SAFETY DATA SHEET

ISE Reference Electrolyte

Version	Revision Date:	Date of last issue: 04-10-2022
1.11	06-06-2024	Date of first issue: 11-12-2015

SECTION 1. IDENTIFICATION

Product name : ISE Reference Electrolyte

Product code : 11360981216

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics Deutschland GmbH

Address : 116 Sandhoferstrasse
Mannheim, 68305
Deutschland

Telephone : +496217590
Telefax : +496217592890
E-mail address : info.dia-sds@roche.com
Emergency telephone
Im Notfall: : Werkschutzzentrale Roche Diagnostics GmbH +49(0)621-759-2203

Giftnotruf: : Mainz +49(0)6131-19240

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals
Refer to product literature for further details.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Potassium chloride (KCl)	7447-40-7	>= 5 - < 10

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice	:	Do not leave the victim unattended.
If inhaled	:	Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	If on skin, rinse well with water.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	None known.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards during fire fighting	:	No information available.
Hazardous combustion products	:	Metal oxides Gaseous hydrogen chloride (HCl).
Further information	:	Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Refer to protective measures listed in sections 7 and 8.

Environmental precautions	:	Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Wipe up with absorbent material (e.g. cloth, fleece). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	Normal measures for preventive fire protection.
Advice on safe handling	:	For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area.
Conditions for safe storage	:	Electrical installations / working materials must comply with the technological safety standards.
Further information on storage conditions	:	See label, package insert or internal guidelines
Materials to avoid	:	No materials to be especially mentioned.
Further information on storage stability	:	No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures	:	No data available

Personal protective equipment

Respiratory protection	:	No personal respiratory protective equipment normally required.
Hand protection		
		In case of contact through splashing:
Material	:	Nitrile rubber
Break through time	:	> 30 min
Glove thickness	:	> 0.11 mm
		In case of full contact:
Material	:	butyl-rubber
Break through time	:	> 480 min
Glove thickness	:	> 0.4 mm
Remarks	:	Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Eye protection	:	Safety glasses

Skin and body protection	:	Protective suit
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	colorless
Odor	:	odorless
Odor Threshold	:	No data available
pH	:	5.0 - 7.0 Concentration: 100 %
Melting point/range	:	30 °F / -1 °C
Boiling point/boiling range	:	203 - 221 °F / 95 - 105 °C
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	The product is not flammable., Does not sustain combustion.
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.044 g/cm3
Solubility(ies)		
Water solubility	:	completely miscible

Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Conductivity	:	115 µS/cm (77 °F / 25 °C)

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	:	No data available
Incompatible materials	:	No data available
Hazardous decomposition products	:	No decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Components:

Potassium chloride (KCl):

Acute oral toxicity	:	LD50 (Rat, female): 3,020 mg/kg GLP: No information available.

Skin corrosion/irritation

Not classified due to lack of data.

Components:

Potassium chloride (KCl):

Species	:	reconstructed human epidermis (RhE)
Exposure time	:	20 min
Method	:	OECD Test Guideline 439
Result	:	No skin irritation
GLP	:	yes

Serious eye damage/eye irritation

Not classified due to lack of data.

Components:

Potassium chloride (KCl):

Result	:	No eye irritation
Exposure time	:	60 min
GLP	:	yes

Respiratory or skin sensitization

Skin sensitization

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

Germ cell mutagenicity

Not classified due to lack of data.

Components:

Potassium chloride (KCl):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: positive
GLP: No information available.

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster lung cells
Method: OECD Test Guideline 473

Result: positive
GLP: No information available.

Carcinogenicity

Not classified due to lack of data.

Components:

Potassium chloride (KCl):

Species	:	Rat, male
Application Route	:	Oral
Exposure time	:	2 Years
GLP	:	No information available.
Remarks	:	No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified due to lack of data.

Components:

Potassium chloride (KCl):

Effects on fetal development	:	Species: Rat, female Application Route: Oral Dose: 3.1, 14.4, 66.8, 310 mg/kg bw Duration of Single Treatment: 6 - 15 d General Toxicity Maternal: NOAEL: 310 mg/kg body weight Developmental Toxicity: NOAEL: 310 mg/kg body weight GLP: No information available.

STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Repeated dose toxicity

Components:

Potassium chloride (KCl):

Species	:	Rat, male
NOAEL	:	1,820 mg/kg
Application Route	:	Oral

Exposure time	:	2 y
Dose	:	110, 450, 1820 mg/kg bw/day
GLP	:	No information available.

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment

Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

Components:

Potassium chloride (KCl):

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 880 mg/l End point: mortality Exposure time: 96 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 203 GLP: No information available.
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 660 mg/l End point: Immobilization Exposure time: 48 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 202 GLP: No information available.
Toxicity to algae/aquatic plants	:	NOEC (Desmodesmus subspicatus (green algae)): > 100 mg/l End point: Growth rate Exposure time: 72 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 201 GLP: yes EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l End point: Growth rate Exposure time: 72 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 201 GLP: yes

Toxicity to microorganisms	:	EC50 (activated sludge): > 1,000 mg/l End point: Respiration inhibition Exposure time: 3 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 209 GLP: no

Ecotoxicology Assessment

Acute aquatic toxicity	:	This product has no known ecotoxicological effects.
Chronic aquatic toxicity	:	This product has no known ecotoxicological effects.
Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

Persistence and degradability

Components:

Potassium chloride (KCl):

Biodegradability	:	Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Bioaccumulative potential

Components:

Potassium chloride (KCl):

Partition coefficient: n-octanol/water	:	Remarks: Not applicable

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential	:	Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Can be disposed as waste water, when in compliance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

49 CFR
Not regulated as a dangerous good

Special precautions for user

Remarks	:	Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards	:	No SARA Hazards
SARA 313	:	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307
This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Water	7732-18-5
Potassium chloride (KCl)	7447-40-7

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

The ingredients of this product are reported in the following inventories:

AIIC	:	On the inventory, or in compliance with the inventory
DSL	:	All components of this product are on the Canadian DSL
NZIoC	:	On the inventory, or in compliance with the inventory
ENCS	:	On the inventory, or in compliance with the inventory
ISHL	:	On the inventory, or in compliance with the inventory
KECI	:	On the inventory, or in compliance with the inventory
PICCS	:	On the inventory, or in compliance with the inventory
IECSC	:	On the inventory, or in compliance with the inventory
TCSI	:	On the inventory, or in compliance with the inventory

TSCA	:	All substances listed as active on the TSCA inventory
TECI	:	On the inventory, or in compliance with the inventory

TSCA list

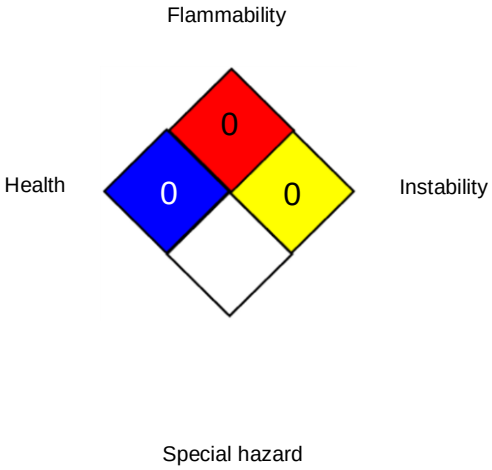
No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

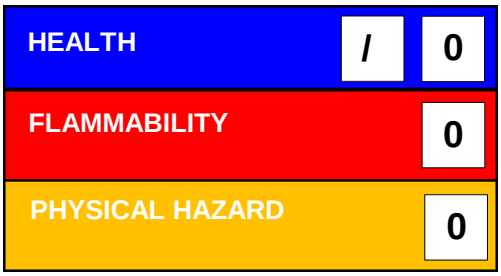
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to

50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 06-06-2024

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.

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