

Poland

SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650) . Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

European Union

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

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

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Not applicable

Persistent Organic Pollutants
Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009
Not applicable

EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Sodium chloride - 7647-14-5	Plant protection agent
Sodium bicarbonate - 144-55-8	Plant protection agent

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Sodium chloride - 7647-14-5	Product-type 1: Human hygiene

International Inventories

TSCA	Contact supplier for inventory compliance status
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AIIC	Contact supplier for inventory compliance status

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

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15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment is not required for this substance

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3
H302 - Harmful if swallowed
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation

Legend
SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	Sk*	Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

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Key literature references and sources for data used to compile the SDS
Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine’s PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
Organisation for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date 18-May-2024

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006
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End of Safety Data Sheet