

Creation Date 23-Aug-2012 Revision Date 10-Dec-2021 Revision Number 3

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Description: <u>Haemophilus influenzae type b Agglutinating Sera</u>

Cat No. : R30166101

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

Recommended Use Laboratory chemicals.
Uses advised against No Information available

1.3. Details of the supplier of the safety data sheet

Company Oxoid Ltd

Wade Road

Basingstoke, Hants, UK

RG24 8PW

Tel: +44 (0) 1256 841144

EU entity/business name Oxoid Deutschland GmbH

Postfach 10 07 53

D-46483 Wesel GERMANY

Tel: + 49 (0) 281 1520 Fax: 49 (0) 281 1521

E-mail address mbd-sds@thermofisher.com

1.4. Emergency telephone number

Chemtrec US: (800) 424-9300 Chemtrec EU: 001-703-527-3887 Chemtrec China: 400 120 4937

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP Classification - Regulation (EC) No 1272/2008

Physical hazards

Based on available data, the classification criteria are not met

Health hazards

Based on available data, the classification criteria are not met

Haemophilus influenzae type b Agglutinating Sera

Revision Date 10-Dec-2021

Environmental hazards

Based on available data, the classification criteria are not met

Full text of Hazard Statements: see section 16

2.2. Label elements

Signal Word None

Hazard Statements

Precautionary Statements

2.3. Other hazards

No information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	EC No	Weight %	CLP Classification - Regulation (EC) No 1272/2008
Phenol	108-95-2	EEC No. 203-632-7	0.5	Acute Tox. 3 (H301)
				Acute Tox. 3 (H311)
				Acute Tox. 3 (H331)
				Skin Corr. 1B (H314)
				Eye Dam. 1 (H318)
				Muta. 2 (H341)
				STOT RE 2 (H373)
Sodium hydroxide	1310-73-2	215-185-5	<0.5	Skin Corr. 1A (H314)
				Eye Dam. 1 (H318)

Component	Specific concentration limits	M-Factor	Component notes
	(SCL's)		
Phenol	Eye Irrit. 2 (H319) :: 1%<=C<3%	-	-
	Skin Corr. 1B (H314) :: C>=3%		
	Skin Irrit. 2 (H315) :: 1%<=C<3%		
Sodium hydroxide	Skin Corr. 1A :: C>=5%	-	-
	Skin Corr. 1B :: 2%<=C<5%		
	Eye Irrit. 2 :: 0.5%<=C<2%		ļ.
	Skin Irrit. 2 :: 0.5%<=C<2%		ļ.

Full text of Hazard Statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Eye Contact Rinse thoroughly with plenty of water, also under the eyelids. Seek immediate medical

attention/advice.

Haemophilus influenzae type b Agglutinating Sera

Skin Contact Wash off immediately with soap and plenty of water. Get medical attention immediately if

symptoms occur.

Ingestion Clean mouth with water and drink afterwards plenty of water. Get medical attention.

Inhalation Remove to fresh air. Get medical attention if symptoms occur.

Self-Protection of the First Aider Ensure that medical personnel are aware of the material(s) involved, take precautions to

protect themselves and prevent spread of contamination.

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

No information available.

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

Notes to Physician 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. Water spray, carbon dioxide (CO2), dry chemical, alcohol-resistant foam.

Extinguishing media which must not be used for safety reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

Hazardous Combustion Products

Carbon oxides, Nitrogen oxides (NOx), Hydrogen bromide.

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes or clothing. Ensure adequate ventilation.

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

Soak up with inert absorbent material. Clean contaminated surface thoroughly.

6.4. Reference to other sections

Haemophilus influenzae type b Agglutinating Sera

Revision Date 10-Dec-2021

Refer to protective measures listed in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid contact with skin, eyes or clothing. Do not breathe mist/vapors/spray. Ensure adequate ventilation.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Keep at temperatures between 2° and 8 °C.

Technical Rules for Hazardous Substances (TRGS) 510 Class 12 Storage Class (LGK) (Germany)

7.3. Specific end use(s)

Use in laboratories

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

List source(s): **EU** - Commission Directive (EU) 2019/1831 of 24 October 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC

Component	The United Kingdom	European Union	Ireland
Phenol	STEL: 4 ppm 15 min	TWA: 2 ppm (8h)	TWA: 2 ppm 8 hr.
	STEL: 16 mg/m ³ 15 min	TWA: 8 mg/m ³ (8h)	TWA: 8 mg/m ³ 8 hr.
	TWA: 2 ppm 8 hr	STEL: 4 ppm (15min)	STEL: 4 ppm 15 min
	TWA: 7.8 mg/m ³ 8 hr	STEL: 16 mg/m ³ (15min)	STEL: 16 mg/m ³ 15 min
	Skin	Skin	Skin
Sodium hydroxide	2 mg/m³ STEL		STEL: 2 mg/m ³ 15 min

Biological limit values

Derived No Effect Level (DNEL) / Derived Minimum Effect Level (DMEL)

See table for values

Component	Acute effects local (Dermal)	Acute effects systemic (Dermal)	Chronic effects local (Dermal)	Chronic effects systemic (Dermal)
Phenol 108-95-2 (0.5)				DNEL = 1.23mg/kg bw/dav

	Component	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
Г	Phenol	DNEL = 16mg/m ³			DNEL = 8mg/m ³
L	108-95-2 (0.5)				
	Sodium hydroxide			DNEL = 1mg/m ³	
	1310-73-2 (<0.5)				ļ

Predicted No Effect Concentration (PNEC)

See values below.

Component	Fresh water	Fresh water	Water Intermittent	Microorganisms in	Soil (Agriculture)
		sediment		sewage treatment	
Phenol	PNEC =	PNEC =	PNEC = 0.031mg/L	PNEC = 2.1mg/L	PNEC =
108-95-2 (0.5)	0.0077mg/L	0.0915mg/kg		_	0.136mg/kg soil dw
		sediment dw			

Component	Marine water	Marine water sediment	Marine water intermittent	Food chain	Air
Phenol	PNEC =	PNEC =			
108-95-2 (0.5)	0.00077mg/L	0.00915mg/kg			
		sediment dw			

8.2. Exposure controls

Engineering Measures

Ensure adequate ventilation, especially in confined areas.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

Personal protective equipment

Eye Protection Wear safety glasses with side shields (or goggles) (European standard - EN 166)

Hand Protection Protective gloves

-	Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
-	Disposable gloves	See manufacturers	-	EN 374	(minimum requirement)
l		recommendations			

Skin and body protection Long sleeved clothing.

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

Respiratory Protection When workers are facing concentrations above the exposure limit they must use

appropriate certified respirators.

To protect the wearer, respiratory protective equipment must be the correct fit and be used

and maintained properly

In case of insufficient ventilation, wear suitable respiratory equipment Large scale/emergency use

Small scale/Laboratory use Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure

limits are exceeded or if irritation or other symptoms are experienced.

When RPE is used a face piece Fit Test should be conducted

Environmental exposure controls No information available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Haemophilus influenzae type b Agglutinating Sera

Physical State Liquid

Appearance Amber

Odor No information available **Odor Threshold** No data available **Melting Point/Range** No data available **Softening Point** No data available **Boiling Point/Range** Not applicable Flammability (liquid) No data available Flammability (solid,gas) No information available **Explosion Limits** No data available

Flash Point Not applicable Method - No information available

Autoignition Temperature No data available Decomposition Temperature No data available

pH 6.6 - 6.8 Viscosity No data available

Water Solubility

Solubility in other solvents

No information available
No information available

Partition Coefficient (n-octanol/water)

Componentlog PowPhenol1.5

Vapor PressureNo data availableDensity / Specific GravityNo data availableBulk DensityNo data availableVapor DensityNo data available

Particle characteristics Not applicable (liquid)

9.2. Other information

SECTION 10: STABILITY AND REACTIVITY

(Air = 1.0)

10.1. Reactivity

None known, based on information available

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

10.4. Conditions to avoid

Incompatible products. Excess heat.

10.5. Incompatible materials

No materials to be especially mentioned.

10.6. Hazardous decomposition products

Carbon oxides. Nitrogen oxides (NOx). Hydrogen bromide.

SECTION 11: TOXICOLOGICAL INFORMATION

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

OXDR30166101

Product Information Product does not present an acute toxicity hazard based on known or supplied information

(a) acute toxicity;

Oral No data available **Dermal** No data available Inhalation No data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Phenol	LD50 = 340 mg/kg (Rat)	LD50 = 630 mg/kg (Rabbit)	-
Sodium hydroxide	LD50 = 325 mg/kg (Rat)	LD50 = 1350 mg/kg (Rabbit)	-

No data available (b) skin corrosion/irritation;

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;

No data available Respiratory No data available Skin

None known

(e) germ cell mutagenicity; No data available

None known

(f) carcinogenicity; No data available

The table below indicates whether each agency has listed any ingredient as a carcinogen

(g) reproductive toxicity; No data available **Reproductive Effects** None known. **Developmental Effects** None known. **Neurological Effects** None known.

(h) STOT-single exposure; No data available

No data available (i) STOT-repeated exposure;

No information available. **Target Organs**

No data available (j) aspiration hazard;

Symptoms / effects,both acute and No information available.

delayed

11.2. Information on other hazards

Endocrine Disrupting Properties Assess endocrine disrupting properties for human health. This product does not contain any

known or suspected endocrine disruptors.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity effects

. Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.

Component	Freshwater Fish	Water Flea	Freshwater Algae
Phenol	4-7 mg/L LC50 96 h	EC50: 10.2 - 15.5 mg/L, 48h	EC50: 0.0188 - 0.1044 mg/L,
	32 mg/L LC50 96 h	(Daphnia magna)	96h static (Pseudokirchneriella
		EC50: 4.24 - 10.7 mg/L, 48h	subcapitata)
		Static (Daphnia magna)	EC50: 187 - 279 mg/L, 72h static (Desmodesmus subspicatus) EC50: = 46.42 mg/L, 96h (Pseudokirchneriella subcapitata)
Sodium hydroxide	LC50: = 45.4 mg/L, 96h static (Oncorhynchus mykiss)		-

Component	Microtox	M-Factor
Phenol	EC50 21 - 36 mg/L 30 min EC50 = 23.28 mg/L 5 min EC50 = 25.61 mg/L 15 min EC50 = 28.8 mg/L 5 min EC50 = 31.6 mg/L 15 min	
	2000 = 01.0 mg/L 10 min	
Sodium hydroxide	-	

12.2. Persistence and degradability No information available

No information available 12.3. Bioaccumulative potential

Component	log Pow	Bioconcentration factor (BCF)
Phenol	1.5	No data available

No information available . 12.4. Mobility in soil

12.5. Results of PBT and vPvB

assessment

No data available for assessment.

12.6. Endocrine disrupting

properties

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

12.7. Other adverse effects

Persistent Organic Pollutant Ozone Depletion Potential

This product does not contain any known or suspected substance This product does not contain any known or suspected substance

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from Residues/Unused **Products**

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Consult local, regional, and national hazardous waste regulations to

ensure complete and accurate classification.

Empty remaining contents. Dispose of in accordance with local regulations. Do not re-use **Contaminated Packaging**

Haemophilus influenzae type b Agglutinating Sera

empty containers.

European Waste Catalogue (EWC) According to the European Waste Catalog, Waste Codes are not product specific, but

application specific.

Other Information Waste codes should be assigned by the user based on the application for which the product

was used.

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

ADR Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

<u>IATA</u> Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards No hazards identified

14.6. Special precautions for user No special precautions required

14.7. Maritime transport in bulk

according to IMO instruments

SECTION 15: REGULATORY INFORMATION

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

Not applicable, packaged goods

International Inventories

Europe (EINECS/ELINCS/NLP), China (IECSC), Taiwan (TCSI), Korea (KECL), Japan (ENCS), Japan (ISHL), Canada (DSL/NDSL), Australia (AICS), New Zealand (NZIoC), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	EINECS	ELINCS	NLP	IECSC	TCSI	KECL	ENCS	ISHL
Phenol	108-95-2	203-632-7	-	-	Х	X	KE-28209	Х	Х
Sodium hydroxide	1310-73-2	215-185-5	-	-	Х	Х	KE-31487	Х	Х

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS
Phenol	108-95-2	X	ACTIVE	Х	-	X	X	X

Haemophilus influenzae type b Agglutinating Sera

Sodium hydroxide	1310-73-2	X	ACTIVE	X	-	Х	Х	Х

Legend: X - Listed '-' - Not Listed KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

Authorisation/Restrictions according to EU REACH

Component	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	· · · · · · · · · · · · · · · · · · ·
Phenol	-	Use restricted. See item 75.	-
		(see link for restriction details)	
Sodium hydroxide	-	Use restricted. See item 75.	-
		(see link for restriction details)	

https://echa.europa.eu/substances-restricted-under-reach

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements
Phenol	108-95-2	Not applicable	Not applicable
Sodium hydroxide	1310-73-2	Not applicable	Not applicable

Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

Not applicable

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. 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.

Take note of Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values

National Regulations

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

WGK Classification Water endangering class = 1 (self classification)

	Component	Germany - Water Classification (VwVwS)	Germany - TA-Luft Class
Ī	Phenol	WGK2	Class I: 20 mg/m3 (Massenkonzentration)
ſ	Sodium hydroxide	WGK1	

Component	France - INRS (Tables of occupational diseases)
Phenol	Tableaux des maladies professionnelles (TMP) - RG 14

Component	Switzerland - Ordinance on the Reduction of Risk from handling of hazardous substances preparation (SR 814.81)	Switzerland - Ordinance on Incentive Taxes on Volatile Organic Compounds (OVOC)	Switzerland - Ordinance of the Rotterdam Convention on the Prior Informed Consent Procedure
Phenol 108-95-2 (0.5)	Prohibited and Restricted Substances		
Sodium hydroxide 1310-73-2 (<0.5)	Prohibited and Restricted Substances		

15.2. Chemical safety assessment

OXDR30166101

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

SECTION 16: OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3

H301 - Toxic if swallowed

H311 - Toxic in contact with skin

H314 - Causes severe skin burns and eye damage

H318 - Causes serious eye damage

H331 - Toxic if inhaled

H341 - Suspected of causing genetic defects

H373 - May cause damage to organs through prolonged or repeated exposure

Legend

CAS - Chemical Abstracts Service

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

IECSC - Chinese Inventory of Existing Chemical Substances **KECL** - Korean Existing and Evaluated Chemical Substances DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

ENCS - Japanese Existing and New Chemical Substances AICS - Australian Inventory of Chemical Substances NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

DNEL - Derived No Effect Level

RPE - Respiratory Protective Equipment LC50 - Lethal Concentration 50%

NOEC - No Observed Effect Concentration

PBT - Persistent, Bioaccumulative, Toxic

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

Predicted No Effect Concentration (PNEC)

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50% POW - Partition coefficient Octanol:Water vPvB - very Persistent, very Bioaccumulative

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

ICAO/IATA - International Civil Aviation Organization/International Air **Transport Association**

MARPOL - International Convention for the Prevention of Pollution from Shins

ATE - Acute Toxicity Estimate VOC - (Volatile Organic Compound)

Key literature references and sources for data

https://echa.europa.eu/information-on-chemicals

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Creation Date 23-Aug-2012 **Revision Date** 10-Dec-2021

Update to GHS format. **Revision Summary**

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006. COMMISSION REGULATION (EU) 2020/878 amending Annex II to Regulation (EC) No 1907/2006

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet