SAFETY DATA SHEET

Ammonia/Ethanol/CO2 Calibrator

Version	Revision Date:	Date of last issue: 10-09-2021
1.11	03-16-2022	Date of first issue: 11-13-2015

SECTION 1. IDENTIFICATION

Product name : Ammonia/Ethanol/CO2 Calibrator

Product code : 20751995190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
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Address : 9115 Hague Road
Indianapolis, IN 46250
USA

Telephone : 1-800-428-5074

Emergency telephone
In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

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

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section GHS Label elements contains the resulting labelling for the kit

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H350 May cause cancer.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

R1

GHS Classification

Carcinogenicity : Category 1A

Components

Chemical name	CAS-No.	Concentration (% w/w)
Ethanol	64-17-5	>= 0.1 - < 1

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 : No information available.

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.
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

R1

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	TWA	1,000 ppm 1,900 mg/m3	NIOSH REL
		TWA	1,000 ppm 1,900 mg/m3	OSHA Z-1
		TWA	1,000 ppm 1,900 mg/m3	OSHA P0
		STEL	1,000 ppm	ACGIH

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

R1

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	The product is not flammable.
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
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.

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 data available

SECTION 11. TOXICOLOGICAL INFORMATION

R1

Acute toxicity

Not classified based on available information.

Components:

Ethanol:

Acute oral toxicity	:	LD50 (Rat, male and female): 10,470 mg/kg Method: OECD Test Guideline 401 GLP: no
Acute inhalation toxicity	:	LC50 (Rat, male and female): 124.7 mg/l Exposure time: 4 h Test atmosphere: vapor Method: OECD Test Guideline 403 GLP: no
Acute dermal toxicity	:	(Rabbit): 17,100 mg/kg GLP: No information available. Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

Ethanol:

Species	:	Rabbit
Exposure time	:	24 h
Method	:	OECD Test Guideline 404
Result	:	No skin irritation
GLP	:	yes

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ethanol:

Species	:	Rabbit
Result	:	Irritating to eyes.
Method	:	OECD Test Guideline 405
GLP	:	No information available.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Ethanol:

Test Type	:	Maximization Test
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Method	:	OECD Test Guideline 406
Result	:	Did not cause sensitization on laboratory animals.
GLP	:	no
Remarks	:	Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

Ethanol:

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: No information available. 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: negative GLP: No information available.
Genotoxicity in vivo	:	Test Type: dominant lethal test Species: Mouse (male) Application Route: Oral Dose: 10 or 40% ethanol in water Method: OECD Test Guideline 478 Result: negative GLP: No information available.

Carcinogenicity

May cause cancer.

Components:

Ethanol:

Species	:	Mouse, male and female
Application Route	:	inhalation (vapor)
Exposure time	:	18 month(s)
Control Group	:	yes
Frequency of Treatment	:	19 hours/day
Method	:	OECD Test Guideline 453
Result	:	negative
GLP	:	No information available.
Remarks	:	Based on data from similar materials

IARC Group 1: Carcinogenic to humans
Ethanol 64-17-5

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 based on available information.

Components:

Ethanol:

Effects on fertility	:	Test Type: Two-generation study Species: Mouse, male and female Application Route: Oral General Toxicity Parent: NOAEL: 20,700 mg/kg body weight Method: OECD Test Guideline 416 Result: No effects on fertility. GLP: No information available.
Effects on fetal development	:	Species: Rat, female Strain: Sprague-Dawley Application Route: Ingestion Duration of Single Treatment: 6 Weeks Developmental Toxicity: NOAEL: 5,200 mg/kg body weight GLP: No information available.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Ethanol:

Species	:	Rat, male and female
LOAEL	:	3156 mg/kg
Application Route	:	Oral
Exposure time	:	14 Weeks
Dose	:	0, 5, 10, 20 mg/Kg
Method	:	OECD Test Guideline 408
GLP	:	yes

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

R1

Ecotoxicity

Components:

Ethanol:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 15,300 mg/l End point: mortality Exposure time: 96 h Test Type: flow-through test Analytical monitoring: yes GLP: No information available.
Toxicity to daphnia and other aquatic invertebrates	:	LC50 (Ceriodaphnia dubia (water flea)): 5,012 mg/l Exposure time: 48 h Test Type: static test GLP: No information available.
Toxicity to algae/aquatic plants	:	EC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l Exposure time: 5 d Analytical monitoring: no Method: OECD Test Guideline 201 GLP: No information available.
Toxicity to fish (Chronic toxicity)	:	NOEC (Danio rerio (zebra fish)): 250 mg/l Exposure time: 120 h GLP: No information available.
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 9.6 mg/l Exposure time: 7 d GLP: No information available.
Toxicity to microorganisms	:	IC50 (activated sludge): > 1,000 mg/l End point: Growth rate Exposure time: 3 h

Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 209
GLP: No information available.
Remarks: Based on data from similar materials

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Persistence and degradability

Components:

Ethanol:

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d
GLP: No information available.

Bioaccumulative potential

Components:

Ethanol:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

Partition coefficient: n-octanol/water : log Pow: -0.35 (75 °F / 24 °C)
pH: 7.4
Method: OECD Test Guideline 107
GLP: No information available.

Mobility in soil

No data available

Other adverse effects

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

R1

CERCLA Reportable Quantity
Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity
Listed substances in the product are at low enough levels to not be expected to exceed the 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 : Carcinogenicity

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

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Ammonia	7664-41-7	>= 0 - < 0.1 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Ammonia	7664-41-7	>= 0 - < 0.1 %

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

Ammonia	7664-41-7
Sodium azide (Na(N3))	26628-22-8

Pennsylvania Right To Know

Water	7732-18-5
Ammonia	7664-41-7
Sodium azide (Na(N3))	26628-22-8

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	:	Not 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.

R1

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H350 May cause cancer.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

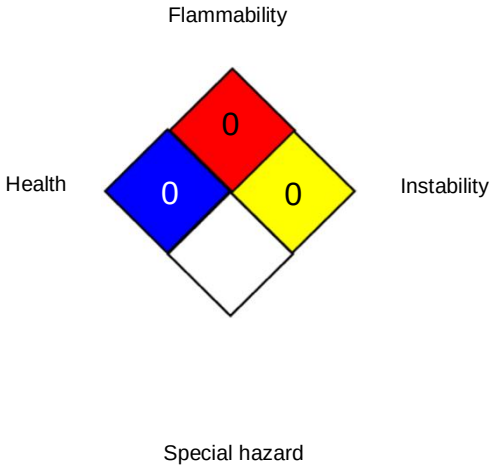
Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

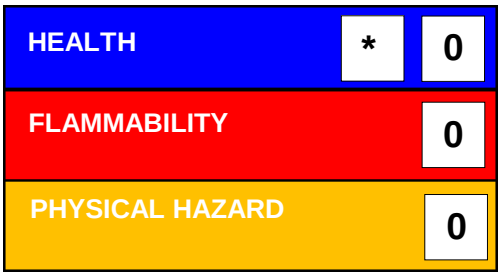
SECTION 16. OTHER INFORMATION

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 : 03-16-2022

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.

US / Z8 / 2104