

<b>List Name</b>
<b>EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Carcinogenicity</b>
<b>List ID:</b>
3218
<b>ListCategory 1:</b>
European Union Legislation
<b>ListCategory 2:</b>
Classification and Labelling
<b>Region:</b>
Europe
<b>Source Language:</b>
English
<b>Date Reviewed:</b>
11/5/2010
<b>Date Updated:</b>
9/17/2009
<b>Abstract:</b>
This list includes substances classified as carcinogens according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).
<b>Document Information:</b>
<p>Regulation (EC) No 1272/2008 on the classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1995/45/EC, and amending Regulation (EC) No 1907/2006, commonly referred to as "the CLP", was adopted December 16, 2008 and published in the Official Journal on December 31, 2008. It entered into force twenty days following publication on January 20, 2009, installing a new classification and labelling system in the EU in line with the Globally Harmonised System (GHS) and republishing all of the "harmonised" classifications previously regulated as a part of the Dangerous Substances Directive (DSD, 67/548/EEC). The Regulation has been amended by Commission Regulation (EC) No 790/2009 of August 10, 2009 amending for the purposes of its adaption to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling, and packaging of substances and mixtures. The CLP requires the classification and labelling of substances and mixtures either placed on the market or subject to Registration or Notification requirements under REACH. Note that the "import" of a substance or mixture automatically constitutes "placing on the market." The CLP does not apply to the following: radioactive substances regulated under Council Directive 96/29/Euratom; substances and mixtures which are subject to customs supervision as long as they do not undergo any treatment or processing if they remain in temporary storage or in a free zone or free warehouse under the intent of re-exportation, non-isolated intermediates; and substances and mixtures for scientific research and development so long as they are not placed on the market if they are used under strictly controlled conditions in accordance with EC workplace and environmental legislation. Further, the regulation does not apply to waste; substances and mixtures identified by Member States as national defense exemptions; and substances and mixtures in the finished state intended for the final user for the following products: medicinal products as defined by Directive 2001/83/EC; veterinary medicinal products as defined by Directive 2001/82/EC; cosmetic products as defined by Directive 76/768/EEC; and medical devices as defined by Directives 90/385/EEC and 93/42/EEC which are invasive or used in direct physical contact with the human body, and by Directive 98/79/EC; food or feedingstuffs as defined by Regulation (EC) No 178/2002. The regulation also does not apply to the transport of dangerous goods by air, sea, road, rail or inland waterways. Essentially the intent of the CLP is to transition the current EU system for classification and labelling to the UN-sponsored Globally Harmonised System while facilitating REACH compliance (related Regulation (EC) No 1907/2006) and requiring the notification of classification and labelling to a central European regulatory authority, the European Chemicals Agency (ECHA), for all substances on the market in the EU. In order to make the transition as smooth as possible, the harmonized classification and labelling data published under the DSD have been reprinted as a part of the CLP in Table 3.2 of Annex VI. Table 3.1 of Annex VI to the CLP contains the same harmonized classification and labelling entries translated into the GHS. For ease of transition, the DSD classifications included in Annex VI include data only relevant through the 29th Adaptation to Technical Progress (ATP) to the DSD. According to the Commission, changes from the 30th and 31st ATPs will be published together as the 1st ATP to the CLP. Since the harmonized classifications in the DSD-format are now regulated under Table 3.2 to the CLP, please note that the classifications as published in the CLP are currently applicable in the EU. The Basics One of the most notable effects of the CLP is that it sets a timeline for the implementation of the GHS-</p>

style classifications in the EU in three phases: before December 1, 2010; between December 1, 2010 and June 1, 2015; and after June 1, 2015, as follows: Before December 1, 2010 - SUBSTANCES may have C&L in accordance with either the DSD or the DSD and the CLP From December 1, 2010 until June 1, 2015 - SUBSTANCES must have C&L in accordance with both the DSD and the CLP Before June 1, 2015 - MIXTURES (formerly called preparations) may have C&L in accordance with the Dangerous Preparations Directive (DPD) or the DPD and the CLP From June 1, 2015 - MIXTURES must have C&L in accordance with the CLP There are derogations to this timeline for substances and mixtures placed on the market before the December 1, 2010 and June 1, 2015 deadlines allowing the deadline to be extended two years before relabelling and repackaging would be necessary to December 1, 2012 for substances and June 1, 2017 for mixtures. Also, for substances and preparations classified before December 1, 2010 and June 1, 2015 in accordance with the DSD and DPD, conversions of the C&L into the GHS-style classifications using the conversion table in Annex VII is permitted. In addition to changing the entire classification and labelling system in the EU, the CLP takes over some of the provisions under REACH requiring the use and determination of harmonised C&L while also making the use of the harmonised classifications under the DSD mandatory. The ECHA will monitor the use of an agreement on harmonised classifications by a C&L notification requirement. Classification and Labelling Notification With the entry into force of the CLP, the requirement for the notification of classification and labelling has moved from REACH to the CLP. According to Article 40 of the CLP, the classification and labelling of substances subject to Registration under REACH and substances within the scope of the CLP that meet the criteria for classification as hazardous and are placed on the market must be notified to ECHA by the manufacturer or importer placing the substance on the market. This notification may also be completed by a "group" of manufacturers or importers. The notification of classification and labelling is intended to facilitate the creation of a classification and labelling inventory which will be publicly available on the ECHA website. The information to be notified and subsequently released by ECHA must include the following points: 1. The identity of the notifier(s) responsible for placing the substance or substances on the market as specified in Annex VI to REACH 2. The identity of the substance or substances as specified in section 2.1-2.3.4 in Annex VI to REACH 3. The classification of the substance or substances according to Article 13 of the CLP 4. An indication as to why the substance or substances has (have) not been classified in hazard classes and categories not mentioned in point 3 above. The following justifications are possible: lack of data; inconclusive data; or data which are conclusive although insufficient for classification 5. Specific concentration limits or m-factors where applicable along with an appropriate justification 6. The label elements specified in Article 17 (d,e,f) which include hazard pictograms, signal words and hazard statements. Supplemental hazard statements in accordance with Article 25(1) are also required. Please note that according to Article 41, where the notification results in different entries in the C&L Inventory, notifiers and registrants will be required to "make every effort" to reach an agreed entry. The CLP sets the deadline for notification of classification and labelling as December 1, 2010, coinciding with the effective date for the use of the new GHS-style classifications for substances and with the first Registration deadline under REACH. For substances placed on the market after December 1, 2010, the classification and labelling notification must be submitted to ECHA within one month of their placing on the market. Please note that the submission of a Registration dossier which includes the classification and labelling information constitutes having fulfilled the C&L Notification requirement. Understanding Table 3.1 Two important terms introduced by the CLP GHS-style classifications include "hazard class" and "hazard category." Hazard class refers to the nature of the hazard, e.g. "Hazardous to the Aquatic Environment", while hazard category refers to the severity of the hazard. For substances listed in Table 3.1 of Annex VI to the regulation, the nature and severity of the hazard are expressed in a single statement, e.g. Aquatic Acute 1. A full listing of hazard classes and categories is given in Table 1.1 in Part 1 of Annex VI to the regulation. Ordering of hazard classes and categories, as given by the Part 1 to Annex VI is as follows: Hazard Class Hazard Category Explosive Unst. Expl. Expl. 1.1 Expl. 1.2 Expl. 1.3 Expl. 1.4 Expl. 1.5 Expl. 1.6 Flammable gas Flam. Gas 1 Flam. Gas 2 Flammable aerosol Flam. Aerosol 1 Flam. Aerosol 2 Oxidizing gas Oxid. Gas 1 Gases under pressure Press. Gas Flammable liquid Flam. Liq. 1 Flam. Liq. 2 Flam. Liq. 3 Flammable solid Flam. Sol. 1 Flam. Sol. 2 Self-reactive substance or mixture Self-react. A Self-react. B Self-react. CD Self-react. EF Self-react. G Pyrophoric liquid Pyr. Liq. 1 Pyrophoric solid Pyr. Sol. 1 Self-heating substance or mixture Self-heat. 1 Self-heat. 2 Substance or mixture which in Water-react. 1 contact with water emits Water-react. 2 flammable gas Water-react. 3 Oxidising liquid Ox. Liq. 1 Ox. Liq. 2 Ox. Liq. 3 Oxidising solid Ox. Sol. 1 Ox. Sol. 2 Ox. Sol. 3 Organic peroxide Org. Perox. A Org. Perox. B Org. Perox. CD Org. Perox. EF Org. Perox. G Substance or mixture Met. Corr. 1 corrosive to metals Acute toxicity Acute Tox. 1 Acute Tox. 2 Acute Tox. 3 Acute Tox. 4 Skin corrosion/irritation Skin Corr. 1A Skin Corr. 1B Skin Corr. 1C Skin Irrit. 2 Serious eye damage/eye irritation Eye Dam. 1 Eye Irrit. 2 Respiratory/skin sensitization Resp. Sens. 1 Skin Sens. 1 Germ cell mutagenicity Muta. 1A Muta. 1B Muta. 2 Carcinogenicity Carc. 1A Carc. 1B Carc. 2 Reproductive toxicity Repr. 1A Repr. 1B Repr. 2 Lact. Specific target organ toxicity STOT Single 1 - single exposure STOT Single 2 STOT Single 3 Specific target organ toxicity STOT Rep. 1 - repeated exposure STOT Rep. 2 Aspiration hazard Asp. Tox. 1 Hazardous to the aquatic Aquatic Acute 1 environment Aquatic Chronic 1 Aquatic Chronic 2 Aquatic Chronic 3 Aquatic Chronic 4 Hazardous to the ozone layer Ozone Due to the very specific and complex nature of potential requirements related to labels and packaging, please refer to Titles III and IV and Annexes I and II to the regulation at the hyperlink above. Since this text is a Regulation at the EU level, it directly applies for all Member States without transposition. Enforcement, however, is still a Member State responsibility as each will have to appoint a competent authority. Also, until December 1, 2011, Member States may maintain any existing and more stringent C&L for substances listed in Annex VI to the CLP provided that they have followed through with notifying the Commission of the difference in the C&L before January 20, 2009 and that they have submitted a proposal for C&L to ECHA by June 1, 2009. Translation

tables to potential EU GHS classifications from the current classifications under Directives 67/548/EEC and 1999/45/EC are given in Annex VII to the regulation. A full list of hazard statements associated with the listed hazard codes is available in Annex III to the CLP. This LOLI list includes substances designated as meeting the criteria for Carcinogenicity according Table 3.1 in Annex VI to the regulation. Each substance is identified by CAS or RR Number and qualified by its hazard category and hazard statement code. A data key, or Index Number, is provided for sorting and identification purposes. The regulation cites several notes for substances in Annex VI that may have a drastic impact on classification and labelling. These notes are as follows: A: The name of the substance must appear on the label in the form of one of the designations given in Part 3 of Annex VI. In Part 3 of Annex VI, use is sometimes made of a general description such as "... compounds" or "... salts". In this case, the supplier is required to state on the label the correct name, due account being taken to Paragraph 1.1.1.4. B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 of Annex VI entries with Note B have a general designation of the following type: "nitric acid ...%". In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis. C: Some organic substances may be marketed either in a specific isomeric form or as a mixture of several isomers. In this case the supplier must state on the label whether the substance is a specific isomer or a mixture of isomers. D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3 of Annex VI. However, such substances are sometimes placed on the market in a nonstabilised form. In this case, the supplier must state on the label the name of the substance followed by the words "non-stabilised". E (Table 3.2): Substances with specific effects on human health (see Chapter 4 of Annex VI, Directive 67/548/EEC) that are classified as carcinogenic, mutagenic and/or toxic for reproduction in categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn). For these substances, the risk phrases R20, R21, R22, R23, R24, R25, R26, R27, R28, R39, R68 (harmful), R48 and R65 and all combinations of these risk phrases shall be preceded by the word "Also". F: This substance may contain a stabiliser. If the stabiliser changes the hazardous properties of the substance, as indicated by the classification in Part 3 of Annex VI, classification and labelling should be provided in accordance with the rules for classification and labelling of hazardous mixtures. G: This substance may be marketed in an explosive form in which case it must be evaluated using the appropriate test methods. The classification and labelling provided shall reflect the explosive properties. H (Table 3.1): The classification and labelling shown for this substance applies to the hazardous property(ies) indicated by the hazard statement(s) in combination with the hazard class(es) and category(ies) shown. The requirements of Article 4 for manufacturers, importers or downstream users of this substance apply to all other hazard classes and categories. For hazard classes where the route of exposure or the nature of the effects leads to a differentiation of the classification of the hazard class, the manufacturer, importer or downstream user is required to consider the routes of exposure or the nature of the effects not already considered. The final label shall follow the requirements of Section 1.2 of Annex I. H (Table 3.2): The classification and label shown for this substance applies to the dangerous property(ies) indicated by the risk phrase(s) in combination with the category(ies) of danger shown. The manufacturers, importers and downstream users of this substance shall be obliged to carry out an investigation to make themselves aware of the relevant and accessible data which exists for all other properties to classify and label the substance. The final label shall follow the requirements of section 7 of Annex VI of Directive 67/548/EEC. J: The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0.1% w/w benzene (Einecs No 200-753-7). This note applies only to certain complex coal- and oil-derived substances in Part 3 of Annex VI. K: The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0.1% w/w 1,3-butadiene (Einecs No 203-450-8). If the substance is not classified as a carcinogen or mutagen, at least the precautionary statements (102-)210-403 should apply. This note applies only to certain complex oil-derived substances in Part 3 of Annex VI. L: The classification as a carcinogen need not apply if it can be shown that the substance contains less than 3% DMSO extract as measured by IP 346 "Determination of polycyclic aromatics in unused lubricating base oils and asphaltene free petroleum fractions - Dimethyl sulphoxide extraction refractive index method", Institute of Petroleum, London. This note applies only to certain complex oil-derived substances in Part 3 of Annex VI. M: The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0.005% w/w benzo[a]pyrene (Einecs No 200-028-5). This note applies only to certain complex coal-derived substances in Part 3 of Annex VI. N: The classification as a carcinogen need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen. This note applies only to certain complex oil-derived substances in Part 3 of Annex VI. P: The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0.1% w/w benzene (Einecs No 200-753-7). When the substance is not classified as a carcinogen at least the precautionary statements (102-)260-262-301 + 310-331 (Table 3.1) or the S-phrases (2-)23-24-62 (Table 3.2) shall apply. This note applies only to certain complex oil-derived substances in Part 3 of Annex VI. Q: The classification as a carcinogen need not apply if it can be shown that the substance fulfils one of the following conditions: - a short term biopersistence test by inhalation has shown that the fibres longer than 20 micrometers have a weighted half-life less than 10 days, or - a short term biopersistence test by intratracheal instillation has shown that the fibres longer than 20 micrometers have a weighted half-life less than 40 days, or - an appropriate intra-peritoneal test has shown no evidence of excess carcinogenicity, or - absence of relevant pathogenicity or neoplastic changes in a suitable long term inhalation test. R: The classification as a carcinogen need not apply to fibres with a length weighted geometric mean diameter less two standard geometric errors greater than 6 micrometers. S (Table 3.1): This substance may not require a label according to

Article 17 (see Section 1.3 of Annex I). S (Table 3.2): This substance may not require a label according to Article 23 of Directive 67/548/EEC (see Section 8 of Annex VI of Directive 67/548/EEC). T: This substance may be marketed in a form which does not have the physical properties as indicated by the classification in the entry in Part 3 of Annex VI. If the results of the relevant method or methods in accordance with Regulation (EC) No 440/2008 show that the specific form of substance marketed does not exhibit this physical property or these physical properties, the substance shall be classified in accordance with the result or results of this test or these tests. Relevant information, including reference to the relevant test method(s)... shall be included in the safety data sheet. U (Table 3.1): When put onto the market gases have to be classified as "Gases under pressure", in one of the groups Compressed gas, Liquefied gas, Refrigerated gas or Dissolved gas. The group depends on the physical state in which the gas is packaged and therefore has to be assigned case-by-case. 1: The concentration stated or, in the absence of such concentrations, the generic concentrations of this Regulation (Table 3.1) or the generic concentrations of Directive 1999/45/EC (Table 3.2), are the percentages by weight of the metallic element calculated with reference to the total weight of the mixture. 2: The concentration of isocyanate stated is the percentage by weight of the free monomer calculated with reference to the total weight of the mixture. 3: The concentration stated is the percentage by weight of chromate ions dissolved in water calculated with reference to the total weight of the mixture. 5: The concentration limits for gaseous mixtures are expressed as volume per volume percentage. 7: Alloys containing nickel are classified for skin sensitization when the release rate of 0.5 micrograms of nickel per square centimeter per week, as measured by the European Standard reference test method EN 1811, is exceeded. A full list of hazard statements associated with the listed hazard codes is available in Annex III to the regulation. Hazard Statement Codes given in this LOLI List are as follows: H350 - May cause cancer [state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard]. H350i - May cause cancer by inhalation. H351 - Suspected of causing cancer [state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard]. Related LOLI Lists List ID 3178 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Acute Toxicity - Dermal List ID 3223 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Acute Toxicity - Inhalation List ID 3177 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Acute Toxicity - Oral List ID 3222 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Aspiration Hazard List ID 3625 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Explosive List ID 3612 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Flammable Aerosol List ID 3220 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Flammable Gas List ID 3194 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Flammable Liquid List ID 3195 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Flammable Solid List ID 3216 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Gases under Pressure List ID 3207 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Germ Cell Mutagenicity List ID 3613 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Hazardous for the Ozone Layer List ID 3219 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Hazardous to the Aquatic Environment List ID 3198 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Organic Peroxide List ID 3196 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Oxidising Gas List ID 3208 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Oxidising Liquid List ID 3190 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Oxidising Solid List ID 3186 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Pyrophoric Liquid List ID 3187 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Pyrophoric Solid List ID 3199 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Reproductive Toxicity List ID 3193 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Respiratory or Skin Sensitisation List ID 3622 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Self-Heating Substance or Mixture List ID 3197 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Self-Reactive Substance or Mixture List ID 3202 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Serious Eye Damage/Eye Irritation List ID 3189 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Skin Corrosion/Irritation List ID 3200 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Specific Target Organ Toxicity - Repeated Exposure List ID 3205 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Specific Target Organ Toxicity - Single Exposure List ID 3617 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Substance or Mixture Corrosive to Metals List ID 3188 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Classifications - Substance or Mixture which in Contact with Water Emits Flammable Gas List ID 3666 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Labelling List ID 3681 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - M-Factors List ID 3677 - EU - CLP (1272/2008) - Annex VI - Table 3.1 - Specific Concentration Limits

**Review Information:**

2007-4 - New. 2008-4 - Updated against September 3, 2008 source - Substances added; data changes to existing substances. 2009-2 - Updated against December 16, 2008 source - Data changes to existing substances. 2009-4 - Updated against August 10, 2009 source - Substances added/deleted; data changes to existing substances.

**Source Information:**

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 Published in the Official Journal of the European Union, December 31, 2008, L353 Amended by: Commission Regulation (EC) No 790/2009 of August 10, 2009 amending for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling, and packaging of substances and mixtures. Available online via Eur-lex, the European Union's

legislative database

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