



DEFECT & INVESTIGATION CENTRE



FOR ACTION BY:

Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
General Manager/Chief Executive of each Agency
General Practitioners

Stoney Road Dundonald
Belfast
Northern Ireland BT16 1US

ADVICE NOTICE (NI) 99/03

Date: 4 August 1999

Telephone 01232 523745
Facsimile 01232 523900
GTN Code 440

| | | |
|---------------------------|---|-----------------------|
| Product | : | GLUTARALDEHYDE |
| Manufacturer/ Supplier | : | VARIOUS |
| Action | : | (SEE SECTION 2 BELOW) |

1. ATTENTION CHIEF EXECUTIVES/GENERAL MANAGERS

This Advice Notice should be brought to the immediate attention of all who need to know, or be aware of it including all staff who are likely to come into contact with glutaraldehyde in accordance with local procedures, and immediate action should be taken as detailed overleaf:

Glutaraldehyde is commonly used for disinfecting endoscopes and other instruments and has been shown to cause respiratory and other health problems in staff. The Health and Safety Executive's publication entitled "EH40: Occupational Exposure Limits" is published annually. EH40/98 indicated that the occupational exposure standard (OES) of 0.2 parts per million (PPM) for glutaraldehyde was being withdrawn from January 1998 and was to be replaced. EH40/99 now indicates a maximum exposure level (MEL) for glutaraldehyde at the lower level of 0.05ppm. In Great Britain their Control of Substances Hazardous to Health Regulations 1999 came into effect on 25 March 1999 and replaced earlier COSHH Regulations. A consequence of these 1999 Regulations is that MELs specified in EH40/99 (and subsequent editions) are legally enforceable. It is anticipated that in Northern Ireland similar legislation will be introduced later this year.

The purpose of this Advice Notice is to advise on these anticipated changes and to the considerable reduction in the MEL for glutaraldehyde. In any event, the present Control of Substances Hazardous to Health Regulations (Northern Ireland) 1995 require prevention, or where this is not reasonably practicable, adequate control regarding exposure of employees to substances hazardous to health. "Adequate" means adequate having regard to the nature of the substances concerned – in the case of glutaraldehyde a respiratory sensitiser – and the nature and degree of exposure to that substance. The Advice Notice also outlines the risk management, cost and service implications which should be considered.

Boards/Trusts should ensure that if appropriate, this information is passed to **ALL** persons having the responsibility for premises registered under "THE REGISTERED HOMES (NI) ORDER 1992".



HEALTH ESTATES
ESTATE POLICY

An Executive Agency of the Department of Health and Social Services

ADVICE NOTICE

2. IMMEDIATE ACTION

Employers should review the steps they are taking to comply with the Control of Substances Hazardous to Health Regulations (Northern Ireland) 1995 and their ability to meet and better the 0.05ppm level for glutaraldehyde. The HSE's *Chemical Hazard Alert Notice 7* and Health Service's Advisory Committee leaflet, *Glutaraldehyde and You* give advice on the action required. An overview of employers duties and COSHH Regulations (NI) 1995 requirements are included in Appendix 1 of this document. Employers should carry out air monitoring in areas where glutaraldehyde is used to assess whether existing control systems are adequate or whether they need to be improved, or replaced. Employers should also explore the cost effectiveness of alternative decontamination regimens (see *Alternatives to glutaraldehyde* below) and/or implement enhanced monitoring arrangements.

Employers who decide to continue using glutaraldehyde and whose systems and/or equipment cannot currently meet the MEL should:

- put revised procedures in place to meet the MEL through improved operational management
- plan a complete modification of current control systems eg ventilation, where the MEL can be met by these means
- replace current arrangements with an effective automated washer/disinfector, where the MEL cannot be met in either of the above ways
- identify operational procedures for handling glutaraldehyde, and provide all necessary personal protective equipment.

Where assessments indicate that action will be necessary which will have a significant impact on service procedures and delivery and/or equipment costs, the matter must be drawn to the attention of commissioning authorities. A financial plan may need to be agreed to enable the implementation of the required action.

The new standard should be drawn to the attention of dental practitioners, GPs undertaking endoscopic procedures, expert advisory panels that review applications to use endoscopes, all theatre staff, all day surgery unit staff, outpatient units where endoscopy takes place, COSHH representatives occupational health departments and to medical staff and nursing executive directors.

3. BACKGROUND AND OTHER INFORMATION

Glutaraldehyde

Glutaraldehyde is a volatile disinfecting and sterilising agent widely used in endoscopy units; day surgery facilities; sterile service departments; urology departments; catheterisation laboratories; dental practice; as a histological fixative and decreasingly, in radiology. It is inexpensive, effective and fast acting, and therefore convenient. *However, exposure to the liquid or vapour has been known to cause a range of problems from irritation of the eyes, nose and throat to skin sensitisation and asthma. Exposure therefore has potential cost implications in terms of staff health and sick leave, litigation and workforce compensation.*

Glutaraldehyde occupational exposure limits

Until January 1998, exposure to glutaraldehyde was controlled to an Occupational Exposure Standard (OES) of 0.2 parts per million. Despite this, and also perhaps owing to poor compliance, sensitisation and occupational asthma still occur. Moreover, no safe level of exposure has been identified. Therefore EH40/99 now indicates a Maximum Exposure Limit (MEL) of 0.05 ppm. It is anticipated that amended Control of Substances Hazardous to Health (COSHH) regulations will come into force later in 1999 in Northern Ireland, which will then make the MEL legally binding.

Reaching the limit is a significant reduction against current practice. However, a MEL requires employers to reduce exposure to as far below the limit as is reasonably practicable.

Interim recommendations

COSHH Regulations (NI) 1995 indicate that employers should first aim to prevent exposure. If this is not feasible, then they should control exposure to as low a level as possible: the number of people exposed, and the duration of their exposure, should be minimised.

Field work on glutaraldehyde

Research (unpublished) on glutaraldehyde levels in several hospitals indicates that most Trusts could achieve the proposed MEL in two ways: first, by tightening up operational guidelines and procedures and second, by introducing improved automated washers and ventilation systems.

Monitoring glutaraldehyde levels

To meet the new requirements it will be necessary to monitor glutaraldehyde levels at least once every twelve months. However, the precise interval will be determined by an appropriate local risk assessment. Guidance on routine monitoring is presented in HSE – *Monitoring Strategies for Toxic Substances (HSG 173)*.

Measuring glutaraldehyde levels

Reference should be made to local occupational health departments. The HSE does not consider current hand-held equipment adequate for measuring airborne glutaraldehyde levels down to the requirements of the new MEL. A number of laboratories have the capacity and expertise to carry out these measurements. Occupational health departments may, if necessary, seek advice from The British Occupational Hygiene Society. The HSE publication “Methods for the Determination of Hazardous Substances” MDHS93 gives a laboratory method (using high performance liquid chromatography) for glutaraldehyde in air measurements. Health Estates, Consultancy Services Directorate may be offering a comprehensive testing service in this field.

Alternatives to glutaraldehyde

Alternatives to glutaraldehyde may be more expensive, slower acting and less convenient. However, they appear not to be associated with serious occupational health problems and therefore offer cost-effective ways of meeting the MEL. The Health Estates Device Bulletin DB9607(NI) issued 14 March 1997 details alternative sterilisation and disinfection processes. The publication *Cleaning and Disinfection of Equipment for Gastrointestinal Endoscopy* is useful as it addresses ways of eliminating or minimising exposure to glutaraldehyde by reviewing alternative disinfectants and the use of automated washer/disinfectors.

4. ENQUIRIES

Enquiries *in writing* regarding this notice should be addressed as follows:

NORTHERN IRELAND DEFECT & INVESTIGATION CENTRE (NIDIC)

Health Estates

Estate Policy

Stoney Road

Dundonald

BELFAST BT16 1US

marked for the attention of Mr Dominic Cafolla

Yours faithfully

Dominic Cafolla

Deputising Defect Centre Manager

HOW TO REPORT DEFECTS

Professional Estate Letter PEL(93)36 issued by Estate Services Directorate, on 27th July 1994 advises Health and Social Services Boards, HSS Trusts and agencies how to notify HPSS about accidents with and defects in medicinal products, buildings and plant, medical devices and other medical and non medical equipment and supplies.

What should employers do?

- You should give priority to preventing your employees being exposed to glutaraldehyde by any route (ie inhalation, ingestion, or contact with the skin).
- Where preventing exposure to glutaraldehyde is not reasonably practicable (eg using a different substance), then you should adequately control exposure by a combination of engineering and process control measures. COSHH Regulations (NI) 1995 recommends that you control exposure to as low a level as is reasonably practicable. The number of people exposed and the duration of their exposure should be minimised.
- You must give all your employees who are, or who may be exposed to glutaraldehyde, sufficient information, instruction and training to understand the potential problems and the precautions they need to take.
- You should make sure that safety representatives, employees or representatives of employee safety are aware of this information and consult on any action that you propose to take as a result.

Complying with COSHH Regulations (NI) 1995 involves:

- **assessing the risks** to health arising from your work;
- **deciding what precautions are needed.** You must not carry out any work which could expose employees to hazardous substances without first considering the risks and the necessary precautions. Unless you have judged the risks correctly, you are unlikely to decide on the right precautions;
- **preventing or controlling exposure.** The advice in this notice, and in the other guidance it refers to, will help you get the assessment and precautions right, but remember that even perfect plans achieve nothing unless they are put into practice;
- **ensuring that control measures are used and maintained** properly, and that any safety procedures which have been laid down are followed;
- **monitoring exposure** of workers to hazardous substances and carrying out appropriate health surveillance, where the assessment has shown these are necessary or where COSHH lays down specific requirements;
- **ensuring that employees are properly informed, trained and supervised.**

Reporting of Adverse Incidents

Occurrences involving glutaraldehyde should be reported to:

Northern Ireland Defect & Investigation Centre (NIDIC)
 Health Estates Agency
 Estate Policy Directorate
 Stoney Road
 Dundonald
 Belfast BT16 1US.
 Tel: 01232 523714
 Fax: 01232 523900

Reporting of adverse incidents and reactions should follow the procedures identified in PEL(93)35, and PEL(93)36, both issued 27 July 1994.

Associated Documentation/Further Information

Health and Safety Executive: Chemical Hazard Alert Notice 7 (CHAN 7), October **1997**. Rev. February 1998.

Health Service's Advisory Committee: *Glutaraldehyde and You*. (Booklet for employers and staff). IAC64 revl. January 1998, published by the Health and Safety Executive.

Health and Safety Executive: EH 40/1999 Occupational Exposure Limits, (GB issue).

Health and Safety Executive: Guidance Booklet *Monitoring Strategies for Toxic Substances* (HSG173).

NHS Executive: HSG(97)6: *NHS Health and Safety Issues*. June 1997.

British Society of Gastroenterology: *Cleaning and Disinfection of Equipment for Gastrointestinal Endoscopy* Working Party Report, 1997.

Health Estates Agency: DB 9607(NI) *Decontamination of Endoscopes*.

Health and Safety Executive: MDHS 93 *Glutaraldehyde in air*.

Addresses

The Health and Safety Executive for Northern Ireland, 83 Ladas Drive, Belfast BT6 9FJ
Tel: 01232 243249, <http://www.hse-ni.org.uk>.

The British Occupational Hygiene Society, Suite 2, Georgian House, Great Northern Road, Derby.
Tel: 01332 298101.

Health and Safety Executive publications are available from HSE Books. Tel: 01787 881185 HSE Infoline: 0541 545500 and <http://www.open.gov.uk/./hse/hsehome.htm>.

Health Estates Agency, Stoney Road, Dundonald, Belfast BT16 1US.
Tel: 01232 520025, Fax 01232 523900.