




MATERIAL SAFETY DATA SHEET

skyla Renal Panel

SECTION 1. PRODUCT IDENTIFICATION	
1.1. Product Name	skyla Renal Panel
Product Number	800-150
1.2. Product description	The product consists of a plastic round disc and encased dried reagents (mixture of chemicals) and diluent. See package insert for detail information.
CAS Number	Mixture of materials
1.3. Company identification	LITE-ON TECHNOLOGY CORPORATION HSINCHU SCIENCE PARK BRANCH No. 8, Dusing Road Hsinchu Science Park, 300 Hsinchu, Taiwan
1.4. Emergency telephone number	For English speaking country please call number : +886-3-5787722

SECTION 2. HAZARDS IDENTIFICATION	
2.1. Classification of the substance or mixture	
Classification according to Regulation (EC) No1272/2008	
This product contains Arsenazo III, Sodium Azide and Triton X-100 at a concentration <0.1%: So, it is not considered dangerous according to Regulation 1272/2008	
2.2. Label elements	
<u>OSHA Hazards</u> : No known OSHA hazards.	
<u>GHS Hazards</u> : No dangerous or hazardous substance or preparation according to the Global Harmonized System (GHS).	
<u>CLP Hazards</u> : No mention is required because this product is not considered dangerous according to Regulation (EC) No1272/2008	
2.3. Other hazards	
This product consists of reagent beads contained a mixture of low hazard lyophilized chemical beads enclosed in a plastic disc. The dangerous substance in concentrations is under 0.1%. Under normal use there is no potential for exposure.	
Although small amounts, Arsenazo III, Sodium Azide and Tritox X-100 are toxic, please see below the table showed out the dangerous substance and hazard statement(s).	
Substance name	Arsenazo III

Classification according to Regulation (EC) No 1272/2008	
Classification	Acute toxicity, Oral (Category 3), H301 Acute toxicity, Inhalation (Category 3), H331 Acute aquatic toxicity (Category 1), H400 Chronic aquatic toxicity (Category 1), H410
Labelling according Regulation (EC) No 1272/2008	
Pictogram	
Signal word	Danger
Hazard statement(s)	H301 + H331 Toxic if swallowed or if inhaled H410 Very toxic to aquatic life with long lasting effects.
Precautionary statement(s)	P261 Avoid breathing dust. P273 Avoid release to the environment. P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P311 Call a POISON CENTER or doctor/ physician. P501 Dispose of contents/ container to an approved waste disposal plant.
Other hazards	none
Substance name	Sodium azide
Classification according to Regulation (EC) No 1272/2008	
Classification	Acute toxicity, Oral (Category 2), H300 Acute aquatic toxicity (Category 1), H400 Chronic aquatic toxicity (Category 1), H410
Labelling according Regulation (EC) No 1272/2008	
Pictogram	
Signal word	Danger
Hazard statement(s)	H300 Fatal if swallowed. H410 Very toxic to aquatic life with long lasting effects.

Precautionary statement(s)	P264 Wash hands thoroughly after handling. P273 Avoid release to the environment. P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P501 Dispose of contents/ container to an approved waste disposal plant.
Other hazards	Sodium Azide may react with lead and copper plumbing to form highly explosive metal azides. Rapidly absorbed through the skin
Substance name	Tritox X-100
Classification according to Regulation (EC) No 1272/2008	
Classification	Acute toxicity, Oral (Category 4), H302 Eye irritation (Category 2), H319 Chronic aquatic toxicity (Category 2), H411
Labelling according Regulation (EC) No 1272/2008	
Pictogram	
Signal word	Warning
Hazard statement(s)	H302 Harmful if swallowed. H319 Causes serious eye irritation. H411 Toxic to aquatic life with long lasting effects.
Precautionary statement(s)	P273 Avoid release to the environment. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Other hazards	none

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Substances

Please see below the table with the dangerous components and non-dangerous components

3.2. Mixtures

The product consists of a plastic round disc and encased dried solid reagents (mixture of chemicals) and diluent. **The dried reagents contain minimal amount of hazardous chemicals**

(**<1%**), and there is **no potential for exposure under normal storage and use conditions.**
 Note: This product is an “article”, not a “hazardous chemical” as regulated under the OSHA communication Standard 29CFR 1910.1200 (See 29 CFR 1910.1200(b)(6)(v)).

Chemical Name	CAS No.	Wt. %
Arsenazo III	1668-00-4	< 0.5 ppm
Sodium Azide	26628-22-8	< 0.1%
Triton X-100	9002-93-1	< 1%

Product contains additional ingredients which offer no hazard as supplied.

SECTION 4. FIRST AID MEASURES
<p>Eye contact: Flush eyes with cold water for 15 minutes. Seek medical attention if irritation develops.</p> <p>Skin contact: Rinse area immediately with plenty of water.</p> <p>Inhalation: Supply fresh air. Seek medical attention if respiratory irritation develops.</p> <p>Ingestion: DO NOT INDUCE VOMITING. Give large quantities of water and seek medical attention.</p>

SECTION 5. FIRE FIGHTING MEASURES
<p>Extinguisher media: Use water spray, foam, dry powders or carbon dioxide.</p> <p>Special protective equipment for firefighters: Wear self contained breathing apparatus.</p> <p>Unusual fire and explosive hazards: Emits toxic fumes under fire conditions from plastic.</p>

SECTION 6. ACCIDENTAL RELEASE MEASURES
<p>Personal precautions: Use personal protective equipment as required.</p> <p>Environmental precautions: Avoid release to the environment.</p> <p>Methods and materials for containment and cleaning up: Place absorbent material on top of, and around the perimeter of the spill. Sweep up the spilled material and decontaminate the area with soap and water or an equivalent cleaner.</p>

SECTION 7. HANDLING AND STORAGE
<p>There is no potential chemical hazards for exposure under normal storage and use conditions.</p> <p>Follow safe chemical handling procedures for handling and storage.</p> <p>7.1. Safe Handling Advice</p> <ul style="list-style-type: none"> - Do not tear the film sticker on the disc. or damage the disc intentionally to avoid the expose of

hazardous chemical.

- Put on appropriate personal protective equipment (e.g. Wear gloves and protective clothing when handling the product) and remove contaminated clothing and/or protective equipment and wash hands after working with the products.
- Eating, drinking, and smoking should be prohibited in areas where this product is handled, stored, and processed.
- Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate.

7.2. Storage

- Store between 2 - 8 °C (35.6 to 46.4 °F).
- Store in original container protected from direct sunlight in a dry, cool, and well-ventilated area, away from food and drink.
- Keep in the original container and sealed until use to avoid environmental contamination.

7.3. Particular use

Device for *In vitro* use only. Refer to the IFU

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

None of the chemicals in this preparation are assigned occupational exposure limits. This product can be safely handled under normal conditions with no control.

8.1. Control Parameters:

This product does not contain relevant quantities of materials with occupational exposure limit values that require setting up procedures. Use only with adequate ventilation.

Although small amounts, the hazards identification in section 2 are toxic, please see below the table showed out the VME and VLE.

Chemical Name	VME (mg/m ³)	VLE (mg/m ³)
Arsenazo III	-	-
Sodium Azide	0,2 mg/m ³	0,4 mg/m ³
Triton X-100	-	-

8.2. Personal Protective Equipment:

Hand Protection: Chemical resistant gloves

Eye Protection: Safety glasses or face shield

Body Protection: Protective work clothing or lab coat.

When the product in used as directed with human blood: Use appropriate personal protection equipment as instructed in an internal blood borne pathogen exposure control plan.

8.3 Environmental Exposure Controls:

There are no potential chemical hazards for exposure under normal storage and use conditions.

Chemical spills should follow safe chemical handling procedures for handling with personal

protective equipment to avoid contacting, ingesting or breathing vapour from the spilled material.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Form: solid	Color: various
ODOR: None	Solubility in water: soluble for solid reagent
Boiling Point: 220°C/428°F (Plastic Disc)	Melting Point: 130°C/266°F (Plastic Disc)
Flammability: Product is not flammable	VOC: None
Solids Contents: 96%	Solution Contents: 4%

SECTION 10. STABILITY AND REACTIVITY
10.1. Reactivity:

This preparation is not known to be reactive violently.

10.2. Chemical stability:

Stable under normal storage conditions between 2-8 °C (35.6 to 46.4 °F) due products claimed expiry date.

10.3. Possibility of hazardous reactions :

No dangerous reactions if the product is used and stored as recommended in the manual.

10.4. Conditions to avoid:

Avoid mixture with a mixture of sodium azide, methylene chloride, dimethyl sulfoxide, and sulfuric acid were being concentrated on a rotary evaporator.

10.5. Incompatible materials

Arsenazo III: Strong oxidizing agents

Sodium Azide: Halogenated hydrocarbon, Metals, Acids, Acid chlorides

Triton X-100: Strong acids, Strong bases, Strong oxidizing agents

10.6. Hazardous decomposition products:

None under normal storage and use conditions

SECTION 11. TOXICOLOGICAL INFORMATION

No information found on Specific Symptoms. The toxicological properties have not been investigated. And adverse health effects are not known nor are expected under normal use. Table below lists the dangerous substance contained in the panel and their toxicology information:

Name of Substance	Acute Toxicity (LD ₅₀ /LC ₅₀)	Chronic Toxicity (CMR)
Arsenazo III	No data available	No data available
Sodium Azide	LD50 Oral-Rabbit-10 mg/kg LC50 Inhalation-Rat-37 mg/kg LD50 Dermal-Rabbit-20 mg/kg	No data available

Triton X-100	LD50 Oral-Rat-1.800 mg/kg LD50 Dermal-Rabbit-8.000 mg/kg	No data available	
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SECTION 12. ECOLOGICAL INFORMATION

The ecological effects have not been investigated. But once the product was used with biological specimen that must be disposed of as biological waste.

SECTION 13. DISPOSAL CONSIDERATIONS

Waste from Residues / Unused Products

- Dispose of non-recyclable Residues / Unused products should be handled as a Chemical waste via a licensed waste disposal contractor.
- This material and its container must be disposed of in a safe way. Care should be taken when handling the Residues / Unused products that have been opened the outer packaging.
- Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws or regulations which vary according to location of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Used Products and Contaminated Packaging

- Dispose of Used products and Contaminated Packaging should be handled as a Biological waste via a licensed waste disposal contractor.
- It must be disposed of in a safe way. Care should be taken when handling the Used products and Contaminated Packaging that have been performed when the product in used as directed with human blood.
- Biological waste should be labeled and handled as special waste. This must be disposed of in compliance with anti-pollution and other laws or regulations which vary according to location of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

SECTION 14. TRANSPORTATION INFORMATION

Keep product at 2-8 °C (35.6 to 46.4 °F) during transportation

14.1. UN No.

DOT and IATA: Not a dangerous good.

ADR Information: Not Applicable.

IMDG: Not a dangerous good.

14.2. Expedition name for united states

DOT and IATA : - ADR : - IMDG: -

14.3. Danger class

DOT and IATA : - ADR : - IMDG: -

14.4. Packing group

DOT and IATA : - ADR : - IMDG: -

14.5. Environmental hazards

DOT and IATA : - ADR : - IMDG: -

14.6. Special precautions for user:

The product does not release or otherwise result in exposure to hazardous chemical under normal conditions of use and transport.

SECTION 15. REGULATORY INFORMATION

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

US OSHA: Not regulated as a hazardous material

US EPA: Hazards to the environment have not been thoroughly investigated

EU Regulations: This MSDS conforms to Regulation(EC) No1272/2008, 1907/2006

15.2. Chemical safety assesement

A Chemical safety Assessment has not been completed for this product.

SECTION 16. OTHER INFORMATION

The information in this sheet is based on the state of our knowledge of the product concerned and following the REACH regulation 1907/2006 / EC and Article 31 of Directive 2001/58 / EC.

Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. Since the conditions and manner of use are outside our control, we make no warranties, express or implied, and assume no liability in the connection with any use of this information (refer to the paragraph 3).

Issue By: LITE-ON TECHNOLOGY CORPORATION HSINCHU SCIENCE PARK BRANCH

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