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	Approved By: QA Manager Prepared By:D.Fraser	DOC HOLDERS LIST: Doc Control.xls
MSDS-003 SimpliRED D-Dimer		

1. IDENTIFICATION OF PRODUCT AND COMPANY

This Safety Data Sheet applies to:

<u>Product Name</u>	<u>Reference Number</u>	<u>Product Code</u>
SimpliRED D-dimer	DSRK4	DSRK4
SimpliRED D-dimer	DSRK4-DADE	DSRK4-DADE
SimpliRED D-dimer	DSRK4-ADI	DSRK4-ADI

All products listed above are minor variants of the same material.

Recommended Use: All these products are *in-vitro* diagnostic tests

Manufacturer

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2. COMPOSITION – Information on Ingredients

The Test Reagent, Positive Control and Negative Control preparations (mixtures) contain 0.05% sodium azide as preservative.

When assessed as per EU Directive 88/379/EC and Approved Criteria for Classifying Hazardous Substances [NOHSC: 1008(1999)], the preparation is classified as NON-HAZARDOUS and NON-DANGEROUS.

The Test Reagent, Positive Control and Negative Control contain protein, salts, buffers, and stabilisers classified as NON-HAZARDOUS and NON-DANGEROUS.


The Reagent, Positive Control and Negative Control preparation contain sodium azide.

<u>Ingredient Name</u>	<u>Concentration Percent by Weight</u>
Sodium azide	0.05%

CAS No: 26628-22-8
EC No: 247-852-1

There is no health hazard classification assigned to preparations containing sodium azide at this concentration.

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3. HAZARD IDENTIFICATION

Potential Health Effects

Eyes

Direct eye contact may cause redness and irritation.

Skin

Prolonged or repeated contact may cause skin irritation. Avoid prolonged or repeated exposure with the skin.

Ingestion

Harmful if swallowed. May cause abdominal pain. Nausea.

Inhalation

None known for solution.

4. FIRST AID MEASURES

Eyes

In case of eye contact, flush eyes with plenty of water for at least 15 minutes. Seek medical attention if irritation persists.

Skin

Promptly wash exposed areas thoroughly with soap and water. If irritation persists, seek medical attention.

Ingestion

Rinse mouth with plenty of water. Seek medical attention.

Inhalation

Remove individual to fresh air. Refer for medical attention if symptoms apparent.

5. FIRE FIGHTING MEASURES

Fire and Explosion Hazards

Non-flammable.

Sodium azide may form explosive azides in metal plumbing.

Extinguishing Media


Use any extinguishing agent suitable for the surrounding fire.

Fire Fighting Instructions

Wear self-contained breathing apparatus and protective protective clothing that is appropriate for fighting a typical fire involving chemical materials.

6. ACCIDENTAL RELEASE MEASURES

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Wear suitable protective clothing. Contain spill by placing suitable absorbent material around edges of the spill and work inward. Carefully scoop up into an appropriate waste container for disposal.

7. HANDLING AND STORAGE

Handling

Wear suitable protective clothing when handling – see section 8.

Observe strict hygiene standards. Do not eat, drink or smoke during handling; wash hands before eating; remove contaminated clothing and protective equipment before entering eating areas.

Keep away from acids (sodium azide reacts strongly) and away from contamination with heavy metals, especially copper, lead, mercury or silver.

Do not allow accumulation in metal plumbing.

Storage

Do not store beyond expiration date. Store at 2° to 8°C. Keep containers tightly closed when not in use.

Store separated from food and foodstuffs.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls

None usually required.

Eye/Face Protection

Safety Glasses or splash goggles may be necessary to prevent skin contact.

Skin Protection

Latex or plastic gloves and other protective clothing as required to prevent skin contact.

Respiratory Protection

None normally required with adequate ventilation

Other / General Protection

None normally required

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Dropper Bottle contains clear solution.

Test Devices contain reagents dried onto a membrane backing.

Odour

Odourless

Basic Physical Properties

Boiling Point / Melting Point (°C): Not Applicable.

Flash Point: Not Applicable.

Flammability: Non-Flammable.

Explosive Properties: Sodium azide may form explosive azides in metal plumbing.

Oxidising Properties: Not Applicable.

Vapour Pressure: Not Applicable (Pascal's or mmHg at 25°).

Specific Gravity: Not Applicable.

Solubility: Water soluble.

10. STABILITY AND REACTIVITY

Stability

Stable

Conditions to Avoid

Do not allow accumulation in metal plumbing.

Materials to Avoid

Acids, metals.

Hazardous Decomposition Products

Oxides of carbon and nitrogen may be formed during thermal decomposition (sodium azide).

11. TOXICOLOGICAL INFORMATION

For potential health effects see section 3.


Miscellaneous Toxicological Information

Carcinogenicity USA National Toxicology Program: no
 International Agency for Research on Cancer: no
 The Occupational Safety and Health Administration (USA): no

Sodium Azide: orl-rat LD50 27mg/kg; skn-rbt LD50 20mg/kg; other acute toxicity data available from National Institute for Occupational Safety and Health, USA (see section 16).

Occupational Exposure Limits: TLV Ceiling as hydrazoic acid vapour 0.11 ppm; as sodium azide 0.29mg/m³.

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Experimental mutagenic and tumorigenic data available from National Institute for Occupational Safety and Health, USA (see section 16).

The health effects noted above are based on extrapolation of data on the pure substance (raw material). To the best of our knowledge, no toxicological health effects have been identified for the product preparation (mixture) under normal conditions of use, although the health effects of the product have not been thoroughly investigated.

Medical Conditions Aggravated by Exposure

None known

12. ECOLOGICAL INFORMATION

This product does not contain any ingredients that are registered on the U.S EPA List of Toxic Chemicals (40 CFR 372), and is therefore not subject to release reporting under section 313 of EPCRA.

Sodium Azide: effect toxic to fish (0.98-8 ppm) and plankton (5-14 mg/L)

Use in accordance with good laboratory practice. Do not waste in the environment.

13. DISPOSAL CONSIDERATIONS

Do not allow accumulation in metal plumbing.

Dispose of in accordance with local regulations.

Used waste products, surplus products or spillage products shall be disposed of in accordance with national and local laws. It is up to the user to classify the waste correctly prior to disposal.

14. TRANSPORT INFORMATION

None


15. REGULATORY INFORMATION

This product is classified in accordance with EEC Directives 88/379/EC and 91/155/EC and subsequent modifications and Australian National Occupational Health and Safety Commission criteria. The health hazard classification (no classification applicable) has been determined based on composition and hazard data of each ingredient.

Physical and health hazard information on the total reagent mixture has not been determined.

Any physical and health hazard information noted is based on a) evaluation of data of the pure ingredient and b) concentration of each ingredient.

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16. OTHER INFORMATION

Refer to Product Instructions for Use for further product information.

Primary References

1. Product Instructions for Use
2. EEC Directives 88/379/EC and 91/155/EC
3. International Chemical Safety Cards Sodium Azide, No. 0950, April 1997
4. NIOSH Registry of Toxic Effects of Chemical Substances # VY8050000, October 2002.