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SPECIFICATION

PSDS IV3000 1 Hand Ported

Approvals

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SPECIFICATION

PSDS IV3000 1 Hand Ported

SPECIFICATION

1. PRODUCT NAME(S):

OPSITE IV 3000 1-HAND PORTED

2. INTENDED USES:

Fixation of intravenous catheters.

3. COMPOSITION:

Hydrophilic Polyurethane film supported by a release coated carrier film and coated with an adhesive which is protected by a release coated paper. A handle comprising of an adhesive coated non-woven fabric is located at one end of the dressing, covered by the film area. The opposite end of the dressing contains a double-sided siliconised release handle. The handle contains three non-woven strips, spread with a cellulose adhesive. One of the strips is printed with black ink, providing the required symbols for the Documentation Label.

Note

Pediatric and non sterile variants do not have a second handle at the bottom containing two strips and a label.

Infusion set variant has a second handle at the bottom but does not contain strips and a label.

4: PHYSICAL AND CHEMICAL PROPERTIES:

Combustible solid.

5. HEALTH HAZARDS:

Health Effects: No health hazard is anticipated during normal handling of this product.

6. FIRST AID:

- a) Inhalation** - Not applicable.
- b) Contact with skin** - Not applicable.
- c) Contact with eyes** - Not applicable.
- d) Ingestion** - Not applicable.

7. FIRE AND EMERGENCY MEASURES:

The product is a combustible solid which gives off toxic fumes, mainly carbon monoxide, carbon dioxide and hydrogen cyanide, when ignited. In case of fire any standard fire extinguisher may be used; wear self-contained breathing apparatus.

8. ACCIDENTAL RELEASE MEASURES:

Not applicable.

9. HANDLING AND STORAGE PRECAUTIONS:

Store in a cool, dry place. Keep away from sources of ignition.

10. EXPOSURE CONTROLS/PERSONAL PROTECTION:

Not Applicable.

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11. STABILITY AND REACTIVITY:

Not Applicable.

12. TOXICOLOGICAL INFORMATION:

See information given in Hazard Information: Health Effects.

13. ECOLOGICAL INFORMATION:

Not Applicable.

14. DISPOSAL:

Controlled incineration/landfill according to local environmental health guidelines.

15. TRANSPORT PRECAUTIONS:

See Handling and Storage Precautions.

16. REGULATORY INFORMATION:

Not applicable.

17. ADDITIONAL INFORMATION:

Not applicable.

18. NAME, ADDRESS AND TELEPHONE NUMBER OF SUPPLIER:

Documentation and Records Department
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This information is provided in accordance with the requirements of the UK Health and Safety at Work Act 1974, and specifically in order to assist users of the product to make their 'assessment of health risks' as required by the UK Control of Substances Hazardous to Health Regulation 2002 (COSHH assessments). Provision of this information does not preclude users from seeking advice from other sources as indicated in the COSHH guides.

This information is intended to cover potential hazards at the place of work and does not detail medical uses, indications, contra-indications and precautions for the treatment of patients.

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REASON FOR CHANGE

Document Version	Section/Paragraph Changed	Change Made	Date
2	Composition	Updated to include new Strips & Labels element of dressing. Change controlled under Project CCA 820.	04/01/07
3	Section 3	Updated to include non-sterile and paediatric variants of product.	16/03/07
4	N/A	Updated to include 9 X 12cm non-sterile dressings 66604009	05/12/2008
05	Product codes	Updated to include 11x14xm PICC dressing 66800512 (as per CCA/1846) IV3000 infusion Set dressing 66800786 (as per CCA/1849)	30/03/11

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Plant Number(s):

None

Product Code(s):

4006, 66004009, 66394006, 66394009, 66604009, 66800512, 66800786

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