Material Safety Data Sheet

Neo-natal TSH ELISA
In-Vitro Diagnostic Use Only

SECTION 1. Company Identification

Product name: Neo-natal TSH ELISA
Catalog No.: 3124-15
Synonyms: N/A
Product description: ELISA-based Diagnostic Kit
Intended Use: Quantitative determination of Thyrotropin concentration in human (neonates) whole blood by a microplate enzyme immunoassay, colorimetric.
For in vitro diagnostic use only. Not for internal or external use in humans or animals.
Kit Storage: 2-8°C

Company: Diagnostic Automation Inc.
Address: 21250 Califa St, Suite 102 & 116,
Woodland Hills, CA 91367, USA.
Website: www.rapidtest.com
Phone: 818-591-3030
Fax: 818-591-8383
E-mail: onestep@rapidtest.com

Emergency phone: Contact your local Emergency Health Provider.

SECTION 2. Hazards Identification

2.1 Classification of the substance or mixture
None.

2.2 Label elements
None.

2.3 Other hazards
None.

SECTION 3. Composition and Ingredients Information

3.1 Substances and/or Mixtures
All concentrations of potentially hazardous substances or mixtures are below the specific concentration limits and M-factors for hazardous identification. As preparations, the product components are not classified as hazardous. The following substance exceeds the generic cut-off value and is listed with its concentration level. At this concentration level, the substance is not hazardous. See section 16 for definitions for all risk and hazards classifications.

3.1.1 N-TSH Calibrators (Dried blood spots)
N/A

3.1.2 Whole Blood Controls (Dried blood spots)
N/A
3.1.3 N-TSH Enzyme Reagent
N/A

3.1.4 N-TSH Biotin Reagent
N/A

3.1.5 Streptavidin Coated Plate
N/A

3.1.6 Substrate reagent
N/A

3.1.7 Wash Solution Concentrate
N/A

3.1.8 Stop Solution

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EC No.</th>
<th>Hazard Code</th>
<th>Hazard Class Category Code</th>
<th>Hazard Statement</th>
<th>Conc. (%w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfuric acid</td>
<td>7664-93-9</td>
<td>231-639-5</td>
<td>C; R35</td>
<td>Skin Corr. 1A</td>
<td>H314</td>
<td>&lt; 4.5%</td>
</tr>
</tbody>
</table>

**SECTION 4. First Aid Measures**

4.1 **Description of first aid measures**

<table>
<thead>
<tr>
<th>General instructions:</th>
<th>Immediately rinse with soap and plenty of water. Use personal protective working aids.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation:</td>
<td>Transport the affected person into the open air. If there are respiratory complaints, oxygen must be administered. If irritation persists, seek medical advice.</td>
</tr>
<tr>
<td>Eye contact:</td>
<td>Rinse with a stream of water for at least 15 minutes. Thorough rinsing must be ensured by opening the eyelids. If irritation occurs, seek medical advice.</td>
</tr>
<tr>
<td>Skin contact:</td>
<td>Wash contacted area with soap and water. Remove contaminated clothing. If irritation occurs, seek medical advice.</td>
</tr>
<tr>
<td>Ingestion:</td>
<td>Do NOT induce vomiting. If conscious, rinse the mouth and administer a large amount of water to dilute the substance. In the case of unconsciousness, never administer anything orally. If irritation occurs, seek medical advice.</td>
</tr>
</tbody>
</table>

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

No data available

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

No data available

**SECTION 5. Firefighting measures**

5.1 **Extinguishing media**


5.2 **Special hazards arising from the substance or mixture**

None.

5.3 **Advice for firefighters**

Wear suitable respiratory equipment – self-contained breathing apparatus, if necessary.
SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Avoid contact with skin and eyes. Wear suitable protective equipment.

6.2 Environmental precautions
Do not allow product to enter sewerage systems, surface and ground water. Avoid soil pollution.

6.3 Methods and material for containment and cleaning up
Cover with suitable absorbing material. After removing the substance, rinse the spot of spilling thoroughly with water and soap. Dispose of waste according to all federal, state, and local regulations.

6.4 Reference to other sections
See Section 8 for personal protective equipment. See Section 13 for appropriate disposal methods.

SECTION 7. Handling and Storage

7.1 Precautions for safe handling
Avoid spills. Avoid contact with eyes and skin. Use suitable protective means to work with the substance. Ensure adequate ventilation of the working area. Follow good manufacturing practices when using product. Do not drink, smoke, or eat in work areas.

7.2 Conditions for safe storage, including any incompatibilities
Kit and unopened components: Store at temperatures between +2 and +8˚C in a dry and dark place until expiration date.
Opened components: Opened reagents are stable for sixty (60) days when stored at 2-8 °C.
For prepared reagents: Diluted wash buffer should be stored at room temperature (2-30 °C) for up to 60 days.

7.3 Specific end uses
Product procedures should be performed by a skilled or trained individual for in vitro diagnostic use only.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters
No substances with occupational exposure limits.

8.2 Exposure controls
Eye/face protection: Safety glasses or goggles with side shields recommended.
Skin protection: Compatible protective gloves recommended. Wash hands after properly removing and disposing of gloves.
Other skin protection: Laboratory coats are recommended.
Respiratory protection: No respiratory protection is required. Use product in rooms enabling good ventilation. If local exhaustion is necessary, general (forced) exhaustion is recommended.
Thermal hazards: None.

SECTION 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

9.1.1. Appearance:
Physical state (at 20°C)
Liquid: Enzyme Reagent, Biotin Reagent, Wash Solution Concentrate, Substrate Solution, Stop Solution
Solid: Calibrators and Controls (Dried blood spots on WHATMAN type 903 filter paper), Microtiter strips
Color
Yellow: Enzyme Reagent
Green: Biotin Reagent
Clear: Stop, Substrate, Wash

9.1.2. Odor: Odorless
9.1.3. Odor threshold: Not applicable
9.1.4. pH value: Stop Solution: <3
Others: 6.8-7.4

9.1.5. Melting point/freezing point: Not determined
9.1.6. Initial boiling point/range: Not determined
9.1.7. Flash point: Not applicable
9.1.8. Evaporation rate: Not determined
9.1.9. Flammability (solid, gas): Not flammable
9.1.10. Upper/lower flammability or explosive limits: Not applicable
9.1.11. Vapor pressure: Not determined
9.1.12. Vapor density: Not determined
9.1.13. Relative density: Not determined
9.1.15. Partition coefficient: n-octanol/water: Not determined
9.1.16. Auto-ignition temperature: Not applicable
9.1.17. Decomposition temperature: Not determined
9.1.18. Viscosity: Not determined
9.1.19. Explosive properties: None
9.1.20. Oxidizing properties: Not determined

SECTION 10. Stability and Reactivity

10.1 Reactivity
No known reactivity hazards associated with product.

10.2 Chemical stability
Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions
No hazardous polymerization.

10.4 Conditions to avoid
Excessive heat and light.

10.5 Incompatible materials
Acids.

10.6 Hazardous decomposition products
Not determined.
SECTION 11.  Toxicology Information

11.1 Toxicological information

Acute toxicity: Not determined.
Skin corrosion/irritation: Not determined.
Serious eye damage/irritation: Not determined.
Respiratory or skin sensitization: Not determined.
Germ cell mutagenicity: Not determined.
Carcinogenicity: No component of this product present at levels ≥ 0.1% is identified as probable, possible or confirmed human carcinogen by NTP (National Toxicology Program), IARC (International Agency for Research on Cancer), or OSHA (Occupational Safety & Health Administration).
Reproductive toxicity: Not determined.
STOT-single exposure: Not determined.
STOT-repeated exposure: Not determined.
Aspiration hazard: Not determined.
Information on likely routes of exposure:
If ingested: No known health effects.
If inhaled: No known health effects.
If contact with skin: No known health effects.
If contact with eyes: No known health effects.
Symptoms related to the physical, chemical, and toxicological characteristics: None after short or long-term exposure.

SECTION 12.  Ecological Information

12.1 Toxicity
Not determined.

12.2 Persistence and degradability
Not determined.

12.3 Bioaccumulative potential
Not determined.

12.4 Mobility in soil
Not determined.

12.5 Results of PBT and vPvB assessment
Not determined.

12.6 Other adverse effects
Not determined.

SECTION 13.  Disposal Considerations

Waste treatment methods
All waste disposals must be carried out in accordance with federal, state, and local legislation and administrative regulations. A licensed professional waste disposal service should be utilized to dispose of material and packaging.
SECTION 14. Transport Information

14.1 UN Number
Not available

14.2 UN proper shipping name
Not available

14.3 Transport hazard class(es)
Not available

14.4 Packing group
Not available

14.5 Environmental hazards
Overland transport (ADR/RID): None
Water transport (AND/IMDG): None
Air transport (ICAO/IATA): None

14.6 Special precautions for user
None

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Not applicable

SECTION 15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
SARA: None.
TSCA: All components in product preparations are listed on the US Toxic Substances Control Act inventory of chemicals or are exempt from listing.

This safety data sheet has been prepared to comply with the requirements of Annex II, European Community Regulation No. 1907/2006 REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) and OSHA (Occupational Safety & Health Administration) 1910.1200, Appendix D.

Chemical safety assessment
None.

SECTION 16. Other information

Revision 2 (2015-May-05): Updated to comply with requirements of Annex II, European Community Regulation No. 1907/2006 (REACH) and OSHA 1910.1200, Appendix D
Revision 1 (2010-Dec-01): Updated to 16 point format
Revision 0 (2005-Dec-22): Initial Creation

<table>
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<tr>
<th>Hazard Statements</th>
<th>Hazard Class and Category Codes</th>
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<tbody>
<tr>
<td>H314</td>
<td>Skin Corr.</td>
</tr>
<tr>
<td>Hazard Codes</td>
<td>Risk Phrases</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>C</td>
<td>Corrosive</td>
</tr>
<tr>
<td>R35</td>
<td>Causes severe burns</td>
</tr>
</tbody>
</table>

The material safety data sheet contains data necessary to ensure safety and health and environmental protection in working with chemical substances. This product is a chemical substance and can be solely used by persons with chemical education at their own risk. DAI 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.

ISO 13485
ISO 9001

Diagnostic Automation/Cortez Diagnostics, Inc.
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Date Adopted 2017-4-6

Ref 3124-15 AccuDiag™ Neo-natal TSH ELISA
Revision #: 2 on 2015-05-05