

SAFETY DATA SHEET

(Corresponding to EC Directive 91/155/EEC)

Date of issue: August 2016
Replaces version of: N/A

Trade Name: Unistik® 3

1. Identification of the product and of the company

1.1 Product Name & Intended Use:

Unistik® 3 Gentle - 30G Gauge – 1.5mm lancing depth
 Unistik® 3 Comfort - 28G Gauge – 1.8mm lancing depth
 Unistik® 3 Normal - 23G Gauge – 1.8mm lancing depth
 Unistik® 3 Extra - 21G Gauge – 2.0mm lancing depth
 Unistik® 3 Neonatal & Laboratory - 18G Gauge – 1.8mm lancing depth

Unistik® 3 is a sterile, single use capillary blood-sampling device, which is supplied pre-cocked and ready for use. The device has a needlepoint that is hidden before use, and automatically retracts after the device has been activated to avoid needlestick injuries and cross infection.

1.2 Company name: Owen Mumford Limited
 Woodstock
 Oxfordshire
 OX20 1TU
 England

1.3 Emergency phone number: +441993 812021
Emergency fax number: +441993 813466
Emergency e-mail: info@owenmumford.co.uk

1.4 Hours: 8.30am – 5.30pm (Monday – Friday).

2. Composition/information on ingredients

| Part Description | Base Material | Patient Contact / Invasive | Contact Duration |
|------------------|-------------------------------------|----------------------------|------------------|
| Body | BASF Polystyrol 495F | Skin Contact | <24h |
| Lancet | Homopolymer Polypropylene HD 810 MO | Skin Contact | <24h |
| Needle | Stainless type X10CrNi 18-8 | Skin Contact | <24h |
| Spring | Heat Treated Stainless Steel | None | N/A |
| Body | BASF Polystyrol 495F | Skin Contact | <24h |

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3. Hazards identification

According to the present state of knowledge, provided that this product (As a finished device) is handled correctly, there is no known danger to humans.

4. First aid measures

- 4.1 After contact with the eyes:** No hazards
- 4.2 After contact with the skin:** No hazards
- 4.3 After inhalation:** No hazards
- 4.4 After ingestion or accident:** If swallowed, seek medical advice immediately.
- 4.5 Symptoms:** No hazards
- 4.6 Notes to physician:** Not applicable
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5. Fire fighting measures.

- 5.1 Extinguishing media:** All suitable, no restrictions
- 5.2 Special advice in case of fire:** None
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6. Accidental release measures.

- 6.1 After spillage, leakage, gas leakage:** Not applicable
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7. Handling and storage

- 7.1 Handling:** No special conditions
- 7.2 Storage:** No special conditions
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8. Exposure controls and personnel protection

- 8.1 Exposure controls:** Not applicable
- 8.2 Industrial hygiene:** Not applicable
- 8.3 Personal protective equipment:** Not applicable
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9. Physical and chemical properties

- 9.2 Colour:** White
- 9.3 Odour:** None
- 9.4 Change in physical state:** None

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|-------------|------------------------------|----------------------------------|
| 9.5 | Flash point: | Not applicable |
| 9.6 | Ignition temperature: | Not applicable |
| 9.7 | Explosion limits: | Not applicable |
| 9.8 | Density: | Not applicable |
| 9.9 | Vapour Pressure: | Not applicable |
| 9.10 | Viscosity: | Not applicable |
| 9.11 | pH value: | Not applicable (at 20 degrees C) |
| 9.12 | Solubility in water: | Insoluble (at 20 degrees C) |

10. Stability and reactivity

Non-applicable, if the device is used in the correct manner, no materials contain latex by design.

11. Toxicological information

Meets the requirements of ISO 10993 Pt5, Cytotoxicity testing (As a finished device).

12. Ecological information

Not applicable due to insolubility in water. This product does not come into contact with the effluent when it is used for its purpose.

13. Disposal considerations:

Local regulations should be adhered to. Incineration in an approved controlled furnace. Disposal of sharps: For disposal, local regulation is binding.

14. Transport information

Regulations are non-applicable

15. Regulatory information

No labelling requirements according to EC Directives.

16. Other information

Product should be stored, handled and used in accordance with safe clinical practices and in conformity with local legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.