Ortho Clinical Diagnostics

SAFETY DATA SHEET

Issuing Date 01-Jun-2015 Revision Date 01-Jun-2015 Revision Number 0

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Code(s) OCDUS1662659B4D

Product Name VITROS Chemistry Products Calibrator Kit 2 - Calibrator 4 Diluent

Pure substance/mixture Mixture

Contains Diethylaminoethanol

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

Recommended Use Aqueous buffer solution

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Importer Supplier

OCD ESC

24, Bld Sebastien Brant BP 30335

Ortho-Clinical Diagnostics, Inc.

100 Indigo Creek Drive

Illkirch Graffenstaden 67411

France

100 Indigo Creek Drive Rochester, NY 14626-5101

For further information, please contact

E-mail Address UK - ukhotline@its.jnj.com

French - hotlinefrance@its.jnj.com German - ocdtechsupport-de@its.jnj.com

Italian - italianhl@its.jnj.com Nordic - nordichotline@its.jnj.com Polish - polskahl@its.jnj.com

Portuguese - Port_OCDhotline@its.jnj.com South Ireland - UKhotline@its.jnj.com Spanish - spanishhotline@its.jnj.com

1.4. Emergency telephone number

Emergency Telephone <u>Transportation Emergencies:</u>

Number US Telephone Number: (800) 424-9300

International and Maritime Telephone Number: +1 (703) 527-3887

US:

(800) 421-3311

Europe	UK 0800 895 963	
_	French 03 88 65 47 33	
	German 0800 181 48 97	
	Italian 800 870 655	
	Nordic 00800 0837 2560	
	Polish 0800 331 13 58	
	Portuguese 800 83 31 43	
	South Ireland +33 (0) 3 88 65 47 63	
	Spanish 900 97 33 25	

Section 2. Hazards identification

2.1. - Classification of the substance or mixture

REGULATION (EC) No 1272/2008

Skin Corrosion/Irritation	Category 1
Serious Eye Damage/Eye Irritation	Category 1
Specific Target Organ Systemic Toxicity (Single Exposure)	Category 3

Physical Hazards

None

2.2. Label Elements



Signal Word

Danger

Hazard Statements

H314 - Causes severe skin burns and eye damage

H335 - May cause respiratory irritation

Precautionary Statements - EU (§28, 1272/2008)

P261 - Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray

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

P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P310 - Immediately call a POISON CENTER or doctor/ physician

2.3. Other information

May cause drowsiness and dizziness.

Section 3. Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Chemical Name	EC-No	CAS-No	Weight %	EU - GHS Substance Classification	REACH No.
Diethylaminoethanol	202-845-2	100-37-8	5.988	Acute Tox. 4 (H302) Acute Tox. 4 (H312) Skin Corr. 1B (H314) Flam. Liq. 3 (H226) Acute Tox. 4 (H332)	No data available

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

Section 4. First aid measures

4.1. Description of first-aid measures

OCDUS1662659B4D - VITROS Chemistry Products Calibrator Kit 2 - Calibrator 4 Diluent

General Advice If symptoms persist, call a physician.

Eye Contact Immediately flush with plenty of water. After initial flushing, remove any contact lenses and

continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Call a physician

or Poison Control Center immediately.

Skin ContactWash off immediately with soap and plenty of water for at least 15 minutes while removing

all contaminated clothing and shoes. Call a physician or Poison Control Center

immediately. Remove and wash contaminated clothing before re-use.

Ingestion Rinse mouth. Drink plenty of water. Do NOT induce vomiting. Never give anything by mouth

to an unconscious person. Consult a physician.

Inhalation IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing

Call a physician or Poison Control Center immediately.

Protection of First-aidersUse personal protective equipment.

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

Most Important Symptoms/Effects Burning. Tearing. Drowsiness. Dizziness.

4.3. Indication of immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

Section 5. Fire-fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media

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

Extinguishing media which must not be used for safety reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases Thermal decomposition can lead to release of irritating gases and vapors.

5.3. Advice for firefighters

Special protective equipment for fire-fighters

As in any fire, wear self-contained breathing apparatus and full protective gear.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Refer to Section 8.

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so.

6.3. Methods and materials for containment and cleaning up

Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see Section 13).

Clean contaminated surface thoroughly.

6.4. Reference to other sections

See Section 12 for additional information.

Section 7. Handling and storage

7.1. Precautions for Safe Handling

Handling

Ensure adequate ventilation. Do not breathe vapors or spray mist. Avoid contact with skin, eyes and clothing. Use only in area provided with appropriate exhaust ventilation. Wear personal protective equipment. Wash thoroughly after handling.

Hygiene Measures

When using, do not eat, drink or smoke. Remove and wash contaminated clothing before re-use. Provide regular cleaning of equipment, work area and clothing.

7.2. Conditions for safe storage, including any incompatibilities

Keep containers tightly closed in a cool, well-ventilated place. Keep in properly labeled containers. Keep out of the reach of children.

7.3. Specific end use(s)

Exposure Scenario

No information available.

Other Guidelines

No information available.

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Chemical Name	EU	The United Kingdom	France	Spain	Germany
Diethylaminoethanol			VME: 10 ppm	S*	MAK: 5 ppm
100-37-8			VME: 50 mg/m ³	VLA-ED: 2 ppm	MAK: 24 mg/m ³
				VLA-ED: 9.7 mg/m ³	Ceiling / Peak: 5 ppm
					Ceiling / Peak: 24
					mg/m³
					Skin
					TWA: 5 ppm
					TWA: 24 mg/m ³
Component	Italy	Portugal	The Netherlands	Finland	Denmark
Diethylaminoethanol		TWA: 2 ppm		STEL: 10 ppm	TWA: 2 ppm
100-37-8 (5.988)				STEL: 49 mg/m ³	TWA: 9.6 mg/m ³
				Skin	Skin

OCDUS1662659B4D - VITROS Chemistry Products Calibrator Kit 2 - Calibrator 4 Diluent

Chemical Name	Austria	Switzerland	Poland	Norway	Ireland
Diethylaminoethanol	Skin	Skin	NDSCh: 26 mg/m ³	TWA: 10 ppm	TWA: 10 ppm
100-37-8	STEL 5 ppm	MAK: 10 ppm	NDS: 13 mg/m ³	TWA: 50 mg/m ³	TWA: 50 mg/m ³
	STEL 24 mg/m ³	MAK: 50 mg/m ³	Skin	Skin	Skin
	MAK: 5 ppm			STEL: 20 ppm	
	MAK: 24 mg/m ³			STEL: 75 mg/m ³	
	Ceiling 5 ppm				
	Ceiling 24 mg/m ³				

Derived No Effect Level Predicted No Effect Concentration (PNEC)

No information available No information available.

8.2. Exposure controls

Engineering Measures

Personal protective equipment

Eve Protection Skin and Body Protection

Hand Protection

Respiratory Protection

Ensure adequate ventilation, especially in confined areas.

Tightly fitting safety goggles. Long sleeved clothing. Impervious gloves.

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

appropriate certified respirators.

Environmental Exposure Controls No information available.

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Liquid Colorless **Physical State Appearance**

Odor Odorless

Property Values Remarks/ - Method 8.0 None known Melting Point/Range No data available None known **Boiling Point/Boiling Range** 100 °C / 212 °F None known None known Flash Point Not determined.

Evaporation rate No data available None known Flammability (solid, gas) No data available None known **Vapor Pressure** 24 mbar (18 mmHg) @ 20°C None known

Vapor Density 0.5 (Air=1) None known **Relative Density** No data available None known No data available Water Solubility None known Solubility in other solvents No data available None known Partition coefficient: n-octanol/waterNo data available None known **Autoignition Temperature** No data available None known **Decomposition Temperature** No data available None known No data available None known **Viscosity**

Explosive Properties No data available **Oxidizing Properties** No data available

9.2. Other information

VOC Content (%) No information available No data available Flammability Limits in Air

Section 10. Stability and reactivity

10.1. Reactivity

No dangerous reaction known under conditions of normal use.

OCDUS1662659B4D - VITROS Chemistry Products Calibrator Kit 2 - Calibrator 4 Diluent

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

Heat.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

Carbon dioxide (CO₂). Carbon monoxide (CO). Nitrogen oxides (NOx).

Section 11. Toxicological information

11.1. Information on toxicological effects

Acute Toxicity

Product Information

Inhalation Irritating to respiratory system.

Eye Contact Irritating to eyes. Causes serious eye damage.
Skin Contact Irritating to skin. Causes severe skin burns.
Ingestion May cause drowsiness and dizziness.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Diethylaminoethanol	= 1300 mg/kg (Rat)	= 1260 mg/kg (Rabbit)	

SensitizationNo information available.Mutagenic EffectsNo information available.Carcinogenic EffectsNo information available.

Reproductive Toxicity
Developmental Toxicity
STOT - single exposure
STOT - repeated exposure
Aspiration Hazard
No information available.
Syes. Skin. Respiratory system.
No information available.
No information available.

Section 12. Ecological information

12.1. Toxicity

Ecotoxicity Effects

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Diethylaminoethanol	EC50 72 h: = 30 mg/L (Desmodesmus subspicatus)	LC50 96 h: 100-220 mg/L static (Leuciscus idus) LC50 96 h: 1660-1920 mg/L flow-through (Pimephales promelas)		EC50 48 h: = 83.6 mg/L (Daphnia magna Straus)

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential.

Chemical Name	Log Pow	
Diethylaminoethanol	0.21	

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

This product does not contain any known or suspected endocrine disruptors.

Section 13. Disposal considerations

13.1. Waste treatment methods

Waste from Residues / Unused

Products

Dispose of in accordance with local regulations.

Contaminated Packaging Empty containers should be taken to an approved waste handling site for recycling or

disposal.

Other Information According to the European Waste Catalogue, Waste Codes are not product specific, but

application specific. Waste codes should be assigned by the user based on the application

for which the product was used.

Section 14. Transport information

IMDG/IMO

14.1. UN-Number UN2686

14.2. Proper Shipping Name 2-Diethylaminoethanol solution

14.3. Hazard Class 8
Subsidiary Class 3
14.4. Packing Group ||

Description UN2686, 2-Diethylaminoethanol solution, 8 (3), II

14.5. Marine Pollutant None.
14.6. Special Provisions None.
EmS No. F-E, S-C

14.7. Transport in bulk according No i

to Annex II of MARPOL 73/78 and

the IBC Code

No information available.

RID

14.1. UN-Number UN2686

14.2. Proper Shipping Name 2-Diethylaminoethanol solution

14.3. Hazard Class8ADR/RID-Labels314.4. Packing GroupII

Description UN2686, 2-Diethylaminoethanol solution, 8 (3), II

14.5. Environmental hazard None. 14.6. Special Provisions None.

OCDUS1662659B4D - VITROS Chemistry Products Calibrator Kit 2 - Calibrator 4 Diluent

Classification Code CF1

ADR

14.1. UN-Number UN2686

14.2. Proper Shipping Name 2-Diethylaminoethanol solution

14.3. Hazard Class 8
ADR/RID-Labels 3
14.4. Packing Group ||

Description UN2686, 2-Diethylaminoethanol solution, 8 (3), II, (D/E)

14.5. Environmental hazard
14.6. Special Provisions
Classification Code
Tunnel Restriction Code
(D/E)

ICAO

14.1. UN-Number UN2686

14.2. Proper shipping name 2-Diethylaminoethanol solution

14.3. Hazard Class 8
Subsidiary Class 3
14.4. Packing Group ||

Description UN2686, 2-Diethylaminoethanol solution, 8 (3), II

14.5. Environmental hazard None. **14.6. Special Provisions** None.

<u>IATA</u>

14.1. UN-Number UN2686

14.2. Proper Shipping Name 2-Diethylaminoethanol solution

14.3. Hazard Class8Subsidiary Class314.4. Packing GroupII

Description UN2686, 2-Diethylaminoethanol solution, 8 (3), II

14.5. Environmental hazardNone.14.6. Special ProvisionsNone.ERG Code8F

Section 15. Regulatory information

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

International Inventories

TSCA Exempt **EINECS/ELINCS** Exempt Exempt **DSL/NDSL** Exempt **PICCS ENCS** Exempt **IECSC** Exempt -**AICS** Exempt **KECL** Exempt

Legend

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

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

15.2. Chemical Safety Assessment

No information available

Section 16. Other information

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

H302 - Harmful if swallowed

H312 - Harmful in contact with skin

H314 - Causes severe skin burns and eye damage

H226 - Flammable liquid and vapor

H332 - Harmful if inhaled

H335 - May cause respiratory irritation

Key literature references and sources for data

www.ChemADVISOR.com/

Issuing Date 01-Jun-2015

Revision Date 01-Jun-2015

Revision Note Initial Release.

This safety data sheet complies with the requirements of Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No. 1907/2006

General Disclaimer

The information provided on this SDS 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.

End of Safety Data Sheet