

MATERIAL SAFETY DATA SHEET

Immuno/Color IM™

Immuno/Color IM™ Reagent; Positive & Negative Control

Cat No: IMC-50; IMC-100

MSDS DATE: 03/07/2013

Complies with 91/155/EEC, 1907/2006 (REACH) and amendments, OSHA's Hazard Communication Standard, 29 CFR 1910.1200; and the requirements of the U.S. Department of Labor Occupational Safety & Health Administration.

Regulatory Status:

This preparation is 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.

SECTION 1: PRODUCT IDENTIFICATION**PRODUCT NAME:** Immuno/Color IM™**SERIES NAME:** IM Color™

DESCRIPTION: Color-enhanced slide agglutination test intended for use in the rapid detection and semi-quantitative measurement of the heterophile antibody of infectious mononucleosis.

Reagent: Contains a suspension of dyed horse erythrocytes in buffer with 0.1% sodium azide as preservative; Positive & Negative Controls: Stabilized human serum or defibrinated plasma containing IM heterophile antibodies with 0.1% sodium azide as preservative.

PRODUCT USE: For In Vitro Diagnostic Use. See product literature for details.

MANUFACTURER: Immunostics, Inc.
1750 Brielle Ave.
Suite A5
Ocean, NJ 07712

Telephone: +1 (732) 918-0770 Toll Free: +1 (800) 722-7505
Emergency: +1 (800) 424-9300 Int'l: +1 (703) 527-3887
Fax: +1 (732) 918-0618
Email: Technical@immunostics.com
Website: www.immunostics.com

SECTION 2: COMPOSITION

COMPOSITION: Mixture consisting of the following components

	IUPAC	SYNONYMS	MOLECULAR FORMULA	IDENTIFIERS
Sodium Azide IMIS: S113	Sodium Azide	Azide, Sodium trinitride, Smite, Azium, Hydrazoic acid & sodium salt	NaN₃ (IARC) carcinogenic classification: Group 3-not classifiable as to its carcinogenicity to humans	CAS 26628-22-8 PUBCHEM N/A EC 247-852-1 UN 1687 RTEC VY8050000



Control sera supplied in the Immuno/Color IM™ Kit was tested and found negative to HIV 1/2 and HCV and non-reactive for Hepatitis B Surface Antigen by FDA approved procedures. Human serum products and patient specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

SECTION 3: HAZARDOUS INGREDIENTS

Classification of the substance or mixture according to (EC) No 1272/2008: The product is not classified according to the CLP regulation.

Classification according to 67/548/EEC or 1999/45/EC: This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by the Occupational Safety and Health Administration Hazard Communication Standard or European Directive 67/548/EEC and 1999/45/EC.

Information concerning particular hazards for human and environment: The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

	OSHA PEL	ACGIH TLV	DFG MAK	NIOSH	Classification: 1999/45/EC & 67/548 EEC	R & S Phrases
Sodium Azide					Labeling	
EU Index: 011-004-00-7	None	0.29 mg/m3 Ceiling	0.2 mg/m3 MAK (inhalable fraction)	0.3 mg/m3 (as NaN ₃) [skin]	 	R28, R32, R50/53 ¹ (S1/2), S28, S45, S60, S61 ²
EU Classification: Highly toxic (T+)						
Dangerous for the environment (N)						

¹ R28: Very toxic if swallowed; R32: Contact with acids liberates very toxic gas; R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

² (S1/2): Keep locked up and out of the reach of children; S28: After contact with skin, wash immediately with plenty of ... (to be specified by the manufacturer); S45: In case of accident or if you feel unwell seek medical advice immediately (show the label where possible); S60: This material and its container must be disposed of as hazardous waste; S61: Avoid release to the environment. Refer to special instructions/safety data sheet.



MATERIAL SAFETY DATA SHEET

Immuno/Color IM™

Immuno/Color IM™ Reagent; Positive & Negative Control

Cat №: IMC-50; IMC-100

MSDS DATE: 03/07/2013

SECTION 4: FIRST AID MEASURES

Primary routes of entry: Eye and skin contact; ingestion; inhalation & skin absorption.

Medical condition Aggravated by Exposure: Eyes/skin hypersensitivity

EYES: 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: 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.

INGESTION: In case of ingestion, contact a poison control center or physician for instructions. Only induce vomiting if directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

INHALATION: Remove from exposure and move to fresh air immediately. If breathing is difficult, give oxygen. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

SECTION 5: FIRE & EXPLOSION HAZARD DATA

GENERAL INFORMATION: As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear.

FLASH POINT: Not applicable.

AUTOIGNITION TEMPERATURE: N/A

HAZARD CLASSIFICATION: Dilute aqueous solution not considered a fire hazard.

HEALTH: ☒ 1 **FLAMMABILITY:** ☒ 0 **REACTIVITY:** ☒ 0 SPECIAL ☐

EXTINGUISHING MEDIA: Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, or dry chemical.

SPECIAL FIRE FIGHTING PROCEDURES: Wear protective clothing. Use self-contained breathing apparatus (NIOSH Certified). No special measures required.

UNUSUAL FIRE AND EXPLOSION HAZARDS: N/A

HAZARDOUS DECOMPOSITION PRODUCTS: When heated to decomposition, may produce hydrazoic acid fumes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

If material is released or spilled, wear all appropriate protective equipment described in Section 8 before cleaning up the spill or handling contaminated material. Wipe up the spill and dispose of the contaminated material. Avoid creating aerosols or dust while cleaning up a spill.

Personal Precautions Use good laboratory procedures; proper personal protective equipment; avoid eye and skin contact.

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

Environmental Precautions Contain spill to prevent migration. Do not flush down the drain. Over a period of time, sodium azide may react with copper, lead, brass, or solder in plumbing systems to form an accumulation of the highly explosive compounds of lead azide and copper azide.

SECTION 7: HANDLING & STORAGE

HANDLING & STORAGE: When not in use, store reagent and controls at 2-8°C (35-46°F) out of direct sunlight. Do not freeze. Prior to use, allow reagents and controls to warm to room temperature. Kit contents are stable until the expiration date printed. Do not get in eyes, on skin, or on clothing. Do not ingest or inhale. Store in a tightly closed container away from oxidizing agents, acidic materials as well as heavy-metal compounds.

OTHER PRECAUTIONS: For *in vitro* diagnostic use. Do not substitute reagents from kits from other manufacturers. To maintain efficacy, store according to the instructions in the product labeling. The reagents in each kit are matched. Reagents from different kits must not be interchanged or pooled. If the kit does not yield expected results when controls are tested, the kit should be discarded. Mix the



MATERIAL SAFETY DATA SHEET

Immuno/Color IM™

Immuno/Color IM™ Reagent; Positive & Negative Control

Cat №: IMC-50; IMC-100

MSDS DATE: 03/07/2013

reagents well before use. Use clean equipment. Traces of detergent or dried reactants on the test slide may adversely affect test performance and results.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

RESPIRATORY PROTECTION: Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional. Use a surgical mask or similar respiratory protection to cover nose, mouth and mucous membranes.

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

EYE PROTECTION: Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.



SKIN PROTECTION: Wear Impervious gloves, such as latex or equivalent, should be worn to prevent skin contact and especially cover any cuts, abrasions or skin lesions. Dispose of gloves as biohazardous material. Wash hands thoroughly after removing gloves. Use extreme caution with any sharp object to avoid percutaneous exposure to material. Wear outer protective garments such as a lab coat or gown.

Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

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.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

SECTION 9: PHYSICAL/CHEMICAL CHARACTERISTICS

pH:	Neutral
Boiling Point:	N/A
Freezing Point:	< -20 °C
Specific Gravity (H ₂ O = 1):	N/A
Vapor Pressure (mm Hg):	N/A
Vapor Density (AIR = 1):	N/A
Evaporation Rate (Butyl Acetate = 1):	N/A
Solubility in Water:	Soluble (Fully Miscible)
Appearance and Odor:	Clear liquid

SECTION 10: STABILITY AND REACTIVITY

STABILITY: Is stable when stored according to approved labeling except when exposed to excessive heat, sparks, open flame, other sources of ignition and incompatible chemicals.

CONDITIONS TO AVOID: Do not freeze. Protect from prolonged exposure to heat, humidity, and light, ignition sources & incompatible materials.

INCOMPATIBILITY (MATERIAL TO AVOID):
Incompatible material: strong oxidizers.
Incompatible materials: acids, heavy metals and their salts.

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: None expected under normal conditions of use.

HAZARDOUS POLYMERIZATION: Hazardous polymerization will not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

PRECAUTIONARY STATEMENTS:



MATERIAL SAFETY DATA SHEET

Immuno/Color IM™

Immuno/Color IM™ Reagent; Positive & Negative Control

Cat №: IMC-50; IMC-100

MSDS DATE: 03/07/2013

CAUTION! 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. Harmful by ingestion. Preparation appearance: clear, colorless liquid.

MATERIAL SAFETY DATA SHEET

Immuno/Color IM™

Immuno/Color IM™ Reagent; Positive & Negative Control

Cat №: IMC-50; IMC-100

MSDS DATE: 03/07/2013**Potential Health Effects:**

Inhalation	Aerosol may cause coughing and sore throat.
Eye	Exposure may cause irritation, redness and watering.
Skin	Contact may cause irritation, dryness and redness. Sodium Azide may be absorbed through the skin and result in systemic effects.
Ingestion	May cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness.
Target Organs	Cardiovascular and central nervous system.

	Oral LD50 Rat	Dermal LD50 Rabbit
Sodium Azide	27 mg/kg	20 mg/kg

Primary Routes of Exposure	The most likely routes of exposure are skin and eye contact.
Potential Effects of Chronic Exposure	Frequent or long-term contact may dry out the skin resulting in dermatitis. Repeated exposure may result in allergic reactions.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
Irritation/Sensitization	May cause sensitization by inhalation and skin contact.
Teratogenicity	None identified.
Mutagenicity	None identified.
Reproductive Toxicity	None identified.

SECTION 12: ECOLOGICAL INFORMATION**Ecotoxicity****Fresh Water Species**

Sodium Azide	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]
--------------	---

Biodegradability	No information available.
Bioaccumulation	No information available.
Mobility	No information available.
Other Adverse Effects	No information available.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

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 Ignitable; Reactive*)

SECTION 14: TRANSPORT INFORMATION

Resource Conservation & Recovery Act (RCRA) Waste Number: P105

Basic Shipping**Description:**

IATA	UN Number: UN 3316
Proper Shipping Name:	Chemical Kit
Hazard Class:	9
Hazard Label:	Miscellaneous
Packing Group:	PG III
Packaging Instruction:	Y915
Special Provisions:	A44 (excepted quantities)

U.S. Department of Transportation (DOT) Consumer Commodity, FORM-D



MATERIAL SAFETY DATA SHEET

Immuno/Color IM™

Immuno/Color IM™ Reagent; Positive & Negative Control

Cat №: IMC-50; IMC-100

MSDS DATE: 03/07/2013

SECTION 15: REGULATORY INFORMATION

US Federal Regulations:

This preparation is a component of an FDA-regulated in vitro diagnostic device.

TSCA (TOXIC SUBSTANCE CONTROL ACT): Present

CERCLA/SARA - Hazardous Substances and their Reportable Quantities: 1000 lb final RQ; 454 kg final RQ

302 Extremely Hazardous Substances EPCRA RQs: 1000 lb EPCRA RQ

302 Extremely Hazardous Substances TPQs: 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)

CERCLA/SARA - 313 - Emission Reporting: 1.0 % de minimis concentration

US State Regulations:

California - 8 CCR Section 339 - Director's List of Hazardous Substances Present

International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

WATER HAZARD CLASS (GERMANY): WGK 2, hazard to waters

Canada

Domestic Substances List (DSL) Present

WHMIS - Classifications of Substances D1A

WHMIS - Ingredient Disclosure List 1 %

WHMIS Status Exempt

SECTION 16: OTHER INFORMATION

ACGIH - Threshold Limits Values - Ceilings (TLV-C)

0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (vapor, as hydrazoic acid)

Canada - Quebec - Occupational Exposure Limits - Ceilings

0.11 ppm Ceiling; 0.3 mg/m³ Ceiling

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - Skin Notations
possibility of significant uptake through the skin

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELs
0.3 mg/m³ STEL

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs
0.1 mg/m³ TWA

Israel - Occupational Exposure Limits - Ceilings

0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (vapor, as Hydrazoic acid)

Korea - Occupational Exposure Limits - Ceilings

0.1 ppm Ceiling; 0.3 mg/m³ Ceiling

Labeling: Hazard: warning: flammable, protect from heat.

Labeling: This package conforms to 49 CFR 173.4

NC Poison Control Center: 1-800-672-1697

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).

DISCLAIMER: The information provided in this Material Data Safety Sheet has been compiled, in good faith, from our experience and data presented in various technical publications. An MSDS for a substance is not primarily intended for use by the general consumer, focusing instead on the hazards of working with the material in an occupational setting. It is believed to be accurate and represents the best information currently available. HOWEVER, IMMUNOSTICS, INC. MAKES 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 Immunostics, Inc. be liable for any claims, losses



MATERIAL SAFETY DATA SHEET

Immuno/Color IM™

Immuno/Color IM™ Reagent; Positive & Negative Control

Cat №: IMC-50; IMC-100

MSDS DATE: 03/07/2013

or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Immunostics, Inc. has been advised of the possibility of such damages. We reserve the right to update MSDS sheets from time to time as new information becomes available. It is the responsibility of the user to verify that they have the latest revision available.

NFPA 704

Health (Blue)		Flammability (Red)	
0	Poses no health hazard, no precautions necessary (e.g., water)	0	Will not burn (e.g., argon)
1	Exposure would cause irritation with only minor residual injury (e.g., acetone)	1	Must be heated before ignition can occur (e.g., mineral oil). Flash point over 93°C (200°F)
2	Intense or continued but not chronic exposure could cause temporary incapacitation or possible residual injury (e.g., ethyl ether)	2	Must be moderately heated or exposed to relatively high ambient temperature before ignition can occur (e.g., diesel fuel). Flash point between 38°C (100°F) and 93°C (200°F)
3	Short exposure could cause serious temporary or moderate residual injury (e.g., chlorine gas)	3	Liquids and solids that can be ignited under almost all ambient temperature conditions (e.g., gasoline). Liquids having a Flash point below 23°C (73°F) and having a Boiling point at or above 38°C (100°F) or having a Flash point between 23°C (73°F) and 38°C (100°F)
4	Very short exposure could cause death or major residual injury (e.g., hydrogen cyanide , phosphine , carbon monoxide)	4	Will rapidly or completely vaporize at normal atmospheric pressure and temperature, or is readily dispersed in air and will burn readily (e.g., propane , hydrogen). Flash point below 23°C (73°F)

Instability/Reactivity (Yellow)		Special (White)	
0	Normally stable, even under fire exposure conditions, and is not reactive with water (e.g. helium)		The white "special notice" area can contain several symbols. The following symbols are defined by the NFPA 704 standard.
1	Normally stable, but can become unstable at elevated temperatures and pressures (e.g. propene)		
2	Undergoes violent chemical change at elevated temperatures and pressures, reacts violently with water, or may form explosive mixtures with water (e.g., phosphorus , potassium , sodium)	OX	Oxidizer (e.g., potassium perchlorate , ammonium nitrate , hydrogen peroxide)
3	Capable of detonation or explosive decomposition but requires a strong initiating source, must be heated under confinement before initiation, reacts explosively with water, or will detonate if severely shocked (e.g. ammonium nitrate)	W	Reacts with water in an unusual or dangerous manner (e.g., cesium , sodium , sulfuric acid)
4	Readily capable of detonation or explosive decomposition at normal temperatures and pressures (e.g., nitroglycerine , Trinitrotoluene)		

<p>CHEMTREC® (24 hours) 1-800-424-9300 (Toll-free in the U.S., Canada, and the U.S. Virgin Islands) For calls originating elsewhere: 703-527-3887 (Collect calls are accepted)</p>	<p>CHEMTEL, INC. (24 hours) 1-888-255-3924 (Toll-free in the U.S., Canada, Puerto Rico and the U.S. Virgin Islands) For calls originating elsewhere: 813-248-0585 (Collect calls are accepted)</p>
<p>INFOTRAC (24 hours) 1-800-535-5053 (Toll-free in the U.S., Canada, and the U.S. Virgin Islands) For calls originating elsewhere: 352-323-3500 (Collect calls are accepted)</p>	<p>3E COMPANY (24 hours) 1-800-451-8346 (Toll-free in the U.S., Canada, and the U.S. Virgin Islands) For calls originating elsewhere: 760-602-8703 (Collect calls are accepted)</p>

The emergency response information services shown above have requested to be listed as providers of emergency response information and have agreed to provide emergency response information to all callers. They maintain periodically updated lists of state and Federal radiation authorities who provide information and technical assistance on handling incidents involving radioactive materials.

NATIONWIDE POISON CONTROL CENTER (United States Only)

Emergency and information calls are answered by the nearest Poison Center (24 hours): **1-800-222-1222** (toll-free in the U.S.).

NATIONAL RESPONSE CENTER (NRC)

The NRC, which is operated by the U.S. Coast Guard, receives reports required when dangerous goods and hazardous substances are spilled. After receiving notification of an incident, the NRC will immediately notify the appropriate Federal On-Scene Coordinator and concerned Federal agencies. Federal law requires that anyone who releases into the environment a reportable quantity of a hazardous substance (including oil when water is, or may be affected) or a material identified as a marine pollutant must **immediately** notify the NRC. When in doubt as to whether the amount released equals the required reporting levels for these materials, the NRC should be notified.

CALL **NRC** (24 hours) **1-800-424-8802** (Toll-free in the U.S., Canada, and the U.S. Virgin Islands)
202-267-2675 in the District of Columbia

Calling the emergency response telephone number, CHEMTREC®, CHEMTEL, INC., INFOTRAC or 3E COMPANY, does not constitute compliance with regulatory requirements to call the NRC