MATERIAL SAFETY DATA SHEET



1. Product and Company Identification

Material name N-geneous® Wide Range CRP Reagent 1

Version # 01

Issue date 05-23-2012

Revision date - Supersedes date -

CAS # Mixture

Part number 80-6652-00; 80-6654-00

Product use For use in the quantitative measurement of C-Reactive Protein (CRP) concentration in serum or

plasma. For In Vitro Diagnostic use only.

Synonym(s) N-geneous® Wide Range CRP Reagent

Manufacturer information

Corporate Headquarters Sekisui Diagnostics, LLC

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Emergency Telephone

Numbers

Europe, Middle East & Africa +1-760-476-3961

Asia Pacific +1-760-476-3960

Access code 333512

2. Hazards Identification

Physical state Liquid.

Appearance Clear, colorless liquid.

Emergency overview The chemical, physical and toxicological properties of this preparation have not been thoroughly

characterized.

OSHA regulatory status This product is not hazardous according to OSHA 29CFR 1910.1200.

Potential health effects

Routes of exposureSkin contact. Eye contact.EyesMay cause eye irritation.SkinMay cause skin irritation.

Inhalation In high concentrations, mists/vapors may irritate throat and respiratory system and cause

coughing.

Ingestion May cause discomfort if swallowed.

Target organs Eyes.

Chronic effects None known.

Signs and symptoms Direct contact with skin and eyes may cause irritiation.

Potential environmental effects The product components are 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

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

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.

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InhalationMove to fresh air. Call a physician if symptoms develop or persist.IngestionIf material is ingested, immediately contact a poison control center.Notes to physicianProvide 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

None known.

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

None known.

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 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 No exposure limits noted for ingredient(s).

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 Clear, colorless liquid.

Physical state Liquid.

Form Liquid.

Color Colorless

Odor Not available.

Odor threshold Not available.

pH 8.5

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Not available. Vapor pressure Not available. Vapor density Not available. **Boiling point** Melting point/Freezing point Not available. Solubility (water) Soluble.

Not available. Specific gravity Not available. Flash point Flammability limits in air, Not available.

upper, % by volume

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 Avoid high temperatures.

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

Sensitization The product contains a small amount of sensitizing substance which may provoke an allergic

reaction among sensitive individuals.

Acute effects May cause discomfort if swallowed.

Local effects Ingestion may cause irritation and malaise.

Chronic effects Repeated inhalation may result in respiratory sensitization.

Carcinogenicity Not classifiable as to carcinogenicity to humans. **Epidemiology** No epidemiological data is available for this product.

Mutagenicity Not classified. Not classified. Reproductive effects

Symptoms and target organs Direct contact with skin and eyes may cause irritiation. **Further information** No other specific acute or chronic health impact noted.

12. Ecological Information

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity**

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 / Not available. Accumulation

Mobility in environmental

media

The product is completely soluble in water.

13. Disposal Considerations

Disposal instructions 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.

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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.

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

Superfund Amendments and Reauthorization Act of 1986 (SARA)

No

No

Hazard categories Immediate Hazard - No

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

Section 302 extremely hazardous substance (40

CRF 355, Appendix A) Section 311/312 (40 CFR

370)

Drug Enforcement Administration (DEA) (21 CFR

1308.11-15)

Not controlled

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

Canadian regulations

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

Not listed.

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US. Massachusetts RTK - Substance List

Not regulated.

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard

(NOM-018-STPS-2000).

16. Other Information

Recommended restrictionsUse 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

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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

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