

Trust Headquarters
Russells Hall Hospital
Dudley
West Midlands
DY1 2HQ

Ref: FOI-112025-0002065

Date: 4.3.26

Address / Email:

Dear

Request Under Freedom of Information Act 2000

Thank you for requesting information under the Freedom of Information Act 2000.

Skin biocide use

I am writing to request information under the Freedom of Information Act 2000. To assist you with this request, I am outlining my query as specifically as possible in the following questions.

If your Trust is unable to answer any of the questions through lack of knowledge of the answer, please state this.

Questions

1. Which product or products does your Trust use for pre-surgical skin antisepsis? - **Chloraprep**
2. Which product or products does your Trust use for skin antisepsis prior to peripheral vascular cannula insertion? - **Clinell 2% chlorhexidine in 70% alcohol wipes**
3. Which product or products does your Trust use for skin antisepsis prior to central venous line or peripherally inserted central venous line insertion? - **Chloraprep**
4. If any of these products are categorised as biocides, for the relevant product/s:
 - a. Has the supplier confirmed Great Britain Biocidal Products Regulation (GB BPR) authorisation?
 - b. Has the Product Type been declared (PT1 Human Hygiene) ?
 - c. Does the Product Type match its use in your Trust?
 - d. If you use the product outside the GB BPR and Product Type authorisation, describe the governance processes that approved this use in your Trust.
 - e. Do the label and marketing materials make medicinal claims that trigger Human Medicines Regulations?
 - f. Is a current Safety Data Sheet provided with the product?
 - g. Are Instructions for Use attached/provided with the product?
 - h. Are concentration, contact time, and application methods relevant to your use of the product clearly stated and clinically appropriate?
 - i. Is compatibility with skin confirmed?
 - j. For biocidal products used for pre-surgical skin antisepsis, is compatibility with surgical materials confirmed?

- k. Is clinical evidence available for the specific formulation and your use of the product?
- l. Does use of the biocide align with NICE guidance?
- m. If used instead of an antiseptic that has MHRA Marketing Authorisation (MA), describe the governance processes that approved the biocide use in your Trust.
- n. If you use a biocide for pre-surgical skin antisepsis, do you declare this to patients and obtain their specific consent for this?
- o. Have you received supplier warranty that regulatory claims and labelling are accurate?
- p. Does your Trust have an established reporting pathway to report adverse events or incidents linked to the biocide to the Health and Safety Executive?
- q. Does your Trust have organisational indemnity / insurance cover for harm attributed to the biocide?

- Unable to answer

If you are dissatisfied with our response, you have the right to appeal in line with guidance from the Information Commissioner. In the first instance you may contact the Information Governance Manager of the Trust.

Information Governance Manager
Trust Headquarters
Russell's Hall Hospital
Dudley
West Midlands
DY1 2HQ
Email: dgft.dpo@nhs.net

Should you disagree with the contents of our response to your appeal, you have the right to appeal to the Information Commissioners Office at.

Information Commissioners Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF
Tel: 0303 123 1113
www.ico.org.uk

If you require further clarification, please do not hesitate to contact us.

Yours sincerely

**Freedom of Information Team
The Dudley Group NHS Foundation Trust**