

MATERIAL SAFETY DATA SHEET

Trichomonas Urine Control Concentrate

Section 1: Product and Company Identification

Material name	Trichomonas Urine Control Concentrate	
Product No.	70-5601-01	
Product description	Aqueous matrix containing non-viable, non-infective trichomonas cells, synthetic urine, and preservative.	
Product use	Intermediate for use in the preparation of the OSOM® Trichomonas Rapid Test Kit.	
Emergency Telephone Numbers	Manufacturer	Corporate Headquarters
Americas: +1-760-476-3962	Sekisui Diagnostics (UK) Ltd	Sekisui Diagnostics LLC
Europe, Middle East	50 Gibson Drive	31 New York Avenue
& Africa: +1-760-476-3961	Kings Hill, West Malling	Framingham, MA 01701
Asia Pacific: +1-760-476-3960	Kent ME19 4AF UK	USA
Access code: 333512	Phone: 44 (0) 1732 220022	Phone: 508-661-1835

Section 2: Hazards Identification

OSHA regulatory status	This preparation is not classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30. None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.
Precautionary statements	The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: slightly opaque liquid.
Potential health effects:	
Routes of exposure	Occupational exposure routes may include eye and skin contact.
Eyes	No data available. Eye exposure may cause irritation, redness and watering.
Skin	No data available. Skin contact may cause irritation, dryness and redness.
Inhalation	No data available.
Ingestion	No data available.
Chronic effects	No data available.
Target organs	Unknown.
Potential environmental effects	Unknown.

Section 3: Composition / Information on Ingredients

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	> 93
EC R-Phrases: None	EC Hazard Class: None		
Sodium chloride	7647-14-5	231-598-3	< 3
EC R-Phrases: None	EC Hazard Class: None		
Urea	57-13-6	200-315-5	< 3
EC R-Phrases: None	EC Hazard Class: None		
Non-viable trichomonas cells	Not Assigned	Not Assigned	< 1
EC R-Phrases: None	EC Hazard Class: None		
Sodium azide	26628-22-8	247-852-1	0.01 - 0.1
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: T+, N		

Section 4: First Aid Measures

First aid procedures:	
Eye contact	Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.
Skin contact	In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.
Inhalation	If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.
Ingestion	In case of ingestion, contact a poison control center or physician for instructions.

MATERIAL SAFETY DATA SHEET

Trichomonas Urine Control Concentrate

Section 5: Fire Fighting Measures

Flammable properties	Dilute aqueous solution not considered a fire hazard.
Suitable extinguishing media	Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.
Unsuitable extinguishing media	Unknown.
Specific hazards arising from the chemical	None expected.
Standard protective equipment and precautions for firefighters	Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

Section 6: Accidental Release Measures

Personal precautions	Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.
Environmental precautions	This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.
Methods and materials for containment and clean-up	Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

Section 7: Handling and Storage

Handling	Follow universal/standard precautions. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.
Storage	Store at 2 - 8°C (36 - 46°F). Do not store with incompatible substances; see Section 10.

Section 8: Exposure Controls / Personal Protection

Exposure guidelines	There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).
Engineering controls	This preparation is aqueous and non-volatile and is not expected to require special ventilation measures. Facilities storing or using this preparation should be equipped with an eyewash fountain.
Personal protective equipment:	
Eye / face protection	Wear appropriate protective safety eye glasses or goggles.
Skin protection	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Hand protection	Wear chemical resistant protective gloves.
Respiratory protection	A respirator is not required under normal conditions of use.
General	Follow company-specific safety procedures.

Section 9: Physical and Chemical Properties

Appearance	Slightly opaque liquid
Odor	Unknown
pH	4.6 - 8.0 (estimate)
Melting point/Freezing point	Not applicable / Not available
Boiling point	Not available
Flash point	Not available
Flammability/explosivity limits in air, upper	Not available
Flammability/explosivity limits in air, lower	Not available
Vapor pressure	Not available
Vapor density	Not available
Specific gravity	1.001 - 1.035 (estimate)
Solubility	Water-soluble
Partition coefficient (n-octanol/water)	Not available
Auto-ignition temperature	Not applicable

MATERIAL SAFETY DATA SHEET

Trichomonas Urine Control Concentrate

Section 10: Chemical Stability and Reactivity Information

Possibility of hazardous reactions	Hazardous polymerization will not occur.	
Chemical stability	Stable under ordinary conditions of use and storage. See Section 7.	
Conditions to avoid	There are no physical conditions known to result in a hazardous situation.	
Incompatible materials:		
Physical properties - chemical incompatibilities		
Sodium azide	26628-22-8	Incompatible with acids, with some metals. Forms explosion-sensitive compounds.
	57-13-6	Heat causes formation of anhydrous ammonia fumes.
Urea		Contact with oxidizers, nitrates may cause fire and explosions. Contact with chlorinating agents including hypochlorite bleaches, may produce explosive nitrogen trichloride. Reacts with nitrosyl perchlorate.
Hazardous decomposition products	None expected under normal conditions of use.	

Section 11: Toxicological Information

Acute effects:		
Toxicological data - Selected LD50s and LC50s		
Sodium azide	26628-22-8	Oral LD50 Rat: 27 mg/kg; Dermal LD50 Rabbit: 20 mg/kg
Sodium chloride	7647-14-5	Inhalation LC50 Rat: >42 g/m3/1H; Oral LD50 Rat: 3 g/kg; Dermal LD50 Rabbit: >10 g/kg
Urea	57-13-6	Oral LD50 Rat: 8471 mg/kg; Dermal LD50 Rat: 8200 mg/kg
Local effects	No data available.	
Chronic effects	No data available.	
Sensitization	No data available.	
Carcinogenicity:		
ACGIH - Threshold Limits Values - Carcinogens		
Sodium azide	26628-22-8	A4 - Not Classifiable as a Human Carcinogen
Mutagenicity	No data available.	
Reproductive effects	No data available.	
Teratogenicity	No data available.	

Section 12: Ecological Information

Ecotoxicity:		
Ecotoxicity - Freshwater Fish Species Data		
Sodium azide	26628-22-8	96 Hr LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 Hr LC50 Lepomis macrochirus: 0.7 mg/L; 96 Hr LC50 Pimephales promelas: 5.46 mg/L [flow-through]
Sodium chloride	7647-14-5	96 Hr LC50 Lepomis macrochirus: 9675 mg/L [flow-through]; 96 Hr LC50 Lepomis macrochirus: 12946 mg/L [static]; 96 Hr LC50 Pimephales promelas: 7650 mg/L [static]
Urea	57-13-6	96 Hr LC50 Leuciscus idus: >3810 mg/L
Ecotoxicity - Microtox Data		
Urea	57-13-6	5 min EC50 Photobacterium phosphoreum: 23914 mg/L
Ecotoxicity - Water Flea Data		
Sodium chloride	7647-14-5	48 Hr EC50 Daphnia magna: 1000 mg/L
Urea	57-13-6	24 Hr EC50 Daphnia magna straus: >10000 mg/L
Persistence and degradability	No data available.	
Bioaccumulation potential	No data available.	
Mobility in environmental media	No data available.	

MATERIAL SAFETY DATA SHEET

Trichomonas Urine Control Concentrate

Section 13: Disposal Considerations

Methods of disposal

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up. Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

Waste classification:

U.S. - California - 22 CCR - Presumed Hazardous Wastes

Sodium azide	26628-22-8	Ignitable; Reactive
--------------	------------	---------------------

U.S. - RCRA (Resource Conservation & Recovery Act) - P Series Wastes - Acutely Toxic Wastes

Sodium azide	26628-22-8	waste number P105
--------------	------------	-------------------

Section 14: Transport Information

Basic shipping description

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

Section 15: Regulatory Information

US Federal Regulations:

This preparation is an intermediate used in the production of an FDA-regulated in vitro diagnostic device.

Inventory - United States - Section 8(b) Inventory (TSCA):

Sodium azide	26628-22-8	Present
Sodium chloride	7647-14-5	Present
Urea	57-13-6	Present

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

Sodium azide	26628-22-8	1000 lb final RQ; 454 kg final RQ
--------------	------------	-----------------------------------

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

Sodium azide	26628-22-8	1000 lb EPCRA RQ
--------------	------------	------------------

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

Sodium azide	26628-22-8	500 lb TPQ (This material is a reactive solid. The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solvent form)
--------------	------------	---

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

Sodium azide	26628-22-8	1.0 % de minimis concentration
--------------	------------	--------------------------------

US State Regulations

U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances

Sodium azide	26628-22-8	Present
--------------	------------	---------

International Regulations:

This preparation is an intermediate used in the preparation of a medicinal product regulated under the Medicinal Products Directive (2001/83/EC) and is exempt from classification under the Dangerous Substances Directive (67/548/EC).

EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification

Sodium azide	26628-22-8	T+;R28_R32_N;R50-53
--------------	------------	---------------------

EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases

Sodium azide	26628-22-8	S:1/2-28-45-60-61
--------------	------------	-------------------

Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Sodium azide	26628-22-8	247-852-1
Sodium chloride	7647-14-5	231-598-3
Urea	57-13-6	200-315-5

Canadian Hazardous Products

WHMIS Status	Exempt
--------------	--------

European Communities Dangerous Substances/Preparations

EC Hazard Class	Exempt
-----------------	--------

Risk Phrases	None
--------------	------

Safety Phrases	None
----------------	------

MATERIAL SAFETY DATA SHEET

Trichomonas Urine Control Concentrate

Section 16: Other Information

Further Information:

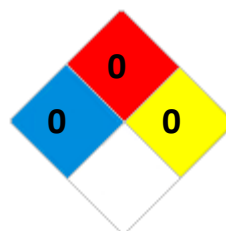
This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

The hazard ratings on this MSDS are for appropriately trained workers using a Hazardous Materials Identification System (HMIS®) or a National Fire Protection Association (NFPA) 704 program. The ratings are estimates and should be treated as such. The hazard rating scales range from (0) minimal hazards to (4) significant hazards or risks. Chronic (long-term) health effects are indicated in the HMIS® by an asterisk (*). HMIS® is a registered trade and service mark of the NPCA. For details on HMIS® ratings visit www.paint.org/hmis. For details on NFPA 704 visit www.nfpa.org.

HMIS® RATINGS

HEALTH	1
FLAMMABILITY	0
PHYSICAL HAZARD	0

NFPA RATINGS



MSDS Origination Date: 12 January, 2005
Version #: 3
Revision Date: 03 December, 2012

Disclaimer:

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Sekisui be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Sekisui has been advised of the possibility of such damages.