



8

Chemicals



## 8 CHEMICALS

Chemicals are controlled under CHIP, which is the short name for the Chemicals (Hazard Information and Packaging for Supply) Regulations. CHIP has been in place for a number of years and has been changed several times to keep up to date with developing science and technology.

The most recent version of CHIP is known as CHIP 4. This is the name for the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009 SR No.230, which came into operation on the 27th July 2009. CHIP implements the Dangerous Substances Directive (No 67/548/EEC) and Dangerous Preparations Directive (No 1999/45/EC) that are due to be replaced by the Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (Regulation (EC) No. 1272/2008) over a transitional period which adopts the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) system in the EU.

CHIP 4 does not introduce any new duties but consolidates previous amendments and ensures that UK law is consistent with the new EU Regulation during the transitional period. Suppliers can use either the CHIP or the CLP classification and labelling of chemicals during the transitional period.

### **Globally Harmonised System of Classification and Labelling of Chemicals (GHS)**

The United Nations (UN) created the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) which aims to have the same criteria for classifying chemicals worldwide according to their health, environmental, physical hazards and hazard communication requirements for labelling and safety data sheets. The GHS is not legally binding and each country has to introduce separate legislation to adopt it.

### **Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulations**

The EU has introduced the Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation ((EC) No 1272/2008) to adopt the GHS system in the EU. The CLP Regulation came into effect on 20 January 2009, subject to a transitional period and is directly-acting in all Member States. This will replace, gradually, the Dangerous Substances Directive, the Dangerous Preparations Directive and CHIP over a transitional period until 1 June 2015 when the CLP Regulation will be fully in force.

The transitional arrangements are:

## **Substances**

### **20 January 2009 to 1 December 2010**

Suppliers must classify substances according to CHIP and may continue to label and package them according to regulations 6 to 11 of CHIP. However, they may, as an alternative, choose to classify, label and package according to CLP. In this case, they must, in addition, continue to classify under regulation 4 of CHIP, but the requirements on labelling and packaging in regulations 6 to 11 of CHIP no longer apply.

### **1 December 2010 to 1 June 2015**

Suppliers must classify substances according to both CHIP and CLP. They must label and package according to CLP.

### **1 June 2015 onwards**

Suppliers must classify, label and package according to CLP.

## **Preparations (Mixtures)**

### **20 January 2009 to 1 June 2015**

Suppliers must classify preparations according to CHIP and may continue to label and package them according to regulations 6 to 11 of CHIP. However, they may, as an alternative, choose to classify, label and package according to CLP. In this case they must, in addition, continue to classify under regulation 4 of CHIP, but the requirements on labelling and packaging in regulations 6 to 11 of CHIP no longer apply.

### **1 June 2015 onwards**

Suppliers must classify, label and package according to CLP.

## **Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009 (CHIP)**

CHIP does not apply to certain chemicals, including those intended for use as medicinal / veterinary products, investigative medicinal products, controlled drugs, waste substances or preparations, to which the Pollution Prevention and Control Regulations 2003 consolidated version produced December 2009 apply, medicinal devices, food, animal feedingstuffs or radioactive substances or preparations. Neither does CHIP apply to any sample taken by an enforcement authority.

Due to the complexities of CHIP, totally comprehensive information cannot be provided. Those pharmacists involved in the supply, labelling or packaging of chemicals are advised to contact the HSENI. Published guidance on HSENI website [www.hseni.gov.uk](http://www.hseni.gov.uk). Additional information can be obtained from HSENI Tel 02890243249

The main objectives of CHIP are:-

- (a) the identification of harmful properties of chemicals (hazards) and the communication of this information to users by means of labels; and
- (b) to cover hazards to health, safety and the environment and use of chemicals both in the home and at work.

CHIP requires suppliers of dangerous substances and dangerous preparations to:-

- (a) identify the hazards (or dangers) of dangerous substances and dangerous preparations they supply (this process is called classification)
- (b) give information about those hazards to the persons they supply - both on the label and methods of marking; certain preparations have particular labelling requirements
- (c) package the substances safely, including appropriate child resistant closures, tactile warning devices and other consumer protection measures and
- (d) retain data pertaining to any dangerous preparation (this will not apply on or after June 2018)

These requirements are known as the supply requirements.

The transportation of chemicals is not the same as the supply. However, persons transporting chemicals by road or rail have similar duties placed on them.

These are known as the carriage requirements and are specified in The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010 SR No. 160. There are exemptions within these Regulations and they also permit the application of derogations and transitional provisions. See the publication "Carriage of Dangerous Goods – Approved Derogations and Transitional Provisions" available as a free download from HSENI website. ([http://www.hseni.gov.uk/cdg\\_approved\\_derogations\\_and\\_transitional\\_provisions\\_leaflet.pdf](http://www.hseni.gov.uk/cdg_approved_derogations_and_transitional_provisions_leaflet.pdf)). Further advice should be sought from HSENI.

## **8.1 SUPPLY REQUIREMENTS**

Classification of dangerous substances and dangerous preparations

The fundamental requirement of CHIP is to assess whether the particular chemical is hazardous (dangerous) or not. If it is, then it must be classified by precise identification of the hazard by assigning a category of danger (e.g., Toxic) and a description of the hazard by allocation of a risk phrase (e.g., Harmful in contact with skin).

The main categories of danger (these are further sub-divided as follows):-

- Substances and preparations dangerous because of their physico-chemical properties - explosive, oxidising, extremely flammable, highly flammable, flammable;
- Substances and preparations dangerous because of their health effects - very toxic, toxic, harmful, corrosive, irritant, sensitising, carcinogenic, mutagenic, toxic for reproduction;
- Substances and preparations dangerous to the environment

CHIP makes it an offence to supply a dangerous chemical before it is classified and it is important that this process is carried out correctly as failure to do so could lead to errors being made in the other requirements of CHIP (i.e., labelling, safety data sheet (SDS) preparation and packaging).

When chemicals are supplied to a pharmacy, they should already have been classified properly by your supplier. If this is the case, then the pharmacist could use this classification of supplies provided he is satisfied that it is correct and the competence of the supplier is known to him.

From 1 June 2015 all dangerous substances and preparations must be classified in accordance with the requirements of CLP Regulations. CHIP makes suppliers of chemicals responsible for the classification of a chemical right throughout its supply chain. Remember, a pharmacist will be the final supplier.

CHIP requires a supplier to exercise "all due diligence" in complying with its legal requirements. This means that if a pharmacist uses the classification assigned by the manufacturer or supplier higher up the supply chain, then he may wish to make appropriate enquiries about the classification to ensure accuracy. If suppliers are known to the pharmacist and there is confidence in their ability, then only simple checks may be necessary. Examples are: a common sense check, for an acid commonly known to cause burns not being classified corrosive and making enquiries with a supplier or from any people the pharmacist knows to be competent in this area.

### **Labels/Safety Data Sheets**

CHIP sets down requirements for the detail of information on the label of products to be provided to persons supplied with dangerous substances and preparations.

Safety Data Sheet (SDS) requirements are no longer part of CHIP. CHIP 4 refers to Annexe 31 of REACH (European Regulation (EC) No 1907 / 2006 on the Regulation, Evaluation, Authorisation and Restriction of Chemicals, which signposts the provisions for SDS. See "REACH and Safety Data Sheets" Leaflet January 2009

## Labelling

Details of information required to be on the label of products to be provided to persons supplied with dangerous substances and preparations are set out in CHIP. For domestic users, the CHIP label will contain all the information required to be given under CHIP.

Pharmacists are advised to supply dangerous substances and preparations in original packs, which should be labelled up to comply with the CHIP regulations. However, as the supplier of the product, you will still be responsible for the labelling and it is advisable to make "due diligence" checks. As a guide pharmacists are advised to check that the requirements of CHIP in relation to the labelling are present (see below) and a common sense check would also be beneficial. In cases where pharmacists are packing down preparations, these must be labelled to comply with CHIP.

Pharmacists regularly preparing their own label products may be interested in a database available from the Health and Safety Executive that can be used to generate labels.

CHIP specifies exactly what must appear on the label of a dangerous substance or preparation. This is potentially dependent on whether it is a substance (usually a single chemical) or preparation (in general terms, a mixture of substances) being labelled. It is also dependent on how it has been classified under CHIP.

The particulars required for labelling a dangerous substance supplied in a package are:

- (a) the name, full address and telephone number of a person in an EEA State who is responsible for supplying the substance, including the pharmacist, whether that person is its manufacturer, importer or distributor;
- (b) the name of the substance being:
  - (i) where the substance appears in Table 3.2 of part 3 of Annex VI of the CLP Regulation, the name or one of the names listed therein for that substance;
  - (ii) where the substance does not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation, an internationally recognised name; and
- (c) the following particulars ascertained in accordance with Part 1 of Schedule 4, namely
  - (i) any indication of danger together with corresponding symbols;
  - (ii) the risk phrases, set out in full; and
  - (iii) the safety phrases, set out in full; and
  - (iv) any EC number and, in the case of a substance which is listed in Table 3.2 of part 3 of Annex VI of the CLP Regulation, the words "EC label".

The particulars required for labelling a dangerous preparation supplied in a package are:

- (a) the name, full address and telephone number of a person in an EEA State who is responsible for supplying the substance, including the pharmacist, whether he be its manufacturer, importer or distributor;
- (b) the trade name or other designation of the preparation; and
- (c) the following particulars ascertained in accordance with Part 1 of Schedule 4, namely
  - (i) indication of the constituents of the preparation which result in its being classified as a dangerous preparation,
  - (ii) any indication of danger, together with corresponding symbols,
  - (iii) the risk phrases, set out in full; and
  - (iv) the safety phrases, set out in full; and
  - (v) in the case of a preparation intended for sale to the general public, the nominal quantity (nominal mass or nominal volume).

Indications such as "non-toxic", "non-harmful", "non-polluting", "ecological", or any other statement indicating that the dangerous substance or preparation is not dangerous or that it is likely to lead to underestimation of the danger of the dangerous substance or preparation must not appear on the package.

Where the package contains such small quantities of that substance or preparation that there is no foreseeable risk, under conditions of supply, use and disposal, arising from that hazardous property to persons handling that substance or preparation or to other persons, the packaging of a dangerous substance or preparation classified in one or more of the categories of danger, harmful, extremely flammable, highly flammable, flammable, irritant or oxidising are not required to be labelled in respect of that hazardous property.

Where the package in which a dangerous substance is supplied does not contain more than 125 millilitres of that substance the risk phrases and safety phrases do not have to be shown if the dangerous substance is classified only in one or more of these categories of danger:

- (i) highly flammable, flammable, oxidising, irritant; or
- (ii) harmful, provided the dangerous substance is not sold to the general public.

Where the package in which a dangerous preparation is supplied does not contain more than 125 millilitres of that substance the risk phrases and safety phrases do not have to be shown if the dangerous preparation is classified only in one or more of these categories of danger:

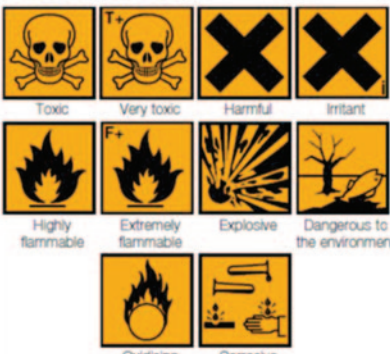
- (i) irritant (except those assigned the risk phrase R41);
- (ii) dangerous for the environment and assigned the N symbol;
- (iii) oxidising; or
- (iv) highly flammable.

The safety phrases do not have to be shown if the dangerous preparation is classified only in one or more of these categories of danger:

- (i) flammable; or
- (ii) dangerous for the environment and not assigned the N symbol.

**Safety data sheets**

**European symbols**



Products you use may be 'dangerous for supply'. If so, they will have a label that has one or more hazard symbols. S


These products include common substances in everyday use such as paint, bleach, solvent or fillers. When a product is 'dangerous for supply', by law, the supplier must provide you with a safety data sheet. Note: medicines, pesticides and cosmetic products have different legislation and don't have a safety data sheet. Ask the supplier how the product can be used safely.

Safety data sheets can be hard to understand, with little information on measures for control. However, to find out about health risks and emergency situations, concentrate on:

- Part 15 of the sheet, which tells you what the dangers are;
- Parts 4 to 8, which tell you about emergencies, storage and handling.

International symbols will replace the European symbols in 2009. Some of them are similar to the European symbols but there is no single word describing the hazard. Read the hazard statement on the packaging and the safety data sheet from the supplier.

**New International symbols**



*Examples of symbols taken from HSE Guidance Note: Working with substances hazardous to health.*

### Dangerous preparations to be supplied to the general public

The label on the packaging of dangerous preparations intended to be supplied to the general public must, in addition to the relevant safety advice, bear the relevant safety phrase S1 (Keep locked up), S2 (Keep out of reach of children), S45 (In case of accident or if you feel unwell seek medical advice immediately (show the label where possible) or S46 (If swallowed, seek medical advice immediately and show the container or label), in accordance with the approved classification and labelling guide.

When the dangerous preparations are classified as very toxic, toxic or corrosive and where it is physically impossible to give the information on the package itself, packages containing such preparations must be accompanied by precise and easily understandable instructions for use including, where appropriate, instructions for the destruction of the empty package.

Pharmacists involved in preparing labels for dangerous substances and dangerous preparations should refer to CHIP and HSE guidance and also Table 3.2 in Annex VI of the CLP Regulation.

## Packaging

It is an offence to supply a dangerous chemical unless it is in a suitable package. The packaging and fastenings should be strong and solid throughout to ensure they will not loosen when subjected to the stresses and strains of normal handling. The container must not be adversely affected by the chemical or react with the chemical to form other dangerous chemicals. Where the package is fitted with a replaceable closure, its integrity must remain with repeated use. Except where a special safety device has been fitted to make the receptacle closable, the package should be designed and constructed so that its contents cannot escape.

In addition, there is a requirement for packaging with a child resistant fastening (CRF) for certain chemicals that are sold to the public containing either:-

- (i) products classified as "toxic, very toxic or corrosive";
- (ii) methanol (3% or more by weight);
- (iii) dichloromethane (1% or more by weight); or
- (iv) substances which have been assigned the risk phrase (R65) in Table 3.2 of part 3 of Annex VI of the CLP Regulation, which states "Harmful: may cause lung damage if swallowed" (except where the chemical is supplied in an aerosol dispenser or a container fitted with a sealed spray attachment);
- (v) substances and preparations which are assigned the risk phrase (R65) and are classified and labelled according to the approved classification and labelling guide, except where such a substance or preparation is supplied in an aerosol dispenser or a container fitted with a sealed spray attachment.

CRFs are not required if it can be shown that a child cannot gain access to the chemical without the help of a tool.

Chemicals sold to the public that are labelled "very toxic, toxic, corrosive, harmful, extremely flammable or highly flammable" must also have a tactile danger warning (normally a small raised triangle) to alert the blind and partially sighted that they are handling a dangerous product. This does not apply to an aerosol dispenser which is classified and labelled only with the indication of danger "extremely flammable" or "highly flammable".

Pharmacists are advised to check that packaging complies with the above before supplying chemicals to the public.

The majority of sales of hazardous chemicals from pharmacies will probably require very little extra work by the pharmacist. It is important, however, to remember the need for due diligence and, when there is a legal obligation, to supply a safety data sheet (SDS).

When a substance or preparation has been classified, labelled and packaged in accordance with the CLP Regulation, the packaging of dangerous substances,

dangerous preparations and certain other preparations, labelling and child resistant fastening, tactile warning devices and other consumer protection measures as detailed above do not apply to that substance from 1 December 2010, or preparation from 1 June 2015.

## **Advertising**

The provisions for advertisements have been removed from CHIP and it is now the CLP Regulation which applies. The CLP Regulation requires all advertisements for a substance classified as hazardous to mention the hazard classes and hazard categories concerned. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) which allows a member of the public to conclude a contract to purchase a dangerous chemical before they have seen the label relating to that chemical (eg via mail order or the internet) must mention the type or types of hazard indicated on the label. The term "advertisement" does not include a price list and therefore this is unlikely to affect the majority of pharmacists.

## **Regulation, Evaluation, Authorisation and restriction of Chemicals (REACH)**

REACH is the European regulation on the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) Regulation ((EC) No 1907/2006) which came into effect on 1 June 2007. The regulations run in parallel to the European CLP regulations. They have direct legal impact within the EU, however, the enforcement is up to the individual Member State. The REACH Enforcement Regulations 2008 apply to the UK and provide for the enforcement of REACH.

REACH covers the registration, pre-registration, evaluation, authorisation, restrictions, classification and labelling and information provision of chemicals.

For further guidance pharmacists are advised to contact [www.hse.gov.uk/reach](http://www.hse.gov.uk/reach) or [ukreachca@hse.gsi.gov.uk](mailto:ukreachca@hse.gsi.gov.uk)

## **Substances of Very High Concern (SVHC)**

REACH contains a list of substances of very high concern, the registration and use of which is subject to further restrictions including authorisation and the provision of information.

SVHCs are substances which are classified as

- carcinogenic, mutagenic or toxic for reproduction (CMR) category 1 or 2;
- persistent, bio-accumulative and toxic (PBT);
- very persistent and very bio-accumulative (vPvB);

- substances not classified as above but where there is scientific evidence of probable serious effects to human health or the environment.

Substances meeting the above criteria may be placed on the Candidate List (published by ECHA) and the Annex XIV List. It is possible that some substances that meet the criteria will not appear on either list.

Pharmacists supplying any substance should check with the HSE whether it is a SVHC and for further guidance refer to [www.hse.gov.uk/reach/svhc.pdf](http://www.hse.gov.uk/reach/svhc.pdf)

### **Safety Data Sheets for substances and preparations (SDS)**

The rules relating to Safety Data Sheets (SDS) are now to be found in the REACH regulations. They were previously covered in the CHIP regulations.

The supplier of a substance or a preparation must provide the recipient with a SDS compiled in accordance with Annex 2 where the substance or preparation is:

- classified
- a PBT or a vPvB
- a SVHC or on the Candidate List; or
- hazardous as it contains at least one substance in an individual concentration less than or equal to: 1% by weight for non-gaseous preparations; 0.2% by volume for gaseous preparations; or less than or equal to: 0.1% by weight for non-gaseous preparations which is a PBT or vPvB in accordance with specified criteria; or
- there are workplace exposure criteria.

A SDS does not need to be provided where dangerous substances or preparations are sold to the general public where sufficient information is given to enable the user to take measures which are necessary for the protection of health and safety and the environment, unless requested by a downstream user or distributor.

The headings under which information must be provided are listed below together with a general description of the information which may be found under each heading. These descriptions are not all encompassing. For further information please contact the HSE.

#### **(1) Identification of the substance/preparation and company/undertaking**

The name of the substance/preparation should be identical to the name used on the label. It should indicate the intended or recommended use of the substance/preparation. The name, full address and telephone number and e-mail address of the competent person responsible for the SDS. Where this person is not in the Member State where the substance or preparation is placed on the market, the full address and telephone number for the person

responsible in that Member State. An emergency telephone of the company and/or relevant advisory body should be added if access to advice in the event of an emergency is not available on the number already given and specify if the phone number is available only during office hours.

**(2) Hazards identification**

The classification of the substance or preparation under the classification rules should be given here. The most important hazards of the substance or preparation to man and the environment should be stated.

**(3) Composition/information on ingredients**

Sufficient information must be given to enable the recipient to readily identify the hazards of the components of the preparation. The hazards of the preparation itself are listed in (2) above.

**(4) First aid measures**

The information should state whether immediate medical attention or professional assistance by a doctor is needed or advisable. The information should be brief and easy to understand by the victim, bystanders and first aiders. Sub-headings should be given for different routes of exposure, e.g. skin and eye contact, inhalation or ingestion. If immediate medical attention or if a specific form of treatment is required, that should be stated.

**(5) Fire fighting measures**

Suitable extinguishing media should be stated, together with details of extinguishing media which are not safe to be used and details of special protective equipment for fire fighters. Exposure hazards arising from the substance or preparation, combustion products and resulting gases should be stated.

**(6) Accidental release measures**

Information should be provided on personal precautions, e.g., "removal of ignition sources", "provision for sufficient ventilation/respiratory protection", environmental precautions, e.g., "keep away from drains, surface and ground water and soil", and methods of clearing up, e.g., "use of absorbent material" "sand". Consideration should also be given to using statements such as "Never use with..." or "Neutralise with...".

**(7) Handling and storage**

This information relates to the protection of human health, safety and the environment and assist the employer in implementing suitable working procedures and organisational measures. Precautions necessary for safe handling, such as measures to prevent dust generation, fire etc. and conditions for storage, e.g., ventilation, temperature, light and humidity, should also be stated. For end products designed for specific use(s) recommendations must refer to the identified use, with reference to industry/sector specific guidance.

**(8) Exposure controls and personnel protection**

This should include the full range of precautionary measures to be taken during use to minimise worker and environmental exposure. It should specify

where necessary the type of equipment to afford suitable protection e.g., respiratory, eye, skin and hand protection.

**(9) Physical and chemical properties**

The following information should be provided:

- Appearance, e.g., white solid;
- odour, if perceptible, a brief description;
- pH; boiling point/melting range;
- flash point;
- flammability (solid, gas);
- explosive properties;
- oxidising properties;
- vapour pressure;
- relative density;
- solubility (water or fat);
- partition coefficient;
- viscosity;
- vapour density;
- evaporation rate;
- other important safety parameters of the product.

**(10) Stability and reactivity**

State the stability of the substance or preparation and the possibility of hazardous reactions occurring under certain conditions of use and also if released into the environment, i.e., conditions to avoid (temperature, pressure, shock, etc.); materials to avoid (water, air, etc.); hazardous materials produced in dangerous amounts on decomposition, addressing specifically the need for and the presence of stabilisers; possibility of a hazardous exothermic reaction; safety significance, if any, of a change in physical appearance of the substance or preparation, hazardous decomposition products, if any, formed upon contact with water and the possibility of degradation to unstable products.

**(11) Toxicological information**

Provide a concise but complete and comprehensive description of the toxicological effects resulting from contact with the substance or preparation. Known delayed and immediate and chronic effects from short and long term exposure should be stated. Information on different routes of exposure and a description of the symptoms related to the physical, chemical and toxicological characteristics should be given.

**(12) Ecological information**

An assessment should be given of the possible effects on the environment in relation to such factors as ecotoxicity, mobility, persistence and degradability, bioaccumulative potential, results of a persistent, bioaccumulative and toxic assessment (BPT) and any other adverse effects.

### **(13) Disposal consideration**

Information should be provided on the dangers associated with disposal. Safety and appropriate methods of disposal should be given together with references to appropriate legislation.

### **(14) Transport Information**

Details of special precautions relating to transport or conveyance, either within or outside premises.

### **(15) Regulatory information**

The health, safety and environmental information on the label as required by Regulation 9 of CHIP should be given. Reference to the Health and Safety at Work (Northern Ireland) Order 1978 and Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003 SR No. 34, Amendment SR No. 288 (COSHH) might also be made.

### **(16) Other information**

Advice on other information which "may be of importance for health and safety of the user and for protection of the environment, e.g., training advice, recommended restrictions on use, further information, i.e., written references and/ or technical contact point, sources of key data used to compile the safety data sheet. A list of the relevant R-phrases referred to under headings (2) and (3) above, the full text of which must be written out in full, must appear under this heading on the SDS. A revised SDS should clearly indicate the information which has been added, deleted or revised (unless this has been indicated elsewhere).

Pharmacists must be able to use the SDS provided by their supplier, who is responsible for the accuracy of the SDS. The pharmacist may wish to make the following 'due diligence' checks: that

- (i) all the safety headings (as detailed above) are present;
- (ii) the SDS is comparable with those for similar products;
- (iii) the sections dealing with safe use/storage, etc, are adequate for the intended application of the pharmacy's customers; and
- (iv) the SDS covers foreseeable eventualities.

### **Substances restricted to professional users**

Certain substances specified in Annex XVII of REACH, in addition to the classification packaging and labelling requirements of dangerous substances and preparations must contain the safety labelling phrase, legible and indelibly marked 'Restricted to professional users'.

The substances to which this restriction applies are those classified as 'carcinogenic', 'mutagenic' or 'toxic to reproduction' and are listed as category 1 or 2. These products are not usually sold through pharmacies and pharmacists should therefore not supply such products for use by the general public.

A SDS and any updated version should be provided free of charge on paper or electronically and be dated, in an official language of the Member State where the substance or preparation is placed on the market. The suppliers must update the SDS as soon as new information on risks and hazards becomes available or there are changes to the authorisation or restrictions imposed. The new, dated version of the information, identified as "Revision: (date)", including the registration number, must be supplied to all persons who have received the substance or preparation within the preceding 12 months. For this reason it would be wise to keep a record of sales of such products.

### **Chloroform and certain other halogenated hydrocarbons**

Chloroform and certain other halogenated hydrocarbons (including carbon tetrachloride) are listed in Annex XVII of REACH, with specific restrictions on their use (and also in Schedule 2 COSHH). Chloroform and carbon tetrachloride must not be used in concentrations equal to or greater than 0.1% by weight, in substances and preparations placed on the market, for sale to the general public and / or in diffusive applications such as in surface cleaning and cleaning of fabrics. In addition to the classification, packaging and labelling requirements of dangerous substances and preparations containing them in concentrations equal to or greater than 0.1% must be legible and indelibly marked with: "For use in industrial installations only". This does not, however, apply to medicinal, veterinary products or cosmetic products as defined in the Directives.

### **Some Relevant References**

- 1 Comprehensive information is available on the websites [www.opsi.gov.uk](http://www.opsi.gov.uk) and [www.hse.gov.uk](http://www.hse.gov.uk) This includes:-
  - The Chemicals (Hazard Information and Packaging for Supply Regulations (Northern Ireland) 2009 SR No. 238  
[www.opsi.gov.uk/sr/sr2009/nisr\\_20090238\\_en\\_1](http://www.opsi.gov.uk/sr/sr2009/nisr_20090238_en_1)
  - CHIP Approved Classification & Labelling Guide. Guidance on Regulations L131 (6th Edition) (Approved for use in NI with SR No. 238)  
[www.hse.gov.uk/pubns/books/l131.htm](http://www.hse.gov.uk/pubns/books/l131.htm)
  - CHIP The Compilation of Safety Data Sheets. Approved Code of Practice L130 (3rd Edition)  
[www.hse.gov.uk/pubns/books/l130.htm](http://www.hse.gov.uk/pubns/books/l130.htm)
  - "The Idiots Guide to CHIP (2002)" INDG350  
[www.hse.gov.uk/pubns/indg350.pdf](http://www.hse.gov.uk/pubns/indg350.pdf)
  - "Read the Label" INDG352  
[www.hse.gov.uk/pubns/indg362.pdf](http://www.hse.gov.uk/pubns/indg362.pdf)
- 2 Guidance on REACH is available on the following:-  
[www.hse.gov.uk/reach](http://www.hse.gov.uk/reach)  
[ukreachca@hse.gsi.gov.uk](mailto:ukreachca@hse.gsi.gov.uk)

## 8.2 CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH (COSHH)

The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003 SR No. 34 (made under The Health and Safety (NI) Order 1978) and as amended, including the Control of Substances Hazardous to Health (Amendment) Regulations (Northern Ireland) 2003 SR No 288 and 2005 SR No 165, "COSHH(NI)", imposes duties on employers to protect employees and other persons who may be exposed to substances hazardous to health. They also impose certain duties on employees concerning their own protection in the workplace.

REACH (the Registration, Evaluation, Authorisation and restriction of Chemicals) will operate alongside COSHH to enable better information on hazards and safe use of chemicals to be passed down the supply chain by chemical manufacturers and importers through improved safety data sheets (SDS).

The COSHH Regulations apply to any place of work including:

- Hospital or community pharmacies
- Pharmaceutical laboratories
- Administrative offices

They cover virtually any substance but are particularly relevant to chemicals, harmful micro-organisms, pesticides and some medicines. The medicines dispensed in a pharmacy are potent chemicals but generally are not harmful to the people in the workplace unless hazards arise in handling (e.g. skin reactions), or in the extemporaneous preparation of products.

'Substances hazardous to health' are those defined in the CHIP Regulations 2009 SR No. 238.

The Regulations require employers to:

- Assess the risk to health from the way a particular substance is used in their own individual workplace and decide on the precautions needed.
- Introduce measures to control the risk to health and to protect people exposed to hazardous substances.
- Ensure that control measures are used, that equipment provided is used correctly and is properly maintained and that procedures are followed.
- Monitor, if necessary, the exposure of workers to hazardous substances and to carry out appropriate health surveillance.
- Inform, instruct and train employees about the risks and precautions that must be taken and prepare plans to deal with accidents, incidents and emergencies. Employees must be aware of labels, data sheets on safety, and instruction manuals available regarding the precautions to be taken when handling the substance.

Risk can be reduced by:

- avoiding use of the substance completely;
- using a safer substance;
- enclosing a particular process;
- extracting by-products;
- improving ventilation or hygiene facilities;
- the use of safer handling procedures;
- use of personal protective equipment (PPE) e.g. gloves, masks, and respirators.

### Some COSHH References

- 1 The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003 SR No. 34 [www.hseni.gov.uk](http://www.hseni.gov.uk)
- 2 Advice on specific procedures can be obtained from the Health and Safety Executive Northern Ireland, 83, Ladas Drive, Belfast BT6 9FR, Tel: 02890 243249, Fax: 02890 235383 and Helpline: 0800 032 0121. Useful information includes:
  - 'Legal Framework of Health and Safety at work in Northern Ireland' [www.hseni.gov.uk/legal\\_framework.pdf](http://www.hseni.gov.uk/legal_framework.pdf)
  - COSHH (NI): A brief guide to the Regulations [www.hseni.gov.uk/coshh\\_booklet.pdf](http://www.hseni.gov.uk/coshh_booklet.pdf)
  - Working with Substances Hazardous to Health - "What you need to know about COSHH" [www.hse.gov.uk/pbns/indg136.pdf](http://www.hse.gov.uk/pbns/indg136.pdf)
  - COSHH Essential Website ([www.coshh-essentials.org.uk](http://www.coshh-essentials.org.uk))
- 3 Additional information and guidance on COSHH is available on [www.hse.gov.uk](http://www.hse.gov.uk) and [www.hseni.gov.uk](http://www.hseni.gov.uk)

## 8.3 BIOCIDES - CITRONELLA OIL AND EUCALYPTUS OIL

Biocidal products are used to control unwanted organisms, such as animals, insects, bacteria, viruses and fungi. They are intended to kill or otherwise exert a controlling effect by chemical or biological means.

Biocidal products are regulated across Europe under the Biocidal Products Directive (BPD)(98/8/EC). In Northern Ireland control of these products is by the Biocidal Products Regulations (Northern Ireland) 2001 SR No 422, as amended by the Biocidal Products (Amendment) Regulations (Northern Ireland) 2010 which came into operation on 19 May 2010 SR No 163.

Citronella oil and Eucalyptus oil (among other active ingredients) have been "identified" under the EU Biocidal Products Directive above, which means that any biocidal products containing these two substances cannot be stored for any purpose (other than export and disposal) within the EU market effective from 1st September 2006.

The HSE website provides further information including a list of biocidal products currently approved under the Control of Pesticides Regulations which are affected by the Biocidal Products Directive 1st September 2006 deadline. Pharmacists are advised to check the list and remove any biocidal products containing citronella oil or eucalyptus oil from sale (<http://www.hse.gov.uk/biocides/liveissues/listbpappcopr.pdf>). Pharmacists should contact the supplier of biocidal products for further advice on affected products.

## **8.4 WASTE MANAGEMENT**

There is considerable legislation and guidance in relation to waste management. The Hazardous Waste Regulations (Northern Ireland) 2005 (SR No 300) and the List of Waste Regulations (Northern Ireland) 2005 (SR No 289) came into force in July 2005 and replaced the Special Waste Regulations (Northern Ireland) 1998 (SR No 289).

The legislation in relation to management of waste is very broad and applies to many different kinds of waste products. The purpose of the legislation is to provide a more effective system of control over special waste from the time of its production to the time of its final destination for disposal or recovery. Waste holders have a duty of care in relation to waste.

Under previous legislation all waste prescription only medicines were classified as special waste but under new regulations only cytotoxic and cytostatic medications will be classified as hazardous waste.

The information in the legislation is both specific and complex and further information in respect of pharmaceuticals should be sought from the Department of the Environment for Northern Ireland and the NI Department of Health, Social Services and Public Safety.

Some sources of information:

[www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk) - including Health Technical Memorandum 07-01 The Safe Management of Healthcare Waste (Northern Ireland)

[www.ni-environment.gov.uk](http://www.ni-environment.gov.uk)

[www.rpsgb.org](http://www.rpsgb.org) - Guidance on Waste

[www.psn.org.uk](http://www.psn.org.uk) - PSNC Contract Workbook 2009-10 Appendix 7

Guidance on Pharmaceutical Waste