

SAFETY DATA SHEET

PRODUCT NAME: HEMOLYNAC.510
PRODUCT CODE: MK-510WD

SDS NUMBER: SDS/ MK-510WD-00
ISSUANCE DATE: 12/04/2020

Section 1 – Identification of the Substance/Mixture and of the Company/Undertaking

Product name:	HEMOLYNAC.510
Product code:	MK-510WD
Supplier:	Nihon Kohden Middle East (Branch)
Address:	QC-4, QC-5, QC-6, QC-7 DAFZA Industrial Park. Al Qusais, Dubai U.A.E
Telephone number:	+971 4-239-9911
Fax:	+971 4-880-0122
Website for contact:	
Emergency telephone number:	+971 4-239-9911 (during working hours)
Recommended use and restrictions on use:	Hemolysing reagent for Nihon Kohden hematology analyzer

Section 2 – Hazards Identification

2.1. Classification of the substance or mixture.

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to EC Regulation 1907/2006 and subsequent amendments.

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments.

Hazard classification and indication: --

2.2. Label elements.

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

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Safety data sheet available for professional users on request.

The product is in conformity with the requirements of in vitro diagnostic medical devices Directive 98/79/EC. Therefore, in accordance with art. 1, 5, d) of Regulation 1272/2008, CLP requirements of labeling do not apply to the product in the finished state, intended for the final user.

2.3. Other hazards.

Information not available.

Section 3 – Composition/Information on Ingredients

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains

Identification.	Conc. %.	Classification 67/548/EEC.	Classification 1272/2008 (CLP).
Tris (hydroxymethyl) aminomethane CAS. 77-86-1 EC. 201-064-4 INDEX. - Reg. no. -	1 - 1,5	Xi R36/37/38	Eye Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H335
BORIC ACID CAS. 10043-35-3 EC. 233-139-2 INDEX. 005-007-00-2	0,6 - 0,7	Repr. Cat. 2 R60, Repr. Cat. 2 R61	Repr. 1B H360FD

Reg. no. 01-2119486683-25-XXXX

Note: Upper limit is not included into the range.

The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet.

T+ = Very Toxic(T+), T = Toxic(T), Xn = Harmful(Xn), C = Corrosive(C), Xi = Irritant(Xi), O = Oxidizing(O), E = Explosive(E), F+ = Extremely Flammable(F+), F = Highly Flammable(F), N = Dangerous for the Environment(N)

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Section 4 – First Aid Measures

4.1. Description of first aid measures.

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

PROTECTIVE MEASURES FOR THE FIRST RESCUE WORKERS: for PPE (personal protection equipment) required for first aid refer to section 8.2 of this safety data sheet.

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

For symptoms and effects caused by the contained substances, see chap. 11.

4.3. Indication of any immediate medical attention and special treatment needed.

Information not available

Section 5 – Fire-fighting Measures

5.1. Extinguishing media.

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

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Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

5.3. Advice for firefighters.

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

Section 6 – Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures.

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions.

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up.

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Check incompatibility for container material in section 7. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

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6.4. Reference to other sections.

Any information on personal protection and disposal is given in sections 8 and 13.

Section 7 – Handling and Storage

7.1. Precautions for safe handling.

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities.

Store only in the original container. Store in a well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).

No use other than specified in Section 1.2 of this safety data sheet

Section 8 – Exposure Controls/Personal Protection

8.1. Control parameters.

Regulatory References:

United Kingdom	EH40/2005 Workplace exposure limits. Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations (as amended).
Éire	Code of Practice Chemical Agent Regulations 2011.
OEL EU	Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC.
TLV-ACGIH	ACGIH 2014

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BORIC ACID

Threshold Limit Value.

Type	Country	TWA/8h		STEL/15min	
		mg/m ³	ppm	mg/m ³	ppm
TLV-ACGIH		2		6	

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ;
 NPI = no hazard identified

8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

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If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS.

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

Section 9 – Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance	Not available.
Colour	Not available.
Odour	Not available.
Odour threshold.	Not available.
pH.	Not available.
Melting point / freezing point.	Not available.
Boiling range	Not available.
Flash point.	> 60 °C.
Evaporation Rate	Not available.
Initial boiling point.	Not available
Flammability of solids and gases	Not available
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Relative density.	Not available.
Solubility	Not available.
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.

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Explosive properties

The product is not explosive on the basis of the composition.

Oxidising properties

Not available.

9.2. Other information.

Information not available

Section 10 – Stability and Reactivity

10.1. Reactivity.

There are no particular risks of reaction with other substances in normal conditions of use.
BORIC ACID: decomposes above 100°C.

10.2. Chemical stability.

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions.

No hazardous reactions are foreseeable in normal conditions of use and storage. BORIC ACID: risk of explosion on contact with acetic anhydride.

10.4. Conditions to avoid.

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials.

Information not available.

10.6. Hazardous decomposition products.

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released. BORIC ACID: boric anhydride, metaboric acid.

Section 11 – Toxicological Information

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled carefully according to good industrial practices. This product may have slight health effects on sensitive people, by inhalation and/or cutaneous absorption and/or contact with eyes and/or ingestion.

11.1. Information on toxicological effects.

Data available for the mixture:

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ACUTE TOXICITY: no data available.
SKIN CORROSION/IRRITATION: no data available.
SERIOUS EYE DAMAGE/IRRITATION: no data available.
RESPIRATORY OR SKIN SENSITISATION: no data available.
CARCINOGENICITY: no data available.
REPRODUCTIVE TOXICITY: no data available.
STOT-SINGLE EXPOSURE: no data available.
STOT-REPEATED EXPOSURE: no data available.
ASPIRATION HAZARD: no data available.

Data available for the substances in the mixture

BORIC ACID

LD50 (Oral). 2660 mg/kg Rat

LD50 (Dermal). > 2000 mg/kg Rabbit

LC50 (Inhalation). > 2,12 mg/l/4h Rat dust

REPRODUCTIVE TOXICITY: exposure of rats at levels up to 17.5 mg B/kg bw in the diet in a 3 generation reproduction study was without adverse effect (Weir RJ & Fisher RS Year 1972, Title Toxicologic studies on borax and boric acid. Toxicology and Applied Pharmacology 23: 351 – 364).

NOAEL maternal toxicity 13.3 mg/kg bw/day - LOAEL developmental toxicity 13.3 mg/kg bw/day (Based on reduced foetal body weight and increased incidence of short rib XIII - OECD Guideline 414)

Section 12 – Ecological Information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or sewers or contaminate soil or vegetation.

12.1. Toxicity.

Information not available.

12.2. Persistence and degradability.

Information not available.

12.3. Bioaccumulative potential.

Information not available.

12.4. Mobility in soil.

Information not available

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12.5. Results of PBT and vPvB assessment.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects.

Information not available.

Section 13 – Disposal Considerations

13.1. Waste treatment methods.

Reuse, when possible. Neat product residues should be considered special non-hazardous waste. Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations. Avoid littering. Do not contaminate soil, sewers and waterways.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations

Section 14 – Transport Information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations

Section 15 – Regulatory Information

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

Seveso category. None.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006. Contained substance.

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Substances in Candidate List (Art. 59 REACH).

BORIC ACID Reg. no.: 01-2119486683-25-XXXX

Substances subject to authorisation (Annex XIV REACH). None.

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Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None.

Substances subject to the Rotterdam Convention: None.

Substances subject to the Stockholm Convention: None.

Healthcare controls.
Information not available.

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

Section 16 – Other Information

H319	Causes serious eye irritation
H315	Causes skin irritation
H335	May cause respiratory irritation.
H360FD	May damage fertility. May damage the unborn child

Text of risk (R) phrases mentioned in section 2-3 of the sheet:

R36/37/38	IRRITATING TO EYES, RESPIRATORY SYSTEM AND SKIN.
Repr. Cat. 2	Reproductive toxicity, fertility, category 2.
R60	MAY IMPAIR FERTILITY.
Repr. Cat. 2	Reproductive toxicity, development, category 2.
R61	MAY CAUSE HARM TO THE UNBORN CHILD.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP

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- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation - WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. Regulation (EC) 286/2011 (II Atp. CLP) of the European Parliament
8. Regulation (EC) 618/2012 (III Atp. CLP) of the European Parliament
9. The Merck Index. - 10th Edition
10. Handling Chemical Safety
11. Niosh - Registry of Toxic Effects of Chemical Substances
12. INRS - Fiche Toxicologique (toxicological sheet)
13. Patty - Industrial Hygiene and Toxicology
14. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
15. ECHA website

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product. This document must not be regarded as a guarantee on any specific product property.

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The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses. Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review: NA