

1. Product and Company Identification

Material name	N-geneous® Wide Range CRP Calibrator Set
Version #	01
Issue date	05-23-2012
Revision date	-
Supersedes date	-
CAS #	Mixture
Part number	80-6647-00, 80-6648-00, 80-6649-00, 80-6650-00, 80-6651-00, 80-6655-00, 600783, 600790,
Product use	For use in the calibration of the N-geneous® Wide Range CRP (C-Reactive Protein) Assay. For In Vitro Diagnostic use only.
Synonym(s)	N-geneous® Wide Range CRP Level 1; N-geneous® Wide Range CRP Level 2; * N-geneous® Wide Range CRP Level 3; N-geneous® Wide Range CRP Level 4; * N-geneous® Wide Range CRP Level 5
Manufacturer information	
Corporate Headquarters	Sekisui Diagnostics, LLC 31 New York Avenue, Framingham, MA 01701 USA www.sekisuidiagnostics.com Phone: 800-332-1042
Emergency Telephone Numbers	Americas 1-760-476-3962 Europe, Middle East & Africa +1-760-476-3961 Asia Pacific +1-760-476-3960 Access code 333512

2. Hazards Identification

Physical state	Liquid.
Appearance	Yellowish brown liquid.
Emergency overview	The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. The human serum in this preparation was tested by FDA-approved methods and found to be negative for the presence of hepatitis B virus surface antigen (HBsAg), human immunodeficiency virus (HIV) 1 & 2 and hepatitis C virus (HCV). However, because no test method can provide complete assurance that infectious agents are absent, this product should be handled as a potentially biohazardous material in accordance with universal/standard precautions.
OSHA regulatory status	This product is not hazardous according to OSHA 29CFR 1910.1200.
Potential health effects	
Routes of exposure	Skin contact. Eye contact.
Eyes	May cause eye irritation.
Skin	May cause skin irritation.
Inhalation	May cause irritation to mucous membrane and respiratory system.
Ingestion	May cause discomfort if swallowed.
Target organs	Eyes. Skin. Respiratory tract.
Chronic effects	No data available.
Signs and symptoms	Ingestion may cause irritation and malaise.
Potential environmental effects	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

Components	CAS #	Percent
Sodium azide	26628-22-8	0.1
Composition comments	All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.	

4. First Aid Measures

First aid procedures

Eye contact

In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin contact

For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.

Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

Ingestion

If material is ingested, immediately contact a poison control center.

Notes to physician

Provide general supportive measures and treat symptomatically.

5. Fire Fighting Measures

Flammable properties

This product is not flammable.

Extinguishing media

Suitable extinguishing media

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media

None known.

Protection of firefighters

Specific hazards arising from the chemical

Sodium azide may form explosive compounds in metal drain lines. When disposing of solutions through plumbing fixture, flush with copious amount of water.

Protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions

Use standard firefighting procedures and consider the hazards of other involved materials.

Hazardous combustion products

Fire will generate toxic and irritating gases.

6. Accidental Release Measures

Personal precautions

Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions

Do not allow to enter drains, sewers or watercourses.

Methods for containment

Absorb spillage with non-combustible, absorbent material.

Methods for cleaning up

Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

Other information

Absorb small leaks or spills with sponge, mop up large spills with plenty of soap and water. Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling

Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.

Storage

Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value
Sodium azide (26628-22-8)	Ceiling	0.29 mg/m ³ 0.11 ppm

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value	Form
Sodium azide (26628-22-8)	Ceiling	0.3 mg/m ³ 0.29 mg/m ³ 0.11 ppm	Vapor. Vapor.

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Sodium azide (26628-22-8)	Ceiling	0.29 mg/m3	Vapor.
		0.11 ppm	

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
Sodium azide (26628-22-8)	Ceiling	0.29 mg/m3

Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value
Sodium azide (26628-22-8)	Ceiling	0.3 mg/m3
		0.11 ppm

Exposure guidelines	Follow standard monitoring procedures.
Engineering controls	Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors. Provide easy access to water supply and eye wash facilities.
Personal protective equipment	
Eye / face protection	Wear approved safety glasses or goggles.
Skin protection	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Respiratory protection	Under normal conditions, respirator is not normally required.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance	Yellowish brown liquid.
Physical state	Liquid.
Form	Liquid.
Color	Yellowish-brown.
Odor	Not available.
Odor threshold	Not available.
pH	7.4 - 7.6
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not available.
Solubility (water)	Soluble.
Specific gravity	Not available.
Flash point	Not available.
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Auto-ignition temperature	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability	Material is stable under normal conditions.
Conditions to avoid	Heat and direct sunlight.
Incompatible materials	Strong oxidizers, strong acids, and strong bases.
Hazardous decomposition products	None known.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

11. Toxicological Information

Toxicological data

Components	Species	Test Results
Sodium azide (26628-22-8)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	20 mg/kg
<i>Oral</i>		
LD50	Rat	27 mg/kg
Sensitization	Not classified.	
Acute effects	May cause discomfort if swallowed.	
Local effects	Causes skin, eye and respiratory tract irritation.	
Chronic effects	No data available.	
Carcinogenicity	Not classifiable as to carcinogenicity to humans.	
ACGIH Carcinogens		
Sodium azide (CAS 26628-22-8)		A4 Not classifiable as a human carcinogen.
Epidemiology	No epidemiological data is available for this product.	
Mutagenicity	Not classified.	
Reproductive effects	Not classified.	
Symptoms and target organs	Ingestion may cause irritation and malaise.	
Further information	No other specific acute or chronic health impact noted.	

12. Ecological Information

Ecotoxicological data

Components	Species	Test Results
Sodium azide (26628-22-8)		
Aquatic		
Crustacea	EC50	Water flea (<i>Daphnia pulex</i>)
		2.8 - 6.2 mg/l, 48 hours
Fish	LC50	Bluegill (<i>Lepomis macrochirus</i>)
		0.68 mg/l, 96 hours
Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.	
Environmental effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.	
Persistence and degradability	No data is available on the degradability of this product.	
Bioaccumulation / Accumulation	Not available.	
Mobility in environmental media	The product is completely soluble in water.	

13. Disposal Considerations

Disposal instructions	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. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.
Waste from residues / unused products	Dispose in accordance with all applicable regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport Information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

TDG

Not regulated as dangerous goods.

15. Regulatory Information**US federal regulations**

This product is not hazardous according to OSHA 29CFR 1910.1200. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Spill: Reportable quantity

Sodium azide (CAS 26628-22-8) 1000 LBS

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Substance: Threshold Planning Quantity

Sodium azide (CAS 26628-22-8) 500 LBS

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: De minimis concentration

Sodium azide (CAS 26628-22-8) 1.0 %

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: Listed substance

Sodium azide (CAS 26628-22-8) Listed.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

Sodium azide: 1000

Superfund Amendments and Reauthorization Act of 1986 (SARA)**Hazard categories**

Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely hazardous substance (40 CFR 355, Appendix A)

No

Section 311/312 (40 CFR 370)

Yes

Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)

Not controlled

Canadian regulations

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

WHMIS status

Non-controlled

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

State regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US - California Hazardous Substances (Director's): Listed substance

Sodium azide (CAS 26628-22-8) Listed.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

US - New Jersey RTK - Substances: Listed substance

Sodium azide (CAS 26628-22-8) Listed.

US. Massachusetts RTK - Substance List

Sodium azide (CAS 26628-22-8) Listed.

US. New Jersey Worker and Community Right-to-Know Act

Sodium azide (CAS 26628-22-8) 500 LBS

US. Pennsylvania RTK - Hazardous Substances

Sodium azide (CAS 26628-22-8) Listed.

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Recommended restrictions Use in accordance with supplier's recommendations.

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings Health: 0
Flammability: 0
Physical hazard: 0

NFPA ratings Health: 0
Flammability: 0
Instability: 0

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 Diagnostics 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 Diagnostics has been advised of the possibility of such damages.