

Safety Data Sheet

Conforms to Regulation (EC) No. 1907/2006 (REACH) and the amendment Regulation (EC) No. 2015/830

EU_EN

SDS prepared by

Bio-Works Sweden AB
Virdings allé 18
SE-754 50 Uppsala, Sweden

Date of issue/Date of revision Dec. 30, 2020

Date of previous issue NA

Revision 1.0

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

1.1 Product identifier

Product Name: **BabyBio IEX Screening Kit**
Article Number: 45 900 001
Product description: Prepacked plastic columns for chromatography.

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

For research use only. Chromatography.

1.3 Manufacturer/Supplier of Material Safety Data Sheet

Bio-Works Sweden AB
Virdings allé 18
SE-754 50 Uppsala, Sweden
Phone: +46 8 5626 7430
E-Mail: info@bio-works.com

1.4 Emergency telephone number

+46 8 5626 7430 (Bio-Works Sweden AB)

National advisory body/Poison Centre

Please contact the regional company representation in your country.

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product definition

Mixture

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

Flam. Liq.3

For the full text of the H-Statements mentioned in this Section, see Section 16.

Ingredients of unknown toxicity

None, based on available information.

Ingredients of unknown ecotoxicity

None, based on available information.

2.2 Label elements

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

Hazard pictogram**Signal word**

Warning

Hazard statements

H226 Flammable liquid and vapour.

Precautionary statements**General**

No information

Prevention

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P241 Use explosion-proof electrical/ventilating/lighting equipment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.

P370 + P378 In case of fire: dry powder/dry chemical, alcohol-resistant foam, or carbon dioxide (CO₂).

Storage

P403 + P235 Store in a well-ventilated place. Keep cool.

Disposal

P501 Dispose of contents/container in accordance with local, regional, national or international regulations.

Hazardous ingredients

Ethanol.

Supplemental label elements

None.

2.3 Other hazards

None known.

SECTION 3: COMPOSITION/INFO ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

Agarose particles in 20% ethanol.

Product/Ingredient name	Identifiers	Content (%)	Classification according to Regulation (EC) No 1272/2008 (CLP) ^{x)}	
			Hazard class and category codes	Hazard statements
Ethanol	CAS: 64-17-5 REACH #: 01-2119457610-43 EC: 200-578-6 INDEX: 603-002-00-5	17-19	Flam. Liq. 2	H225

x) See List of abbreviations in section 16.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes

None

Inhalation

Not expected to be a significant hazard under anticipated conditions of normal use. If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Skin contact

Remove/Take off immediately all contaminated clothing and shoes. Rinse skin with water/shower. Consult doctor in case of complaints.

Eye contact

Remove contact lenses, if present and easily done. Rinse eyes with plenty of water for at least 10 minutes. Consult doctor if irritation occurs.

Ingestion

Not expected to be a significant hazard under anticipated conditions of normal use. Remove victim to fresh air. Rinse mouth with water. If the victim is conscious, give small quantities to drink. Do not give anything to drink or eat if the person is unconscious. Do not induce vomiting. Consult doctor for advice.

Self-protection of first aider

Wear personal protection equipment (PPE).

4.2 Most important symptoms and effects, both acute and delayed

Inhalation

No known significant effects or critical hazards.

Skin contact

No known significant effects or critical hazards.

Eye contact

No known significant effects or critical hazards.

Ingestion

Upon ingestion of large quantities: Dizziness, vomiting, narcosis, respiratory paralysis.

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use dry powder/dry chemical, alcohol-resistant foam, or carbon dioxide (CO₂).

Unsuitable extinguishing media

Do not use water jet.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture

Flammable liquid and vapour. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion. Runoff to sewer may create fire or explosion hazard.

Hazardous combustion products

In the event of fire may produce hazardous combustion gases or vapours, including carbon dioxide and carbon monoxide

5.3 Advice for firefighters

Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Wear self-contained breathing apparatus. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment according to Section 8.

For emergency responders

If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

Avoid discharge into soil, waterways, drains and sewers.

6.3 Methods and material for containment and cleaning up

Small spill

Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill

Stop leak if without risk. Move containers from spill area. Cover drains. Use spark-proof tools and explosion-proof equipment. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined 'areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non combustible, absorbent material e.g. sand, earth, vermiculite or and place in container for disposal according to local regulations. Dispose of product and contaminated absorbent material according to local, regional, national or international regulations.

6.4 Reference to other sections

See SECTION 1 for emergency contact information

See SECTION 8 for personal protection information

See SECTION 13 for waste treatment information

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Protective measures

Always wear recommended protective equipment, see SECTION 8. Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapour or mist. Use adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers may retain product residue and can be hazardous. Do not reuse container. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and

material handling) equipment. Take precautionary measures against electrostatic discharges.

Advice on general occupational hygiene

Eating, drinking and smoking must be prohibited in areas where this material is handled, stored and processed. Users should wash hands before eating, drinking and smoking. Remove protective equipment and clothing, and contaminated clothing, before entering eating areas. See Section 8 for additional information.

7.2 Conditions for safe storage, including any incompatibilities

Store at 4 to 30°C (39 to 86°F). Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct in a well-ventilated area. Do not store with incompatible materials (see Section 10) or food and drinks. Do not store close to ignition sources or hot surfaces. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

7.3 Specific end use(s)

Research sector

Recommended for laboratory use.

Industrial sector

Guidance not available.

SECTION 8: LIMIT EXPOSURE

8.1 Control parameters

Occupational exposure limits (OEL)

Geographical area	Ethanol CAS: 64-17-5
EU OEL (TWA)	None
EU OEL (STEL)	None
Austria	GKV_MAK (Austria, 10/2017). KZW: 3800 mg/m ³ , 3 times per shift, 60 minutes. KZW: 2000 ppm, 3 times per shift, 60 minutes. MAK - daily mean value: 1900 mg/m ³ , 3 times per shift, 8 hours. MAK - daily mean value: 1000 ppm, 3 times per shift, 8 hours.
Bulgaria	Bulgaria Ministry of Labor and Social Policy and Ministry of Health (Bulgaria, 1/2012). Limit values 8 hours: 1000 mg/m ³ 8 hours.
Belgium	Limit Values (Belgium, 9/2017). Limit value: 1907 mg/m ³ 8 hours. Limit value: 1000 ppm 8 hours.
Czech Republic	NVCR PEL/NPK-P (Czech Republic, 1/2016). NPK-P: 3000 mg/m ³ 15 minutes. NPK-P: 1596 ppm for 15 minutes. TWA: 1000 mg/m ³ 8 hours. TWA: 532 ppm 8 hours.
Denmark	The Danish Working Environment Authority (Denmark, 10/2012). Average values: 1900 mg/m ³ 8 hours. Average values: 1000 ppm 8 hours.
Estonia	Occupational Exposure Limits Regulation No. 293 (Estonia, 3/2018). SHORT TERM EXPOSURE LIMIT: 1900 mg/m ³ for 15 minutes. SHORT TERM EXPOSURE LIMIT: 1000 ppm 15 minutes. LIMIT VALUE: 1000 mg/m ³ for 8 hours. LIMIT VALUE: 500 ppm for 8 hours.
Finland	National Institute for Occupational Health, Ministry of Social Affairs and Health (Finland, 1/2017).

	HTP values 15 min: 2500 mg/m ³ 15 minutes. HTP values 15 min: 1300 ppm for 15 minutes. HTP values 8 h: 1900 mg/m ³ 8 h. HTP values 8 h: 1000 ppm for 8 h.
France	Ministry of Labor (France, 10/2016). Notes: Ministry of Labor (INRS Ed 984 brochure, July 2012). indicative limit values ELV: 9500 mg/m ³ 15 minutes. Form: Risk of allergy VLE: 5000 ppm 15 minutes. Form: Risk of allergy TWA: 1900 mg/m ³ 8 hours. Form: Risk of allergy TWA: 1000 ppm 8 hours. Form: Risk of allergy 1900 mg/m ³
Germany	DFG MAK value list (Germany, 7/2017). Peak limitation: 1520 mg/m ³ , 4 times per shift, 15 minutes. Peak limitation: 800 ppm, 4 times per shift, 15 minutes. 8-hour mean value: 380 mg/m ³ 8 hours. 8-hour average: 200 ppm 8 hours. TRGS 900 AGW (Germany, 5/2018). Short-term value: 1920 mg/m ³ 15 minutes. Short term value: 1000 ppm 15 minutes. Shift average: 960 mg/m ³ 8 hours. Shift average: 500 ppm 8 hours.
Greece	Ministry of Labor and Social Affairs (Greece, 2/2012). Exposure Limit: 1900 mg/m ³ 8 hours. Exposure Limit: 1000 ppm 8 hours.
Hungary	EüM-SzCsM joint decree (Hungary, 12/2011). CK: 7600 mg/m ³ for 15 minutes. AK: 1900 mg/m ³ for 8 hours.
Ireland	STEL: 1000 ppm 15 min
Italy	No exposure limit value known.
Lithuania	Lithuanian Hygiene Standards HN 23 (Lithuania, 10/2007). TPRV: 1900 mg/m ³ for 15 minutes. TPRV: 1000 ppm for 15 minutes. IPRV: 1000 mg/m ³ for 8 hours. IPRV: 500 ppm 8 hours
Latvia	Cabinet Regulation No. 325 - RES (Latvia, 6/2015). AER 8 h: 1000 mg/m ³ 8 h.
Luxembourg	None
Norway	FOR-2011-12-06-1358 (Norway, 1/2018). Average values: 950 mg/m ³ 8 hours. Average values: 500 ppm 8 hours.
Netherlands	MinSZW Legal Limit Values (The Netherlands, 2/2017). Recorded via the skin. Legal limit value TWA, 8 hours: 260 mg/m ³ 8 hours. Legal limit value TWA, 15 min.: 1900 mg/m ³ 15 minutes.
Poland	Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the highest permissible concentration and intensity factors harmful to health in the work environment (i.e. Journal of Laws 2018, item 1286) (Poland, 11/2017). NDS: 1900 mg/m ³ 8 hours.
Portugal	Portuguese Quality Institute (Portugal, 11/2014). VLE-CD: 1000 ppm 15 minutes.
Romania	GD 1218/2006 with subsequent amendments and completions (Romania, 1/2012). Short term: 9500 mg/m ³ 15 minutes. Short term: 5000 ppm 15 minutes. VLA: 1900 mg/m ³ 8 hours. VLA: 1000 ppm 8 hours.
Slovakia	Regulation of the Government of the SR c. 355/2006 (Slovakia, 2/2018). Average NPEL: 960 mg/m ³ 8 hours. NPEL average: 500 ppm 8 hours. Short-term NPEL: 1920 mg/m ³ 15 minutes. NPEL short term: 1000 ppm 15 minutes.
Slovenia	Rules on the protection of workers from the risks related to exposure chemical substances at work (Slovenia, 6/2015). MV: 1900 mg/m ³ for 8 hours. MV: 1000 ppm 8 hours. KTV: 7600 mg/m ³ , 4 times per shift, 15 minutes. KTV: 4000 ppm, 4 times per shift, 15 minutes.
Spain	INSHT (Spain, 2/2018).

	VLA-EC: 1910 mg/m ³ 15 minutes. VLA-EC: 1000 ppm 15 minutes.
Sweden	AFS 2018: 1 (Sweden, 2/2018). KGV: 1900 mg/m ³ 15 minutes. KGV: 1000 ppm 15 minutes. NGV: 1000 mg/m ³ 8 hours. NGV: 500 ppm 8 hours.
Switzerland	SUVA (Switzerland, 1/2018). Notes: not temporary STEL: 1920 mg/m ³ 15 minutes. STEL: 1000 ppm 15 minutes. TWA: 960 mg/m ³ 8 hours. TWA: 500 ppm 8 hours.
United Kingdom	EH40/2005 WELs (United Kingdom (UK), 12/2011). TWA: 1920 mg/m ³ 8 hours. TWA: 1000 ppm 8 hours.
US NIOSH (REL/PEL)	TWA: 1000 ppm TWA: 1900 mg/m ³
Canada	CA Alberta Provincial (Canada, 4/2009). 8 hrs OEL: 1880 mg/m ³ 8 hours. 8 hrs OEL: 1000 ppm 8 hours. CA Quebec Provincial (Canada, 1/2014). TWA _{EV} : 1880 mg/m ³ 8 hours. TWA _{EV} : 1000 ppm 8 hours. CA British Columbia Provincial (Canada, 6/2017). STEL: 1000 ppm 15 minutes. CA Ontario Provincial (Canada, 1/2018). STEL: 1000 ppm 15 minutes. CA Saskatchewan Provincial (Canada, 7/2013). STEL: 1250 ppm 15 minutes. TWA: 1000 ppm 8 hours.

Recommended monitoring procedure

Workplace atmosphere monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following:

European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy)

European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents)

European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents)

Reference to national guidance documents may also be required.

DNELs/DMELs (Derived No Effect Level)

Identification: Ethanol EC: 200-578-6 CAS: 64-17-5	Exposure pattern		Route	DNEL Value
	Worker DNEL, acute	Local effects	inhalation	1900 mg/m ³
	Worker DNEL, longterm	Systemic effects	dermal	343 mg/kg Body weight
	Worker DNEL, longterm	Systemic effects	inhalation	950 mg/m ³
	Consumer DNEL, acute	Local effects	inhalation	950 mg/m ³
	Consumer DNEL, longterm	Systemic effects	dermal	206 mg/kg Body weight
	Consumer DNEL, longterm	Systemic effects	inhalation	114 mg/m ³
	Consumer DNEL, longterm	Systemic effects	oral	87 mg/kg Body weight

PNECs (Predicted no-effect concentration)

Identification: Ethanol EC: 200-578-6 CAS: 64-17-5	Hazard assessment conclusion	PNEC Value	Assessment factor
	PNEC Fresh water	0.96 mg/l	10
	PNEC Marine water	0.79 mg/l	100
	PNEC Fresh water sediment	3.6 mg/kg sediment dw	NA
	PNEC sediment (marine water)	2.9 mg/kg sediment dw	NA
	PNEC soil	0.63 mg/kg soil dw	1000
	PNEC oral	0.38 g/kg food	90
	PNEC Sewage treatment plant	580 mg/l	10

8.2 Exposure controls

Appropriate engineering controls

Use adequate ventilation using explosion-proof equipment. Use process enclosures, local exhaust ventilation or other engineering controls to airborne contaminants below any recommended or statutory limits, and gas, vapour or dust concentrations below any lower explosive limits.

Individual protection measures

The personal protective equipment selected must comply with the EC Council Directive 89/686/EEC.

Hygiene measures

Wash hands, forearms and face after handling the product, before eating, smoking and using the lavatory and at the end of the working period. Remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location and regularly tested.

Eye/face protection

Use safety glasses, and/or face shield.

Hand protection

Use chemically resistant protective gloves that comply with the standard EN374; e.g., gloves based on butyl rubber or neoprene, 0.7 mm thickness or more, with breakthrough time of 2 hours or more.

Body protection

Flame retardant antistatic clothing, e.g., lab coat or when required antistatic overalls, boots and gloves. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Refer to European Standard EN 1149 for further information on electrostatic properties of protective clothing.

Respiratory protection

Select a respirator based on the hazard and potential for exposure, which meets the appropriate standard or certification. Ensure proper fitting, training, and other important aspects of use. Recommended filter type: Filter A according to DIN 3181. Maintenance, cleaning and testing must be done according to the manufacturer, and properly documented.

Environmental exposure controls

Do not let product enter drain. Emissions from equipment or ventilation should be checked to ensure they comply with the requirements of the environmental protection legislation. Consider the use of fume scrubbers, filters or engineering modifications to the process equipment to reduce emissions.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Agarose particles in 20% ethanol or 20% ethanol and 0.2 M sodium acetate for BabyBio S.

9.1 Information on basic physical and chemical properties

Physical state	Suspension
Color	White to off-white
Odour	Alcohol
Odour threshold	180 ppm
pH	No information available.
Melting point/freezing point	No information available.
Initial boiling point and boiling range	No information available.
Flash point	38°C, closed cup
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Upper/lower flammability or explosive limits	No information available.
Vapour pressure	No information available.
Vapour density	No information available.
Relative density	No information available.
Solubility(ies)	Ethanol soluble in water, particles insoluble.
Partition coefficient: n-octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity	No information available.
Explosive properties	No information available.
Oxidising properties	No information available.

9.2 Other information

No additional information available.

SECTION 10: STABILITY AND REACTIVITY

Product is stable. Reactivity data not available.

10.1 Reactivity

Vapour/air-mixtures are explosive at intense heating.

10.2 Chemical stability

Stable

10.3 Possibility of hazardous reactions

No hazardous reactions known under normal use or storage.

10.4 Conditions to avoid

Heating and sources of ignition.

10.5 Incompatible materials

Strongly oxidizing materials.

10.6 Hazardous decomposition products

No hazardous decompositions products produced under normal use or storage.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute oral toxicity

Ingestion causes nausea and vomiting.

Acute inhalation toxicity

LC50 Inhalation Vapor (Rat) - 124700 mg/m³ - 4 hours.

Irritation

No information available

Corrosivity

No information available

Sensitisation

No information available

Mutagenicity

No information available

Carcinogenicity

No information available

Reproductive toxicity

No information available

Teratogenicity

No information available

Repeated dose toxicity

No information available

SECTION 12: ECOLOGICAL INFORMATION

Not available. We are not aware of any other hazards for the product.

12.1 Toxicity

Ingredient name	Ethanol CAS: 64-17-5
Short-term toxicity to fish	Ethanol is of very low toxicity to fish LC50 for freshwater fish: 14 200 mg/L
Long-term toxicity to fish	Not required - ethanol has a very low short-term toxicity to fish.
Short-term toxicity to aquatic invertebrates	Ethanol is not to be classified toxic to the environment according to the classification system of the EU (CLP). EC50/LC50 for freshwater invertebrates: 5 012 mg/L
Long-term toxicity to aquatic invertebrates	Ethanol is practically non-toxic to aquatic invertebrates based on survival. Based on reproductive parameters, it would be classified as slightly toxic. EC10, LC10 or NOEC for freshwater invertebrates: 9.6 mg/L
Toxicity to aquatic algae and cyanobacteria	Ethanol is slightly toxic to the green algae <i>Chlorella vulgaris</i> . EC50 for freshwater algae: 275 mg/L

EC10 or NOEC for freshwater algae: 11.5 mg/L
--

12.2 Persistence and degradability

Ethanol is degraded readily in fresh water in 20 days.

12.3 Bioaccumulative potential

None.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

PBT Not applicable.

vPvB Not applicable.

12.6 Other adverse effects

No known significant effects or critical hazards.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Hazardous waste

This product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

Waste treatment methods

The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of local, regional, national or international environmental protection and waste disposal legislation. Dispose of mentioned materials must be done via approved waste disposal contractor. Waste must not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. The emptied container may contain residues of the product and must be disposed of accordingly.

European waste catalogue (EWC)

According to Decision 2014/955/EU list of waste pursuant to Directive 2008/98/EC.

Waste code

07 07 99

Waste designation

Wastes not otherwise specified

Packaging

Waste treatment methods

The generation of waste should be avoided or minimised wherever possible. Packaging waste should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

SECTION 14: TRANSPORTATION INFORMATION

Not classified; IATA special provisions A 58- Aqueous solutions containing 24% or less alcohol by volume is not subject to these regulations.

14.1 UN number

Not applicable.

14.2 UN proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packing group

Not available.

14.5 Environmental hazards

None.

14.6 Special precautions for user

Transport in closed container, upright and secure. The person transporting the product must know what to do in the event of an accident or spillage.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not available.

SECTION 15: REGULATORY INFORMATION

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer.

None of the substances are listed.

Regulation (EC) No 850/2004 of the European Parliament on persistent organic pollutants and amending Directive 79/117/EEC.

None of the substances are listed.

Regulation (EC) No 649/2012 concerning the export and import of dangerous chemicals.

None of the components are listed. None of the substances are listed.

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

Regulation (EC) No 19707/2006 (REACH)

Regulation (EC) No 19707/2006 (REACH)

Annex XIV – List of substances subject to authorisation

None of the substances are listed.

Annex XVII – Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

None of the substances are listed.

Other regulations

Directive 2008/105/EC – Environmental quality standards in the field of water policy Annex I – Environmental quality standards (EQS)

No information.

German water hazard classes (Wassergefährdungsklassen) (VwVwS) Annex 2 – Substances hazardous to water

Ethanol Hazard class 1 – low hazard

DIRECTIVE 2012/18/EU (Seveso III)

Ethanol P5c Flammable liquid Category 2 Limit 5000 tonnes

15.2 Chemical safety assessment

No information available.

SECTION 16: OTHER INFORMATION

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification		Justification
Mixture	Substance	
Flam. Liq. 3, H226	Ethanol: Flam. Liq. 2, H225	Concentration <20% gives a flash point of 38 °C which is between ≥ 23°C and 60°C

H-Statements

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

P-Statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 Keep container tightly closed.

P240 Ground and bond container and receiving equipment.

P241 Use explosion-proof electrical/ventilating/lighting equipment.

P242 Use non-sparking tools.

P243 Take action to prevent static discharges.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.

P370 + P378 In case of fire: use dry powder/dry chemical, alcohol-resistant foam, or carbon dioxide (CO₂)

P403 + P235 Store in a well-ventilated place. Keep cool.

P501 Dispose of contents/container in accordance with local, regional, national and international regulations.

Abbreviations

BCF	Bioconcentration factor
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DMEL	Derived Minimal Effect Level
DNEL	Derived No Effect Level
EQS	Environmental Quality Standard
IC50	Lethal concentration in water required to kill 50% of the population
LC50	Lethal concentration required to kill 50% of the population

LD50 Lethal dose required to kill 50% of the population
 LLV Lower Limit Value
 MAC Maximum Allowable Concentration
 NIOSH National Institute for Occupational Safety and Health
 NOEC No Observed Effect Concentration
 OELs Occupational Exposure Limits
 PBT Persistent, Bioaccumulative and Toxic
 PNEC Predicted No Effect Concentration
 STEL Short-Term Exposure Limits
 TLV Threshold Limit Value
 TWA Time-Weighted Average
 vPvB very Persistent, very Bioaccumulative and/or Toxic

Revision

Version	Changes	Date
1.0	First version	2020-12-30