

MATERIAL SAFETY DATA SHEET

SECTION1 PRODUCT AND COMPANY IDENTIFICATION

| | |
|------------------------|---|
| Product name: | Human AMY2 (Amylase Alpha 2, Pancreatic) CLIA Kit |
| Catalog Number: | E-CL-H1318 |
| Application | For research use only |

SECTION2 HAZARDS IDENTIFICATION

| Component Items | Physical form | Hazardous Ingredient | Concentration | CAS No. |
|---------------------------|--|----------------------------|---------------|------------|
| Biotinylated Detection Ab | Odorless and colorless, liquid | Proclin 300 | 0.04% | 55965-84-9 |
| Assay diluent | Odorless and colorless, liquid | Proclin 300 | 0.04% | 55965-84-9 |
| HRP Conjugate | Odorless and colorless, liquid | Proclin 300 | 0.04% | 55965-84-9 |
| Standard | Odorless and white/faint yellow Clear powder/ solid | Proclin 300 | 0.04% | 55965-84-9 |
| Substrate A | Odorless and colorless, liquid | N,N-Dimethylformamide(DMF) | 2% | 68-12-2 |
| | | Sodium tetraphenylborate | 0.05% | 143-66-8 |
| Substrate B | Odorless and colorless, liquid | Carbamide peroxide(CP) | 0.05% | 124-43-6 |

2.1 HAZARD STATEMENT

Classification according to GHS

Signal Word: WARNING



Danger symbol:

2.1.1 Proclin 300

H317: May cause an allergic skin reaction.

2.1.2 N,N-Dimethylformamide(DMF)

H315: Causes skin irritation.

H319: Causes serious eye irritation.

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H332: Harmful if inhaled.

H335: May cause respiratory irritation.

2.1.3 Sodium tetraphenylborate

H315: Causes skin irritation.

H319: Causes serious eye irritation.

H335: May cause respiratory irritation.

2.1.4 Carbamide peroxide(CP)

H302: Harmful if swallowed.

H312: Harmful in contact with skin.

H332: Harmful if inhaled.

H335: May cause respiratory irritation.

2.2 PRECAUTION STATEMENT

Classification according to GHS

2.2.1 Proclin 300

P261: Avoid breathing dust/fumes/gas/mist/vapours/spray.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P302+352: IF ON SKIN: Wash with plenty of soap and water.

P333+313: If skin irritation or rash occurs: Get medical advice/attention.

2.2.2 N,N-Dimethylformamide(DMF)

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P264: Wash hands thoroughly after handling.

P271: Use only outdoors or in a well-ventilated area

P280: Wear protective gloves and protective clothing.

P302+352: IF ON SKIN: Wash with plenty of soap and water.

P304+P312: IF INHALED: Call a POISON CENTER or doctor/physician if you feel unwell.

P304+P340: IF INHALED: Remove victim 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.

2.2.3 Sodium tetraphenylborate

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P264: Wash hands thoroughly after handling.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P302+352: IF ON SKIN: Wash with plenty of soap and water.

P305 + P351 + P338: IF in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.2.4 Carbamide peroxide(CP)

P264: Wash hands thoroughly after handling.

P270: Do not eat, drink or smoke when using this product.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P302+352: IF ON SKIN: Wash with plenty of soap and water.

SECTION3 COMPOSITION/INFORMATION ON INGREDIENTS

| Ingredient | Percent | CAS No. | EC No. |
|----------------------------------|---------|------------|-----------|
| Sodium chloride | 0.8% | 7647-14-5 | 231-598-3 |
| Potassium chloride | 0.02% | 7447-40-7 | 231-211-8 |
| Disodium phosphate dodecahydrate | 0.12% | 10039-32-4 | 231-448-7 |
| Potassium dihydrogen phosphate | 0.02% | 7778-77-0 | 231-913-4 |
| Tris | 1% | 77-86-1 | 201-064-4 |
| EDTA | 0.1% | 60-00-4 | 200-449-4 |
| Glycerol | 5% | 56-81-5 | 200-289-5 |
| Tween20 | 0.5% | 9005-64-5 | 500-018-3 |
| Protective protein | 1% | 9048-46-8 | 232-936-2 |
| Luminol | 0.1% | 521-31-3 | 208-309-4 |
| Mannitol | 2% | 69-65-8 | 200-711-8 |
| PVP40 | 0.35% | 9003-39-8 | -- |
| Proclin 300 | 0.04% | 55965-84-9 | -- |
| N,N-Dimethylformamide (DMF) | 0.1% | 68-12-2 | 200-679-5 |
| Sodium tetrphenylborate | 0.05% | 143-66-8 | 205-605-5 |
| Carbamide peroxide(CP) | 0.05% | 124-43-6 | 204-701-4 |
| Water | 88.75% | 7732-18-5 | 231-791-2 |

SECTION4 FIRST-AID MEASURES

Classification according to GHS

4.1 General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

4.2 If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

4.3 In case of skin contact

Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Consult a physician.

4.4 In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

4.5 If swallowed

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

SECTION5 FIRE FIGHTING MEASURES

5.1 Suitable extinguishing media

Suitable: Water spray, alcohol-resistant foam, dry chemical, carbon dioxide or appropriate foam.

For small fires, use media such as “alcohol” foam, dry chemical or carbon dioxide.

For large fires, apply water from as far as possible. Use large quantities of water applied as a mist or spray. Solid streams of water may be ineffective. Cool affected containers with flooding quantities of water.

5.2 Special precautions for fire-fighters

Protective Equipment: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

5.3 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides, Hydrogen chloride gas.

SECTION6 ACCIDENTAL RELEASE MEASURES

6.1 Person-related safety precautions

Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapors accumulating to form explosive concentrations. Vapors can accumulate in low areas.

6.2 Measures for environmental protection

Prevent further leakage or spillage if safe to do so. Do not let enter drains. Discharge into the environment must be avoided.

6.3 Measures for containment and cleaning

Contain spillage, and then collect with non-combustible absorbent material (eg. sand, diatomaceous earth, vermiculite). Place in a container for disposal according to local regulations. Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal. Sweep up and shovel. Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13). Keep in suitable, closed containers for disposal.

SECTION7 HANDLING AND STORAGE

7.1 Handling

Wear appropriate protective clothing and safety gloves.

Avoid inhalation.

Avoid contact with eyes, skin and clothing.

Mechanical exhaust required.

Keep away from ignition sources, heat and flame.

No smoking at working site.

Incompatibilities: Strong oxidizing agents, Strong acids. Handling and unloading should be light, to prevent packaging broken, damp and cause losses.

Working place should be equipped with appropriate varieties and quantities of fire fighting equipment and leakage emergency treatment equipment.

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7.2 Storage

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Keep away from heat, sparks and flame.

Keep away from sources of ignition.

Incompatible: Strong oxidizing agents, Strong acids.

Storage place should be equipped with appropriate varieties and quantities of fire fighting equipment and leakage emergency treatment equipment.

SECTION8 EXPOSURE CONTROL/PPE

8.1 Engineering Controls

Mechanical exhaust required. Safety shower and eye bath.

8.2 Personal Protective Equipment

Respiratory: Government approved respirator if needed.

Eye/face: Chemical safety goggles if needed.

Clothing: Wear appropriate protective clothing.

Hand/skin: Protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body protection: Wear suitable protective clothing according to the concentration and amount of the substance at the workplace.

8.3 Other Protect

No smoking, drinking and eating at working site. Wash thoroughly after handling.

SECTION9 PHYSICAL/CHEMIICAL PROPERTIES

9.1 Proclin 300

Appearance: Liquid

Odour: No data available

Odour threshold: No data available

pH 4.1 at 100 g/L

Melting point/freezing point: -40 °C

Initial boiling point and boiling range: 189 °C

Flash point: 118 °C - closed cup

Evaporation rate: No data available

Flammability (solid, gas): No data available

Upper/lower flammability or explosive limits: No data available

Vapour pressure: No data available

Vapour density: No data available

Relative density: 1.03 g/cm³

Water solubility: Soluble

Partition coefficient: noctanol/water: No data available

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Auto-ignition temperature: No data available

Decomposition temperature: No data available

Viscosity: No data available

Explosive properties: No data available

Oxidizing properties: No data available

9.2 N,N-Dimethylformamide(DMF)

Appearance: Liquid Upper/lower

Flammability or explosive limits: No data available

Upper/lower flammability or explosive limits: No data available

Odor: No data available

Odor threshold: No data available

Vapor density: No data available

Vapor pressure: No data available

pH: No data available

Relative density: No data available

Melting point/freezing point: No data available.

Boiling point/Boiling range: No data available

Partition coefficient: noctanol/water: No data available

Auto igniting: No data available

Flash point: No data available

Decomposition temperature: No data available

Water solubility: No data available

Viscosity: No data available

Evaporation rate: No data available

Flammability (solid, gas): No data available

9.3 Sodium tetrphenylborate

Appearance: White solid

Odour: No data available

Odour threshold: No data available

pH 8 at 50 g/L at 20 °C

Melting point/freezing point: 300°C

Initial boiling point and boiling range: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability (solid, gas): No data available

Upper/lower flammability or explosive limits: No data available

Vapour pressure: No data available

Vapour density: No data available

Relative density: No data available

Water solubility: ca.50 g/L at 20 °C - soluble

Partition coefficient: noctanol/water: No data available

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Viscosity: No data available

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Explosive properties: No data available

Oxidizing properties: No data available

Other safety information: Bulk density 0.50 g/L

9.4 Carbamide peroxide (CP)

Appearance: White crystalline

Odour: No data available

Odour threshold: No data available

pH: No data available

Melting point/freezing point: 90 - 93 °C - lit.

Initial boiling point and boiling range: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability (solid, gas): No data available

Upper/lower flammability or explosive limits: No data available

Vapour pressure: 23.3 mmHg at 30 °C

Vapour density: No data available

Relative density: 1.390 g/cm³ at 20 °C

Water solubility: No data available

Partition coefficient: noctanol/water: No data available

Auto-ignition temperature: No data available

Decomposition temperature: > 60 °C

Viscosity: No data available

Explosive properties: No data available

Oxidizing properties: The substance or mixture is classified as oxidizing with the category 3. Other safety information:

Bulk density 0.6 - 0.7 g/L

SECTION10 STABILITY AND REACTIVITY

10.1 Reactivity

No data available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

Heat, flames and sparks.

10.5 Incompatible materials

Strong oxidizing agents, Light sensitive, Alcohols, Organic materials, Heavy metals, Powdered metals, Strong reducing agents, Amines, Mercaptans.

10.6 Hazardous decomposition products

Other decomposition products: No data available.

Hazardous decomposition products formed under fire conditions: Carbon oxides, Nitrogen oxides (NO_x), Sulphur oxides, Hydrogen chloride gas.

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SECTION11 TOXICOLOGICAL INFORMATION**11.1 Proclin 300**

Acute toxicity

LD₅₀ Oral - Rat - 862 mg/kg

LD₅₀ Dermal - Rabbit - 2,800 mg/kg

Skin corrosion/irritation

Skin - Rabbit Result: Corrosive Serious eye damage/eye irritation

Eyes - Rabbit Result: Corrosive to eyes

Respiratory or skin sensitisation - Guinea pig Result: May cause sensitisation by skin contact.

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

11.2 N,N-Dimethylformamide(DMF)

LD₅₀ Oral - Rat - 2,800 mg/kg (N,N-Dimethylformamide)

LC₅₀ Inhalation - Rat - 4 h - 9 - 15 mg/L (N,N-Dimethylformamide)

LD₅₀ Dermal - Rabbit - 1,500 mg/kg (N,N-Dimethylformamide)

Skin – Human (N,N-Dimethylformamide)

Result: Mild skin irritation - 24 h

Serious eye damage/eye irritation: No data available

Eyes – Rabbit (N,N-Dimethylformamide)

Result: Moderate eye irritation

Mutation in mammalian somatic cells.

Carcinogenicity: This product is or contains a component that is not classifiable as to its classification (N,N-Dimethylformamide)

IARC: 3 - Group 3: Not classifiable as to its carcinogenicity to humans (N,N-Dimethylformamide)

11.3 Sodium tetrphenylborate

LD₅₀ Oral - Rabbit: 288 mg/kg

LD₅₀ Oral - Rat - 288 mg/kg

11.4 Carbamide peroxide(CP)

LD₅₀ = 4060 mg/kg (skin-rat)

Carcinogenicity:

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

SECTION12 ECOLOGICAL INFORMATION**12.1 Proclin 300**

Ecotoxicity

No data available.

Persistence and degradability

No data available

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Bioaccumulative potential

No data available

Mobility in soil

No data available

Results of PBT and vPvB assessment

No data available

Other adverse effects

No data available

12.2 N,N-Dimethylformamide(DMF)**Ecotoxicity**

Toxicity to fish: flow-through test LC50 - Lepomis macrochirus (Bluegill sunfish) - 7.100 mg/L - 96 h(N,N-Dimethylformamide) (US-EPA)

Toxicity to daphnia and other aquatic invertebrates: static test EC50 - Daphnia magna (Water flea) - 13.100 mg/L - 48 h(N,N-Dimethylformamide) (OECD Test Guideline 202)

Toxicity to algae: static test EC50 - Desmodesmus subspicatus (green algae) - > 1.000 mg/L - 72 h(N,N-Dimethylformamide) (DIN 38412)

Toxicity to bacteria: static test EC50 - Vibrio fischeri - 12.300 - 17.500 mg/L - 5min(N,N-Dimethylformamide) Remarks: (External MSDS)

Persistence and degradability

Biodegradability: aerobic - Exposure time 21 d(N,N-Dimethylformamide) Result: 100 % - Readily biodegradable. (OECD Test Guideline 301E)

Biochemical Oxygen Demand (BOD): 900 mg/g(N,N-Dimethylformamide) Remarks: (Lit.)

Theoretical oxygen demand: 1.863 mg/g(N,N-Dimethylformamide) Remarks: (Lit.)

Bioaccumulative potential

Bioaccumulation: Cyprinus carpio (Carp) - 56 d (N,N-Dimethylformamide)

Bioconcentration factor (BCF): 0,3 - 1,2 (OECD Test Guideline 305C)

Remarks: Does not significantly accumulate in organisms.

Mobility in soil

No data available

Results of PBT and vPvB assessment

No data available

Other adverse effects

Stability in water: - ca.50d(N,N-Dimethylformamide)

Test substance: Water

Remarks: reaction with hydroxyl radicals(calculated)(Lit.)

12.3 Sodium tetraphenylborate**Ecotoxicity**

No data available.

Persistence and degradability

No data available.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

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Results of PBT and vPvB assessment

No data available.

Other adverse effects

No data available.

12.4 Carbamide peroxide (CP)**Ecotoxicity**

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available.

Mobility in soil

No data available

Results of PBT and vPvB assessment

No data available

Other adverse effects

No data available

SECTION 13 DISPOSAL CONSIDERATION**13.1 Disposal methods**

Dispose of waste in accordance to applicable national, regional, or local regulations. Burn in a chemical incinerator equipped with an afterburner and scrubber b highly flammable. Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

13.2 Contaminated packaging

Dispose in the same manner as unused product.

SECTION 14 TRANSPORT INFORMATION

RID/ADR: Non-Hazardous for Transport: This substance is considered to be non-hazardous for transport.

IATA: Non-Hazardous for Air Transport.

IMO: Non-Hazardous for Sea Transport.

SECTION 15 REGULATORY INFORMATION

This material safety data sheet complies with the requirements of Regulation (EC) No. 1272/2008 and its amendments.

SECTION 16 OTHER INFORMATION

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide.

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