

SAFETY DATA SHEET

SDS No.: 73588E

Issue Date: December 10, 2002

IDENTITY

AUTION Sticks 9EB**1. PRODUCT □ COMPANY IDENTIFICATION****PRODUCT NAME:** AUTION Sticks 9EB**PRODUCT IDENTIFICATION:**

This product is an in vitro diagnostic reagent strip intended for the determination of Glucose, Protein, Bilirubin, Urobilinogen, pH, Blood, Ketones, Nitrite and Leucocytes in urine.

This is intended for professional use with the AUTION Analyzer.

MANUFACTURER: ARKRAY FACTORY, Inc.

Address: 1480 Kojumeda, Konan-Cho, Koka-Gun, Shiga 520-3306, Japan

SUPPLIER:(In Japan) ARKRAY, Inc.

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

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

Facsimile: +81-75-661-9435

AUTHORIZED REPRESENTATIVE:(In EUROPE) ARKRAY, Inc. European Office

Address: Schumannstr. 109 40237 Düsseldorf Germany

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

Facsimile: +49-211 6980164

2. COMPOSITION / INFORMATION ON INGREDIENTS

This reagent is composed of a plastic strip affixed with reagent areas for Glucose, Protein, Bilirubin, Urobilinogen, pH, Blood, Ketones, Nitrite and Leucocytes determination and a pad for calibration. They contain a little amount of chemical substances as follows:

Glucose

Composition	CAS No.	Symbol and R -phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
Glucose oxidase(GOD)	9001-37-0	---	---	700 I.U.	1.0 or less
Peroxidase(POD)	9003-99-0	---	232-668-6	175 P.U.	1.0 or less
4-Aminoantipyrine(4-AAP)	83-07-8	---	201-452-3	14.0 mg	1.0 or less
1-Naphthole-3,6-disulfonic acid, disodium salt	313222-89-8	---	---	14.0 mg	1.0 or less

Protein

Composition	CAS No.	Symbol and R -phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
Tetrabromophenol blue(TBPB)	4430-25-5	---	---	0.35 mg	1.0 or less

Bilirubin

Composition	CAS No.	Symbol and R -phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
2-Methyl-5-nitroaniline	99-55-8	---	---	1.9mg	1.0 or less
Sodium nitrite	7632-00-0	---	231-555-9	1.0mg	1.0 or less

Urobilinogen

Composition	CAS No.	Symbol and R-phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
3,3'-Dimethoxy-4,4'-diazo-biphenyl tetrafluoride borate	---	---	---	0.16 mg	1.0 or less

pH

Composition	CAS No.	Symbol and R-phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
Bromocresol green	76-60-8	---	200-972-8	0.07 mg	1.0 or less
Bromoxyleneol blue	4007-59-5	---	2547804	0.72 mg	1.0 or less

Blood

Composition	CAS No.	Symbol and R-phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
Cumen hydroperoxide(CHP)	80-15-9	---	2012547	30.0 mg	1.0 or less
3,3'-5,5'-Tetramethylbenzidine (TMBZ)	54827-17-7	---	2593646	15.0 mg	1.0 or less

Ketones

Composition	CAS No.	Symbol and R-phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
Sodium nitroprusside	13755-38-9	---	238-373-9	12.0 mg	1.0 or less

Nitrite

Composition	CAS No.	Symbol and R-phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
Sulfanilamide	63-74-1	---	2005-63-4	3.9 mg	1.0 or less
N-1-Naphthyl-ethylenediaminedihydrochloride (NEDA-2HCl)	1465-25-4	---	215-981-2	0.3 mg	1.0 or less

Leucocytes

Composition	CAS No.	Symbol and R-phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
3-(N-Toluenesulfonyl-L-alanyloxy) indole(TAI)	---	---	---	0.49 mg	1.0 or less
2-Methoxy-4-(n-morpholino-benzenediazoniumu(MMB)	67801-08-5	---	---	0.17 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.

* See section 2.4 Directive 2001/58/EC

The 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 at temperature between from 1 to 30. avoiding humidity, direct sunlight or heat. Improper storage may cause insufficient performance of test strips. Do not use deteriorated, discolored or blackened test strips.

Use test strips as soon as possible after opening the container.

Avoid contamination by volatile chemicals.

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 consists of a plastic strip affixed with reagent areas.

pH: Not available

10. STABILITY REACTIVITY

Condition to avoid: Sunlight, heat

Stability and Reactivity: Stable

Materials To Avoid: Volatile chemicals

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 compliance 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

MODIFICATION LIST

December 10, 2002 : Prepared

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.

SAFETY DATA SHEET

SDS No.: 73558E
Issue Date: December 10, 2002

IDENTITY

AUTION Sticks 10EA

1. PRODUCT & COMPANY IDENTIFICATION

PRODUCT NAME: AUTION Sticks 10EA

PRODUCT IDENTIFICATION:

This product is an in vitro diagnostic reagent strip intended for the determination of Glucose, Protein, Bilirubin, Urobilinogen, pH, Specific Gravity, Blood, Ketones, Nitrite and Leucocytes in urine.

This is intended for professional use with the AUTION Analyzer.

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2. COMPOSITION / INFORMATION ON INGREDIENTS

This reagent is composed of a plastic strip affixed with reagent areas for Glucose, Protein, Bilirubin, Urobilinogen, pH, Specific Gravity, Blood, Ketones, Nitrite and Leucocytes determination and a pad for calibration. They contain a little amount of chemical substances as follows:

Glucose

Composition	CAS No.	Symbol and R-phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
Glucose oxidase(GOD)	9001-37-0	---	---	700 I.U.	1.0 or less
Peroxidase(POD)	9003-99-0	---	232-668-6	175 P.U.	1.0 or less
4-Aminoantipyrine(4-AAP)	83-07-8	---	201-452-3	14.0 mg	1.0 or less
1-Naphthole-3,6-disulfonic acid, disodium salt	313222-89-8	---	---	14.0 mg	1.0 or less

Protein

Composition	CAS No.	Symbol and R-phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
Tetrabromophenol blue(TBPB)	4430-25-5	---	---	0.35 mg	1.0 or less

Bilirubin

Composition	CAS No.	Symbol and R-phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
2-Methyl-5-nitroaniline	99-55-8	---	---	1.9mg	1.0 or less
Sodium nitrite	7632-00-0	---	231-555-9	1.0mg	1.0 or less

Urobilinogen

Composition	CAS No.	Symbol and R-phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
3,3'-Dimethoxy-4,4'-diazo-biphenyl-tetrafluoride borate	---	---	---	0.16 mg	1.0 or less

pH

Composition	CAS No.	Symbol and R-phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
Bromocresol green	76-60-8	---	200-972-8	0.07 mg	1.0 or less
Bromoxylene blue	4007-59-5	---	2547804	0.72 mg	1.0 or less

Specific Gravity

Composition	CAS No.	Symbol and R-phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
Di(2-ethylhexyl) phosphoric acid (D-2-EHPA)	298-07-7	---	---	8.0 mg	1.0 or less
Bromothymol blue	76-59-5	---	200-971-2	0.7 mg	1.0 or less

Blood

Composition	CAS No.	Symbol and R-phrases(*)	EINECS No.	Concentration	
				(in 100strips)	(wt%)
Cumen hydroperoxide(CHP)	80-15-9	---	2012547	30.0 mg	1.0 or less
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Ingestion

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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.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Limit: Not available

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

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9. PHYSICAL & CHEMICAL PROPERTIES

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16. OTHER INFORMATION

MODIFICATION LIST

January 12, 1998 : Prepared

December 10, 2002 : Revised all items according to "Directive 2001/58/EC".

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