



A sector group of CEFIC

ECPI Guide to Classification and Labelling

This booklet provides additional information to the legal requirements of

1. The Dangerous Substances Directive

67/548/EEC (DSD) as amended and adapted to technical progress

2. The Dangerous Preparations Directive

88/379/EEC (DPD) as amended and adapted to technical progress

3. The Safety Data Sheet Directive

91/155/EEC as amended by 93/112/EEC

4. The EU Marketing and Use Directive

76/769/EEC as amended and adapted to technical progress

5. Control of Major-accident Hazards involving

Dangerous Substances Directive (96/82/EC)



Responsible Care® is the worldwide chemical industry's commitment to continual improvement in all aspects of Health, Safety and Environment performance and to openness in communication about its activities and achievements.

Through Responsible Care, ECPI member companies and partners continually improve their safe management of chemicals in a manner that is responsive to the public.

Classification and Labelling

Chemicals are fundamental to our everyday lives. Not only are they the basis for the fertilisers, pesticides and food additives that improve our nutrition and for the pharmaceuticals that benefit our health, they are also essential for the production of many of the man-made materials on which our standard of living now depends.

Through constant research, industry endeavours to ensure that the use of such chemicals in end-products does not adversely affect our health and safety or the environment. In the case of phthalate plasticisers, more than € 110 million has been spent on research during more than 40 years of safe production and use making phthalates one of the best evaluated groups of substances.

A significant part of this research addresses the intrinsic properties of chemicals, e.g. their possible adverse physical, health or environmental effects. The manufacture, transportation and use of chemicals in Europe is closely regulated at national and EU level and the volume of such regulation has increased rapidly in recent years. In 1967 the EU established a classification and labelling scheme for substances (DSD), which in 1988 was extended to preparations (DPD). Classification and Labelling is one component of the EU chemicals management and applies to existing and all new chemical substances and preparations.

The classification of substances is based on establishing the possible adverse effects of their intrinsic properties, their hazards – by the use of tests and evaluating the results of those tests against standards or criteria. It is only when the intrinsic properties meet the criteria that chemicals are deemed to be hazardous. The specific objective of this is to enable the establishment of any necessary protective measures required (e.g. safety gloves) during normal handling and use.

There are two basic concepts that need to be considered here, hazard and risk. Some relevant definitions from ISO 11014 are:

Harm: Physical injury and/or damage to health or property

Hazard: A potential source of harm

Risk: The probable rate of occurrence of a hazard causing harm; and the degree of severity of the harm

Safety: Freedom from unacceptable risk of harm

It is commonly accepted that $\text{Hazard} \times \text{Exposure} = \text{Risk}$.

In Europe, much, but not all the relevant legislation we face, is based on classification, which is hazard based.

One of the consequences of classification is labelling, which requires a pictorial representation of the main hazards of a chemical and a series of statements, inappropriately named 'Risk Phrases', stating its hazards. Both are designed to provide immediate information to users, in the same way that road signs are used to inform drivers of traffic hazards and regulations.

Risks are identified separately at different stages in the manufacturing and use life cycle according to numerous Directives and ultimately as part of the European Risk Assessment process. Here the focus is on the likelihood of coming into contact with the substance (exposure).

Classification has no effect on articles containing such substances and these do not have to be labelled.

The purpose of classification is to identify the hazardous intrinsic properties of substances. It is important to remember that hazard is different to risk.

A hazard does not necessarily put you at risk

Hazards and the risks associated with them are everywhere, but when known measures can be taken to minimise or eliminate risk. When we go up or down stairs it is possible that we might fall, but the likelihood is that we will not. Stairs are a hazard, the likelihood of injury is known as the risk. The latter is often expressed as a fraction like 1 in 100 or 1 in a million. Everything we do exposes us to hazards. However, it is HOW we do things that determines the risk.

It is also the case that some hazards are only significant if we do something in large amounts or for long periods of time. Drinking too much water can cause the brain to expand and kill you, but it is unlikely that many of us would ever drink the amount necessary over a short period of time. Smoking one cigarette in your life will not have much of an effect. Smoking 60 a day for 40 years will probably lead to developing some kind of respiratory problem, if not worse.

We often assume, quite wrongly, that natural products or processes are better for us than man-made ones. But standing in the sun for too long is much more harmful than listening to a mobile phone. And whilst you'd have to drink a vast amount for it to be a problem, a single cup of coffee contains more carcinogens than most of the synthetic substances we ever encounter.

In the United States Ethyl Alcohol is classified as a reproductive toxicant. Drinking wine or other alcoholic beverages may be beneficial in moderation, but if consumed to excess they can have adverse effects on health.

The first rule of toxicology is that all substances produce an effect, but it is the dose that decides whether the effects are adverse or beneficial.

The European Union's classification process

The European Union's classification and labelling process is designed to indicate the hazard of chemical substances, not the statistical risk they may pose through normal, or even extreme, use. The hazard's 'critical end-point' is determined from the effects obtained in high dose animal studies which are designed to give conservative results so as to afford protection to all sectors of the population, rather than an assessment of realistic exposure levels from everyday handling or use of the product.

Using this conservative methodology the European Chemicals Bureau has decided that DEHP and DBP should be classified as Category 2 reproductive toxicants. This means that 'based on clear evidence in animal studies', DEHP and DBP should be regarded 'as if they impaired fertility and/or caused developmental toxicity in humans'.

As part of its 'Responsible Care' programme, industry had already been classifying DEHP and DBP as Category 3 reproductive toxicants since 1994. The EU authorities have now chosen to interpret the available data more conservatively and classify it as Category 2.

A Category 2 product requires the display of a 'skull and crossbones' symbol, rather than the existing 'St. Andrew's Cross', upon the labels of vessels containing the substance. This merely reflects the more conservative interpretation of the data, not that the risk has changed.

Indeed, the substances are no more dangerous than previously, either in a preparation or as part of a finished article.

Under the Marketing and Use Directive, a Category 2 product is likely to be considered for restriction from sale to the general public unless a case is made that a specific use in a preparation is both necessary and safe. This will not affect DEHP because it only ever reaches consumers as a constituent of finished articles which do not require labelling. The industry's own regulatory practice has meant that most requirements with respect to workers handling the substances have already been met.

It is worth remembering that this hazard labelling is based upon tests that involve administering high doses of the substances to animals over prolonged periods.

Under conditions of normal handling and use human exposure never reaches these levels. Furthermore, ECPI doubts whether effects observed in rodents during these tests with phthalates would occur in primates and is currently trying to establish if this is the case.

It would not be the first time that such variation in mechanistic effects between species had been observed. Last year the World Health Organisation's International Agency for Research on Cancer downgraded DEHP from 'possibly carcinogenic to humans' to 'unclassifiable as to its carcinogenicity to humans', recognising that the mechanism causing cancer in rodents was not relevant to primates.

Classification of Di (2-ethylhexyl) phthalate (DEHP) and Di-n-butyl phthalate (DBP)

In May 2000 the Commission Classification and Labelling Working Group considered proposals submitted for the classification of DEHP and DBP.

The environmental hazard data for DEHP was considered by the appropriate EU Working Group who reached the conclusion that classification for environmental effects was not justified.

Separately it was also agreed that DEHP should not be classified as having the potential to cause cancer in line with the February 2000 decision of the World Health Organisation's International Agency for Research on Cancer (IARC).

However, the Working Group, in interpreting the available data, decided to classify DEHP as a Category 2 reproductive toxicant for both fertility and developmental effects.

Similarly, it also decided that DBP should be classified as a reproductive toxicant in Category 2 for developmental effects and Category 3 for fertility effects. DBP was also considered by the appropriate EU Working Group for its environmental effects and the conclusion was that it should be classified as dangerous for the environment.

The proposals were approved by the Technical Progress Committee (TPC) in January 2001 and by the European Commission in March 2001.

Please note:

A form of common confusion is that the same pictogram (the skull and crossbones) is used for substances that are classified for acute or chronic toxicity, as Very Toxic or Toxic as well as for those classified as Carcinogenic, Mutagenic or Toxic for Reproduction in Category 1 or 2. These are different effects and may attract different downstream consequences under other European Community legislation.

Your obligations

The EU Marketing and Use Directive 76/769/EEC when next amended is likely to specify that DBP and DEHP may not be sold as a substance or in a preparation to the general public and that they should be labelled 'restricted to professional users'.

Substances and preparations in Category 2 must carry the skull and crossbones label and relevant risk and safety phrases. However plasticised PVC as sold to the general public is an article and not subject to this requirement.

Producers of substances and preparations classified as hazardous are required to provide Safety Data Sheets to their customers.

Workplace Safety Requirements

For substances in categories 1, 2 and 3 the Chemical Agents At Work Directive 98/24/EC and Directive 92/85/EEC on the safety of pregnant, recently delivered and breast feeding women requires employers to carry out a risk assessment and identify such measures as personal protection and ventilation which may be required. If these measures are not adequate to ensure compliance with occupational limits, other measures such as changes to production procedures or even substitution have to be considered.

The necessary risk assessments should include the measurement of occupational exposure of workers to ensure they are working within given limits. More detailed guidance for carrying out such a risk assessment is contained in section II Article 4 of the Chemical Agents At Work Directive 98/24/EC.

Safety Data Sheets

Each person involved in handling dangerous substances or preparations should be provided with written instructions on the properties of the chemicals, including illustrations and pictograms.

These safety instructions, usually referred to as Safety Data Sheets (SDS), should be stored in a place easily accessible at the workplace. Your usual supplier will provide updated Safety Data Sheets when changes are necessary.

Implementation of the updated labelling

The new classification and labelling requirements for DEHP and DBP have to be incorporated within the legislation of Member States by July 30 2002. Under their commitment to Responsible Care® and with reference to Art. 6 of 67/548/EEC phthalate producers are taking the initiative to begin labelling earlier than this date. For practical reasons deliveries of DEHP and DBP will begin to carry the new labelling from August 1 2001.

Labelling

The label is the basic tool to keep the user informed on the classification and the most important safety precautions.

This requirement also applies to preparations* containing 0.5% or more of a substance classified as dangerous.

The label must be in the national, official language(s) and must conform to minimum size requirements:

- ▶ Containers of up to 3 litres – label must be at least 52x74mm
- ▶ More than three litres but less than 50 litres – at least 74x105mm
- ▶ More than 50 litres but less than 500 litres – at least 105x148mm
- ▶ More than 500 litres – at least 148x210mm

Each symbol must cover at least one-tenth the surface area of the label.

* One component, such as DEHP, is referred to as a substance whereas a mixture, composed of two or more substances, is called a preparation.

The label must carry the following information:

1. Trade name
2. The name, address and telephone number of the manufacturer, importer or distributor
3. The chemical name of the substance (in the case of a preparation, the chemical names of certain hazardous components in accordance with EU legislation)
4. Danger symbols (DEHP must carry the skull and crossbones, DBP must carry the skull and crossbones and the dead fish and tree symbol)
5. Risk Phrases (R-phrases):
DEHP: R60 (may impair fertility) and R61 (may cause harm to the unborn child)
DBP: R62 (possible risk of impaired fertility) and R61 (may cause harm to the unborn child) and R50 (very toxic to aquatic organisms)
6. Safety Phrases (S-phrases):
DEHP: S53 (Restricted to professional users – Attention - Avoid exposure – Obtain special instructions before use) and S45 (In case of accident or if you feel unwell seek medical advice immediately – show the label where possible);
DBP: S53, S45, and S61 (Avoid release to the environment. Refer to special instructions/safety data sheet).

DI (2-ETHYLHEXYL) PHTHALATE (DEHP)



May impair fertility

May cause harm to the unborn child

Restricted to professional users. Attention – Avoid exposure – Obtain special instructions before use

In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)

Bloggs Chemicals Ltd, Widget Road, London, United Kingdom

Telephone 0000 111 2222 Fax 0000 111 2223

An example of how the new labelling for DEHP may look. The exact layout and appearance may differ according to country and manufacturer but it must contain the basic information stipulated.

The Relevant Legislation

Dangerous Substances Directive (67/548/EEC)

The Council Directive on Dangerous Substances specifies the hazard classification, packaging and labelling requirements for dangerous substances supplied in the European Union. The technical content of the Directive is contained in a number of Annexes which are revised from time to time by means of Commission Directives known as Adaptations to Technical Progress.

Article 6 of 67/548/EEC requires all substances to be correctly classified on the basis of available data.

Dangerous Preparations Directive (88/379/EEC – being replaced by 1999/45/EC)

The Council Directive on Dangerous Preparations specifies the hazard classification, packaging and labelling requirements for chemical preparations (mixtures or solutions composed of two or more substances). When a dangerous substance is used as part of a preparation, the producer is required to determine or calculate the content and apply the correct classification and labelling.

Safety Data Sheet Directive (91/155/EEC) as amended by 93/112/EEC

The Commission Directive on Safety Data Sheets defines the EC system for provision of specific information relating to dangerous preparations and substances.

The EU Marketing and Use Directive – 76/769/EEC as adapted and amended

Directive 76/769/EEC on the marketing and use of dangerous substances establishes harmonised rules to remove obstacles to intra-EU trade arising from restrictions in Member States applying to dangerous sub-

stances, preparations and articles. It also establishes harmonised rules where there is a consensus that these are needed to protect human health, the environment and the interests of consumers.

Control of Major-accident Hazards involving Dangerous Substances Directive (96/82/EC)

The Council Directive on the control of major-accident hazards involving dangerous substances sets out the safety measures and reporting procedures which must be put in place when dangerous substances are stored or used at an establishment.

The Directive lists the categories of dangerous substances involved and the quantity of each which must be present to trigger various procedures. It should be emphasised that the categories relate to substances with acute hazards such as those classified as 'Very Toxic' and 'Toxic' but not those which are classified 'Carcinogenic, Mutagenic or Toxic for Reproduction Cat 1 and 2'.

Confusion arises because all these substances carry the same label - 'Toxic, skull and crossbones', but their classifications and associated Risk Phrases are very different. Thus the Directive does not apply to DEHP.

Substances classified as 'Dangerous for the Environment' – the dead fish and tree symbol (N) together with the risk phrases R50 or R51 and R53, are subject to the Directive. DBP is classified as N, R50 and is therefore subject to the Directive with the following qualifying quantities:

- ▶ 200 te for Articles 6 and 7 – operator to notify competent authority and prepare a major- accident prevention policy.
- ▶ 500 te for Article 9 – operator to produce a regular safety report.

Users should also familiarise themselves with the following legislation which is applicable:

- ▶ The Pregnant Workers Directive (92/85/EEC)
- ▶ Protection of Young People at Work Directive (94/33/EC)
- ▶ Chemical Agents at Work Directive (98/24/EC)

- ▶ Control of Substances Hazardous to Health (COSHH) Guidance document
- ▶ Product Liability Directive (85/374/EEC)

Copies of the relevant legislation can be found on the web sites: www.dehp-facts.com and www.dbp-facts.com

Further Questions and Answers

Do I have to label the products I make?

There is no requirement to label articles such as flooring, cable, PVC sheet etc.

However, if you supply DEHP or DBP or a preparation containing 0.5% or more of either substance to your customers, it will be classified and have to be labelled. If your preparation contains other components that are classified then you should take into account the appropriate legislation.

Clear definitions on what has to be labelled in your particular circumstances and in your market should be sought from your own legal advisors. However, it is our understanding that plastisols and powder blends will both have to be classified and labelled but that granules/chip compound may not have to be labelled if your product meets the exemptions allowed in the Annex VI guide. Nevertheless an SDS must still be supplied. For more information on exemptions please refer to the section towards the back of the Dangerous Substances Directive (67/548/EEC) headed alloys, preparations containing polymers, and preparations containing elastomers.

DBP is classified as a Category 3 substance for fertility and a Category 2 for developmental effects. What is the right labelling?

It has to carry the higher of the two classifications – therefore the skull and crossbones label. Additionally it must be labelled with both R-phrases.

DBP, or preparations containing 25% or more DBP, will additionally carry a fish and tree symbol reflecting its environmental hazard.

Will there be a difference in labelling with regards to the packaging used?

The skull and crossbones label will appear on drums and small containers. For road tankers there is no requirement to carry a label.

DEHP is not classified dangerous for transport and there is no need to carry any TREMCARDS. However suppliers usually give the SDS to their transport company so that the risks can be properly assessed when cleaning tankers.

For DBP some national legislation refers to EU classification so you should refer to local legislation as appropriate.

Further Questions and Answers

Is it safe to handle labelled substances?

The labelling indicates the hazard. Provided that the necessary precautions have been taken e.g. ventilation and personal protection for the workers, such substances can be handled safely.

When should I start looking for alternatives?

For substances in categories 1, 2 and 3 the Chemical Agents Directive 98/24/EC and Directive 92/85/EEC on the safety of pregnant, recently delivered and breast feeding women requires employers to carry out a risk assessment and identify such measures as personal protection and ventilation which may be required. If these measures are not adequate to ensure compliance with occupational limits, other measures such as changes to production procedures or even substitution have to be considered.

The necessary risk assessments should include the measurement of occupational exposure of workers to ensure they are working within given limits. More detailed guidance for carrying out such a risk assessment is contained in section II Article 4 of the Health and Safety of Workers Directive 98/24/EC.

What will the required occupational exposure levels be?

These vary from country to country so these should be checked with your local authorities.

Am I required to inform the unions of the change to classification?

This depends on the individual agreements that you have with your unions. However, as the classification and labelling primarily involves the safety of workers it would be our suggestion that you do so because you are anyway legally bound to inform your employees. You may wish to point out that to a very large extent the regulations only require you to do what has already been necessary whilst handling a Category 3 product.

For many users there may be no changes necessary because you are already using and handling other substances with a Category 2 classification.

Is there a central source of information to help me deal with questions from employees or with guidance on interpreting the relevant legislation?

Basic information relating to the classification and labelling of DEHP and DBP, including questions and answers to help you answer queries from employees and the relevant legislation listed on page 7 of this guide, is available on the respective web sites <http://www.dehp-facts.com> and <http://www.dbp-facts.com>

DEHP and DBP plasticisers of choice

Di(2-ethylhexyl) phthalate (DEHP), also known as di-octyl phthalate (DOP), accounts for 45% of all plasticiser usage in western Europe and as such is generally considered as the industry standard. The reason for this is that it is in the mid range of plasticiser properties. It is the phthalate ester of the alcohol 2-ethyl hexanol, which is normally manufactured by the dimerisation of butyraldehyde, the butyraldehyde itself being synthesised from propylene.

The widespread sales of DEHP plasticiser are a reflection of its all around plasticising performance and its provision of adequate properties for a great many cost-effective, general purpose products. It possesses reasonable plasticising efficiency, fusion rate and viscosity (of great importance for plastisol applications).

Di-n-butyl phthalate (DBP), also known as dibutyl phthalate, is a specialist plasticiser often used in combination with other high molecular phthalates.

DBP is used extensively in the adhesives industry to plasticise polyvinyl acetate (PVA) emulsions. The low viscosity and compatibility of DBP make it ideally suited for PVA-based adhesives for bonding cellulosic materials. Depending on the amount of plasticiser used, the handling and application properties of PVA adhesive can be varied greatly.

DBP is an excellent solvent for many oil-soluble dyes, insecticides, peroxides and other organic compounds. It is used as an antifoam agent and as a fibre lubricant in textile manufacturing.

DBP is also used in the coatings industry as a primary plasticiser-solvent for nitrocellulose lacquers. It contributes excellent flexibility at low temperatures and is especially desirable because of its broad compatibility with modifying resins.

FOR FURTHER INFORMATION:

Please refer to the web sites

<http://www.dehp-facts.com> and <http://www.dbp-facts.com>

Specific information relating to your local market can be obtained from your supplier but if you need general assistance, please contact the European Council for Plasticisers and Intermediates (ECPI).

Avenue E. Van Nieuwenhuyse 4, Box 1

B-1160 Brussels, Belgium

Telephone: 0032 2 676 7260

Fax: 0032 2 676 7216

e-mail: ccr@cefic.be



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This guide is intended only as a supplement to the relevant legislation.

Whereas it is based on our best understanding of the requirements, users should check the relevant directives and seek legal advice as necessary.