

HSE INFORMATION SHEET

Chemical manufacture, import and supply: classification, labelling and packaging

European Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures – the ‘CLP Regulation’

Summary – the new CLP Regulation will mean a few changes for chemical suppliers, especially those who manufacture, import and formulate chemicals. Chemical users will see new designs, wording and symbols on product hazard labels. Where chemical suppliers have been fully compliant with the CHIP regulations, the CLP Regulation should present an evolutionary step in classification and labelling, and migration to the new system should not be too arduous, although change will be necessary.

This sheet should be read in partnership with the **CHIP Information Sheet**.

New European Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures – the ‘CLP Regulation’

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New European Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures – the ‘CLP Regulation’

Section 1.

Purpose of the CLP Regulation

1. The European Regulation (EC) No: 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation), is a new directly-acting Regulation which is replacing the existing European legislation on chemical classification, labelling and packaging – the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (99/45/EC). Both directives are implemented in Great Britain by the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 – CHIP¹ (4th consolidated version).
2. The Regulation came into force across all European Union (EU) Member States on 20 January 2009.
3. The CLP Regulation adopts, throughout the EU, the UN Globally Harmonised System on classification and labelling of chemicals. The GHS, as it is known, is an international voluntary agreement which seeks to establish a single chemical classification and labelling system across the world.
4. CLP applies to chemicals that are **placed on the (EU) market**. ‘Placed on the market’ means supplying or making available, whether in return for payment or free of charge, to a third party. In CLP, ‘import’ is also deemed to be placing on the market.
5. Like CHIP, CLP does not apply to certain specialised chemicals such as medicines and cosmetics. These and other exceptions are described in Article 1 of the CLP Regulation.
6. CLP applies to either a substance, a mixture (formerly a preparation) or both. Detailed definitions of these terms can be found in Article 2 of the Regulation itself or in Appendix 2 to this document.

Section 2.

Background – the UN Globally Harmonised System on classification and labelling of chemicals (GHS)

7. The GHS has its background in the World Summits of 1992 and 2002, when countries from across the world agreed to work together with industry representatives and others to agree a classification and labelling system that

¹ Northern Ireland has its own regulations: Chemicals (Hazard Information and Packaging for Supply) (Northern Ireland) Regulations 2009

can be used world-wide. This followed increasing concern that the systems used throughout the world differed to such a wide degree that the level of protection for people and the environment was inconsistent, and that the differences created unnecessary barriers to international trade.

8. In response, the United Nations (UN) agreed to establish such a system. The resulting GHS sets out internationally accepted definitions and criteria to identify the hazards of chemicals and to communicate those hazards via labels and safety data sheets.
9. As a voluntary international agreement, GHS is not legally binding. Therefore, countries or blocs of countries (i.e. the EU), have to adopt its criteria and terminology through national or regional legislation.
10. The EU has achieved this through the direct-acting CLP Regulation. Over a transitional period lasting until June 2015, the CLP Regulation will replace the existing European system on the classification, labelling and packaging of chemicals (see sections 7 and 8).

Section 3.

Key features of the CLP Regulation

11. The CLP Regulation:

- **entered into force in all EU Member States², including the UK, on 20 January 2009;**
- **is a direct-acting regulation** in all EU member states, including the UK. This means it does not require transposing into national legislation like a directive;
- **replaces the requirements of the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC)** relating to the classification, packaging and labelling of substances and preparations over a transitional period lasting until 2015;
- **introduces new GHS based terminology** for certain aspects of the classification and labelling system, e.g:
 - *hazard class* – means the nature of the physical, health or environmental hazard
 - *hazard category* – means the division of criteria within each hazard class, specifying hazard severity
 - *hazard pictogram* – replaces the hazard symbols with a new design and three new symbols
 - *signal word* – means a word that indicates the relative level of severity of hazards, e.g:
 - ‘Danger’ – used to indicate more severe hazard categories
 - ‘Warning’ – used to indicate less severe hazard categories
 - R-phrases become *hazard statements*;

² Including the non-EU countries of the European Economic Area (EEA) – Norway, Iceland and Liechtenstein

- S-phrases become *precautionary statements*
 - *Mixture/s* – replaces the word ‘preparation/s’
 - (see also Appendix 2)
- **identifies each specific ‘actor’ in the chemical supply chain** – *manufacturers, importers, downstream users* (a person other than the manufacturer or importer who uses a substance or mixture in the course of his industrial or professional activities), and *distributors*;
- **adopts the majority of the GHS hazard classes** (nature of the hazard) **and hazard categories** (severity of the hazard);
- **keeps a few aspects of the existing EU system**, where these do not contradict the GHS, to maintain existing EU standards (e.g. harmful to the ozone layer);
- introduces new provisions for a **Classification and Labelling Inventory** and the need to **notify** certain substances and substances in mixtures to the Inventory;
- **still provides a list of harmonised classifications** (now appear in Tables in Part 3 of Annex VI) (see sections 10, 11 and 12);
- **can be enforced** in Great Britain through the authority provided in Regulation 14 of the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 – CHIP.

12. Like CHIP, in CLP classification can be achieved through two routes:

- i. by applying the legally binding ‘harmonised’ substance classifications. These are agreed by national experts from all EU Member States, at EU level, (approximately 8000 substances have been assigned a harmonised classification); and
- ii. self-classification, meaning suppliers have to classify the substance or mixture (preparation) for themselves.

Section 4.

Important - European Chemicals Agency (ECHA)

13. Like the European REACH Regulation³, CLP is overseen by the European Chemicals Agency or ECHA⁴. ECHA is based in Helsinki.

14. The mission of the European Chemicals Agency is to:

- manage all REACH and CLP tasks by carrying out or co-coordinating the necessary activities (ECHA manages the new CLP Classification and Labelling Inventory);
- ensure a consistent implementation at Community level;
- provide Member States and the European institutions with the best possible scientific advice on questions related to the safety and the socio-economic aspects of the use of chemicals.

³ ECHA's web pages on REACH: http://echa.europa.eu/reach_en.asp

⁴ ECHA's web site can be viewed here: http://echa.europa.eu/home_en.asp

Section 5.

Important - CLP Guidance and other compliance information

15. As the CLP Regulation is a direct-acting European regulation, guidance on its interpretation and application must be consistent across all Member States. ECHA has responsibility for the CLP Regulation, including the provision guidance. National Member State helpdesks are also available to duty-holders. Aside from some direction on HSE's CLP web pages⁵, there is no national guidance (GB or UK) on CLP.

16. The CLP Regulation itself, together with a range of guidance is available from ECHA. All Member States were able to contribute to and agree this guidance (see Appendix 1 for a list of web addresses).

17. The guidance includes:

- **Introductory Guidance on the CLP Regulation** – describes the basic obligations and procedures in the Regulation and who has responsibility for carrying them out.
- **Guidance on the application of the CLP criteria** – a more technical document designed for those who have responsibility for deciding on the actual chemical classifications. The guidance provides general principles of classification and labelling under the CLP Regulation as well as detailed guidance on the classification criteria for the classification and labelling of substances and mixtures.
- **Frequently Asked Questions (FAQs)** - the frequently asked questions have been agreed by and between the national CLP helpdesks, representatives of the European Commission and ECHA. They are one of the results of the cooperation of the national helpdesks in the context of Help Net. The FAQs try to provide practical and technical advice for the application of the rules of CLP. **Important** – the FAQs are updated every few months as more practical experience is obtained.
- **Practical Guide on Notification** – this is of particular importance as it provides an excellent summary of the new duty to notify substances to the Classification and Labelling Inventory.
- **Notification web-based tools** – ECHA manages the various web-based tools that are available for notification. There are two systems in use – REACH-IT and IUCLID 5. ECHA has provided lots of technical support in the form of FAQs and user manuals, although they can be lengthy and navigating around them is not always easy.

18. Questions about the CLP Regulation should be directed to the national CLP Helpdesk (shared with the REACH Competent Authority). But duty-holders should also be encouraged to look at the ECHA web site and ECHA's guidance publications.

19. The UK CLP Helpdesk address is: ukreachca@hse.gsi.gov.uk

⁵ HSE web site - CLP Regulation: <http://www.hse.gov.uk/ghs/eureg.htm>

20. The CLP Regulation is also supported by pages on the HSE web site. The web pages expand on the information provided in this circular and provide the necessary links to ECHA guidance⁶.

Section 6.

Transitional arrangements for the CLP Regulation and parallel running with CHIP

21. The CLP Regulation is already in force across the EU and will replace the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC), which CHIP implements, through a transitional period. The transitional period ran to **1 December 2010** (for substances) and continues until **1 June 2015** (for mixtures).
22. After 1 June 2015, chemical suppliers must comply only with the CLP Regulation.
23. For mixtures, chemical suppliers can apply the provisions of the CLP Regulation, as an alternative to CHIP, ahead of the mandatory compliance dates. But the suppliers will need to ensure that they continue to classify according to CHIP as required by the CLP Regulation's transitional arrangements.
24. Therefore, changes have been made to the CHIP regulations to align the national legislation with the changes brought in through the CLP Regulation's transitional arrangements.
25. The Tables below summarise the CLP transitional arrangements:

Substances

1st December 2010 – 1st June 2015	Suppliers must classify substances according to both CHIP and CLP. They must label and package according to CLP.
1st June 2015 onwards	Suppliers must classify, label and package according to CLP.

⁶ HSE web pages: CLP Regulation – <http://www.hse.gov.uk/ghs/eureg.htm>

Mixtures [formerly 'preparations']

20th January 2009 – 1 st 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 mixtures 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 will then no longer apply.
1 st June 2015 onwards	Suppliers must classify, label and package according to CLP.

Section 7.

Extension of the CLP transitional arrangements

26. There are certain limited circumstances where these transitional arrangements for substances and preparations can be extended. The **re-labelling** and **re-packaging** of substances and preparations which are labelled, packaged and *already* in the supply chain on the above dates, may be delayed until 1 December 2012 (for substances) and 1 June 2017 (for preparations).

27. Note – there are no extensions available for *re-classification* changes.

Section 8.

Consequential effect of the CLP Regulation on CHIP

28. Once the transitional period in the CLP Regulation comes to an end, from 1 June 2015, the Dangerous Substances Directive and the Dangerous Preparations Directive will be fully repealed and will no longer have any legal effect.

29. As a consequence, CHIP will also come to an end from 1 June 2015, **with the exception of the enforcement provisions in Regulation 14 which allow relevant enforcing authorities to continue to enforce the CLP Regulation** (as they currently do).

Section 9.

New hazard pictograms (symbols) in the CLP Regulation

30. The CLP hazard pictograms are very similar to the CHIP hazard symbols, just a slightly different shape and in different colours.




However, the CLP Regulation also introduces three entirely new hazard pictograms. These are:



The above pictogram reflects serious longer term health hazards such as carcinogenicity and respiratory sensitisation



The above pictogram refers to less serious health hazards such as skin

irritancy/sensitisation applies to many circumstances where the CHIP  symbol is applied



The above pictogram means 'Contains gas under pressure'

31. The wording on hazard labels should be in English when supplied in the UK market – both for professional and consumer use. Other languages, in addition to English, may also be used where the chemical is placed on the market in other EU countries.

Section 10.

Important – harmonised classifications under CLP and the withdrawal of HSE's Approved Supply List (ASL)

32. The HSE Approved Supply List (ASL) was published in Great Britain and reproduced the list of dangerous substances that had been assigned harmonised classifications and accompanying labelling requirements agreed by all EU Member States and which appeared in Annex I to the Dangerous Substances Directive (67/548/EEC).

33. On its entry into force on 20 January 2009, the CLP Regulation repealed in full Annex I of the Dangerous Substances Directive.
34. However, the CLP Regulation immediately re-enacted the detail of Annex I. The list of harmonised classifications can now be found in Table 3.2 in part 3 of Annex VI of CLP. These harmonised classifications and accompanying labelling requirements are legally binding on all chemical suppliers.
35. As a consequence, **the ASL is discontinued and should no longer be used.**
36. Annex VI of CLP reflects the latest set of agreed harmonised classifications as well as the latest revisions to existing entries.
37. The entries in Table 3.1 of Annex VI are expressed using the criteria and terminology set out in the CLP Regulation and should be used when applying the harmonised classifications under CLP. Table 3.1 to the CLP reproduces the same list of substances that appear in Table 3.2. The entries in Table 3.2 are expressed using the 'old' criteria and terminology set out in the Dangerous Substances Directive (i.e CHIP).
38. When the transitional period is over (from 1 June 2015), Table 3.2 will be repealed.
39. Annex VI is only available in electronic form. The legal text can be found in the European Commission's Official Journal⁷. However, readers may find it more accessible to use a searchable version on the web site of the European Commission's Joint Research Centre (formerly the European Chemicals Bureau).⁸
40. Annex VI can be searched by several different criteria – CAS number; EC number; index number; substance name. Until 1 June 2015, the substance search results will show both the Table 3.1 results together with the Table 3.2 results.

Section 11.

Important - New CLP harmonised classifications and ATPs

41. As with the existing system, newly agreed harmonised classifications and accompanying labelling requirements will be introduced through Adaptations to Technical Progress (ATPs). Like their parent Regulation, the ATPs will not require national transposition. Once adopted, the ATPs, published as European Commission Regulations, will become directly-acting on all Member States from the specified date.

⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF>

⁸ <http://ecb.jrc.ec.europa.eu/classification-labelling/>

42. The 1st ATP to the CLP Regulation was published on 5 September 2009. Its entries became legally binding in all Member States on 1 December 2010. The 1st ATP was published as Commission Regulation (EC) No 790/2009. It comprised all the detail originally agreed in the 30th and 31st ATPs to the Dangerous Substances Directive.

43. Both Tables 3.2 and 3.1 have been updated to reflect the 1st ATP. The Tables will continue to be updated as further ATPs are agreed.

Section 12.

Important - CLP Annex VI - Tables 3.2 and Table 3.1 – identified errors

44. When the European Commission transferred the entries from Annex I to Table 3.2 in the new Annex VI, a number of errors were made. As a result, some of the entries in Table 3.2, and the corresponding entry in Table 3.1, are incorrect.

45. Strictly speaking, the incorrect entries are legally binding until they are amended by an ATP. In the interim, where a duty-holder identifies an incorrect entry, they should be encouraged to use the correct classification and accompanying hazard label requirements.

Section 13.

Important – withdrawal of HSE Approved Code of Practice (ACoP) on the Compilation of Safety Data Sheets (3rd edition) (out of date)

46. The legal provisions relating to safety data sheets (SDS) now appear in Article 31 and Annex II of the European REACH Regulation. As a consequence, the ACoP on the *Compilation of Safety Data Sheets* is now out of date.

47. HSE will be consulting on its formal removal in 2011 now that ECHA and the European Commission have produced a revision of the supporting guidance on SDS in Annex II of REACH. Suppliers should be referred to the REACH Annex II guidance if help is needed.

48. It is recognised that the ACoP was considered very helpful to suppliers and some may still refer to it. However they should be reminded that it no longer has any legal standing in the interim period until it is formally withdrawn.

49. Questions about the compilation of SDS should be referred to the national REACH Competent Authority Helpdesk.⁹ For specific matters relating to the enforcement of REACH, the REACH compliance team should be contacted.¹⁰

⁹ ukreachca@hse.gsi.gov.uk

¹⁰ reachcompliance@hse.gsi.gov.uk

Section 14.

CLP Enforcement arrangements

50. Although the CLP Regulation is directly acting on all EU Member States, Article 43 requires Member States to put in place the necessary arrangements to enforce the Regulation.
51. In Great Britain, it was decided to extend the existing enforcement provisions in CHIP to include the CLP Regulation.
52. The enforcement arrangements for the CLP Regulation are therefore the same as for CHIP 4. CHIP regulation 14 sets out the powers to enforce the CLP Regulation. Enforcement action can be taken with immediate effect, where duty holders have decided to apply CLP rather than CHIP ahead of the mandatory compliance dates. The penalties and sanctions are also the same for proven breaches of the CLP Regulation as for CHIP (s33 of HSWA and Schedule 3A of the Health and Safety Offences Act 2008 refer).
53. Until 31 May 2015, Regulation 14 of CHIP 4 allows inspectors to continue to take relevant enforcement action where a duty-holder has applied the provisions of the CHIP regulations.

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Appendix 1

Guidance and other compliance information

Chemical manufacture, import and supply: classification, labelling and packaging

New European Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures – the ‘CLP Regulation’

European Chemicals Agency:

CLP Regulation – home page

http://echa.europa.eu/clp_en.asp

Introductory guidance

http://guidance.echa.europa.eu/docs/guidance_document/clp_introduutory_en.pdf

Guidance on the application of the CLP criteria

http://guidance.echa.europa.eu/docs/guidance_document/clp_en.pdf

Frequently asked questions

http://echa.europa.eu/clp/clp_help/clp_faq_en.asp

Practical Guide to notification

http://echa.europa.eu/doc/publications/practical_guides/pg_7_clp_notif_en.pdf

Notification on-line tools support guidance

http://echa.europa.eu/help/help_docs_en.asp

<http://iuclid.echa.europa.eu/index.php?fuseaction=home.documentation&type=public>

HSE web pages:

Globally Harmonised System (GHS) – home page

<http://www.hse.gov.uk/ghs/index.htm>

CLP Regulation – home page

<http://www.hse.gov.uk/ghs/eureg.htm>



Appendix 2

Chemical manufacture, import and supply: classification, labelling and packaging

New European Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures – the ‘CLP Regulation’

Dangerous Substances Directive/Dangerous Preparations Directive and the European CLP Regulation (No 1272/2008) – key terms compared*

<u>Terms used:</u>	<u>DSD/DPD:</u>	<u>CLP Regulation:</u>
Mixture/s	Term not used in DPD; identical to definition of ‘preparation’ in <i>DPD (DPD Article 2)</i>	This term means the same as “preparation” under DPD; Definition: “A mixture or solution composed of two or more substances” (<i>CLP Article 2(8)</i>). The CLP definition of a mixture differs slightly from that of the UN GHS which may well be applied outside of the EU
Preparation/s	Definition: “Mixtures or solutions composed of two or more substances” (<i>DPD Article 2</i>)	Term not used in CLP; identical to definition of ‘mixtures’ in CLP
Hazardous	Term not used in DSD or DPD	A substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in CLP Annex I, is hazardous (<i>CLP Article 3</i>)
Dangerous	Substances or mixtures fulfilling the criteria for the categories of danger set out in DSD, (<i>DSD Article 2(2)</i>)	Term not used in CLP; REACH and other Community acts will refer to explicit CLP classifications which reflect the previous scope of “dangerous”
Category of danger	The nature of a hazard (danger) of a substance or preparation	Term not used in CLP; REACH and other Community acts will refer to explicit CLP classifications which reflect the previous scope of “dangerous”
Hazard class / hazard category (CLP)	Term not used in DSD / DPD	The nature / severity of a physical, health or environmental hazard (<i>CLP Article 2(1) and 2(2)</i>)
Indication/s of danger	A short description of the hazard (danger) posed by a substance. For example, ‘Explosive’ or ‘Corrosive’	No equivalent under CLP
Danger symbol	Pictorial presentation of the danger posed by dangerous substances and mixtures (Annex II to DSD). For example, this symbol indicates	Term not used with the same meaning in CLP; instead, “pictogram” is used. Equivalent but not always identical to the pictograms used under CLP

	<p>an oxidising substance or preparation</p> 	<p>For example, this pictogram indicates an oxidising substance or mixture</p> 
	<p>Many CLP pictograms are similar but not identical to the symbols relating to certain categories of danger under DSD and DPD</p>	
<p>Pictogram (see Danger symbol")</p>	<p>Term not used in DSD; instead, "danger symbol" is used. Equivalent but not always identical to the danger symbols used under DSD and DPD</p>	<p>A graphical composition that includes a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information on the hazard concerned (<i>CLP Article 2(3)</i>)</p>
<p>Signal word</p>	<p>No equivalent in DSD or DPD</p>	<p>The words 'Danger' or 'Warning' are used to indicate the severity of the hazard (<i>CLP Article 2(4)</i>)</p>
<p>Risk phrase (R-phrase)</p>	<p>Indication of intrinsic hazards (<i>DSD Article 23, as set out in Annex III to DSD</i>)</p> <p>For example, R38: Irritating to the skin</p>	<p>Term not used in CLP; instead, "hazard statement" is used. Equivalent but not always identical to the hazard statements under CLP</p> <p>For example, H315: Causes skin irritation</p>
<p>Hazard statement</p>	<p>Term not used in DSD / DPD; instead, "risk phrase" is used. Equivalent but not always identical to the risk phrases used under DSD (<i>DSD Article 23, as set out in Annex III to DSD</i>)</p> <p>For example, R38: Irritating to the skin</p>	<p>Hazard statements describe the nature of the hazards of a substance or mixture, including, where appropriate, the degree of hazard (<i>CLP Article 2(5)</i>)</p> <p>For example, H315: Causes skin irritation</p>
<p>Safety phrase (S-phrase)</p>	<p>Phrases related to the safe use of the substance (<i>DSD Article 23, as set out in Annex IV to DSD</i>)</p> <p>For example, S2: Keep out of the reach of children</p>	<p>Term not used in CLP; instead, "precautionary statement" is used. Equivalent but not always identical to the precautionary statements used under CLP</p> <p>For example, P102</p>
<p>Precautionary statement</p>	<p>Term not used in DSD or DPD; instead, "safety phrase" is used. Equivalent but not always identical to the safety phrases under DSD (<i>DSD Article 10</i>)</p> <p>For example, S2: Keep out of the reach of children</p>	<p>A description of the measure or measures recommended to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use (<i>CLP Article 2(6)</i>)</p> <p>For example, P102: Keep out of reach of children</p>
<p>Supplier</p>	<p>Term used in DSD or DPD</p>	<p>Any manufacturer, importer, downstream user or distributor placing on the</p>

		market a substance, on its own or in a mixture, or a mixture (<i>CLP Article 2(26)</i>), see also section 2 of ECHA introductory guidance
Substance/s	Chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the mixtures and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (<i>DSD Article 2</i>)	A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any identified impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (<i>CLP Article 2(7)</i>)

*Extract from Section 6 of European Chemicals Agency (ECHA) Guidance: Basic guidance to Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures