



SAFETY DATA SHEET

This safety data sheet complies with the requirements of:
SS586: 2008 (2014)

Revision date 14-Jul-2022

Revision Number 1

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

Product identifier

Product Name EQAS Therapeutic Drug Monitoring Program

Other means of identification

Catalogue Number(s) BC10

Pure substance/mixture Mixture

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

Uses advised against No information available

Details of the supplier of the safety data sheet

Corporate Headquarters

Bio-Rad Laboratories Inc.
1000 Alfred Nobel Drive
Hercules, CA 94547
USA

Manufacturer

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Legal Entity / Contact Address

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Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Singapore: 65-31581349

SECTION 2: Hazards identification

GHS Classification

Label elements

Signal word

Warning

Hazard statements

H361 - Suspected of damaging fertility or the unborn child
Contains Gentamicin, sulfate (salt) May produce an allergic reaction

Precautionary Statements - Prevention

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

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other hazards which do not result in classification**SECTION 3: Composition/information on ingredients****Substance**

Not applicable

Mixture

Chemical name	EC No	CAS No	Weight-%
Sodium chloride	231-598-3	7647-14-5	5 - 10
Trade secret	.?	-	0.3 - 0.999
Acetaminophen	203-157-5	103-90-2	0.1 - 0.299
Lithium carbonate	209-062-5	554-13-2	0.1 - 0.299
Theophylline	200-385-7	58-55-9	0.01 - 0.099
Caffeine	200-362-1	58-08-2	0.01 - 0.099
Gentamicin, sulfate (salt)	215-778-9	1405-41-0	0.01 - 0.099
Methotrexate	200-413-8	59-05-2	0.001 - 0.01

Non-hazardous
ingredients

Proprietary

Balance

SECTION 4: First aid measures**Description of first aid measures****General advice**

No hazards which require special first aid measures.

Inhalation

Remove to fresh air.

Eye contact

Call a physician. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Skin contact

Wash with soap and water.

Ingestion

Call a physician.

Most important symptoms and effects, both acute and delayed**Symptoms**

No information available.

For emergency responders**Self-protection of the first aider**

No information available.

Indication of any immediate medical attention and special treatment needed**Note to physicians**

Treat symptomatically.

SECTION 5: Firefighting measures**Suitable Extinguishing Media**

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the chemical

Specific hazards arising from the chemical None known.

Special protective actions for fire-fighters

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**Personal precautions, protective equipment and emergency procedures**

Personal precautions Ensure adequate ventilation.

For emergency responders Use personal protection recommended in Section 8.

Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

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 Clean contaminated surface thoroughly.

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

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

SECTION 7: Handling and storage**Precautions for safe handling**

Advice on safe handling Ensure adequate ventilation.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place.

SECTION 8: Exposure controls/personal protection**Control parameters**

Occupational exposure limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

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

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin and body protection Wear suitable protective clothing.

Hand protection Wear suitable gloves.

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.

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

Appearance powder or cake, lyophilised

Colour yellow

Odour Slight.

Odour threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	7.30-7.90	
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapour pressure	No data available	None known
Vapour density	No data available	None known
Relative density	No data available	None known
Water solubility	Soluble in water	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known

Other information No information available

SECTION 10: Stability and reactivity**Reactivity**

Reactivity No information available.

Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid

Conditions to avoid None known based on information supplied.

Incompatible materials

Incompatible materials None known based on information supplied.

Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information**Information on likely routes of exposure****Product Information**

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

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

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity**Numerical measures of toxicity**

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

ATEmix (oral) 38,231.20 mg/kg

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium chloride	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h

Sodium salicylate	= 930 mg/kg (Rat)	> 2000 mg/kg (Rat)	
Trade secret	= 2600 mg/kg (Rat)		
Acetaminophen	= 1944 mg/kg (Rat)		
Pentanoic acid, 2-propyl-, sodium salt (1:1)	= 670 mg/kg (Rat)		
Trade secret	= 17 g/kg (Rat)		
2,5-Pyrrolidinedione, 3-ethyl-3-methyl-	= 1820 mg/kg (Rat)		
Lithium carbonate	= 525 mg/kg (Rat)	> 3000 mg/kg (Rabbit)	> 2.17 mg/L (Rat) 4 h
Phenobarbital	= 162 mg/kg (Rat)		
Vancomycin hydrochloride	> 10 g/kg (Rat)		
Diphenylhydantoin, sodium salt	= 1530 mg/kg (Rat)		
Theophylline	= 225 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 6.7 mg/L (Rat) 4 h
Caffeine	= 367.7 mg/kg (Rat)	> 2000 mg/kg (Rat)	= 4.94 mg/L (Rat) 4 h
Carbamazepine	= 1957 mg/kg (Rat)		
Primidone	= 1500 mg/kg (Rat)		
Gentamicin, sulfate (salt)	> 5 g/kg (Rat)		
Tobramycin	> 7500 mg/kg (Rat)		
Methotrexate	= 135 mg/kg (Rat)		
1-Propanamine, 3-(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-ylidene)-N-methyl-, hydrochloride	= 405 mg/kg (Rat)		
Salicylic acid	= 891 mg/kg (Rat)	> 2 g/kg (Rat)	> 900 mg/m ³ (Rat) 1 h
Cyclosporin A	= 1480 mg/kg (Rat)		
1-Propanamine, 3-(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-ylidene)-N,N-dimethyl-, hydrochloride	= 240 mg/kg (Rat)		
Digoxin	= 28270 µg/kg (Rat)		

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

Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.

Reproductive toxicity Based on available data, the classification criteria are not met.

STOT - single exposure Based on available data, the classification criteria are not met.

STOT - repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Classification not possible.

SECTION 12: Ecological information

Ecotoxicity

Ecotoxicity

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

Chemical name	Algae/aquatic plants	Fish	Crustacea
Sodium chloride	-	LC50: 4747 - 7824mg/L (96h, <i>Oncorhynchus mykiss</i>) LC50: 5560 - 6080mg/L (96h, <i>Lepomis macrochirus</i>) LC50: 6020 - 7070mg/L (96h, <i>Pimephales promelas</i>) LC50: 6420 - 6700mg/L (96h, <i>Pimephales promelas</i>) LC50: =12946mg/L (96h, <i>Lepomis macrochirus</i>) LC50: =7050mg/L (96h, <i>Pimephales promelas</i>)	EC50: 340.7 - 469.2mg/L (48h, <i>Daphnia magna</i>) EC50: =1000mg/L (48h, <i>Daphnia magna</i>)
Trade secret	EC50: =2500mg/L (72h, <i>Desmodesmus subspicatus</i>)	LC50: 750 - 1020mg/L (96h, <i>Pimephales promelas</i>) LC50: =1060mg/L (96h, <i>Lepomis macrochirus</i>)	EC50: =825mg/L (48h, <i>Daphnia magna</i>) EC50: =83mg/L (48h, <i>Daphnia magna</i>)
Acetaminophen	-	LC50: =814mg/L (96h, <i>Pimephales promelas</i>)	EC50: 6.1 - 14mg/L (48h, <i>Daphnia magna</i>)
Lithium carbonate	-	LC50: =30.3mg/L (96h, <i>Oncorhynchus mykiss</i>)	-
Caffeine	-	LC50: =151mg/L (96h, <i>Pimephales promelas</i>)	-

Persistence and degradability

Persistence and degradability No information available.

Bioaccumulative potential

Bioaccumulation There is no data for this product.

Chemical name	Partition coefficient
Acetaminophen	1.098
Theophylline	-0.008
Caffeine	-0.091

Mobility

Mobility in soil No information available.

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
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Sodium chloride	The substance is not PBT / vPvB
Trade secret	The substance is not PBT / vPvB
Acetaminophen	The substance is not PBT / vPvB
Lithium carbonate	The substance is not PBT / vPvB PBT assessment does not apply
Caffeine	The substance is not PBT / vPvB

Other adverse effects

Other adverse effects No information available

SECTION 13: Disposal considerations**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

ADR Not regulated

IMDG Not regulated
Transport in bulk according to Annex II of MARPOL and the IBC Code No information available

IATA Not regulated

SECTION 15: Regulatory information**Safety, health and environmental regulations/legislation specific for the substance or mixture****Singapore****Environmental Public Health Act**

Dispose of waste product or used containers according to local regulations.

Hazardous Waste (Control of Export, Import and Transit) Act

It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Take note that wastes may be subject to export, import, or transit controls pursuant to the Basel convention and/or local regulations implementing the Basel convention.

Poison

Verify that licence requirements are met Verify that requirements related to using, handling, and storing substances subject to prohibition, authorisation or restriction are met

Chemical name	Poison	Poison Schedule Number
Lithium carbonate	X	First schedule Second schedule Third schedule
Theophylline	X	First schedule Second schedule Third schedule

Methotrexate	X	First schedule Third schedule
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Strategic Goods (Control) Act

Verify that requirements related to using, handling, and storing substances subject to prohibition, authorisation or restriction are met.

Chemical name	Strategic Goods (Control) Act
Lithium carbonate	1C233

Workplace Safety and Health Act

Comply with the health and safety at work laws.

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

International Inventories

Contact supplier for inventory compliance status

SECTION 16: Other information**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

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

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) (AELG(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
 Australia 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)
 Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
 Organization for Economic Co-operation and Development High Production Volume Chemicals Program
 Organization for Economic Co-operation and Development Screening Information Data Set
 RTECS (Registry of Toxic Effects of Chemical Substances)
 World Health Organization

Label elements

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Revision Note

Significant changes throughout SDS. Review all sections.

This safety data sheet complies with the requirements of: SS586: 2008 (2014)

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