Ortho Clinical Diagnostics

SAFETY DATA SHEET

Issuing Date 01-Jun-2015 **Revision Date** 02-Mar-2016 **Revision Number** 1

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

1.1. Product identifier

Product Code(s) OCDUK1142561DR

Product Name **VITROS Immunodiagnostic Products B12/Folate Denaturant Reagent**

Pure substance/mixture Mixture

Contains Sodium hydroxide

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

Recommended Use Diagnostic agent

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Importer
Ortho-Clinical Diagnostics
1500 Boulevard Sébastien Brant
B.P. 30335
67411 Illkirch
CEDEX, France

Supplier
Ortho-Clinical Diagnostics
Felindre Meadows
Pencoed
Bridgend
CF35 5PZ
United Kingdom

For further information, please contact

E-mail Address
UK - ukhotline@orthoclinicaldiagnostics.com
France - hotlinefrance@orthoclinicaldiagnostics.com
Germany - ocdtechsupport-de@orthoclinicaldiagnostics.com
Italy - italianhl@orthoclinicaldiagnostics.com
Nordic - nordichotline@orthoclinicaldiagnostics.com
Poland - service_pl@pl.diasorin.com
Portugal - port_ocdhotline@orthoclinicaldiagnostics.com
Irish Republic - ukhotline@orthoclinicaldiagnostics.com
Spain - spanishhotline@orthoclinicaldiagnostics.com

1.4. Emergency telephone number

Emergency Telephone Number

Transportation Emergencies:
US Telephone Number: (800) 424-9300
International and Maritime Telephone Number: +1 (703) 527-3887

US:
(800) 421-3311

Europe	UK 0 800 895963 France 03 88 65 47 33 Germany 0 800 181 48 97 Italy 800 87 06 55 Nordic 00 800 08372560 Poland 48 (22) 223 62 65 Portugal 0 800 833143 Irish Republic 00 800 08372560 Spain 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

Physical Hazards

None

2.2. Label Elements



Signal Word **Danger**

Hazard Statements
H314 - Causes severe skin burns and eye damage

Precautionary Statements - EU (§28, 1272/2008)
P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection
P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P303 + P361 + P353 - IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower
P363 - Wash contaminated clothing before reuse
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/ physician

2.3. Other information
Causes burns.

Section 3. Composition/information on ingredients

3.1. Substances
3.2. Mixtures

Chemical Name	EC-No	CAS-No	Weight %	EU - GHS Substance Classification	REACH No.
Sodium hydroxide	215-185-5	1310-73-2	4.82	Skin Corr. 1A (H314)	No data available
Boric acid	233-139-2	10043-35-3	2.97	Repr. 1B (H360FD)	No data available

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

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Chemical Name	CAS-No	Weight %	Candidate List of Substances of Very High Concern for Authorization
Boric acid	10043-35-3	2.97	x

Section 4. First aid measures

4.1. Description of first-aid measures

General Advice	Immediate medical attention is required.
Eye Contact	Immediate medical attention is required. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area.
Skin Contact	Immediate medical attention is required. Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.
Ingestion	Immediate medical attention is required. Do NOT induce vomiting. Drink plenty of water. Never give anything by mouth to an unconscious person. Remove from exposure, lie down. Clean mouth with water and afterwards drink plenty of water. Call a physician or Poison Control Center immediately.
Inhalation	Move to fresh air. Call a physician or Poison Control Center immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
Protection of First-aiders	Use personal protective equipment. Avoid contact with skin, eyes and clothing.

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

Most Important Symptoms/Effects No information available.

4.3. Indication of immediate medical attention and special treatment needed

Notes to Physician Product is a corrosive material. Use of gastric lavage or emesis is contraindicated. Possible perforation of stomach or esophagus should be investigated. Do not give chemical antidotes. Asphyxia from glottal edema may occur. Marked decrease in blood pressure may occur with moist rales, frothy sputum, and high pulse pressure. 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
None known.

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
Evacuate personnel to safe areas. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Keep people away from and upwind of spill/leak.

Refer to protective measures listed in Sections 7 and 8.

6.2. Environmental precautions
Do not allow material to contaminate ground water system. Should not be released into the environment. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

6.3. Methods and materials for containment and cleaning up
Wipe up with absorbent material (e.g. cloth, fleece).

Clean contaminated surface thoroughly.

6.4. Reference to other sections
Personal protection equipment (PPE) - Refer to Section 8. Disposal - Refer to Section 13.

Section 7. Handling and storage

7.1. Precautions for Safe Handling
Handling
Ensure adequate ventilation. Wear personal protective equipment. Avoid contact with skin, eyes and clothing. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation at machinery.

Hygiene Measures
When using, do not eat, drink or smoke. Avoid contact with skin, eyes and clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing before re-use. Keep away from food, drink and animal feeding stuffs. Contaminated work clothing should not be allowed out of the workplace. Provide regular cleaning of equipment, work area and clothing.

7.2. Conditions for safe storage, including any incompatibilities
Do not freeze. Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep in properly labeled containers.

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
Sodium hydroxide 1310-73-2		STEL: 2 mg/m³	TWA: 2 mg/m³	STEL: 2 mg/m³	
Boric acid 10043-35-3				STEL: 6 mg/m³ TWA: 2 mg/m³	TWA: 10 mg/m³ Ceiling / Peak: 10 mg/m³ TWA: 0.5 mg/m³
Component	**Italy**	**Portugal**	**The Netherlands**	**Finland**	**Denmark**
Sodium hydroxide		Ceiling: 2 mg/m³		Ceiling: 2 mg/m³	Ceiling: 2 mg/m³

1310-73-2 (4.82)					
Boric acid 10043-35-3 (2.97)		STEL: 6 mg/m³ TWA: 2 mg/m³			
Chemical Name	**Austria**	**Switzerland**	**Poland**	**Norway**	**Ireland**
Sodium hydroxide 1310-73-2	STEL 4 mg/m³ TWA: 2 mg/m³	STEL: 2 mg/m³ TWA: 2 mg/m³	STEL: 1 mg/m³ TWA: 0.5 mg/m³	Ceiling: 2 mg/m³	STEL: 2 mg/m³
Boric acid 10043-35-3		STEL: 1.8 mg/m³ TWA: 1.8 mg/m³			TWA: 2 mg/m³ STEL: 6 mg/m³

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

Derived No Effect Level No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering Measures Showers.
Eyewash stations.
Ventilation systems.

Personal protective equipment

Eye Protection Tightly fitting safety goggles. Face-shield.
Skin and Body Protection Impervious clothing. Boots. Chemical resistant apron.
Hand Protection Impervious gloves.
Respiratory Protection 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

Physical State Liquid. **Appearance** Colorless, Aqueous solution.
Odor None.

Property	**Values**	**Remarks/ - Method**
pH	> 12	None known
Melting Point/Range	No data available	None known
Boiling Point/Boiling Range	No data available	None known
Flash Point	Not determined.	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Vapor Pressure	No data available	None known
Vapor Density	No data available	None known
Relative Density	No data available	None known
Water Solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition Temperature	No data available	None known
Decomposition Temperature	No data available	None known
Viscosity	No data available	None known
Explosive Properties	No data available	
Oxidizing Properties	No data available	

9.2. Other information

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

Section 10. Stability and reactivity

10.1. Reactivity
No dangerous reaction known under conditions of normal use.

10.2. Chemical stability
Stable under normal conditions.

10.3. Possibility of hazardous reactions
None under normal processing.

10.4. Conditions to avoid
Do not freeze. Contact with acids liberates toxic gas. Exposure to air or moisture over prolonged periods.

10.5. Incompatible materials
Acids.

10.6. Hazardous decomposition products
Thermal decomposition can lead to release of irritating gases and vapors.

Section 11. Toxicological information

11.1. Information on toxicological effects

Acute Toxicity

Product Information	.
Inhalation	Harmful if inhaled.
Eye Contact	Causes serious eye damage.
Skin Contact	Causes severe skin burns.
Ingestion	Harmful if swallowed. Ingestion of corrosive substances can cause burns of the upper digestive and respiratory tract.

Chemical Name	LD50 Oral	LD50 Dermal	Inhalation
Sodium hydroxide	-	1350 mg/kg (Rabbit)	-
Boric acid	= 2660 mg/kg (Rat)	>2000 mg/kg (Rabbit)	>0.16 mg/L (Rat) 4 h

Sensitization	No information available
Mutagenic Effects	No information available.
Carcinogenic Effects	Contains no ingredients above reportable quantities listed as a carcinogen.
Reproductive Toxicity	May impair fertility. May cause harm to the unborn child.
Developmental Toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Other Adverse Effects	No information available.
Aspiration Hazard	May be harmful if swallowed and enters airways.

Section 12. Ecological information

12.1. Toxicity

Ecotoxicity Effects
Harmful to aquatic organisms. Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to	Daphnia Magna (Water

			Microorganisms	Flea)
Sodium hydroxide		LC50 96 h: = 45.4 mg/L static (Oncorhynchus mykiss)		
Boric acid				EC50 48 h: 115 - 153 mg/L (Daphnia magna)

12.2. Persistence and degradability

No information available

12.3. Bioaccumulative potential

No information available.

Chemical Name	Log Pow
Boric acid	-0.757

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 Do not re-use empty containers.

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 UN1824
14.2. Proper Shipping Name Sodium hydroxide solution
14.3 Hazard Class 8
14.4. Packing Group II
Description UN1824, Sodium hydroxide solution, 8, II
14.5. Marine Pollutant None.
Environmental hazard None.
14.6. Special Provisions None.
EmS No. F-A, S-B
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

RID

14.1. UN-Number	UN1824
14.2. Proper Shipping Name	Sodium hydroxide solution
14.3. Hazard Class	8
14.4. Packing Group	II
Description	UN1824, Sodium hydroxide solution, 8, II
14.5. Environmental hazard	None.
14.6. Special Provisions	None

ADR

14.1. UN-Number	Not regulated.
14.2. Proper Shipping Name	Not regulated.
14.3. Hazard Class	None.
14.4. Packing Group	Not regulated.
14.5. Environmental hazard	None.
14.6. Special Provisions	None.

IATA/ICAO

14.1. UN-Number	UN1824
14.2. Proper Shipping Name	Sodium hydroxide solution
14.3. Hazard Class	8
14.4. Packing Group	II
Description	UN1824, Sodium hydroxide solution, 8, II
14.5. Environmental hazard	None.
14.6. Special Provisions	None.
ERG Code	8L

Section 15. Regulatory information

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

Candidate List of Substances of Very High Concern for Authorization
This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

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

15.2. Chemical Safety Assessment
No information available

Section 16. Other information

Full text of H-Statements referred to under sections 2 and 3
H360FD - May damage fertility. May damage the unborn child
H314 - Causes severe skin burns and eye damage

Key literature references and sources for data
www.ChemADVISOR.com/

Issuing Date	01-Jun-2015
Revision Date	02-Mar-2016
Revision Note	SDS sections updated, 1.

This safety data sheet complies with the requirements of Commission Regulation (EU) 2015/830 of 28 May 2015 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