CE

Material Safety Data Sheet

Vitamin B12 ELISA

1. IDENTIFICATION OF THE PREPARATION AND COMPANY NAME

Product Name: **Vitamin B12 ELISA**
Catalog No: 3125-15
Synonyms: N/A
Intended Use: Laboratory Use
Use of substance/preparation: Determination of Cortisol concentration in human serum and plasma by a microplate colorimetric assay

2. Information on product /preparation composition

The product contains the following hazardous substances and those with the following highest permissible concentrations in the working environment:

A. Vitamin B12 Calibrators (human sera with determined Vitamin B12 concentrations)

Identification numbers	*Chemical name of substance*	*Concentrations*	*Risk and safety statements*
CAS: 2682-20-4 EC (EINECS): 220-239-6 Merck Index:	2-Methyl-4-isothiazolin-3-one	0.015 %	R22-34-43
CAS: 30007-47-7 EC (EINECS): 250-001-7 Merck Index:	5-Bromo-5-nitro-1, 3-dioxane (BND)	0.015 %	R21/22

B. Vitamin B12 Enzyme Reagent - (Vitamin B12 analog coupled to horse radish peroxidase enzyme, in stabilizing solution)

Identification numbers	*Chemical name of substance*	*Concentrations*	*Risk and safety statements*
CAS: 2682-20-4 EC (EINECS): 220-239-6 Merck Index:	2-Methyl-4-isothiazolin-3-one	0.015 %	R22-34-43
CAS: 30007-47-7 EC (EINECS): 250-001-7 Merck Index:	5-Bromo-5-nitro-1, 3-dioxane (BND)	0.015 %	R21/22

C. Vitamin B12 Biotin Reagent - (anti-Vitamin B12 in stabilizing solution, biotin conjugated)

Identification numbers	*Chemical name of substance*	*Concentrations*	*Risk and safety statements*
CAS: 2682-20-4 EC (EINECS): 220-239-6 Merck Index:	2-Methyl-4-isothiazolin-3-one	0.015 %	R22-34-43
CAS: 30007-47-7 EC (EINECS): 250-001-7 Merck Index:	5-Bromo-5-nitro-1, 3-dioxane (BND)	0.015 %	R21/22

D. Microtiter strips (96 wells, coated with streptavidin, vacuum sealed)

Identification numbers	*Chemical name of substance*	*Concentrations*	*Risk and safety statements*
CAS: 7558-79-4 EC (EINECS): Merck Index: None	Sodium Phosphate Dibasic	0.015 %	R22-34-43, S26
CAS: 26628-22-8 EC (EINECS): Merck Index: None	Sodium Azide	<0.01%	R20/21/22, S23, S24/25, S26, S28.1

E. Wash solution concentrate (10x)

Identification numbers	*Chemical name of substance*	*Concentrations*	*Risk and safety statements*
CAS: 2682-20-4 EC (EINECS): 220-239-6 Merck Index:	2-Methyl-4-isothiazolin-3-one	0.015 %	R22-34-43
CAS: 30007-47-7 EC (EINECS): 250-001-7 Merck Index:	5-Bromo-5-nitro-1, 3-dioxane (BND)	0.015 %	R21/22

F. Substrate (TMB) solution

Identification numbers	*Chemical name of substance*	*Concentrations*	*Risk and safety statements*
CAS: 54827-17-7 EC (EINECS): 259-364-6 Merck Index: None	3,3',5,5'-Tetramethylbenzidine	< 1 %	R20/21/22-36/37/38-40, S26-36/37
CAS: 67-68-5 EC (EINECS): 200-664-3 Merck Index: 12,3308	Dimethylsulfoxide	< 1 %	R36/37/38, S23-26-36
CAS: 10384-4 EC (EINECS): 203-424-6 Merck Index: None	Acetanilide	< 1 %	R36/R37/R38, 526-36

G. Stop solution

Identification numbers	*Chemical name of substance*	*Concentrations*	*Risk and safety statements*
CAS: 7664-93-9 EC (EINECS): 231-639-5 Merck Index: 12,9147	Sulfuric acid	1.96 %	S26-30-45

H. Releasing Agent

Identification numbers	*Chemical name of substance*	*Concentrations*	*Risk and safety statements*
CAS: 1310-73-2 EC (EINECS): 215-185-5 Merck Index:	Sodium hydroxide	< 2 %	R35, (S1/2), S26, S37/39, S45
CAS: 151-50-8 EC (EINECS): 205-792-3 Merck Index:	Potassium cyanide	< 0.02 %	R26/27/28, R32, R50/53, (S1/2), S7, S28, S29, S45, S60, S61

I. Stabilizing Agent

Identification numbers	*Chemical name of substance*	*Concentrations*	*Risk and safety statements*
CAS: 3483-12-3 EC (EINECS): 222-468-7 Merck Index:	Dithiothreitol	< 0.02 %	R21/22, R36/37/38, S24/25

J. Neutralizing Buffer

Identification numbers	*Chemical name of substance*	*Concentrations*	*Risk and safety statements*
CAS: 7558-80-7 EC (EINECS): Merck Index:	Sodium Phosphate monobasic	< 8.3 %	R20/21/22, S26

Risk symbols

T+	Very toxic
Xi	Irritant
C	Corrosive

Risk phrases

R20/21/22	Harmful by inhalation, in contact with skin and if swallowed
R21/22	Harmful in contact with skin and if swallowed
R22	Harmful if swallowed
R26/27/28	Very Toxic by inhalation, in contact with skin and if swallowed
R28	Very Toxic if swallowed
R32	Releases very toxic gas in contact with acids
R33	Danger of cumulative effects
R34	Causes burns
R36/37/38	Irritating to eyes, respiratory system and skin
R40	Possible risk of irreversible effects
R43	May cause sensitization by skin contact

Safety phrases

S13	Keep away from food, drink and animal feeding stuffs
S23	Do not breath spray
S24/25	Avoid contact with skin and eyes
S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S28.1	After contact with skin, wash immediately with plenty of water
S30	Never add water to this product

3. Substance/preparation hazards data

When used, the most adverse impacts of the substance/preparation on human health include:

The followed components can damage health if ingested and/or can irritate eyes and skin: Stop solution, Streptavidin-HRP Conjugate, Biotin-labelled Ab Concentrate, Biotin-Ab Diluent, Substrate (TMB) solution, Human Calibrators, Wash solution concentrate. The Stop solution contains sulfuric acid in total concentration < 5% and is not classified as "Corrosive" or "Irrigating". The Quality controls (Human serum matrix calibrators) contain thimerosal and ε-aminocaproic acid in total concentrations < 0.1% and are classified as "Harmful". The Quality controls are based on HIV-1, HIV-2 and HbsAg negative human sera and must be handled as potentially infectious material. The Wash solution concentrate contains thimerosal in total concentration < 0.1% and is classified as "Harmful".

4. First aid instructions

General instructions: Immediately rinse with soap and plenty of water. Use personal protective working aids.

If inhaled: Transport the affected person into the open air. When there are respiratory complaints, oxygen must be administered. When irritation persists, seek medical advice.

In case of skin contact: The contaminated clothing and footwear must be taken off; the affected skin must be rinsed with plenty of water. Use soap to completely remove the substance. When irritation persists, seek medical advice.

In case of contact with eyes: Remove contact lenses. Rinse with a stream of water for at least 15 minutes. Thorough rinsing must be ensured by opening the eyelids using sterile (clean) fingers. When irritation persists, seek medical advice.

If ingested: Rinse the mouth, administer a big amount of water to dilute the substance. In the case of unconsciousness, never administer anything orally. Seek medical advice.

5. Extinguishing measures

Suitable fire-extinguishing media: Carbon dioxide, dry powder, foam, water.
Thermal decomposition: No thermal decomposition degradation products are expected.
Special hazards: None.
Special protective means for firemen: None.

6. Incidental leakage measures

Safety measures to protect humans: Avoid contact with skin and eyes.
Environmental safety measures: Avoid penetration into sewerage systems, surface and ground water.
Avoid soil pollution.
Recommended cleaning and disposal methods: Cover with suitable absorbing material. After removing the substance, rinse the spot of spilling thoroughly with water and soap.

7. Handling and storage instructions

Handling instructions: Avoid contact with skin, eyes and clothing. Use suitable protective means to work with the substance.
Storage instructions: Store at temperatures between + 2 and + 8°C in a dry and dark place.

8. Exposition checking and protection of persons

Technical measures: Do not eat, drink and smoke when working with the kit. Use the kit only in rooms enabling good ventilation.
Local exhaustion is necessary, general (forced) exhaustion is recommended.
Personal protective means – protection of respiratory organs: None
Personal protective means – eye protection: Protective glasses
Personal protective means – hand protection: Protective gloves (wash your hands before and after work)
Personal protective means – body protection: Protective clothing

9. Physical/chemical properties

State (at 20°C):
Solid: Microtiter strips
Liquids: Calibrators, Enzyme reagent, Conjugate buffer, Biotin reagent, Wash solution concentrate, Substrate solution, Stop Solution, Neutralizing Buffer, Releasing Agent, Stabilizing Agent.

Color:
Caramel to reddish: Enzyme, Conjugate Buffer, Biotin reagent,
Colorless: Stop solution, Wash solution concentrate, Substrate
Creamy to white: Calibrators
Smell (odor): Stabilizing agent (disagreeable odor)
pH value (at 25°C): Stop solution: < 1
Others: 6.8 - 7.4

Melting temperature (temperature range) (°C):	No data available.
Boiling temperature (temperature range) (°C):	No data available.
Flash point (°C):	No data available.
Inflammability:	No data available.
Vapor tension (°C):	No data available.
Water solubility:	Soluble.

Partition coefficient a-octanol/water: No data available.

10. Stability and reactivity

Conditions to be avoided: Heat
Substances and materials with which the product is not allowed to get in touch: Acids
Hazardous decomposition products: Not known
Other data: No hazardous polymerization

11. Toxicological information

The product contains ε-aminocaproic acid in total concentration 0.03%, thimerosal in total concentration 0.05% and sulfuric acid in total concentration 1.96%.
Acute toxicity-LD50 orally, rat (mg/kg): Not known
Acute toxicity-LD50 dermally, rat or rabbit (mg/kg): Not known
Acute gingivostomatitis LD50: Not known
Acute toxicity-LD50 inspiration: Not known
Irritability: No data available
Mutagenicity: No data available
Reproduction toxicity: No data available
Tests on animals: No data available
Other data: Sodium azide damages centre neural system, it causes tachycardia, it reduces hemic pressure, abbreviates respiration, causes headache, vomiting and nausea.

12. Environmental information

Water hazard class: 2 (water-damaging substances)

13. Disposal information

The manner of disposing the substance/preparation:
Mix or dissolve the material in a combustible solvent and burn up in a facility whose equipment matches all regulations in effect. Every waste disposal must be carried out in coincidence with national and local legislation or administrative regulations respectively.
Packages:
In coincidence with local legislation, or administrative regulations respectively.

14. Transportation information

Overland transportation (ADR/RID): As a mixture, the substance is subject to no limitations.
Transatlantic transportation (IMDG): As a mixture, the substance is subject to no limitations.

Air transportation (ICAO/IATA): ***As a mixture, the substance is subject to no limitations.***

15. Information on legal regulations

According to the Act No. 157/1998 Coll. on chemical substances and chemical preparations and on amendments in some other laws and acts, components contained in the Diagnostic Automation, Inc. ELISA kits are non-hazardous substances in said concentrations. Diagnostic Automation, Inc. ELISA kit is subject to special marking regulations according to the EC regulations (28/10/1999).

16. Additional Information

The material safety data sheet contains data necessary to ensure safety and health and environmental protection in working with chemical substances. The above-stated data match the contemporary state of knowledge and experience and are in coincidence with legal regulations currently in effect. This product is a chemical substance and can be solely used by persons with chemical education at their own risk.

Diagnostic Automation, Inc. kits are designed for biomedical research. The manufacturer has no responsibility for damage caused by unsuitable use and by disrespecting the enclosed working instructions.
The above-stated information cannot be considered as complete and must be understood to be only a methodical instruction.

Quality Control
Diagnostic Automation/Cortez Diagnostics, Inc.
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