

THE DANGEROUS SUBSTANCES AND PREPARATIONS (NICKEL) (SAFETY) REGULATIONS 2000

Guidance Note

BACKGROUND

1. The main objective of the legislation is to safeguard public health. The presence of nickel in certain objects coming into direct and prolonged contact with the skin may cause sensitisation of humans to nickel and may lead to allergic reactions (nickel dermatitis).

2. In 1976, Council Directive 76/769/EEC, the Marketing and Use of Dangerous Substances and Preparations Directive was introduced. It sought to harmonise the marketing and use of dangerous substances and preparations in the European Community for the first time. In 1994, Council Directive 94/27/EC, the 12th Amendment to Directive 76/769/EEC was adopted. It introduced measures to counteract nickel sensitisation and requested the European Committee for Standardisation (CEN) to publish test methods standards to demonstrate the conformity of products with the Directive. Member States were required to implement the Directive not more than 6 months after the publication of the titles and references of those harmonised European standards in the Official Journal of the European Communities (OJEC). The relevant standards are BS EN 1810:1998, BS EN 1811: 1999 and BS EN 12472:1999. Notification of these standards was finally published in the OJEC on 20th July 1999.

3. This Guide seeks to provide practical advice with respect to the Regulations as they implement the Directive in United Kingdom. The advice may vary in other Member States of the EU. In the UK, the Guide does not carry any legal authority and does not replace the provisions of the Regulations. Only the Regulations as interpreted by the Courts have force of law. If you require further advice or information, you should contact your Enforcement Authority: Local Authority Trading Standards Department (Great Britain) or District Council (Northern Ireland).

4. THE REGULATIONS

Regulation 1 (2)

The Regulations came into force on **20 July 2000** in relation to the supply of products manufactured in or imported into the United Kingdom. Similarly, the Regulations came into force on **20 July 2000** in relation to products manufactured in or imported into the United Kingdom, on behalf of another person.

However, where the products are supplied by wholesale/retail, the regulations shall come into force on **20 July 2001**.

Products manufactured for export to countries outside of the European Union Member States are not covered by these Regulations.

Dates were set with reference to the date of publication of the European Standards in the Official Journal of the European Commission. The CEN tests were published on 20th July 1999. Governments in Member States had six months from that date to implement the Directive 94/27/EC into their individual national legislation i.e. 20 January 2000.

5. Interpretation Apart from the provisions of the Consumer Protection Act 1987 and the General Products Safety Regulations SI 1994/2328, there are no restrictions on the sale of any product to the consumer that was placed on the market prior to the implementation of the Directive into UK law, i.e. before 20 January 2000. Therefore, the Regulations do not apply to any complete item that was placed on the market before the date of implementation. It is the view of the Department that the Directive and Regulations do not apply to second-hand goods. However, this is only the Department's view and does not carry any legal authority, and does not replace the provisions of the Regulations. Dealers in second hand

goods requiring further advice are advised to contact their Enforcement Authority: Local Authority Trading Standards Department (Great Britain) or District Council (Northern Ireland) or to obtain their own legal advice.

Placing on the market means 'the first making available in return for payment or free of charge, with a view to distribution, use, or both, on the Community Market.'

An item is placed on the market when it is in its final manufactured form, prior to packaging.

It is now not permissible for manufacturers/importers to place on the market any products that do not comply with the Regulations.

Wholesalers and Retailers have until 20 July 2001 to enable them to sell those non-compliant goods to the consumer. After 20 July 2001, any non-compliant products that were placed on the market between the date of implementation and 20 July 2000 will not be able to be sold to the consumer.

Replacement or spare parts containing nickel are subject to the same Regulations. If you require further help, contact your local Enforcement Authority for advice.

6. Regulation 3 (1)

The definition of a 'post assembly' is the part of the item designed and manufactured for insertion into the wound, caused by piercing the human body during the period of epithelization. The post assembly would include the piece that goes through the wound, plus any faces of items that hold the piece in and against the wound.

This does not preclude the use of decorative items on the outside of the post assembly that are **not** intended to come into direct and prolonged contact with the skin.

The Regulations use the term "homogeneous", which is understood to mean 'consisting of parts all of the same kind, uniform'. In the context of the Regulations, it appears that there are two possible meanings, and ultimately only the European Court of Justice (ECJ) can decide which should apply.

The first is that it is a requirement that all parts of the post assembly consist of the same material - i.e. the post and the 'butterfly' clip on a stud earring are of the same composition.

The alternative meaning is that homogeneity refers only to the nickel content of the post assembly. This would mean that if traces of nickel are present, they are evenly distributed but it does not mean that all parts of the post assembly must be made from the same material.

Thus a post could be fabricated from metal and be fastened to the ear with a plastic 'butterfly' clip. In both cases, the nickel content of the post-assembly components must be less than 0.05%.

In principle, nickel should not be used in post assemblies intended for use during the period of epithelization, but where it is present, it must be uniformly dispersed throughout the post assembly with a nickel content of below 0.05% by mass.

The less stringent interpretation of homogeneous mentioned above would probably not preclude the use of solders and coating materials whereby the substrate, solder and coating each contain less than 0.05% nickel, provided the post assembly does not release nickel at a level greater than the unsoldered and uncoated substrate used in its manufacture (i.e. the post assembly may be made of various components providing that each component contains less than 0.05% nickel and has no effect on the nickel release of the other components.

The British Standard Specification reference test method for the measurement of nickel content is BS EN 1810:1998.

7. Regulation 3(2)

'Direct and prolonged contact' means actually touching the skin under normal use, for continuous periods of time. The list contained in **Regulation 3(2)** is indicative of the type of product to which the Regulations refer.

Because the list of items named is purely indicative not exclusive and gives examples only exclusion does not constitute exemption, even for products already on the market. It does not preclude any new developments or products.

It is the trader's responsibility to consider the individual piece and decide which parts will be in direct and prolonged contact with the skin. Where there is any doubt, advice should be sought from your local Enforcement Authority.

The reaction of sensitised people to nickel release varies from person to person and can take place over a short or long period. It is possible that the skin of some sensitised people may react to items that conform to **Regulations 3(1), 3(2), 3(3) or 3(4)**.

The British Standard Specification reference test method for the measurement of nickel release is BS EN 1811:1999 - 'reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin.

The Regulation prohibits the supply of any product that comes into direct and prolonged contact with the skin and has a rate of nickel release greater than 0.5 micrograms per square centimetre per week.

8. Regulation 3(6)

The British Standard Specification reference test method for the measurement of nickel release after wear and corrosion is BS EN 12472:1999 - 'method for the simulation of the wear and corrosion for the detection of nickel release from coated items.' The test is designed to ascertain the durability of the coating and it is **not** a guarantee that the product itself will last for two years and includes BS EN 1811:1999.

9. Test Methods

The three Standards BS EN 1810:1998, BS EN 1811:1999 and BS EN 12472:1999 were developed as an integral part of Directive 94/27/EC.

BS EN 1810:1998, the reference test method for nickel content is applicable to Regulation 3(1) only.

BS EN 1811:1999 is the reference test method for nickel release.

BS EN 12472:1999 is a method for the simulation of wear and corrosion of coated items.

Further tests have been developed to check for nickel release from alloys and coatings.

These screening tests will probably be published as a CEN report (based on prEN 12471).

These tests are **not** intended as a replacement for BS EN 1811:1999, but are designed to assist the Industry.

10. Due Diligence

Anyone wishing to place items on the market for sale must recognise that they have a legal obligation to ensure that items meet the requirements of the legislation. The proof of this is known as showing 'due diligence'. In order to create a balance of fairness, a specific 'due diligence' defence is commonly included in strict liability laws. To use this defence, a person must prove that he took 'all reasonable steps' **and** exercised 'all due diligence' to avoid an offence being committed.

The 'due diligence' defence is not unique to this area of law. This means that there is a body of case law, usually in relation to consumer protection issues, which can be drawn upon for guidance. Of course, no two cases are the same but a consideration of the judicial decisions does reveal the following key principles:

- sitting back and doing nothing is unlikely to be sufficient. However, the nature of the necessary positive action will depend upon the individual circumstances;
- taking reasonable steps is likely to involve setting up a system of control that has regard to the risks involved. The control system must cover all the regulatory requirements;
- 'due diligence' means ensuring the proper operation of that system. The operation of the system should be kept under review and be amended as necessary;
- any defence is likely to fail where there was a reasonable step that could have been taken but was not; and
- what is reasonable in terms of 'due diligence' will always depend on the particular circumstances. For example, the scale of your business operations may have a bearing on the systems that it will be considered reasonable for you to put into place.

11. What Does This Mean in Practice?

Assess the risk. It will not be enough for the control or quality system that is put in place to simply follow general procedures outlined in a book. The system must relate to the structure and nature of the business. The principles and practices outlined here can only be illustrative. You need to consider your own business and set up a system that suits its requirements.

Plan for compliance. For each stage in the manufacturing/import or wholesale purchasing process, you should identify the reasonable steps that you could take to verify compliance. These steps will form the basis of a control system.

Document it. Write down your control system so that others in your business can follow it. Unless you do so, it will be difficult to show to enforcement authorities or the courts the steps that you have taken. Staff responsible for the following the system should be properly trained and updated in the operation of the system.

Maintain the system. In order to demonstrate 'due diligence', you will need to show that the control system actually operates in practice. There will need to be a system of checks to confirm that it is being followed.

Review the system. Your system should also be regularly reviewed to ensure that it remains effective. As part of this you should put in place an errata system to detail how any non-compliance discovered is corrected. No system will be 100% foolproof. The important point is to show that failures have been acted upon to prevent similar occurrences.

12. Home Authority Advice

Local Authority enforcement will be based around the LACOTS Home Authority principle. The principle is designed to promote good practice and thereby protect the consumer and encourage fair-trading, consistency and common sense. In practice it means that the home authority (usually the one covering the area where the headquarters of a business is based) will aim to:

- place special emphasis on goods and services originating within the area;
- provide businesses with a single source of guidance and advice on compliance matters including 'due diligence'. Guidance given to a business by their home authority will generally be recognised by all authorities;
- liaise closely with other local trading standards authorities; and
- support a system for the resolution of problems and disputes.

13. Testing

It is advisable that an appropriately accredited testing house should carry out tests. Some organisations may have their own testing facilities and may be happy to rely on their own testing. However, it is advisable that an accredited testing house periodically checks in-house measurements.

14. Stock

Non-compliant stock placed on the market between 20 January 2000 and 20 July 2000 can be sold to the consumer by the wholesaler/retailer only until 20 July 2001.

For those businesses that carry stock, it is advisable to have it independently audited to verify the made up stock held, prior to the date of implementation of the Directive (20 January 2000). **Stock held before that date can be sold for an unlimited period to the consumer, provided that it does not contravene the General Products Safety Regulations 1994.**

From 20 July 2000, only compliant products can be placed on the market.

You may also hold stock which does not comply but which is for sale outside of the EU. It is essential to ensure that such stock is clearly identified.

15. Labelling

Labelling is not a requirement of the regulations. However, in order to advise consumers using products that are not suitable for use during the period of epithelization, traders are encouraged to label products accordingly.

16. Other Descriptions

Other descriptions such as 'nickel free', 'hypo-allergenic', 'nickel safe' etc are **not covered by the Regulations** and will continue to be covered by the Trade descriptions Act 1968. If you wish to use such descriptions, it is your responsibility to ensure that they are accurate and that you have sufficient evidence to substantiate these claims.

'Nickel free' is an absolute claim, the obvious message to the consumer is that any items so described:

- a) contain no nickel; and
- b) will therefore not promote a nickel allergic reaction.

Its use, under the Trade Descriptions Act, is only possible if nickel is present at concentrations that will not be material. What is material is a matter for the Courts to decide.

In doing so, evidence suggesting that a nickel sensitive reaction is unlikely to occur at concentrations below 100 parts per million or 0.01% by mass is likely to be influential.

'Final Consumer' is understood to be the Consumer or end user.

17. Further Information

If you have any further queries, you may contact the Jewellery Distributors Association or the British Jewellers' Association, who will give advice to members free of charge. Otherwise you may contact the DTI or your local Trading Standards office. (See Appendix 1 for addresses and telephone numbers).

The Nickel Development Institute (01527 584777) may be contacted for advice on release of nickel from nickel containing alloys.

The DTI will publish any revisions to the Regulations or supporting Test Standards as they occur.

19. Appendix 1

The Jewellery Distributors' Association
Federation House 10, Vyse Street,
Hockley
Birmingham B16 6LT
0121 237 1107
0121 236 3921 fax

The British Jewellers' Association
Federation House 10 Vyse Street,
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Birmingham
B16 6LT 0121 237 1112
0121 237 1113 fax

Department of Trade and Industry Consumer Safety Unit
Room 432
1 Victoria Street,
London
SW1 0ET
0207 215 0366
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