

# Material Safety Data Sheet (MSDS)

SPOTCHEM™ II Amy-Wide

Part Numbers: 77142

For use with the SPOTCHEM EZ Analyzer. SP-4430

**U.S. Distributor:**

ARKRAY USA, Inc.

5182 West 76<sup>th</sup> Street

Edina, MN 55439

Technical Support Phone: 855.646.3108

**SAFETY DATA SHEET**

SDS No.: 77486

IDENTITY

**SPOTCHEM™ II Amy-Wide****1. PRODUCT & COMPANY IDENTIFICATION****PRODUCT NAME:** SPOTCHEM™ II Amy-Wide**PRODUCT IDENTIFICATION:**

This product is an in vitro diagnostic reagent strip intended for the quantitative determination of  $\alpha$ -amylase activity in serum or plasma. This is intended for professional use with the SPOTCHEM Analyzer.

**MANUFACTURER:** ARKRAY, Inc.

Address: 57 Nishi Aketa-Cho, Higashi Kujo, Minami-Ku, Kyoto 601-8045, Japan

Telephone number &amp; Emergency telephone number: +81-75-662-8958

Facsimile: +81-75-661-9435

**EUROPEAN REPRESENTATIVE:** (In EUROPE) ARKRAY Europe, B. V.

Address: Prof. J. H. Bavincklaan 5, 1183 AT Amstelveen, The Netherlands

Telephone number &amp; Emergency telephone number: +41-20-545-2450

Facsimile: +41-20-545-2459

**2. 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:

**Amy-Wide**

Composition	CAS No.	Symbol and R-phrases	EINECS No.	Concentration	
				(in 100strips)	(wt%)
Benzylidenine-p-nitrophenyl-maltoheptaoside (BG7-pNP)	151-21-3	---	---	28.1 mg	17.0 or less
Glucoamylase	9032-08-0	---	---	189.0 I.U.	6.0 or less
$\alpha$ -Glucosidase	9001-42-7	---	---	210.0 I.U.	2.0 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: -----

**3. HAZARDS IDENTIFICATION**

May be harmful if ingested.

May cause eye and skin irritation.

**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 LC<sub>50</sub>:** 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.

---