

Material Safety Data Sheet (MSDS)

SPOTCHEM™ II Total Bilirubin

Part Numbers: SE77106 and 77135

For use with the SPOTCHEM EZ Analyzer. SP-4430

U.S. Distributor:

ARKRAY USA, Inc.

5182 West 76th Street

Edina, MN 55439

Technical Support Phone: 855.646.3108

SAFETY DATA SHEET

SDS No.: 77371E

IDENTITY

SPOTCHEM™ II Total Bilirubin**1. PRODUCT & COMPANY IDENTIFICATION****PRODUCT NAME:** SPOTCHEM™ II Total Bilirubin**PRODUCT IDENTIFICATION:**

This product is an in vitro diagnostic reagent strip intended for the quantitative determination of total bilirubin in serum or plasma. This is intended for professional use with the SPOTCHEM Analyzer.

MANUFACTURER: ARKRAY FACTORY, Inc.

Address: 1480 Koji, Konan-cho, Koka-shi, Shiga, 520-3306, Japan.

Telephone number & Emergency telephone number: +81-748-86-6901

Facsimile: +81-748-86-5347

EUROPEAN REPRESENTATIVE: ARKRAY, Inc. European Office

Address: Schumannstr. 109 40237 Düsseldorf Germany

Telephone number & Emergency telephone number: +49-211 6980162

Facsimile: +49-211 6980164

2. HAZARDS IDENTIFICATION

May be harmful if ingested.

May cause eye and skin irritation.

3. COMPOSITION / INFORMATION ON INGREDIENTS

This reagent is composed of a plastic strip to which a multi-layered test field containing reagents is affixed, and contains a little amount of chemical substances as follows:

Total Bilirubin

Composition	CAS No.	Symbol and R-phrases	EINECS No.	Concentration	
				(in 100strips)	(wt%)
Sulfanilic acid	121-57-3	---	204-482-5	12.0 mg	1.0 or less
Sodium nitrite	7632-00-0	---	231-555-9	4.8 mg	1.0 or less
Dyphyline	---	---	---	7.9 mg	1.0 or less

This product is not classified as a dangerous preparation according to 1999/45/EC and 67/548/EEC and following amendments and modifications.

The product identification of danger: SYMBOL: -----, R-phrases: -----

4. FIRST-AID MEASURES**Eye Contact**

Immediately wash eyes with plenty of clean water for at least 15 minutes and seek medical advice.

Skin Contact

Immediately wash thoroughly with water and soap. Immediately seek medical advice if it causes itchiness and inflammation etc.

Ingestion

Rinse mouth, give plenty of water to dilute the substance. Never give anything by mouth to an unconscious person. Immediate medical treatment is required.

5. FIRE-FIGHTING MEASURES

Extinguishing Media: water etc.

Special Fire-Fighting Procedures: None

6. ACCIDENTAL RELEASE MEASURES

Individual protection: Use personal protective devices.

Please refer to point 8 for specific protection measures.

Environmental precautions: Dispose in compliance to the law in force. Clean spillage area.

Cleaning methods: Rinse with running water.

7. HANDLING & STORAGE

For in vitro diagnostic use only.

Store the reagent strip in a refrigerator at temperatures between 2-8°C(35.6-46.4° F).

Use the reagent strip prior to its expiration.

Once the aluminum foil package containing the reagent strip has been opened, the reagent strip must be used immediately.

See the package insert for further handling information.

8. EXPOSURE COTROLS / PERSONAL PROTECTION

Occupational Exposure Limit: Not available

Eye Protection: Use safety goggles (glasses), if necessary.

Skin Protection: Use rubber gloves and suitable protective clothing, if necessary.

9. PHYSICAL & CHEMICAL PROPERTIES

Appearance: This is a dry reagent strip and is composed of a plastic strip to which a multi-layered test field containing reagents is affixed.

pH: Not available

10. STABILITY & REACTIVITY

Condition to avoid: Sunlight, heat and humidity

Stability and Reactivity: Stable under normal conditions

Materials To Avoid: Not available

Hazardous Decomposition Products: Not available

11. TOXICOLOGICAL INFORMATION

Irritation (skin, eye) : May cause irritating skin and eyes

Acute toxicity : Not available as the mixture

Sensitizing: Not available as the mixture

Chronic Toxicity: Not available as the mixture

Mutagenicity: Not available as the mixture

Carcinogenicity: IARC; Not listed, NTP; Not listed, OSHA; Not listed, ACGUH; Not listed

Reproductive Toxicity: Not available as the mixture

12. ECOLOGICAL INFORMATION

Ecotoxicity : hr LC₅₀: Not available

Mobility: Not available

Persistence and degradability: Not available

Bioaccumulative potential: Not available

Other adverse effect: Not available

13. DISPOSAL CONSIDERATION

Dispose of used strips as biohazardous waste in accordance with all applicable regulations. Any disposal practice must be in complicated with company, local, state, and federal laws and regulations. (Contact country, local or state environmental agency for specific rules.)

14. TRANSPORT INFORMATION

IATA: Not restricted as the mixture.

15. REGULATORY INFORMATION

This product is not classified as a dangerous preparation according to 1999/45/EC and 67/548/EEC and 2001/58/EC.

16. OTHER INFORMATION

The above information contained herein is based on the data available to us and is believed to be correct. However, ARKRAY, Inc. bears no warranty, expresses or implies regarding the accuracy of these data or the results to be obtained from the use thereof.

ARKRAY, Inc. assumes no responsibility for injury caused from the use of the product described herein.
