

Classification of consumer products under the EU CLP Regulation: what to consider when caring for contact dermatitis patients

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Summary

Possibly hazardous chemical substances and mixtures need to be clearly and correctly classified and labelled, in order for their hazards to be properly identified and communicated. As dermatologists may encounter cases of harm to patients induced by chemicals, such as chemical burns, and irritant and allergic contact dermatitis, it is essential for them to be aware of the EU CLP Regulation and its potential pitfalls. Manufacturers are required by CLP to classify their products according to the rules given in the CLP Regulation. The enforcement duty lies with the Member States and their competent authorities. Dangerous non-food consumer products have to be reported to the European Commission to be entered into the Rapid Alert System for Dangerous Non-food Products (RAPEX) notifications. The sheer complexity of the CLP Regulation and lack of awareness of its ramifications by companies, competent authorities, consumer associations and the public at large may prevent efficient enforcement actions. When dermatologists become aware of inappropriately labelled chemicals, they should inform the competent authorities.

Key words: classification; CLP Regulation; corrosivity; irritancy; labelling and packaging of substances and mixtures; RAPEX; REACH; sensitization.

A paramount goal of the EU Member States has been to promote economic and social progress for their peoples (1). To achieve the desired economic effects, an internal market was created (2), allowing the free movement of goods, persons, services, and finances (3). However, the free movement of goods may be prohibited or restricted for the protection of health and life of humans, animals, or plants (4). Thus, the EU has the duty to safeguard the functioning of its internal market by the free movement of goods, while at the same time ensuring a high level of protection of human health and the environment. This applies in particular to chemicals that are essential for the functioning and growth of the EU economy, whose

sales in the EU amounted to €527 billion in 2013 (5), but exposure to which may also pose a risk to the health of consumers. In Germany, 207 000 human exposures to different noxious products were reported by poison centres, with chemical/physicochemical agents accounting for 26% (of these, cleaning and maintenance products accounted for 46%) and products of daily use accounting for 14% (of these, cosmetics accounted for 40%) (6). Thus, there is a need for intensified supervision of compliance and/or regulatory action by the EU and Member States to prevent human exposure to possibly dangerous chemicals.

Regulation of Chemicals in the EU Including the CLP Regulation

The regulation of chemicals in the EU has not been very systematic. A recent article mentioned 156 separate pieces of current EU legislation that concern the control and use of chemicals (7). However, the most important

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components of the current EU legislation on chemicals are the REACH Regulation and the CLP Regulation.

The REACH Regulation (8) entered into force on 1 June 2007, and introduced a new system for controlling chemicals across the EU. The CLP Regulation (9) amended the REACH Regulation, entered into force 20 January 2009, and repealed Directives 67/548/EEC and 1999/45/EC on 1 June 2015. It was intended to implement the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) developed within the United Nations, thus enabling a worldwide consistent system of chemical classification and labelling. With 426 915 words, it is a large piece of legislation, and this in itself may be a barrier to implementation by companies as dutyholders under the CLP Regulation.

As stated in its preamble, the aim of the CLP Regulation is twofold: first, to ensure a high level of protection of human health and the environment; and second, to ensure the free movement of chemical substances, mixtures and certain specific articles, while enhancing competitiveness and innovation.

The CLP Regulation consists of 62 articles, followed by seven annexes. Annex I contains the classification and labelling requirements for hazardous substances and mixtures, starting with general principles and then specifying classification requirements for physical hazards, health hazards, environmental hazards, and an additional EU hazard class (hazardous to the ozone layer). Annex II contains the special rules for labelling and packaging of certain substances and mixtures. Annex III contains the list of hazard statements, supplemental hazard information, and supplemental label elements. Annex V lists the hazard pictograms. Annex VI contains the harmonized classification and labelling for certain hazardous substances. Annex VII provides a table of translation from classification under Directive 67/548/EEC to classification under the CLP Regulation.

For substances and mixtures placed on the market, the classification requirements bind 'manufacturers, importers and downstream users' [Article 1 (b) (i)], whereas the labelling and packaging requirements bind 'suppliers' [Article 1 (b) (ii)]. Certain substances are exempt from the CLP Regulation, such as radioactives [Article 1 (2) (a)] and those falling under specific regulations, such as medicinal products, cosmetics, and foodstuffs [Article 1 (4)]. This leads to inconsistent labelling requirements for substances falling under specific regulations, e.g. cosmetics, medicaments, or medical devices, with the last of these frequently representing a black box regarding ingredients to be identified in the patch test clinics. With specific regulations not being consistently harmonized, the lack of a horizontal approach to

hazard identification and risk assessment at the European level may occur, as illustrated by the methylisothiazolone fiasco. Article 2 provides definitions of terms within the CLP Regulation. Articles 5 and 6 define the relevant available information for the purposes of determining whether a substance or a mixture poses a physical, health or environmental hazard. These information sources include data generated in accordance with methods defined in Article 8 (3), epidemiological and human data, any other information generated in accordance with section 1 of Annex XI to Regulation (EC) No. 1907/2006, any new scientific information (referring only to substances, and not to mixtures), and any other information generated under internationally recognized chemical programmes (Article 5 and Article 6). Evaluation of the above information may lead to a decision to classify substances and mixtures (Article 13). This classification has to be communicated in the form of labelling (Article 17 to Article 22), to include hazard pictograms (Article 19), signal words (Article 20), hazard statements (Article 21), and precautionary statements (Article 22).

The European Chemical Agency (ECHA) issued a 'Guidance on the Application of the CLP Criteria', to assist, primarily, manufacturers or importers in applying classification and labelling criteria (10), which itself comprises 662 pages. However, this document 'does not constitute legal advice', as stated in the Legal Notice; it is not legally binding, and will not assist those bound by the Regulation to classify products when challenged in courts.

The Concepts of Hazard, Risk, Hazard Identification, and Risk Characterization

In order to understand the CLP Regulation, an understanding of the terms 'hazard', 'risk', 'hazard identification' and 'risk characterization' is necessary. Chemicals that are potentially noxious to human health or the environment may constitute a hazard, but, for a risk to be present, exposure is necessary. Thus, risk is represented by the equation: $\text{risk} = \text{hazard} \times \text{exposure}$. Hazard identification refers to the identification of potentially noxious chemicals, for example by sensitization assays. Hazard characterization is the ranking of noxious properties in terms of potency. Risk characterization, then, refers not only to the potency of noxious properties, but especially to the modes and probabilities of exposure.

Classification and Misclassification of Chemicals According to the CLP Regulation

Classification of chemical substances and mixtures is performed according to specific classification criteria

(algorithmic approach). Provided that these criteria are fulfilled, the substance and mixture has to be classified into a specific category, with the resulting requirement to label it with a pictogram, a signal word, a hazard statement, and precautionary statements referring to prevention, response, storage, and disposal. Categories of special interest to dermatologists are skin corrosion (Hazard Statement H314: Causes severe skin burns and eye damage), skin irritation (Hazard Statement H315: Causes skin irritation), and skin sensitization (Hazard Statement H317: May cause an allergic skin reaction). These hazard statements are part of the GHS, and are intended to replace the well-known R-phrases.

For instance, a substance or mixture is categorized as 'skin corrosive' if it is a substance that, in an animal test, produces destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least 1 tested animal after exposure for up to 4 h (11). In contrast, a substance or mixture is categorized as 'skin irritant' if it produces reversible damage to the skin following application for up to 4 h. If neither event occurs, the substance or mixture is not classified. In practice, the classification procedure may be a rather complicated algorithm, as straightforward results of animal experiments are frequently not available, and tests on animals are discouraged by the CLP Regulation (12). Tests on non-human primates are explicitly prohibited for the purposes of the CLP Regulation.

Physicians, in particular dermatologists and occupational physicians, should take into account that misclassification may occur in two ways:

- A substance or mixture could be 'underclassified', that is, not classified if, in fact, it would need to be classified, or could be falsely classified in a lower category, if, in fact, it would need to be classified in a higher category.
- On the other hand, a substance or mixture could be 'overclassified', that is, classified if, in fact, it would need not to be classified, or falsely classified in a higher category, if, in fact, it would need to be classified in a lower category.

Both types of misclassification may be detrimental to the aims of consumer protection:

- An underclassification would falsely lead a consumer to underestimate the actual hazard of a substance or mixture, thus possibly leading to unprotected exposure with negative health effects.
- On the other hand, an overclassification, although possibly not leading to an unsafe exposure, might lead to unnecessary and costly prevention measures.

If exposure occurs with no resulting damage, this might lead to the false perception of consumers that the labelling and hazard statement may be disregarded, with a possible negative effect on preventive measures taken by consumers in handling chemicals for which protection against health-damaging effects is actually required.

- There may be inconsistent labelling, for example concerning household detergents. The fact that classification under the CLP Regulation is probably not applied consistently by manufacturers can easily be shown by examining household detergents in supermarkets for labelling and hazard statements. For example, for common dishwashing liquids, there may be comparable (and usually safe) products on the shelves that show no classification, others that may be classified as irritant, and some that may even be possibly classified as corrosive, depending on the classification method used by the manufacturer. This can hardly be explained by data underlying the classification procedure, but can be explained by different approaches used by manufacturers to follow the classification algorithm of the CLP Regulation. A uniform approach to CLP classification is still lacking. It could be achieved by initiatives of industry itself (13), but also by enforcement actions of Member States and, indirectly, by the courts, stimulated by consumers' or physicians' actions. Regarding detergents, it is of note that they fall under specific EU legislation [Regulation (EC) No. 648/2004 and Annex VII (EU Directive 907/2006)], whereas, according to Article 11 Regulation (EC) No. 648/2004, their safety labelling still falls under the CLP Regulation.

Enforcement of the CLP Regulation

Enforcement and reporting are dealt with in Article 46 of the CLP Regulation. Member States are required 'to take all necessary measures, including maintaining a system of official controls, to ensure that substances and mixtures are not placed on the market, unless they have been classified, labelled, notified and packaged in accordance with this Regulation' [Article 46 (1)], and they are required to report to the ECHA every 5 years on the results of the official controls [Article 46 (2)]. Practically, enforcement will depend on measures at the national level, which will need inspections and possible legal actions if acts of non-compliance by dutyholders under the CLP Regulation are detected (14). Member States shall introduce penalties for non-compliance with the CLP Regulation and shall take all measures necessary to ensure that the

CLP Regulation is applied (Article 47). The ECHA has set up an Enforcement Forum composed of representatives of the Member States and additional experts that 'coordinates a network of Member State authorities responsible for enforcement' (15).

Further enforcement may occur under the General Product Safety (GPS) Regulations 2005 (16), which requires that no producer shall place a product on the market unless the product is a safe product [Article 5 (1)]. In the context of the GPS Regulations, a 'safe product' is defined as 'a product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons'. Furthermore, under Article 7 (1) of the GPS Regulations, 'a producer shall provide consumers with the relevant information to enable them (i) to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and (ii) to take precautions against those risks'. Considering the classification and labelling of chemical substances and mixtures, the provision of misinformation to consumers by false classification and labelling might be an offence under Article 7 (1) of the GPS Regulations. Enforcement of the GPS Regulations is the duty of the enforcement authorities [(Article 10 (1)], namely, the local Trading Standards offices. Furthermore, the GPS Regulations provide for complaints procedures (Article 37), under which 'complaints may be submitted by any person on product safety and on surveillance and control activities, which complaints shall be followed up as appropriate'. This gives a right to consumers and dermatologists to report unsafe products in the market.

Non-conformity Reporting to the European Commission

Dangerous non-food consumer products have to be reported by the national authorities to the EU under Article 5 (3) of the GPS Regulations 2005 (16), where they are entered into the Rapid Alert System for Dangerous Non-food Products (RAPEX) notifications, and they are published regularly on the Commission website to inform the public (17). The information may also be derived from producers or distributors who organize recalls of the products that they have found to pose a risk to consumers' health. A search in the RAPEX system for 'CLP' and 'notifying country = any', 'product = chemical'

performed in March 2017 yielded 36 hits for the years since 2007, when the CLP Regulation entered into force. Brand, batch number, detailed kind of risk, measures taken by economic operators and measures ordered by public authorities are reported. For example, a cleaning product 'Power Kitchen cleaner product -Keukenreiniger extra krachtig' is reported from The Netherlands with the following detailed description: 'The product poses a chemical risk because it contains a basic solution with over 4% of sodium hydroxide – The product must therefore be classified as "Corrosive". There is no pictogram "C" on the label, and there is incorrect labelling of risk and safety warnings. The packaging has no child-resistant closure, and there is no tactile warning. There are no contact details of the supplier on the label. The product does not comply with the Regulation on the classification, labelling and packaging of substances and mixtures (CLP, EC No. 1272/2008) and also not with the Dangerous Preparations Directive (1999/45/EC).'

If dermatologists identify a dangerous product that is inadequately labelled, they should inform their national authority for evaluation and notification of the Commission to have it entered into the RAPEX database. However, considering that the national poison centre data range in the hundreds of thousands of reported events, the low number of reports in the RAPEX system may indicate considerable underreporting through this channel.

Shortcomings and Suggestions for Reform

Considering the complexity of the CLP Regulation, it may be assumed that both manufacturers and enforcing authorities may struggle to consistently comply with this legislation. This problem is increased by the delegation of the task of enforcing the CLP Regulation to Member States, who may perform this task in a non-uniform way.

Suggestions for reform will have to focus on a reduction in the complexity of the CLP Regulation, which would be the duty of the Commission, as it has to initiate and review secondary legislation under the Treaties.

The ECHA accumulates the expert knowledge to detect misclassifications; however, sufficient manpower is necessary at the national and European levels to actually screen products on the markets of the Member States and to inform Member States about findings of misclassifications, to strengthen their ability to take immediate enforcement action. As a second, more far-reaching reform, consideration could be given to partially transferring the duty to enforce the CLP Regulation from the Member States to a European Agency, in this case to the ECHA.

Finally, enforcement of the CLP Regulation may occur indirectly through actions taken by consumers against

Table 1. Contacts of the Member States' CLP-competent authorities and designated national authorities

Country	CLP-competent authority/authorities
Austria	Federal Ministry for Agriculture, Forestry, Environment and Water Management
Belgium	Federal Public Service – Health, Food Chain Safety and Environment
Bulgaria	Ministry of Environment and Water
Croatia	Ministry of Health
Cyprus	Ministry of Labour, Welfare and Social Insurance
Czech Republic	Ministry of Environment of the Czech Republic
Denmark	Danish Environmental Protection Agency
Estonia	Health Board
Finland	Finnish Safety and Chemicals Agency
France	Ministry of Environment, Energy and Marine Affairs Ministry of Employment
Germany	Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) Federal Institute for Occupational Safety and Health (BAuA), Federal Office for Chemicals/Authorization of Biocides Federal Ministry of Labour and Social Affairs (BMAS)
Greece	Ministry of Finance, General Chemical State Laboratory, Directorate of Energy, Industrial and Chemical Products
Hungary	National Public Health Centre
Iceland	The Environment Agency of Iceland
Ireland	Health and Safety Authority Department of Agriculture, Food and the Marine (DAFM) Pesticide Registration and Control Divisions
Italy	Ministry of Health of Italy
Latvia	Latvian Environment, Geology and Meteorology Centre
Liechtenstein	Office of Environmental Protection
Lithuania	Environmental Protection Agency
Luxembourg	Environment Protection Agency Ministry of Sustainable Development and Infrastructure
Malta	Malta Competition and Consumer Affairs Authority
The Netherlands	Ministry of Health, Welfare and Sport
Norway	Norwegian Environment Agency Norwegian Labour Inspection Authority Directorate for Civil Protection and Emergency Planning
Poland	Bureau for Chemical Substances
Portugal	Directorate-General of Health Portuguese Environment Agency Portuguese Agency for Competitiveness and Innovation
Romania	Ministry of Environment, Waters and Forests Ministry of Health National Environmental Protection Agency
Slovak Republic	Ministry of Economy of the Slovak Republic, Centre for Chemical Substances and Preparations
Slovenia	Chemicals Office of the Republic of Slovenia, Ministry of Health
Spain	Ministry of Health, Social Services and Equality Ministry of Agriculture, Food and Environment
Sweden	Swedish Chemicals Agency
United Kingdom	Health and Safety Executive

The information is based on the European Chemical Agency (ECHA) (<https://echa.europa.eu/de/contacts-of-the-member-state-competent-authorities>)

Table 2. The CLP Regulation: 'Learning points' for dermatologists

- The CLP Regulation requires manufacturers to classify chemical substances and mixtures placed on the EU market regarding physical, health or environmental hazards
- Suppliers are bound by labelling and packaging requirements
- Classified chemical substances and mixtures have to be labelled with a pictogram, a signal word, a hazard statement, and precautionary statements referring to prevention, response, storage, and disposal
- Categories of special interest to dermatologists are:
 - a. Skin corrosion (Hazard Statement H314: Causes severe skin burns and eye damage)
 - b. Skin irritation (Hazard Statement H315: Causes skin irritation)
 - c. Skin sensitization (Hazard Statement H317: May cause an allergic skin reaction)
- Misclassification may occur as 'overclassification' or 'underclassification'; in addition, mislabelling may occur
- Dermatologists identifying a dangerous product that is inadequately labelled should inform their national CLP-competent authority for evaluation and notification of the European Commission to have it entered into the RAPEX database (Rapid Alert System for Dangerous Non-food Products/RAPEX notifications)

manufacturers and distributors of dangerous products under the law of negligence and the EU consumer law (18), which makes manufacturers strictly liable for death, injury, loss or damage caused by defective products. This, however, requires awareness of consumers' rights derived from the CLP Regulation in making individual claims. Information should be provided by consumer associations, but also the national competent authorities.

A dermatologist encountering a product not complying with the CLP Regulation should proceed to inform the competent national authority in charge; this information may be transmitted in an informal letter, email, fax, or telephone call. A list of the national CLP-competent authorities is shown in Table 1.

Conclusion

The objective of the CLP Regulation is to ensure a classification of possibly hazardous chemical substances and mixtures, in order for their hazards to be properly identified and communicated, thus allowing consumers to take appropriate measures to protect themselves from the possibly damaging effects. Manufacturers are required by the CLP Regulation to classify their products according to the rules given in the CLP Regulation, aided by the ECHA Guidance. The duty of enforcing the CLP Regulation lies with the Member States. The fact that only a few cases of non-compliance with the CLP Regulation are being reported through the RAPEX system may either indicate a high compliance, or reflect a lack of inspections assessing not only classification and labelling as such, but also

their appropriateness, considering that the classification procedure is highly complex, requiring expert knowledge. In practice, enforcement actions by the competent authorities, but also claims under civil law by consumers, may be hindered by the lack of resources and manpower of the competent authorities, the sheer complexity of the CLP Regulation, and unawareness of the ramifications of the CLP Regulation by consumer associations and the public at large. From a dermatological point of view, suggestions for improvement therefore include strengthening of the manpower of national and European authorities so that they are able to closely monitor compliance with

the above-mentioned regulations, the dissemination of knowledge and information to dermatologists and consumers regarding their rights under the CLP Regulation, consideration of revision of the CLP Regulation to reduce its complexity, and improved enforcement by enabling the ECHA to play a greater role in the detection of cases of non-compliance. Dermatologists encountering products that do not comply with the CLP Regulation should inform the competent national authorities, so that the products can be entered into the RAPEX database of the European Commission. See Table 2 for 'learning points' for dermatologists.

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