POCKET GUIDE

FOR DOWNSTREAM USERS
AND DISTRIBUTORS OF CHEMICALS

REACH AND CLP ESSENTIALS

ChemSM-HUB

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Institut für Ökologie und Politik GmbH

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fundația ROMTENS

Lodz University of Technology

Nofer Institute of Occupational Medicine

ChemSM-HUB

Pocket Guide for Downstream Users and Distributors of Chemicals

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LEGAL NOTE

This document aims to assist users in complying with their obligations under the REACH* and CLP** Regulations. However, users are reminded that the text of the REACH and CLP Regulations are the only authentic legal references and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The ChemSM--HUB Team does not accept any liability with regard to the use that may be made of the information contained in this document.

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EC) No 1907/2006 of 18.12.2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC |and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).
Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1563452182503&uri=CELEX:02006R1907-20190107

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EC) No 1272/2008 of 16.12.2008 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 of 31.12. 2006 (OJ L 353, 31.12.2008, p. 1). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1563452427540&uri=CELEX:02008R1272-20181201

DISCLAIMER

The European Commission's support for the production of this publication does not constitute an endorsement of the contents, which reflect the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

PREFACE

The ChemSM-HUB pocket guide offered to you was created during the project Chemical Safety Management Training Hub for Chemicals Users, financed by the European Commission under the Erasmus+ program. The project is implemented by the Nofer Institute of Occupational Medicine, Lodz, Poland in cooperation with the Lodz University of Technology and other partners from Germany (OEKOPOL GMBH), Romania (ROMTENS FOUNDATION) and Greece (ASTIKI MIKERDOSKOPIKI ETAIREIA PROLEPSIS, Institute of Preventive Medicine, Environmental and Occupational Health) and is addressed to downstream users (DU) and distributors (D) of chemicals. This guide is a complementary part of the emerging chemical safety training package, which will be available free of charge on-line from the project website (ChemSM-Hub) starting in mid-2020. In addition, a mobile application for Android devices is being created, in which users will find the key terms, definitions and procedures of REACH and CLP Regulations.

NOFER INSTITUTE OF OCCUPATIONAL MEDICINE

Nofer Institute of Occupational Medicine in Lodz (NIOM) was founded in 1954. It is a scientific-research institution that deals, in general, with the issues of public and environmental health with special emphasis on subjects associated with broadly understood occupational medicine. The elementary task of the Institute is to perform scientific research as well as to conduct implementation and expertise works in the field of occupational and environmental health hazards and risks. In the realization of its tasks the Institute cooperates with universities, the Polish Academy of Sciences, research institutes and other scientific units, scientific and occupational associations, non-governmental organizations, healthcare units in the country as well as with equivalent organizations and institutions abroad.

http://www.imp.lodz.pl/home_en/

Lodz University of Technology

Lodz University of Technology (TUL) came into existence in 1945 as governmental, public body. More than 21000 students are currently studying at the University (including 800 PhD students). The educational and scientific tasks of the University are carried out by about 3,000 staff members. TUL is a leader in research on numerous areas of science and technology in Poland and abroad. A large number of the research concerns applications of the new IT technologies in the areas of biotechnology, electronics, telecommunication, computer science, materials engineering, technologies and nanotechnologies, medicine, environmental protection, biomedical engineering, textile engineering, etc. TUL cooperates with over 300 institutions in 40 countries. It takes part in EU Framework Programs (15 projects in FP5, 30 in FP6, 23 in FP7) and in Horizon 2020, Erasmus Mundus and Erasmus+

https://www.p.lodz.pl/en/

Ökopol
Institut für Ökologie und Politik GmbH

OEKOPOL GMBH (Institute für Ökologie und Politik) is a well-known environmental-focused consulting group based in Germany, active at the European level for over 25 years. Ökopol's experts work on a broad variety of environmentally relevant areas including chemicals' legislation, waste management and waste legislation, prevention and control of industrial installations and policies on environmentally sound products, in order to assist with conservation of resources and to limit the use of hazardous substances.

https://www.oekopol.de/en/

PARTNERS IN PROLEPSIS

Institute of Preventive Medicine, Environmental and Occupational Health, Greece, Prolepsis, a civil non for profit organization, was established in 1990 in Athens. With a strong belief in health being a fundamental right, Prolepsis has undertaken a leading role in the field of public health, by designing and implementing initiatives on various health issues and in different sectors (e.g. education, workplace) targeting a wide range of audiences, such as children and adolescents, women, migrants, and the elderly, and different types of occupational groups, such as health professionals, as well as policy makers, other NGOs and decision makers. As a coordinator or a partner Prolepsis has participated in approximately 50 EU co-funded and numerous national projects implementing research, applied and educational initiatives, aiming at health promotion and education of the public, policy change and tackling health inequalities.

http://www.prolepsis.gr/en/

fundatia ROMTENS

ROMTENS FOUNDATION is a non-governmental organization with more than 20 years' experience in Workplace Health Promotion. It is the first Romanian organization that organized such activities on national level and the only Romanian organization member of the European Network for Workplace Health Promotion. At the same time, in the last 10 years, we have gathered expertise – nationally and at the European level – regarding programs and projects evaluation & monitoring, having been evaluated more than 60 training courses (Kirkpatrick model) and over 100 informing and education campaigns, 10 websites, as well as research programs, public policies and organizations. In the last 18 years, Romtens organized accredited training courses for physicians, managers and employees for more than 4000 participants.

http://romtens.ro/en/

ACKNOWLEDGEMENTS

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1. INTRODUCTION

1. INTRODUCTION

The chemical industry is one of the largest EU production sectors. Nowadays, chemical safety management in the workplaces is related to the obligations imposed on companies by the EU provisions of the REACH and CLP Regulations. The REACH Regulation has initiated numerous changes to European legislation on chemical safety management (CSM). The fundamental novelty was the transfer of the burden of responsibility for chemical safety from Member States to companies. After the entry into force of the REACH Regulation, small and medium-sized companies have the same tasks as large companies and cannot be exempted from any chemical safety obligations. The REACH Regulation defines the company's obligations depending on its role in the supply chain, whereas the CLP Regulation - its obligations related to the classification, labelling and packaging of chemicals.

The changes introduced by REACH mainly concern provisions of placing chemicals on the market and flow of information on safe use of chemicals in the supply chain. The identification and communication of safe conditions of use (CoU), including risk management measures (RMM), are put to improve the level of protection of human health and the environment. Companies belonging to DU and D, as well as other actors in the supply chain, should take the necessary risk control measures in accordance with the chemical safety assessment of substance/mixture as well as provide appropriate recommendations to other actors in the supply chain.

REACH and CLP Regulations apply in a synergistic manner with other EU and national regulations, such as: chemical agents at work: Directive 98/24/EC, carcinogenic or mutagenic substances at work: Directive 2004/37/EC, industrial emissions: Directive 2010/75/EU, biocidal products Regulation: 528/2012 and others. These provisions have the same scope and philosophy as REACH and CLP. For example, information from registration dossiers and chemical safety reports provides information that helps in the implementation of good practices by DU and D of chemicals.

Issues regarding synergies between REACH/CLP and other acts, but also regarding double Regulation and regulatory gaps require separate discussion.

Although REACH and CLP entered into force in 2007, 2009 respectively, there are still companies in which the knowledge of managers and key personnel on new legal regulations is insufficient and even negligible. The analysis of the literature and the results of the survey showed that many companies, especially small and micro, still have many problems in understanding the REACH and CLP Regulations or interpret them incorrectly. There is a widespread belief that these regulations are too complex and, in addition, the legal rules they contain evolve all the time, which causes additional problems. Companies for example, have problems with defining their legal obligations under the REACH and CLP Regulations.

REACH and CLP apply to legal entities established in the European Union and the other Member States of the European Economic Area, i.e. Norway, Iceland and Liechtenstein.

The ChemSM-HUB Pocket Guide offered to you is a complementary part of training materials created during the project Chemical Safety Management Training Hub for Chemicals Users, co-funded by the European Commission under the Erasmus+ Programme. The project was implemented by the Nofer Institute of Occupational Medicine, Poland in cooperation with the Lodz University of Technology, Poland and other partners from Germany (OEKOPOL GMBH), Romania (ROMTENS FOUNDATION) and Greece (ASTIKI MIKERDOSKOPIKI ETAIREIA PROLEPSIS) and is addressed to downstream users (DU) and distributors (D) of chemicals.

The overall objective of this ChemSM-HUB Pocket Guide was to create a source for downstream users and distributors of chemicals to help them meet the obligations imposed on companies under the REACH and CLP Regulations. In particular, the authors aimed to familiarize readers with information enabling understanding of basic concepts as well as basic REACH and CLP procedures, the role and obligations of companies in the supply chain, rules of communication between companies in the supply chain, etc. The guide also presents a table of content for both regulations, in order to familiarize readers with the scope of issues covered by REACH and CLP and to familiarize them with the titles of individual articles, which are often quoted in the content of the guide.

The entire training package along with the Pocket Guide is available free of charge on the project website (https://chemsm--hub.eu) since mid-2020. In addition, during the implementation of the project, a mobile application was created for devices with the Android system, explaining the basic terms, definitions and procedures of REACH and CLP Regulations.

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2. LIST OF APPLICABLE ACRONYM AND ABBREVIATIONS

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CAS the chemical scientific database, owned by the American Chemical Society (ACS)

CAS Number the number of the chemical in the CAS registry that identifies the substance

ChemSM-HUB Chemical Safety Management Training Hub for Chemicals Users – title of the project implemented under the Erasmus+ program (project No: 2017-1-PL01-KA202-038432)

CLP REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EC) No 1272/2008 of 16.12.2008 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 of 31. 12. 2006 (OJ L 353, 31.12.2008, p. 1). The latest consolidated version can be found on the EUR- LEX: EU law website.

CLH Harmonised Classification And Labelling

CMR Cancerogenic, Mutagenic and Reprotoxic substances

CoU Conditions of use (OCs + RMMs)

CSA Chemical Safety Assessment

CSM Chemical Safety Management

CSR Chemical Safety Report

D Distributor

DNEL Derived No Effect Level

DSD Dangerous Substances Directive 67/548/EWG

DPD Dangerous Preparations Directive 1999/45/WE

DU(s) Downstream User(s)

DU CSR Downstream User Chemical Safety Report

ECHA European Chemicals Agency

EEA European Economic Area

ES Exposure Scenario

EINECS European Inventory of Existing Commercial Chemical Substances

EUSES European Union System for the Evaluation of Substances

GHS Globally Harmonised System

IUCLID International Uniform Chemical Information Database

OC Operational conditions of use

PBT Persistent, Bioaccumulative and Toxic substance

PNEC Predicted No Effect Concentration

PPORD Product and Process Oriented Research and Development

PROC Process category

QSAR Quantitative Structure-Activity Relationship

RAC Risk Assessment Committee

RCOM Response to the Comments

REACH REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EC) No 1907/2006 of 18.12.2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1). The latest consolidated version can be found on the EUR-LEX: EU law website.

RMMs Risk Management Measures

SDS Safety Data Sheet (or MSDS – Material Safety Data Sheet), extended-SDS (SDS containing exposure scenarios)

SEAC Socio-Economic Analysis Committee

SR&D Scientific Research and Development

SVHC Substances of Very High Concern

t/a tons per year

vPvB very Persistent and very Bioaccumulative substance

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3. USEFUL LINKS

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The texts of the REACH and CLP Regulations can be found at:
Eur-Lex, the database of European Union legal acts:

- REACH Regulation can be found here in all EU official languages.
- CLP Regulation in all EU official languages can be found here.

It is recommended to search for the latest consolidated versions of the regulations. For example, when you are looking for a REACH Regulation, go to the EUR-LEX: EU law website https://eur-lex.europa.eu/homepage.html?locale=en, enter No 1907/2006 into the search engine (quick search), then click on the latest consolidated version. You can also use the bookmark "Find results by document number", for example enter year: 2006, number: 1907 and as document type select regulation, then go to the latest consolidated version, then select proper language and format (HTML or PDF).

Other information, including information to help you determine the obligations imposed on companies by the REACH and CLP Regulations, can be obtained:

1. ECHA, European Chemicals Agency https://echa.europa.eu/
   The ECHA website https://echa.europa.eu/publications includes tools and practical advice to support companies in meeting obligations imposed by the REACH and CLP Regulations, including:
   - practical guides;
   - guides in a nutshell;
   - guidelines;
   - information brochures;
   - templates;
   - other publications;
   - a special NAVIGATOR program to help define the company's obligations under REACH and find appropriate guidelines to fulfill these obligations.
2. Cefic, The European Chemical Industry Council https://cefic.org/
3. REACH Centrum https://www.reachcentrum.eu/index.php
4. EU-OSHA, European Agency for Safety and Health at Work, https://osha.europa.eu/en

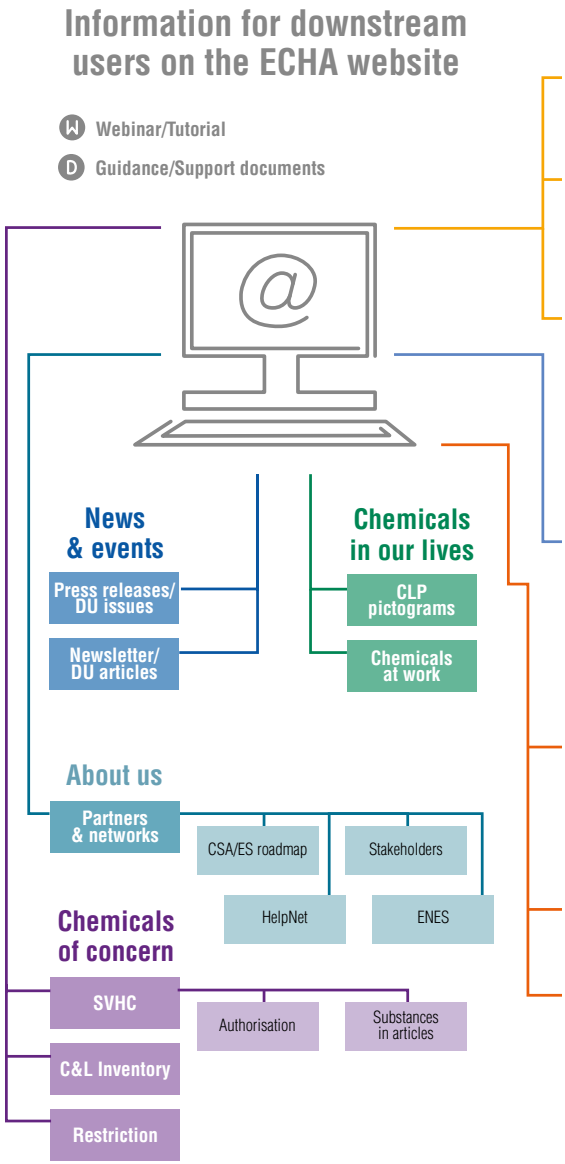
4. INFORMATION FOR DOWNSTREAM USERS ON THE ECHA WEBSITE

4. INFORMATION FOR DOWNSTREAM USERS ON THE ECHA WEBSITE

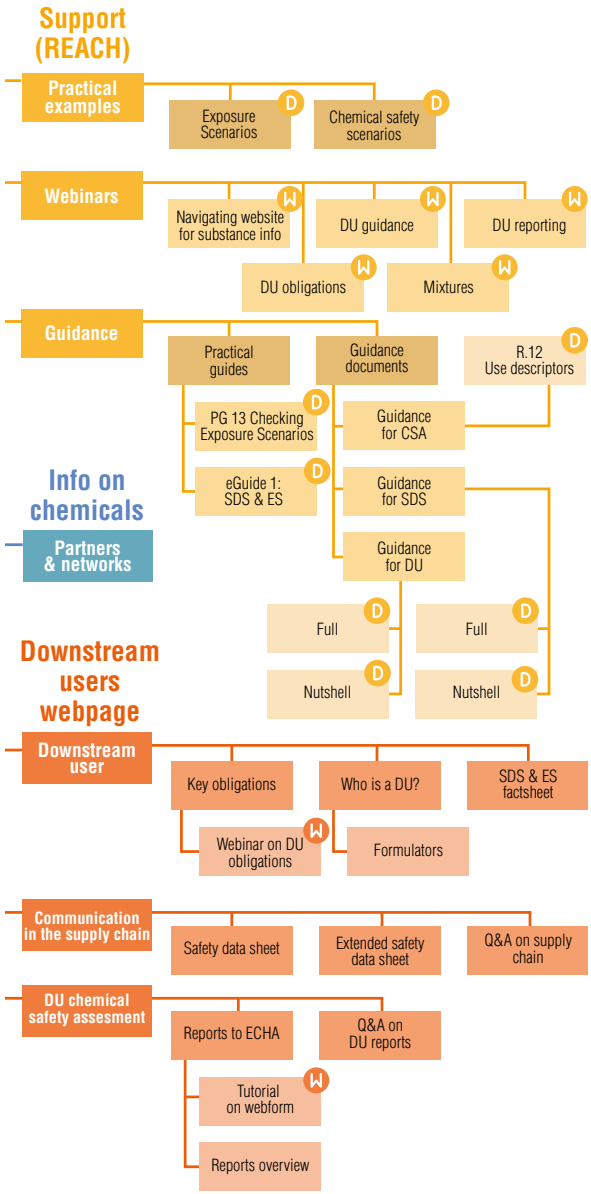
The ECHA website serves communication between the Agency and businesses. The information published on the ECHA website is of a great importance to downstream users. The website is a source of information on substances and also allows companies to track the status of a substance, e.g. whether the substance has been identified as SVHC, is it on the candidate list or has been included in Annex XVII of REACH. A very important function of the ECHA websites is to provide guides as well as all the useful information about the procedures imposed on companies by the REACH Regulation. Picture 1 shows what information and support, downstream users can find on the ECHA website.Included link leads to ECHA website dedicated to DU.

Information submitted to the European Chemicals Agency (ECHA) during registration of chemicals is collected by the Agency. Part of the information is available only to the competent institutions of the Member States, while the majority is publicly available. The ECHA website provides

- Registered substances database (the data from registration dossiers submitted to ECHA),
- C&L Inventory database (classification and labelling information on notified and registered substances received from manufacturers and importers),
- Harmonised classification and labelling (Table 3, Annex VI CLP),
- Candidate List (companies may have immediate legal obligations following the inclusion of a substance in the Candidate List resulting from Articles 7, 31 and 33 of the REACH Regulation),
- Authorisation list (list of substances subject to the authorisation procedure included in Annex XIV of REACH),
- Substances restricted under REACH (list of substances included in Annex XVII of REACH).



Picture 1: Information for downstream users on the ECHA website (Source: ECHA, https://echa.europa.eu/regulations/reach/downstream-users)



The table below presents datebases to be found on ECHA websites.

Table 1. Databases available to the public on ECHA websites.

Type of information	www address		Information provided
Registered substances	https://echa.europa.eu/information-on--chemicals/registered-substances		Substance name, EC No, CAS No, registration type, submission type, total tonnage band. Classification and labelling of substances, properties, physicochemical properties, ecotoxicity, fate of substances in the environment, toxicity, toxicological and ecotoxicological data, DNEL, PNEC, safe use guidelines, and others.
Database for classification and labelling	https://echa.europa.eu/information-on--chemicals/cl-inventory-database		Basic data on the classification and labelling of notified and registered substances received from producers and importers.
Harmonised classification and labelling of substances according to Table 3 Annex VI CLP*	https://echa.europa.eu/information-on--chemicals/cl-inventory-database		Index No., International Chemical Identification, EC No, CAS No, Classification (Hazard Class and Category Code(s), Hazard statement Code(s)), Labelling (Pictogram, Signal Word Code(s), Hazard statement Code(s), Suppl. Hazard statement Code(s)), Specific Conc. Limits, M-factors, Notes (Table 3, Annex VI CLP).
Candidate list	https://echa.europa.eu/web/guest/candidate-list-table		Substance name, EC No, CAS No, Date of inclusion, Reason for inclusion (Article 57(a) - carcinogenic, category 1A or 1B; Article 57(b) - mutagenic, category 1A or 1B; Article 57(c) - toxic for reproduction, category 1A or 1B; Article 57(d) - persistent, bioaccumulative and toxic (PBT); Article 57(e) - very persistent and very bioaccumulative (vPvB); Article 57(f) - equivalent level of concern having probable serious effects to human health (and/or) the environment), Decision, IUCLID dataset.
Authorisation list	https://echa.europa.eu/authorisation-list		Substance name, EC No, CAS No, Entry No, Latest application date, Sunset date (date from which the placing on the market and the use of that substance shall be prohibited unless an exemption applies or an authorisation is granted, or an authorisation application has been submitted before the application date also specified in Annex XIV, but the Commission decision on the application for authorisation has not yet been taken).

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Type of information	www address		Information provided
Substances restricted under REACH	https://echa.europa.eu/substances-restricted-under-reach		Substance name, EC No, CAS No, Entry No (entry number in Annex XVII to REACH (Restriction list)), Conditions (information on the restriction conditions on the manufacture, placing on the market and use of substances, mixtures and articles), Appendices (links to appendices concerning certain restricted substances).

ECHA website provides access to the following IT-TOOLS (inter alia) FOR DATA SUBMISSION:

- REACH-IT plays a central role in dossier submission and communication between ECHA and companies. The new version of REACH-IT , available as of 21 June 2016, from this date will only accept dossiers prepared in IUCLID 6 format. REACH-IT now makes sure that dossiers cannot be submitted individually if a registration already exists (the ‚one substance, one registration' principle of REACH).
- IUCLID, since its version 6, is built as a platform meant to provide regulatory authorities and industry with a set of tools to manage information on chemicals, using a common format, facilitating the reuse and exchange of the data.
- Chesar is an application developed by ECHA, which aim is to help companies to carry out their chemical safety assessments (CSAs) and to prepare their chemical safety reports (CSRs) and exposure scenarios (ESs) for communication in the supply chain.
- QSAR Toolbox is a software application intended to be used in filling gaps in (eco)toxicity data needed for assessing the hazards of chemicals. The Toolbox incorporates information and tools from various sources into a logical workflow, which involves grouping chemicals into chemical categories.

Further information can be obtained by using:

- Guidance and tools for downstream users – in brief [PDF][EN]
- Videos, tips and presentations for downstream users
- Guidance for downstream users [PDF][EN]
- Guidance for downstream users in a nutshell [PDF][EN]
- Webinar on Guidance for downstream users
- Practical Guide 17: How to prepare a downstream user chemical safety report [PDF][EN]
- Practical Guide 13: How downstream users can handle exposure scenarios [PDF][EN]

*Access path to the harmonised classification and labelling: Go to the „C&L Inventory" using the above address, click on the C&L Inventory tab, enter the name of the substance e.g. vinyl chloride or a numeric identifier, then select: „Search only substances with harmonised classification and labelling", then click search. As a result, you get a table, in which in the first column, the name of the substance is given, e.g. vinyl chloride. Click on this name and InfoCard appears for e.g. vinyl chloride. In the InfoCard, in „Key datasets" section choose „C&L Inventory". The classification of this substance is displayed: harmonised (blue) and below the classification of notifiers (producers or importers) (yellow).

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5. CONTENS OF REACH REGULATION

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Annex XVI	Socio-economic analysis
Annex XVII	Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

6. CONTENS OF CLP REGULATION

6. CONTENS OF CLP REGULATION

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7. BASIC CONCEPTS AND TERMS USED IN THE REACH AND CLP REGULATIONS

7. BASIC CONCEPTS AND TERMS USED IN THE REACH AND CLP REGULATIONS

REACH REGULATION

TITLE I GENERAL ISSUES
Chapter 2 Definitions and general provision
Article 3 Definitions
Article 4 General provision

CLP REGULATION

TITLE I GENERAL ISSUES
Article 2 Definitions

REACH has introduced a number of terms which may differ from their use under previous legislation. The following are the terms that are fundamental for understanding the REACH and CLP Regulations:

Actors in the supply chain: *means all manufacturers and/or importers and/or downstream users and/or distributors in a supply chain* (Article 3 (17) REACH).

Agency: means the European Chemicals Agency (ECHA), Helsinki, Finland, which is the central body established under the provisions of the REACH Regulation (Article 3 (18) REACH, Article 2 (23) CLP). The Agency deals with the registration, evaluation of chemicals, authorisation and restrictions procedures, creation and publishing of a list of substances of very high concern - SVHC (Candidate List). The Agency publishes guidance, practical guides, brief guides, guidelines, information sheets, templates that are available from the ECHA website at: https://echa.europa.eu/support/guidance. The ECHA website is also equipped with a special NAVIGATOR program to help define the company's obligations under REACH and find appropriate guidelines to fulfil these obligations. The website https://echa.europa.eu works theoretically in all the languages of the Member States, but currently many issues are only in the English version.

ECHA - the coordination and implementation center of REACH

Article: *means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition* (Article 3 (3) REACH, Article 2 (9) CLP); EXAMPLES: textiles, electronic chips, toys. If the articles contain substances from the candidate list, this results in additional obligations for companies, including DU and D. Manufacturers and importers of articles are obligated to register substances that are intended to be released from articles if their total content in articles exceeds 1 t/a, and to notify ECHA of substances on the candidate list if they are present in a concentration >0.1% w/w and the total amount of substance present in the products exceeds 1 t/a. It is possible to waive this obligation if the manufacturer or importer can exclude exposure of people or the environment (Article 7 (3) REACH). The suppliers of articles have the obligation to provide the recipients with information regarding substances on the candidate list contained in the articles in a concentration >0.1% w/w. (Article 33 (1) REACH), as well as consumers at their request (Article 33 (2) REACH) within 45 days of receipt of the request. This information should contain instructions for safe use of the article, or at least the name of the substance.

Authorisation (one of the REACH processes): means the authorisation procedure - one of the regulatory tools of the REACH aiming to ban the use of substances of very high concern (SVHC) included in the Annex XIV of REACH, so as to substitute them by technically and economically feasible alternatives. This process concerns manufacturers, importers and downstream users of substances. Only representatives of foreign manufacturers can also apply for an authorisation. After placing the substance in Annex XIV, it can not be placed on the market or used after a given date (the sunset date), unless the use has been authorised or the use is exempt from the authorisation requirement.

An application for an authorisation to continue or start using and placing substances included in the Authorisation List (Annex XIV of REACH) should be submitted to ECHA. The application may include uses of the substance by the applicant, downstream users or both. The purpose of this application is to show that no alternatives are immediately available, that the risks are controlled and the social and economic benefits of using substances outweigh the risks to human health or the environment. The application for authorisation must be submitted before the last application date (LAD), set 18 months before the sunset date. The application is considered by the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC). RAC and SEAC consider the application and issue a final opinion after public consultation, which is sent to the European Commission. After 3 months from receipt of the Committee's opinion, the European Commission prepares a draft decision on the granting or refusal of authorisation. It is possible to authorise the use of SVHC if the applicant can demonstrate that the risks arising from the use of the substance are adequately controlled or that the socio economic benefits outweigh the risks and that there are no suitable alternatives (see chapter 8.3).

Bridging methods (bridging principles): means the methods for classification of mixtures due to risks to human health or the environment, where the mixtures have not been tested, but there is sufficient data on similar tested mixtures and individual hazardous components (section 1.1.3 in Annex I of CLP and each section of Parts 3 and 4 of the same Annex). Bridging rules are not used to classify mixtures due to physical hazards. There are the following bridging principles: "Dilution, Batching, Concentration of highly hazardous mixtures, Interpolation within one toxicity category, Substantially similar mixtures, Review of classification where the composition of a mixture has changed, Aerosols". Bridging methods and examples are described in the ECHA Guidance on the Application of the CLP Criteria [PDF][EN].

Bureau for Chemical Substances: means the central office of a government administration body that exercises statutory control over the placing on the market of chemical products. The office supports the Inspector for Chemical Substances in the implementation of his tasks.

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Candidate List (Candidate List of Substances of Very High Concern - SVHC Substances): means an inventory of substances that have serious effects on human health or the environment, known as substances of very high concern. The SVHC substances included in the Candidate List and then included in Annex XIV of REACH are subject to the pre-release authorisation procedure. ECHA regularly submits its recommendations to the European Commission, which decides to include these substances in Annex XIV.

C&L Inventory: means the C&L database available on the ECHA website. The database contains information on the classification and labelling of notified and registered substances.

CAS number: number assigned to a particular chemical substance by the American organization Chemical Abstracts Service (CAS), allowing for the identification of substances. The CAS number is one of the most commonly used means of identifying chemical substances.

Chemical Safety Assessment (CSA): means a procedure that defines the conditions for the safe use of a substance at all stages of its existence. The assessment concerns producers and importers of all substances subject to registration, produced or imported in quantities of at least 10 t/a (Annex I of REACH). The CSA results are reported by the registrants in the chemical safety report (CSR), which is part of the registration dossier. Also, DU can make his own chemical safety assessment and document it in DU CSR. The CSA distinguishes three basic stages, although not all of them must occur throughout the entire procedure. The first stage is the hazard assessment, which consists of:

1. Hazard assessment:
- for human health;
- resulting from physicochemical properties;
- for the environment;
- persistence, bioaccumulation and toxicity (PBT) and very persistent and very bioaccumulative (vPvB) assessments.

If, as a result of the four stages mentioned above, the registrant concludes that the substance meets the criteria for classification as dangerous or has been rated as belonging to the PBT or vPvB category, the chemical safety assessment shall comprise the following two additional stages.

2. Exposure assessment, including the generation of one or more exposure scenarios (or, where appropriate, the determination of appropriate use and exposure categories) and exposure estimation.
3. Risk characteristics.

Chemical safety assessment is not required:

1. if the substance is contained in the mixture in concentration below the concentration limit for classification of mixtures (Annex I of REACH);
2. if the substance is used to develop technology/research.

Chemical Safety Report (CSR): means a chemical safety report that documents the chemical safety assessment undertaken as part of the REACH registration process. The report is the key source from which the registrant provides information to all users of chemicals through the exposure scenarios. It also forms a basis for other REACH processes including substance evaluation, authorisation and restriction.

The chemical safety assessment is carried out to demonstrate that the risks from the exposure to a substance, during its manufacture and use, are controlled when specific operational conditions and risk management measures are applied. These conditions of use of a substance constitute the exposure scenario, which is an essential component of the chemical safety report.

Development of CSR according to Annex I of REACH applies to:

1. producers/importers of substances that are subject to the registration process, if they are manufactured or imported in an amount of at least 10 t/a.
2. DU of substances for which exposure scenarios for a given direction of use (or use of his recipients) were not specified during the registration process.
3. manufacturers, importers or downstream users of substances subject to the authorisation system under REACH. This applies to situations where a substance is listed in Annex XIV

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of the REACH Regulation, and the company interested in further manufacture, import or use of this substance is forced to participate in the authorisation procedure, regardless of turnover. Depending on the role of the applicant applying for authorisation in the supply chain, the CSA / CSR are prepared by the producer, importer or downstream user, as part of the application for authorisation according to the Annex I or Annex XII of REACH, or both of them.

4. producers or importers of articles containing substances that are to be released from this article if such use has not yet been registered. A CSR report is required if the substance is contained in these articles in quantities exceeding 10 t/a.

CLP classification: means the classification of a substance/mixture in terms of hazards, based on the criteria specified in the CLP Regulation. Manufacturer, importer, and DU are required to classify the substances themselves if this substance does not have harmonised classification (Annex VI CLP), and it has dangerous properties. For substances for which there is a harmonised classification (Annex VI CLP), the harmonised hazard classification is legally binding for the classes and differentiations covered in this entry. Classes and further variations in the types of hazards not included in the entry should be assessed and categorized on their own based on the criteria set out in the CLP Regulation. Self-classification aims to determine whether a chemical or a mixture poses a physical, health and/or environmental hazard and to adequately inform other actors in the supply chain about the hazards by appropriate labelling when the product is placed on the market. The obligation does not depend on volume of the substance/mixture being produced/imported.

CLP Regulation: means Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging. The regulation introduces a new system for the classification and labelling of chemicals across the EU based on the Globally Harmonised System of the United Nations (UN GHS). The CLP Regulation is directly related to the REACH Regulation, establishes hazard statements, precautionary statements and pictograms providing information in the context of ensuring adequate protection of human health and the environment. The word CLP is an acronym from the first letters of the three main regulatory processes - classification, labelling, packaging of chemicals;

Collective control measures (technical control measures): means different types of ventilation systems that ensure proper interior ventilation, and thus improve the air parameters at work sites.

Community Customs Territory: covers the following countries: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Croatia, Denmark (except for Greenland and Faroe Islands), Estonia, Finland (including Aland Islands), France (including Monaco and overseas departments - French Guiana, Guadeloupe, Martinique and Réunion, without overseas Saint-Pierre and Miqelon and Mayotte), Greece, Spain (except Ceuta and Melilla), the Netherlands (European part), Ireland, Lithuania, Luxembourg, Latvia, Malta, Germany (except Busingen and Helgoland), Poland, Portugal, Romania, Slovakia, Slovenia, Sweden, Hungary, Italy (except the Livogno and Campione d'Italia customs enclaves), United Kingdom of Great Britain and Northern Ireland (including Channel Islands and Isle of Man).

The REACH system operates in the EEA and EFTA states, with the exception of Switzerland and according to Decision of the EEA Joint Committee No 25/2008 of 14 March 2008, the term "Member State (s)" used in the REACH Regulation should be understood to include, in addition to its meaning in the Regulation, the EFTA States.

Concentration limits: means the specific concentration limits assigned to a given substance and the generic concentration limits assigned to the hazard class/category, indicating a threshold, at or above which the presence of the substance in another substance or mixture, whether as an identified impurity, additive or component, causes this substance or mixture to be classified as hazardous. The generic concentration limits are specified in Parts 3-5 of Annex I of the CLP. The specific concentration limits are given in Annex VI CLP (Table 3). For classification

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purposes, specific concentration limits take precedence over generic concentration limits, even when the specific concentration limit is higher than the generic concentration limit for a given hazard class and category.

In order to mention a substance as a mixture constituent in subsection 3.2 of the safety data sheet, the smallest concentration limit, specific or general for a given hazard class and category, shall be taken into account (table below).

List of hazard classes, hazard categories and concentration limits for which a substance shall be listed as a substance in a mixture in subsection 3.2 of SDS (29.5.2015 L 132/14 Official Journal of the European Union EN 1.1). However if the specific concentration limit is less than the concentration limit mentioned in the table below, the smaller one shall be used for the purposes of listing in section 3.2 of the safety data sheet.

Table 2. List of hazard classes, hazard categories and concentration limits due to which the substance is listed as a substance in a mixture in subsection 3.2

Hazard Class and Category	Concentration limit (%)
Acute toxicity, category 1, 2 and 3	≥0.1
Acute toxicity, category 4	≥1
Skin corrosion/irritation, category 1, subcategories 1A, 1B, 1C and category 2	≥1
Serious damage to eyes/eye irritation, category 1 and 2	≥1
Respiratory/skin sensitisation	≥0.1
Germ cell mutagenicity, category 1A and 1B	≥0.1
Germ cell mutagenicity, category 2	≥1
Carcinogenicity, category 1A, 1B and 2	≥0.1
Reproductive toxicity, category 1A, 1B, 2 and effects on or via lactation	≥0.1
Specific target organ toxicity (STOT) - single exposure, category 1 and 2	≥1
Specific target organ toxicity (STOT) - repeated exposure, category 1 and 2	≥1
Aspiration hazard	≥10
Hazardous to the aquatic environment - Acute, category 1	≥0.1
Hazardous to the aquatic environment - Chronic, category 1	≥0.1
Hazardous to the aquatic environment - Chronic, category 2, 3 and 4	≥1
Hazardous for the ozone layer	≥0.1

If the specific concentration limit is less than the concentration limit mentioned in the table above, the smaller one shall be used for the purposes of listing in section 3.2 of the safety data sheet.

Consumer: means a natural person making a legal transaction with an entrepreneur which is not directly related to his business or professional activity, eg. the buyer of goods or services or user of any resources or goods. The consumer is not considered DU.

Descriptors of use: means a system of standardized description of uses developed by ECHA to facilitate chemical risk assessment

and supply chain communication, containing 5 categories of descriptors: sector of use (SU), product category (PC), process category (PROC), environmental release category (ERC), article category (AC). They are used, e.g. in the substance registration dossier in the description of identified uses and in the title section of exposure scenarios. Application descriptors (PC, PROC, ERC, AC) can be used as input parameters to derive exposure estimates in modelling tools such as ECETOC-TRA (a free tool developed by the European Centre for Ecotoxicology and Toxicology of Chemicals - ECETOC for Targeted Risk Assessment - TRA) and EUSES.

Sector of use (SU): describes in which sector the substance is used. 3 main sectors: SU3: industrial; SU21: consumer; SU22: professional.

Process category (PROC): describes the application techniques or process type. Process category, operational conditions and risk management measures determine the level of occupational exposure for workers and professional users. Example: PROC7: Industrial spraying; PROC8a: Transfer of substance or mixture (charging/discharging) from/to vessels/ large containers at dedicated facilities.

Product category (PC): describes the types of chemical products in which a substance is used. Product category, operational conditions and risk management measures primarily determine the level of consumer exposure. Examples: PC9a: Coatings and paints, thinners, paint removers; PC39: Cosmetics, personal care products.

Article Category (AC): describes the type of article (including plastics and dried mixture) in which the substance has been processed. Examples: AC2: Machinery, mechanical appliances, electrical/electronic articles; AC13: Plastic articles.

Environmental Release Category (ERC): describes the broad conditions of use from an environmental perspective, based on those characteristics that give a first indication of the potential release of the substance to the environment. Determines the level of environmental exposure. Examples: ERC2: Formulation of preparations; ERC6a: Industrial use resulting in the manufacture of another substance (use of intermediates); ERC8a: Wide dispersive indoor use of processing aids in open systems.

Sector of use (SU), product category (PC) and article category (AC) describe market sectors while PROCs and ERCs describe specific activities.

Distributor: *means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties* (Article 3 (14) REACH, Article 2 (20) CLP). The category of distributors also includes entities that change the brand name of a substance into a new one as long as they do not perform any activities referred to in REACH as "use". EXAMPLES: a person who retails cleaning products, a detergent warehouse worker, a company selling disinfectants to a cleaning company, any entity that only stores and makes available substances and mixtures to third parties. If the distributor performs any activities specified as use, he/she is considered as DU.

NOTE

The DISTRIBUTOR category includes:
- entities conducting retail trade;
- entities conducting wholesale trade;
- entities that change the brand name of a substance to a new one, as long as they do not perform any activities referred to in REACH as use.

Downstream user: *means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities* (Article 3 (13) REACH, Article 2 (19) CLP).

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DU can be found in many industries, most of them are SMEs. The term "downstream user" in the context of the REACH and CLP Regulations includes: a formulator, end user, manufacturer of articles, a filler, an industrial user, a professional user. The reimporter and importer are not DU but have DU rights and obligations if their non-Community supplier has appointed an ‚only representative' for the purposes of acting as a registrant established in the Community. Distributors or consumers are not considered DU. EXAMPLE of downstream users: mobile cleaning companies, professional painters, construction companies, furniture companies, clothing companies, farmers, and users of lubricants for equipment, shoemakers, formulators of mixtures.

NOTE

The DOWNSTREAM USER category includes:

- entities transferring a substance from one container to another (re-filler);
- manufacturers of mixtures e.g. manufacturers of paints, cosmetics, glue, windscreen washer fluids (formulators);
- manufacturers of articles e.g. manufacturers of screws, drywall, furniture;
- professional end-users of the substance in their own form, in a mixture, in an article (other than industrial activity), e.g. painters, varnishers, cleaners;
- industrial end-users of substances in their own form or in a mixture using them in an industrial process (these substances do not remain in the product), for example, entities cleaning the surface before galvanizing.

Downstream User Chemical Safety Report (DU CSR): means a chemical safety report that documents the chemical safety assessment undertaken as part of the REACH registration process developed by downstream users, for substances for which no exposure scenarios for the given direction of use (or use of his recipients) were specified during the registration process. These are specific cases of unidentified or identified uses that the registrant considered undesirable (uses advised against). It also takes into account the situations when DU wants to keep information about his use confidential (Article 37 REACH). In such a situation, the DU, who is not required to register, prepares the DU CSR in accordance with Annex XII of REACH, and in each case when the guidelines refer to Annex I of REACH.

NOTE

DU should be aware of the difficulties and problems they may encounter when preparing this complicated and costly report. Therefore, the DU should definitely avoid using the substance in a different way from the one indicated in the exposure scenario received from the supplier or ensure that the supplier includes its use in the exposure scenario. In order to avoid creating own DU CSR, a downstream user may:

- introduce the conditions set out in the exposure scenario provided;
- use a substituting substance / mixture that does not require the development of an exposure scenario;
- ask supplier to include his (DU) use in the CSR and recognize this use as identified;
- look for another supplier who will provide an exposure scenario covering his use.

REMEMBER

DU is not obliged to prepare a DU CSR if:

- SDS for a given substance is not required (because, for example, it is not classified as hazardous);
- in the case of substances for which CSR is not required at all (for example, as the registered tonnage is <10 t/a);
- the concentration of the substance in the mixture being produced is lower than the lowest thresholds defined in Article 14 (2) REACH;
- if the substance is used only for the purpose of research into products and the production process and their development.

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NOTE

If the substance is used in a total quantity <1t/a – there is still an obligation to identify and apply appropriate risk control measures and to include this information, if necessary, in a safety data sheet to be provided to recipient.

DU's own use: means industrial or other professional use of a DU.

ECHA: means the European Chemicals Agency.

ECHA Guides: means publications, available on the ECHA website, at: https://echa.europa.eu/en/practical-guides, providing additional information and clarifications to legal provisions.

EC number: means a seven-digit number with the structure XXX-XXX-X assigned to a chemical in the European Inventory of Existing Chemical Substances (EINECS), the European List of Notified Chemical Substances (ELINCS) or in the list of chemical substances listed in the publication "No-longer polymers".

EFTA States: means Iceland, Liechtenstein, Norway and Switzerland.

End user (an entity included in the DU category): means an entity that uses chemical products but does not supply them to further entities in the supply chain. This category includes industrial end users and professional end users.

European Economic Area, EEA: free trade area and the common market, covering the countries of the European Union and the European Free Trade Association (EFTA), with the exception of Switzerland.

Exposure scenario (ES): means a set of conditions, including operational conditions and risk management measures to adequately control the risks to human health and the environment. Exposure scenarios cover the entire life cycle of the substance, including formulation, industrial and professional end-use, consumer use and use in articles. ES may cover one specific process or use or several processes or uses as appropriate (Article 3 (37) REACH); ESs are developed for identified uses as a part of chemical safety assessment for substances with certain hazardous properties registered in quantities of at least 10 t/a per registrant. The format and content for an exposure scenario is not specified in REACH but stakeholders have agreed a common format and content. This includes the following sections:

- Title section;
- Conditions of use affecting exposure;
- Exposure estimation (this may include the risk characterization ratio); and
- Guidance to downstream users to evaluate if their use is within the boundaries of the exposure scenario.

ES is attached to the safety data sheet if the hazardous substance is registered in an amount of at least 10 t/a per registrant (extended safety data sheet).

Formulator (entity classified in the DU category): means a producer of mixtures that supplies other entities in the supply chain. EXAMPLES: paint manufacturer, tile adhesive manufacturer, laundry detergent manufacturer, person who uses the mixture to prepare other mixtures. The formulator is anyone who prepares the mixture when no chemical reaction takes place during mixing.

REMEMBER

FORMULATOR: refers to the producer of mixtures as well as aqueous and solvent solutions. A formulator purchasing substances outside the Community, e.g. in Switzerland or Japan, is considered an IMPORTER (he/she has the rights and obligations of an importer).

Globally Harmonised System of Classification and Labelling of Chemicals (GHS): classification and labelling system for substances and mixtures developed by the UN to harmonize the existing classification and labelling standards used in different

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countries. So far implemented in over 60 countries, including the whole European Union, by the CLP Regulation.

Harmonised classification and labelling (CLP): means a harmonised classification and labeling procedure that legally applies throughout the European Union, implemented by the CLP Regulation. The CLP classification is the implementation of the globally harmonised classification and labelling of chemicals (UN GHS) in the European Union. The current version of CLP is based on the seventh revised version of the GHS (UN) of 21.08.2017, but also uses the basic procedures found in DSD and DPD. The CLP classification in several hazard categories has more classes than the GHS classification, which increases the level of protection in comparison to the GHS classification.

Harmonised classifications are listed in Table 3 of Annex VI CLP (list of harmonised classification and labelling of hazardous substances) and should be used by all actors in the supply chain. Table 3 contains the index number of the chemical substance, International Chemical Identification, EC number, CAS number, classification elements (hazard classes, category codes and hazard statements codes), elements of the label (pictograms, signal word codes, hazard statement codes, supplementary hazard statement codes), specific concentration limits, M factors and notes.

Table 3. An example of a harmonised classification and labelling of substance (Table 3, Annex VI, CLP)

INDEX NO	INTERNATIONAL CHEMICAL IDENTIFICATION	EC NO	CAS NO	CLASSIFICATION			LABELLING			SPECIFIC CONC. LIMITS, M FACTORS	NOTES
				Hazard Class and Category Code(s)	Hazard statement Code(s)		Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
001-001-00-9	hydrogen	215-605-7	1333-74-0	Flam. Gas 1 Press. Gas	H220		GHS02 GHS04 Dgr	H220			U

The meaning of the notes listed in the column Notes of Table 3 of Annex VI CLP is as follows:

SUBSTANCES

Notes relating to the identification, classification and labelling of substances (Annex VI, 1.1.3.1.,CLP)

Note A: *Without prejudice to Article 17(2), the name of the substance must appear on the label in the form of one of the designations given in Part 3. In Part 3, 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 of section 1.1.1.4.*

Note 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 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.*

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Note 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.*

Note 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. However, such substances are sometimes placed on the market in a non-stabilised form.*
In this case, the supplier must state on the label the name of the substance followed by the words „non stabilised".

Note 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, classification and labelling should be provided in accordance with the rules for classification and labelling of hazardous mixtures.*

Note 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.*

Note 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.*

Note 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 (P102-)P210-P403 should apply. This note applies only to certain complex oil-derived substances in Part 3.*

Note 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.*

Note 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.*

Note 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.*

Note 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 (P102-)P260-P262-P301 + P310-P331 shall apply. This note applies only to certain complex oil-derived substances in Part 3.*

Note Q: *The classification as a carcinogen need not apply if it can be shown that the substance fulfils one of the following conditions:*

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- *a short term biopersistence test by inhalation has shown that the fibres longer than 20 µm 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 µm have a weighted halflife 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.*

Note 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 µm.*

Note S: *This substance may not require a label according to Article 17 (see Section 1.3 of Annex I) (Table 3).*

Note T: *This substance may be marketed in a form which does not have the physical hazards as indicated by the classification in the entry in Part 3. If the results of the relevant method or methods in accordance with Part 2 of Annex I of this Regulation show that the specific form of substance marketed does not exhibit this physical property or these physical hazards, 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.*

Note U: *When put on the market gases have to be classified as „Gases under pressure", in one of the groups compressed gas, liquefied gas, refrigerated liquefied 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. The following codes are assigned: Press. Gas (Comp.) Press. Gas (Liq.) Press. Gas (Ref. Liq.) Press. Gas (Diss.) Aerosols shall not be classified as gases under pressure (See Annex I, Part 2, Section 2.3.2.1, Note 2).*

MIXTURES

Notes relating to the classification and labelling of mixtures (Annex VI, 1.1.3.2.,CLP)

Note 1: *The concentration stated or, in the absence of such concentrations, the generic concentrations set out in this Regulation are the percentages by weight of the metallic element calculated with reference to the total weight of the mixture.*

Note 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.*

Note 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.*

Note 5: *The concentration limits for gaseous mixtures are expressed as volume per volume percentage.*

Note 7: *Alloys containing nickel are classified for skin sensitisation when the release rate of 0.5 µg Ni/cm2/week, as measured by the European Standard reference test method EN 1811, is exceeded.*

Note 8: *The classification as a carcinogen need not apply if it can be shown that the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is less than 0.1%.*

Note 9: *The classification as a mutagen need not apply if it can be shown that the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is less than 1%.*

Identified use: means the use of a substance on its own or in a mixture, or the use of a mixture that is intended by a participant (DU) of the supply chain, including his own use, or use of which he/she is notified in writing by direct DU (Article 3 (26) REACH). According to REACH, the identified use together with the conditions of safe use is included (manufacturer's and importer's obligation) in the registration dossier (CSR). In case of substances manufactured or imported in quantities of 10 t/a per registrant, exposure scenarios are developed for identified uses. The information on safe use conditions is provided for identified uses in the safety data sheet (section 1.2). If DU decides to develop his own CSR, identified uses and a description of conditions of safe use (risk management measures) must also be included in DU CSR.

Import: *means the physical introduction into the customs territory of the Community* (Article 3 (10) REACH, Article 2 (16) CLP). Import is considered as "placing on the market" (Article 3 (12) REACH, Article 2 (18) CLP).

Importer: *means any natural or legal person established within the Community who is responsible for import* (Article 3 (11) REACH, Article 2 (17) CLP).

Importer when "only representative" is appointed: acts as DU (he/she has DU rights and obligations) if the supplier from outside the Community has nominated an only representative for the purpose of acting as a registrant established in the Community. EXAMPLE: if an entity established in Poland produces paints with the ingredients imported from the USA and an American manufacturer has appointed the „only representative" established in the EU, in this case the „only representative" becomes an importer and the paint producer in Poland becomes DU.

INCI name: means the name according to the International Nomenclature of Cosmetic Ingredients - a naming system designed to unify the naming of cosmetic ingredients. At present, according to European Union law, cosmetic products must have a description of ingredients in all Member States;

Individual control measures: means measures, with which the employer is obliged to provide employees in order to protect the health and life of employees, eg. safety shoes, protective clothing, respiratory protection equipment.

Industrial end user (an entity included in the DU category): means an entity that uses chemical products at an industrial plant but does not supply them to other entities in the supply chain. EXAMPLES: entities using surface cleaners prior to electroplating or users of intermediates in chemical synthesis.

Intended release: means intended release of the substance from the article. EXAMPLE: the perfumed toy is a product with the intended release of the substance, because the fragrances contained in the toy are released in order to increase its attractiveness.

Intermediate: *means any substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (e.g. „synthesis")* (Article 3 (15) REACH). Different types of intermediates are defined under REACH: non-isolated intermediates, isolated intermediates including on-site (non transported) isolated intermediates, transported isolated intermediates.

IUPAC name: *means the name according to the International Union of Pure and Applied Chemistry.*

Manufacturer: *means any natural or legal person established within the Community who manufactures a substance within the Community* (Article 3 (9) REACH, Article 2 (15) CLP).

Manufacturing: *means production or extraction of substances in the natural state* (Article 3 (8) REACH, Article 2 (14) CLP).

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M-factor: means the coefficient used to classify a mixture by calculation with respect to the concentrations of a constituent substance classified as hazardous to the aquatic environment, acute exposure category 1 or chronic exposure category 1. The M factor is set by manufacturers, importers and downstream users. The M factor is not determined for substances for which the M-factor is given in the list of harmonised classification and labelling (Annex VI of the CLP Regulation 1272/2008).

Mixture (chemical mixture, formerly preparation): *means a mixture or solution composed of two or more substances* (Article 3 (2) REACH) (Article 2 (8) CLP). EXAMPLES : paints, adhesives, cosmetics, lubricants, detergents, aqueous and solvent solutions.

National helpdesks: means information centers present in each Member State, created on the basis of Article 124 REACH, which obliges Member States to set up national information centers to provide manufacturers, importers, downstream users and any other interested parties with advice regarding their liability and obligations under the Regulation. The list of National helpdesks is available on the ECHA website here. National information centers are to help enterprises, especially SMEs.

NAVIGATOR: means a tool to help define the obligations under REACH, available on the ECHA website, at: https://echa.europa.eu/pl/support/guidance-on-reach-and-clp-implementation/identify-your-obligations/navigator.

Non-isolated intermediates: means substances that appear between two consecutive chemical reactions and that are not removed from the system, except sampling.

Only representative: means a natural or legal person established in Europe designated by companies established outside the EEA who assume the roles and responsibilities of importers in order to meet the requirements of the REACH Regulation. The company for which the only representative imports substances / mixtures / products is not DU, but has the rights and duties of DU. Only representatives may represent several non-EEA suppliers, but they must keep their information separately. A non-EEA company must inform the importer(s) in the same supply chain about appointing an only representative. These importers are then considered as downstream users under REACH.

REMEMBER

The ‚only representative' takes over the importer's obligations related to the registration. The company for which he/she imports products from outside the EEA takes over the rights and obligations of the downstream user."

Placing on the market: *means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market* (Article 3 (12) REACH, Article 2 (18) CLP).

Producer of an article (an entity included in the DU category): *means any natural or legal person who makes or assembles an article within the Community* (Article 3 (4) REACH, Article 2 (10) CLP).

Product with intended release of substance: means an article whose one function is deliberate release from articles. EXAMPLE: a perfumed toy is a product with the intended release of a substance, increasing its attractiveness.

Professional end user (an entity included in the DU category): means an entity that uses chemical products outside of an industrial plant, in a workshop, at the customer's premises or in an education or healthcare facility, but not provide them to other entities in the supply chain. EXAMPLES: construction companies, mobile cleaning companies, professional painters, floor covering contractors, farmers and users of lubricants for devices such as chain saws, refinishers, laundry workers, smokers in the boiler room.

REACH-IT: means the central IT system that supports Industry, Member State competent authorities and the European Chemicals

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Agency to securely submit, process and manage data and dossiers. These three parties each have access to specific functions of REACH-IT which they can use to fulfill their requirements under the REACH and CLP Regulations. REACH-IT also provides a secure communication channel between these three parties to help them coordinate the processing and evaluation of data and dossiers.

REACH Regulation: means Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 aimed at ensuring a high level of protection of human health and the environment through registration, evaluation, authorisation and restriction of chemicals. The word REACH is an acronym from the first letters of the regulation's title - registration, evaluation, authorisation and restriction of chemicals.

Re-brander (entity included in the Distributor category): means an entity placing its own brand on a product produced by another entity. It is a subcategory of distributors in the supply chain. However, if the re-brander, in addition to storing and changing the brand, performs activities referred to in REACH as „use", eg. transferring a substance/mixture from one container to another, it is classified as a downstream user category and has DU responsibilities.

Recipient of an article: *means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers* (Article 3 (35) REACH).

Recipient of a substance or a preparation: *means a downstream user or a distributor being supplied with a substance or a preparation* (Article 3 (34) REACH).

Re-filler (entity included in the DU category): means a refillable unit that transfers substances or mixtures from one container to another, usually when changing the packaging or trade name; EXAMPLES: a service provider or entrepreneur conducting a refill business.

Registrant: *means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance* (Article 3 (7) REACH). The registrant prepares most of the documents required under REACH. The registrant has the right to obtain from the DU information on the appropriateness of the risk management measures (RMM) proposed, in particular when proposed RMM are inappropriate.

Registrant's own use: *means an industrial or professional use by the registrant* (Article 3 (25) REACH).

Registration (one of the REACH processes): means obligatory registration of all chemical substances (with the exception of those specified in Article 2 of REACH) on its own, as part of a mixture or in an article (article from which the substance is released under normal or reasonably foreseeable conditions of use). Registration applies to substances manufactured or imported in quantities of at least 1 t/a per one producer/importer. Registration is carried out before placing the substance on the market, by submitting a registration dossier at ECHA via the REACH-IT portal.

In the case of producers or importers of an article, the obligation to register a substance applies if the substance in the article has not previously been registered for such use.

REMEMBER

Mixtures and articles are not subject to registration, only chemical substances contained in them.

REMEMBER

TWO RULES:
1. NO DATA – NO MARKET, which means that an unregistered substance can not be authorised to be placed on the market;
2. ONE SUBSTANCE – ONE REGISTRATION, which means that manufacturers and importers of the same substance must jointly submit registration dossier.

Registration dossier: means the documentation submitted to ECHA in REACH-IT by the registrant of a chemical substance (manufacturer or importer), which consists of:

1. technical documentation, containing:
   - general information on the registrant;
   - substance identification;
   - information on the production and uses of the substance;
   - classification and labelling of the substance;
   - guidelines for safe use;
   - information on exposure.

The scope of technical documentation depends on the tonnage of the substance produced/registered (ANNEX VII-X REACH).

2. chemical safety report (CSR) is required in the case of a substance manufactured or imported in an amount of at least 10 t/a per registrant.

Registration number: means a unique number generated by the IT system of the REACH-IT when the registration dossier for a given substance is complete. ECHA will forward the registration number and the date of registration to the registrant(s) concerned without delay. From that moment on, the registration number assigned should be used in any further correspondence relating to the registration procedure (Article 20 (3) REACH).

Reimporter (entity acting as DU, but not included in the DU category): means an importer of a substance on its own or in a mixture which was originally produced in the Community and was registered by another entity in the same supply chain. The reimporter has the rights and duties of DU in the supply chain.

Restriction (one of four main REACH procedures): means regulatory measures to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions may limit or ban the manufacture, placing on the market or use of a substance (Annex XVII of REACH). A restriction can apply to any substance on its own, in a mixture or in an article, including those that do not require registration. Restrictions setting out conditions for the placing on the market of substances apply to both domestic production and imports. Community-wide restrictions apply to substances incorporated into Annex XVII of REACH to protect human health and the environment against unacceptable risks associated with these chemicals. Information on restrictions is provided in section XV of the safety data sheet, according to REACH, and if there is no obligation to provide a safety data sheet, the supplier is obliged to provide the recipient with:

- details of each application of the restriction;
- information necessary to identify and apply equivalent risk management measures;
- the registration numbers of the substances concerned by the above information.

Annex XVII to REACH Regulation on EUR-Lex: see latest consolidated version.

Annex XVII on ECHA website: https://echa.europa.eu/en/substances-restricted-under-reach

Retailer (an entity included in the Distributor category): means an entity that stores and places on the market substances, mixtures or articles, making them available to end-users and/or professional users in retail sales. It is a subcategory of distributors in the supply chain. However, if in addition to storing and changing the brand the retailer performs other activities referred to in REACH as „use", eg. transferring a substance/mixture from one container to another, he/she falls into the category of downstream user and bears DU duties. For example, filling or mixing paints in a warehouse is considered as use under REACH, so by doing such activities he/she becomes DU.

Risk Assessment Committee (RAC): means the Committee that issues opinions on substance risks for human health and the environment on behalf of ECHA under the REACH processes (restriction and authorisation) and CLP (harmonised classification and labelling). Final decisions are taken by the European Commission (Article 70 REACH).

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Risk control measures (risk management measures -RMM): means measures and procedures that reduce the risk of exposure to an acceptable level. The term „risk control" is used because it is often impossible to completely eliminate the risk. The risk control process requires paying attention to all regulatory and international standards that may be required from the employer. Occupational Safety and Health regulations may require specific controls of specific hazards depending on the legal regulations. Typical risk control measures include individual and collective control measures, good health and safety practices, chemical safety training, compliance with safety rules, and the implementation of automated equipment. The registrant informs downstream users about appropriate risk management measures for any particular use of the substance. The person responsible for chemical safety in a company is required to provide employees with RMM.

More info on RMM you can find at Guidance on information requirements and chemical safety assessment Chapter R.13: Risk management measures and operational conditions https://echa.europa.eu/documents/10162/13632/information_requirements_r13_en.pdf

Safety data sheet, SDS or material safety data sheet, MSDS: means a document prepared in accordance with Annex II to REACH. The safety data sheet is an integral part of the system created under REACH.

The information provided in the SDS is divided into 16 sections defined in Annex II to REACH.

THE OBLIGATION TO POSSESS AND PROVIDE SDS down the supply chain concerns:

- substances or mixtures that meet the criteria for classification as hazardous under the CLP Regulation;
- substances which are persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) in accordance with the criteria contained in Annex XIII of REACH; or
- substances that are for any other reason on the candidate list of substances subject to the authorisation procedure in accordance with Article 59 (1) REACH (Article 31 (1) REACH).

- mixtures that, although not meeting the criteria for classification as posing hazard under CLP, require the development of a safety data sheet and make it available on request (Article 31 (3) REACH) and comments on Tables 3.4.6, 3.6.2, 3.7.2, 3.8.3 and 3.9.4 from Annex I to CLP.

SDS is not legally required for substance which is not classified as hazardous (see above), however, it is a good practice for suppliers to provide SDS for all chemical substances/mixtures.

REMEMBER

There is an obligation to have and to provide a safety data sheet of substances / mixtures that meet the above criteria regardless of the volume of their production, import or application. Whenever a safety data sheet is required, the DU must provide his users in the safety data sheet with information on the hazards and conditions of safe use and appropriate risk management advice.

Safety data sheet extended, extended SDS: means the safety data sheet extended with exposure scenarios for the identified uses that they contain. Applies to hazardous substances registered in quantities of 10 tonnes or more per year. It contains a summary of key information obtained from the chemical safety assessment carried out in accordance with REACH.

Safety data sheet „on request": means a safety data sheet which the supplier is required to provide to the professional occupant at his request (Article 59 (2) CLP, Article 31 (3) REACH) if the mixture does not meet the criteria for classification as hazardous in accordance with CLP title I and CLP title II but includes:

a) in concentrations of at least 1% by weight separately in the case of mixtures not present in the form of gas and at least 0.2% vol. in the case of mixtures in the form of gas, a substance that poses a risk to human health or the environment; or

b) in concentrations of at least 0.1% by weight separately in the case of mixtures which are not in the form of gas, at least one

substance that is carcinogenic, category 2 or toxic for reproduction, category 1A, 1B and 2, has skin sensitization, category 1, or is a respiratory sensitiser, category 1, or affects lactation or is harmful to breastfed babies or is persistent, bioaccumulative and toxic (PBT) according to the criteria set out in Annex XIII REACH or very persistent and very bioaccumulative (vPvB) according to the criteria set out in Annex XIII REACH or which has been placed on the list drawn up in accordance with Article 59 (1) REACH for reasons other than those referred to in point a); or

c) a substance for which maximum occupational exposure limits have been determined in the Community.

SEVESO: means legal regulations concerning the control of major-accident hazards related to hazardous substances, known as Seveso II Directives.

Small and medium-sized enterprises (SMEs): *means small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises* (Article 3 (36) REACH).

Socio-Economic Analysis Committee (SEAC): means the Committee that issues opinions on behalf of ECHA on the socio-economic impact of possible legislative actions on chemicals under the REACH processes (restrictions, authorisation). Final decisions are taken by the European Commission (Article 71 REACH).

Substance: *means 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 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* (Article 3 (1) REACH, Article 2 (7) CLP).

Substances CMR (carcinogenic, mutagenic or toxic to reproduction): means a group of compounds classified as carcinogenic, mutagenic or toxic to reproduction, classified in categories 1 or 2 (Annex I CLP).

Substances PBT (persistent, bioaccumulative and toxic): means persistent, bioaccumulative and toxic substances. It is a group of compounds with high resistance to degradation caused by abiotic and biotic factors, with a high level of bioaccumulation and high toxicity. The criteria for the identification of PBT substances are presented in Annex XIII of REACH.

Substances PPORD (Product and Process Oriented Research and Development): means substances manufactured, imported or used in product and production process research and development.

Substances SR&D (Scientific Research and Development): means substances manufactured, imported or used in scientific research and development. These substances are exempt from the authorisation procedures and restrictions that normally apply even for substances manufactured or imported in quantities below 1 t/a.

Substances SVHC (substances of very high concern): means a group of substances of very high concern which includes:

- CMR substances meeting the criteria for classification in hazard class:
  - » carcinogenicity, category 1A or 1B,
  - » germ cell mutagenicity, category 1A or 1B,
  - » reproductive toxicity, category 1A or 1B,
- PBT substances - persistent, bioaccumulative, toxic substances (PBT), in accordance with the criteria in Annex XIII of REACH;
- vPvB substances - very persistent and very bioaccumulative substances, in accordance with the criteria in Annex XIII of REACH;
- other substances such as endocrine disrupters or persistent, toxic, bioaccumulative substances or very persistent substances that are very bioaccumulative and do not meet the above criteria, for which there is scientific evidence of likely serious effects on human health or to the environment giving cause for concern equivalent to the concerns raised by other substances mentioned above and which are identified in each case individually in accordance with the procedure set out in Article 59 REACH.

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Substances SVHC are first placed on the candidate list published by ECHA and then in Annex XIV of REACH. These substances are subject to a pre-release authorisation procedure.

Substances UVCB (Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Material): means substances of unknown or variable composition, reaction complex products or biological materials.

Substances vPvB (very persistent and very bioaccumulative): means very persistent and very bioaccumulative substances. It is a group of compounds with very high resistance to degradation caused by abiotic and biotic factors, and with a very high level of bioaccumulation. The criteria for identifying vPvB substances are presented in Annex XIII of REACH.

Summation method: the method used to classify mixtures in terms of hazards to the aquatic environment. The calculation must take into account the joint contribution of all substances classified as acute cat. 1, chronic cat. 1, chronic cat. 2 and chronic cat. 3. In order to classify the hazards that the mixture poses for the aquatic environment, the „relevant ingredients" of the mixture are considered, which are identified taking into account two factors: 1. the classification of the ingredient, 2. its concentration in the mixture.

Supplier of an article: *means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market* (Article 3 (33) REACH).

Supplier of a substance or a mixture: *means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture* (Article 3 (32) REACH, Article 2 (26) CLP).

Unidentified use: means a use that is not included in the CSR and exposure scenarios prepared by the supplier (manufacturer, importer) and for which safe use conditions have not been developed, eg. safe operating conditions and the necessary risk control measures were not provided in the exposure scenarios. According to Article 37 REACH, each DU has the right to inform his supplier of the not included use so as to become an identified use. Alternatively, DU can prepare his own chemical safety report - DU CSR, which will take into account his use. Alternatively, DU may also adapt his activities to the conditions of use specified in the exposure scenarios provided by the supplier. Another option is to look for another supplier who will provide an exposure scenario covering his use. If the DU develops his own chemical safety assessment (CSA) and then document it in the DU CSR for uses not covered in the exposure scenarios prepared by the supplier, the CSA must be made available on request, but it need not be sent to ECHA. The only obligation for downstream user in this situation is to notify ECHA for which use the DU has carried out the chemical safety assessment and who is the supplier of the substance.

Use: *means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation* (Article 3 (24) REACH, Article 2 (25) CLP). The description of uses is a key condition for the chemical safety assessment in the registration documentation. It also plays an important role for DU, in particular as regards verification whether their use has been included in the exposure scenarios provided in the supply chain, and consequently whether safe working conditions (risk management measures) have been defined for these uses. Example of use: preparing a mixture that consists of several steps, including handling of raw materials and filling of containers, mixing and filling process, cleaning of containers.

Uses advised against: means the use for which the registrant did not specify the conditions of safe use in the exposure scenarios. This is a use that the registrant is aware of (because, for example, he/she has learned about it from DU or has such knowledge). The registrant may consider the use to be unsafe after a chemical safety assessment or discourage such use for precautionary reasons without even assessing it. Information on uses advised against is listed in section 1.2 of the safety data sheet.

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8. MAIN PROCEDURES OF THE REACH REGULATION

REACH REGULATION

TITLE II GENERAL ISSUES

Chapter 1 REGISTRATION OF SUBSTANCES

General obligation to register and information requirements

Chapter 2 Substances regarded as being registered

Chapter 3 Obligation to register and information requirements for certain types of isolated intermediates

REGISTRATION means the registration of chemicals in the ECHA Agency via the REACH-IT platform. The registration concerns MANUFACTURERS AND IMPORTERS OF CHEMICAL SUBSTANCES and in some cases producers and importers of articles established in the EU. Registrants are required to collect and generate data on the substance on its own, in a mixture and in the article that they manufacture or import to assess the risk associated with this substance. Under certain conditions (when the production or import volume is at least 10 t/a) it is required to perform a chemical safety assessment (CSA) and document this assessment in the chemical safety report (CSR) and then recommend downstream users and distributors appropriate risk management measures. The CSA is a part of registration dossier.

REMEMBER

All chemicals are subject to registration in their own form, in a mixture and in some cases in the articles, irrespective of whether they pose a hazard or not, with the exception of those specified below, and which are produced or imported in an amount of at least 1 t/a for one producer or importer.

Substances recovered as a result of treating waste on their own or in a mixture must be registered in accordance with REACH if they are harvested in quantities greater than 1 t/a.

NOTE

Substances completely exempt from registration are (Article 2 REACH):

- radioactive substances;
- substances temporarily stored under customs supervision, provided that they are not transformed or processed in any way;
- substances used for defence and covered by national exemptions;
- non-isolated intermediates.

REMEMBER

Waste, as defined in EU waste legislation, is excluded from REACH, but products recovered from waste are not.

NOTE

The registration requirements do not apply to substances used in:

- scientific and development research;
- food and feed;
- medicinal products.

Registration is not required for substances

- posing a minimal risk to health and/or the environment due to their basic properties (eg. water, nitrogen) listed in Annex IV of REACH;
- occurring in nature (e.g. minerals, metal ores that are not chemically modified) in which registration is considered inappropriate or unnecessary. (see Annex V of REACH);
- already registered and then exported and re-imported into the EEA by an entity operating in the supply chain;
- already registered and recovered in the waste recovery process.

REMEMBER

Polymers are currently exempted from the obligation to register, however, producers and importers of polymers may be required to register monomers or other substances used for the production of polymers. Reused or recycled substances already registered and remarketed are also exempted from registration.

REMEMBER

MIXTURES and ARTICLES are NOT subject to registration but any substances contained in them are subject to registration if their content is at least 1 t/a. In the case of ARTICLES, above mentioned applies to substances intended to be released from articles.

The registration requirement applies to the manufacturer or importer of each individual substance. In the case of ARTICLES, the registration requirement applies to producers or importers of an article if the substance has not previously been registered for such use.

REMEMBER

The producer of mixtures is a formulator in the light of the REACH Regulation, so he/she is not obliged to register.

How does registration affect DU? The registration procedure provides information on hazards and risks associated with the substance. Information on recommended risk management measures for specific uses is specified in the chemical safety report. Conducting the Chemical Safety Assessment in accordance with Annex I of REACH is mandatory for each substance registered in an amount of 10 or more t/a. Examples of report templates are available on ECHA website.

8.2. EVALUATION

REACH REGULATION

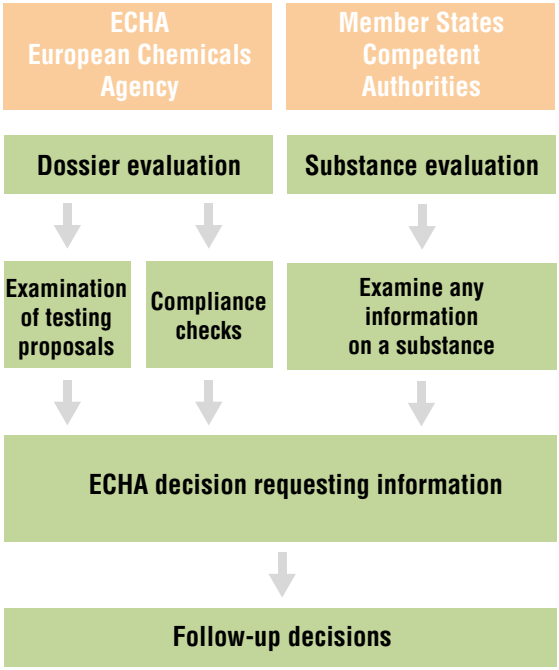
TITLE VI EVALUATION

EVALUATION means assessment of the registration documentation and evaluation of the substance. ECHA and Member States evaluate the information submitted by companies to examine the quality of registration documentation, to approve or disapprove animal tests and to clarify whether a substance constitutes a risk to human health or the environment.

The evaluation under REACH focuses on three different areas:

- examination of testing proposals submitted by registrants;
- checking compliance of documentation submitted by registrants;
- evaluation of the substance.

Picture 2. Evaluation procedure scheme (Source: ECHA)



8.3. AUTHORISATION

Authorisation concerns substances of very high concern due to their impact on health and the environment (SVHC substances). It means conditional admission to trade/use of SVHC substances placed in Annex XIV of REACH (after placed them first on so-called the Candidate List available on the ECHA website.). After incorporating the substance in Annex XIV, it can not be placed on the market or used. An exception is the situation when the use has been authorised or the use is not subject to the authorisation requirement.

The authorisation procedure aims to promote the gradual replacement of SVHCs with appropriate substitutes. Annex XIV is in the form of a table that lists the SVHC substances to be authorised, indicating their properties that led to their inclusion in the list,

and the exempted uses from the authorisation requirement as well as the transitional arrangements. All manufacturers, importers, as well as DU wishing to place on the market or use the substances listed in Annex XIV must submit an application to the ECHA for authorisation, specifying what use it applies to, and attach CSR and analysis of possible substitutes and their risks.

Applications are evaluated by the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC), which formulates working opinions. ECHA sends these opinions to the European Commission, Member States and the applicant. Authorisations shall be granted on condition that it is demonstrated that the risks to health or the environment are well controlled or the socio-economic benefits outweigh the risks to human health or the environment and there are no substitutes (alternatives).The authorisation indicates the persons to whom the authorisation was granted, the identity of the substance and the authorised use.

Each authorisation shall have a reference number which the manufacturer or downstream user must incorporate in the label of the substance/mixture containing that substance before placing it on the market and provide it in Section 2 of SDS. Any downstream user of a substance subject to authorisation must notify ECHA, which maintains an up-to-date register of downstream users using substances requiring authorisation.

REMEMBER

Substances with the following properties are considered to be SVHC (Article 57 REACH):

- substances meeting the criteria for carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A or 1B, as outlined in the CLP Regulation;
- persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances, as described in Annex XIII of REACH;
- any substance that has been subject to individual assessment, which raises no less concern than substances classified as CMR or PBT/vPvB.

REMEMBER

The SVHC identification process includes a 45-day public consultation. When a substance is identified as SVHC, it is placed on the candidate list. Placing on the candidate list immediately imposes certain obligations on suppliers of substances, including:

- delivery of a safety data sheet;
- informing about safe use;
- answering consumer questions within 45 days and;
- ECHA notifications, if the delivered article contains SVHC in amounts exceeding at least 1 t/a per manufacturer/importer, and the concentration of substances in the articles exceeds 0.1% (w/w).

REMEMBER

The SVHC substances are placed on the so-called Candidate List, which is published on the ECHA website. The list is called candidate, because substances placed on it are candidates for inclusion in Annex XIV of REACH (list of substances subject to the authorisation).

Scope of authorisation

- If the applicant is a manufacturer, only representative of producer or importer, this authorisation covers further uses down the supply chain: producer, only representative of producer or importer, formulator, DU, end user.
  Producer/importer (Applicant)» Formulator»DU»End user
- If the applicant is a formulator, the authorisation covers the applicant himself, his customers (lower level of the supply chain) and his direct supplier (one level up in the supply chain) if the supplier places the substance on the market, but does not use it himself.
  Producer/importer (direct supplier)»Formulator (Applicant) »DU»End user
- If the applicant is a DU, the authorisation covers only DU customers, it does NOT cover entities up the supply chain.
  Producer/importer»Formulator»DU (Applicant)»End user

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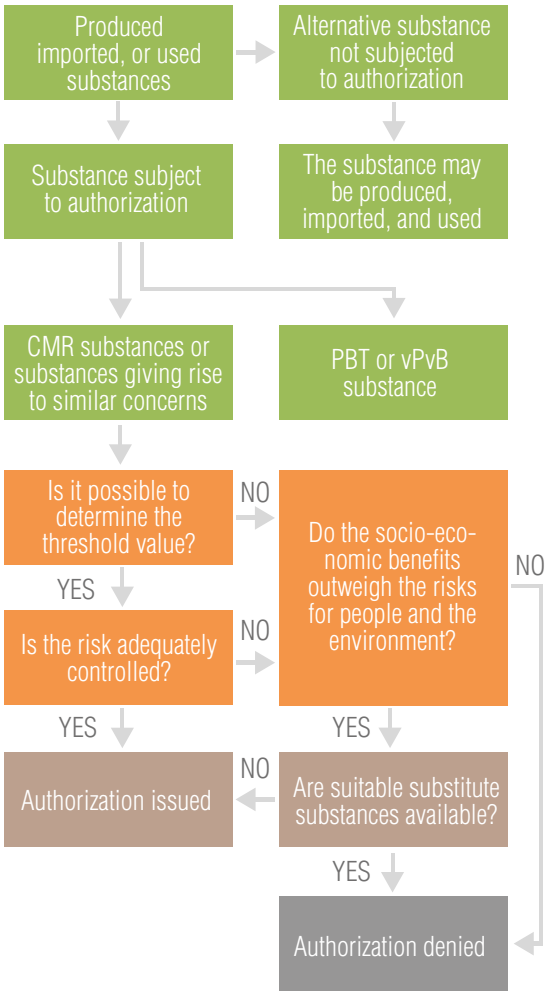
Candidate List is available on ECHA website (in English):
https://echa.europa.eu/candidate-list-table
Online version of latest Annex XIV is available on ECHA website
https://echa.europa.eu/de/authorisation-list

Picture 3. Authorisation scheme (Source: ECHA)



NOTE

STAGES OF THE Authorisation PROCESS
- Candidate list (CMR, PBT, vPvB or substances causing similar concern)
- Annex XIV REACH (list of substances subject to the authorisation)
- Application for authorisation

8.4. RESTRICTIONS

	REACH REGULATION
TITLE VIII	**RESTRICTIONS ON THE MANUFACTURING, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES AND MIXTURES**
Chapter 1	**General issues**
Article 67	General provisions
Chapter 2	**Restrictions process**
Article 68	Introducing new and amending current restrictions
Article 69	Preparation of a proposal
Article 70	Agency opinion: Committee for Risk Assessment
Article 71	Agency opinion: Committee forSocio-economic Analysis
Article 72	Submission of an opinion to the Commission
Article 73	Commission decision

RESTRICTION is an instrument to protect human health and the environment from hazards that can not be accepted. It is a process of applying restrictions on the manufacture, placing on the market (including transport) or use of substances on their own, in mixtures and articles, including those substances that do not require registration, for example substances manufactured or imported in quantities below 1 t/a or some polymers.

Restrictions may also impose any relevant conditions, such as requirements for technical measures or specific labeling. A list of these substances is included in Annex XVII of REACH.

On-site isolated intermediates, substances used in scientific research and development, and substances posing hazards to human health only in relation to their use in cosmetics are excluded from the scope of substances to which the restriction set out in the REACH Regulation applies.

For substances for which authorisation is required, ECHA may propose restrictions. At the request of the European Commission or Member State, ECHA prepares documentation in accordance with Annex XV of REACH. When it becomes evident that the use of restrictions is the most appropriate means of risk reduction, they are implemented. The documentation is assessed by the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC), which formulate working opinion on the restriction. The Agency publishes this opinion and then submits it to the Commission, which ultimately decides whether or not to amend the Annex XVII by introducing new restrictions or changing existing ones.

9. IDENTIFICATION OF THE ACTORS ROLE IN THE SUPPLY CHAIN

9. IDENTIFICATION OF THE ACTORS ROLE IN THE SUPPLY CHAIN

The obligations imposed on the company under REACH and CLP depend on its role in the supply chain. Therefore, the most important is to determine this role, as well as to check whether the entity has one or several roles in the supply chain. Even for one substance, an enterprise may have several roles: for example, the manufacturer of a given substance may also use it to formulate a mixture or to manufacture an article. The table on the next page defines the roles of individual entities in the supply chain.

Table 4. Defining the role of the actors in the supply chain.

Actors (entities) in the supply chain			Defining the role of the actors (entities) in the supply chain
MANUFACTURER of the substance on its own or in mixtures			Entities producing the substance on its own or in mixtures.
IMPORTER of the substance on its own or in mixtures			Entities importing the substance on its own or in mixtures.
DOWNSTREAM USER (DU)	FORMULATOR of mixtures		Entities preparing mixtures, if no chemical reaction occurs during mixing.
	RE-FILLER		Entities that transfer substances or mixtures from one container to another usually during the change of packaging or trade name. This action is considered as use in REACH.
	INDUSTRIAL END USER of the substance on its own or in mixtures - using chemical products in an industrial plant		Entities using substances in an industrial process that do not remain in the product (used as processing aids and then removed after production) in the context of an industrial process, eg. users of surface cleaners prior to galvanizing. They are end users because the substances and mixtures they use are no longer provided to other DU.
	PROFESSIONAL END USER of the substance on its own or in mixtures		Entities using substances or mixtures in professional activities not included in industrial processes. Craftsmen and service providers, both those who have a permanent place of work, workshops or not, operating at the customer's premises or in an educational or healthcare facility, eg. building contractors, mobile cleaning companies, professional painters, floor covering contractors, etc. They are end users because the substances and mixtures used in their professional activities are no longer provided to another DU.
	ARTICLE PRODUCER		Entities incorporating substances into articles, including introducing them into the article structure, eg. dyeing textile fibers, applying substances on the surface of the article eg. painting steel.

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Actors (entities) in the supply chain			Defining the role of the actors (entities) in the supply chain
Non-DU entities, but having rights and obligations like DU	IMPORTER OF SUBSTANCE FROM A SUPPLIER NOT ESTABLISHED IN THE EU in a situation where he/she appointed an only representative who registered the substance		Importers of substances from outside the EU, if they have appointed an only representative who registered the substance. The only representative appointed by IMPORTER acts as an importer in the supply chain, and the importer performs the functions of DU.
	REIMPORTER OF SUBSTANCE		Entities importing substances on their own or in a mixture that were originally produced on EU territory. The reimporter acts as a DU in the supply chain.
DISTRIBUTOR (D) of the substance on its own or in mixtures	RETAILER		Entities obtaining a chemical substance or mixture in the EEA, storing it and then placing it on the market for someone else (also under their own brand). If the entity only gives its brand, it is a distributor within the meaning of REACH. However, if in addition to branding it uses a product in the meaning of REACH, eg. by transferring a substance from one container to another, this is a DU. DISTRIBUTORS are NOT: • entities buying of chemicals outside the EEA and placing them directly on the EEA market. These are IMPORTERS; • entities buying chemicals in the EEA and mixing them with other chemicals, diluting them or filling containers before delivery to other entities. They are DU.
	WHOLESALER		
	WAREHOUSE WORKER		
	ENTITY CHANGING THE BRAND NAME OF THE SUBSTANCE TO A NEW ONE, when it does not carry out any activities (other than storage) specified in REACH as use.		

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9.1. LEGAL OBLIGATIONS OF DISTRIBUTORS

REMEMBER

THE CATEGORY OF DISTRIBUTOR INCLUDES:
- entities conducting retail trade;
- entities conducting wholesale trade;
- entities that change the brand name of a substance into a new one, as long as they do not perform any activities identified as use under REACH (except for storage, which are listed in the definition of „use").

OBLIGATIONS IN THE LIGHT OF THE REACH REGULATION

1. To comply with the ban on placing unregistered substances on the EU market

NOTE

The requirements of REGISTRATION applies to ALL CHEMICAL SUBSTANCES, regardless of whether they pose a hazard or not, with the exception of those that have been exempted from registration (see chapter 8.1.).

THE ONLY PARTICIPANTS TO WHOM THE REQUIREMENTS OF REGISTRATION APPLY, ARE:
- EU producers and importers of substances in its own form or in mixtures in quantities of at least 1 t/a;
- EU producers and importers of articles, if the article contains a substance in an amount above 1 t/a, and the substance will be released under normal or reasonably foreseeable conditions of use;
- „Only representatives" located in the EU, appointed by the manufacturer, formulator or manufacturer of an article, from outside the EU, in order to fulfill the obligations of importers.

2. To determine and apply of appropriate risk management measures specified in the safety data sheet or in other information provided by suppliers

Every actor in the supply chain must use guidelines regarding exposure control measures (e.g. technical control measures, including specific ventilation and personal protective equipment, including respiratory, face, hands, eyes protection), which are included in the safety data sheet or otherwise provided.

3. To update safety data sheet

According to REACH, the obligation to update the safety data sheet refers to the supplier, as well as the distributor, when (Article 31 (9) REACH):
- only new information will appear that may affect risk management measures,
- new information on hazards;
- in the case of granting or refusing authorisation;
- if a restriction is applied.

REMEMBER

Distributor who becomes newly aware of significant information regarding chemical hazards should:
- revise the labels for the chemical within three months
- revise the SDS for the chemical within three months

4. To storage the information

Information on a substance or mixture should be kept for at least 10 years from the date of the last delivery (Article 36 REACH).

5. To verify own role in the supply chain

If the entity storing chemical substances or mixtures performs other activities than storage and change of the brand into a new one, falls under a different category of entities in the supply chain (takes over the duties of other entities in the supply chain) e.g. if a distributor
- buys chemicals outside the EEA and places them directly on the EEA market - he/she is an importer;

- performs activities other than storage defined as use in REACH - he/she is a DU.

OBLIGATIONS IN RELATION TO RECIPIENTS

1. To communicate down the supply chain

REMEMBER

As long as the DISTRIBUTOR does not carry out any operations or activities, he has only the obligation to provide adequate INFORMATION IN BOTH WAYS OF THE SUPPLY CHAIN in safety data sheet, if it is required, or in other way, if the safety data sheet is not required.

Means of communication according to Article 31, 32, 33 REACH:

- using safety data sheet (SDS)
- using safety data sheets on request
- in other way, if the safety data sheets are not required

The basic carrier of information provided in the supply chain is the safety data sheet (developed in accordance with Annex II of REACH), which the distributor receives and provides free of charge (in paper or electronic version) with chemicals no later than on the first delivery.

According to Article 31 (1) REACH (amended by Article 58 CLP), a safety data sheet must be provided even without the request of an actor taking part in the supply chain, if the substance/mixture meets certain criteria.

REMEMBER

The distributor is obliged to provide the safety data sheet to his recipients free of charge.

The provision of a safety data sheet applies to hazardous substances and mixtures (Article 31 REACH), irrespective of the volume of production, import and use.

The provision of an extended safety data sheet applies to substances and mixtures presenting a risk (Article 31 REACH), registered in an amount of at least 10 t/a on the registrant.

The provision of safety data sheet on request applies under certain conditions (Article 31 (3) REACH) for mixtures that do not meet the criteria for classification as dangerous under the CLP Regulation.

The safety data sheet does not apply to articles. In the case of articles containing SVHC substances, the distributor is obliged to provide his recipients with sufficient information that will allow safe use of the article, including - as a minimum - the name of the dangerous substance.

REMEMBER

There is an obligation to provide SDS (Article 31 REACH):
a) when the substance or mixture meets the criteria for classification as hazardous under CLP;

b) when the substance is persistent, bioaccumulative and toxic in accordance with the criteria in Annex XIII of REACH; OR when the substance is very persistent or very bioaccumulative in accordance with the criteria in Annex XIII of REACH;

c) when this is the substance of very high concern (SVHC) and is on the Candidate List (Article 59 (1) REACH) for reasons other than those referred to in point a) and b).

- using safety data sheet on request of the recipient conducting professional activity for non-classified mixtures

Mixtures which are not classified as hazardous, but which contain specified concentrations of certain hazardous substances, also require a safety data sheet to be provided on request of recipients engaged in professional activities, e.g. owners of cleaning companies.

REMEMBER

There is an obligation to provide SDS of a mixture on request, if the mixture (Article 31 (3) REACH) (Article 59 (2) CLP):

- contains a substance posing a hazard to human health or the environment (in concentrations of at least 1% w/w for

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mixtures not in the form of gas and at least 0.2% volume for gas mixtures);
- contains PBT or vPvB or SVHC (at a concentration of at least 0.1% w/w for mixtures not in the form of gas); or
- contains a substance for which maximum occupational exposure limits have been determined in the Community.

NOTE

REACH does not contain any regulations requiring the provision of a safety data sheet to a natural person, understood as a consumer, but at the same time does not contain regulations prohibiting voluntary delivery.

- in other way, if the safety data sheet is not required

  If a safety data sheet is not required, the supplier, including the distributor, must provide the recipient with the following information in a different way (Article 32 REACH):
- registration numbers;
- details related to each grant or refusal of authorisation in a given supply chain;
- details of each application of the restriction in production, placing on the market and use of substances, mixtures and articles (Annex XVII to REACH);
- information necessary to identify and implement appropriate risk control measures;
- any other available and relevant information about the substance.

REACH does not specify the format in which hazard information is to be provided if a safety data sheet is not required.
The supplier must consider which format will be the most appropriate for each recipient.

PROPOSED ALTERNATIVE WAYS OF PROVIDING THE INFORMATION IN THE SUPPLY CHAIN (Article 32 REACH):
- optional in the form of a safety data sheet;
- in a separate section of the Technical Data Sheet;
- in the form of an information leaflet;
- in other formats.

2. To provide the registration numbers

The registration number should be always provided, if SDS is required in section 1 (substances) or in section 3 (mixtures), otherwise in a different way.

3. Resulting from placing the substance on the Candidate List

Inclusion of a substance in the Candidate List immediately imposes certain obligations on its suppliers, including:
- providing an updated safety data sheet or develop it if the safety data sheet has not yet been applied;
- informing on safe use;
- answering consumer questions within 45 days.

Substances

Each supplier of a substance from the Candidate List (from the European Union and the European Economic Area) must immediately provide the recipients with a safety data sheet - updated or developed from the outset, if it was not yet in force.

Mixtures

Each supplier (from EU and EEA) of mixtures that are not classified as hazardous, containing at least one substance from the Candidate List in a concentration of ≥0.1% by weight for non-gaseous mixtures and ≥0.2% vol. for gas mixtures, must provide recipients, at their request, with a safety data sheet.

Articles

Each supplier (from EU or EEA territory) of articles containing a substance from the Candidate List in a concentration >0.1% w/w must provide the recipients of the articles with sufficient information (which is available) and make the information available free of charge at the consumer's request within 45 days from receiving the request (Article 59 (1) REACH). The information should include instructions for the safe use of the article, or at least the name of the substance (Article 33 REACH).

4. To provide details related to each grant or refusal of authorisation in a given supply chain

If the entity is only a DISTRIBUTOR, it is his duty only to provide information related to each grant or refusal of authorisation in a given supply chain in a safety data sheet or in another alternative way if a safety data sheet is not required.

5. To provide details of each application of the restriction

If the entity is only a DISTRIBUTOR, it is his only obligation to provide details of any application of the restriction on production, placing on the market and use of substances, mixtures and articles (Annex XVII REACH) in a safety data sheet or in another alternative way if the safety data sheet is not required.

6. To provide information necessary to identify and implement appropriate risk control measures.

If the entity is only a DISTRIBUTOR, its only obligation is to provide the information necessary to identify and implement appropriate risk control measures in a safety data sheet or in another alternative way if a safety data sheet is not required.

OBLIGATIONS IN RELATION TO SUPPLIERS

1. To check the safety data sheet received from suppliers

It is necessary to ensure that the safety data sheet is in the appropriate national language and contains information required by national legislation, e.g. regarding health and safety or disposal of waste.

2. To inform suppliers on the uses of his recipients

The DISTRIBUTOR should check whether the uses of his recipients are included in the safety data sheet and in the supplier's exposure scenarios. If these uses are not included, the DISTRIBUTOR should notify his supplier (manufacturer, importer) in writing of this use in order to include it in the registration dossier (to consider it as an identified use).

3. To provide new information on the hazardous properties of a substance or a mixture

Distributor who become newly aware of significant information regarding chemical hazards shall provide this information to his supplier.

4. To promptly inform suppliers if the risk management measures recommended in the safety data sheet are inadequate

REMEMBER

Each supplier, including a distributor, is obliged to inform his suppliers:

- when he has got new information about hazards (immediately);
- on unidentified (not included in the safety data sheet or exposure scenarios) uses of his or his recipients (within 12 months);
- if the recommended risk management measures are not adequate (immediately).

OBLIGATIONS IN THE LIGHT OF CLP REGULATION

Proper labelling and packaging is the responsibility of manufacturers, formulators, importers and distributors. A distributor re-labelling or re-packaging such products to place his own brand bears the same responsibility for labelling and packaging as manufacturers, formulators and importers.

1. To classify substances and mixtures placed on the market

According to Article 4 CLP, chemicals placed on the market must be classified and labeled regardless of tonnage, in accordance with the rules set out in this Regulation.

2. Regarding the possibility of using an existing classification

It is possible to use the classification for a given substance or mixture already established in accordance with Title II of CLP by another participant in the supply chain, for example in the safety data sheet received (Article 4 CLP).

3. To label substances and mixtures

Substances and mixtures must be labelled in accordance with Title III of CLP (Article 17-33 CLP).

4. To package substances and mixtures

Substances and mixtures must be packaged in accordance with Title IV of CLP (Article 35 CLP).

5. To storage the information

All information required for classification and labelling in accordance with CLP must be collected and stored for a period of at least 10 years after the last delivery of the substance or mixture. This information should be kept with the information required to fulfill the obligations under REACH (Article 49 CLP).

If you use a classification developed by another participant in the supply chain, make sure that all information required for classification and labelling (eg, safety data sheet) has been kept for review for at least 10 years after the last delivery of the substance or mixture.

9.2. LEGAL OBLIGATIONS OF DOWNSTREAM USERS (DU)

	REACH REGULATION
TITLE V	**DOWNSTREAM USERS**
Article 37	Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures
Article 38	Obligation for downstream users to report information
Article 39	Application of downstream user obligations

NOTE

THE CATEGORY OF DOWNSTREAM USER INCLUDES:

- entities transferring the substance from one container to another (re-fillers);
- mixture manufacturers e.g. manufacturers of paints, cosmetics, glue, windscreen washer fluids (formulators);
- articles manufacturers e.g. manufacturers of screws, drywall, furniture;
- professional end users of the substance in its own form, in a mixture, in an article (other than industrial activity), e.g. painters, varnishers, cleaners;
- industrial end users of substances in their own form or in a mixture using them in an industrial process (these substances do not remain in the product), e.g. entities cleaning the surface before galvanization.

OBLIGATIONS IN THE LIGHT OF REACH REGULATION

DU is not obliged to register substances

REMEMBER

THE ONLY PARTICIPANTS TO WHOM THE REGISTRATION REQUIREMENTS APPLY ARE:

- EU producers and importers of substances in their own form or in mixtures in quantities of at least 1 t/a;
- EU producers and importers of articles, if the article contains a substance in an amount above 1 t/a, and the substance will be released under normal or reasonably foreseeable conditions of use;
- „Only representatives" located in the EU, appointed by the manufacturer, formulator or manufacturer of an article established outside the EU, in order to fulfill the obligations of importers.

1. Obligation to comply with the ban on placing unregistered substances on the EU market

Downstream users must ensure that their suppliers have pre-registered and then fully registered their substances.

2. To determine and apply appropriate exposure control measures in accordance with the safety data sheet or other information provided by the supplier

Each actor in the supply chain must use recommendations regarding exposure control measures (e.g. technical control measures, including specific ventilation and personal protective equipment, including respiratory, face, hands, eyes protection), which are included in the safety data sheet provided by the supplier or communicated in other way.

In the case of extended safety data sheet (containing exposure scenarios), the DU must additionally check whether these exposure scenarios include his own use and conditions of use, and if NO, he/she must take one of the following alternative actions:

- introduce the conditions specified in the provided exposure scenario (extended safety data sheet); or
- ask his supplier to include the use in the Chemical Safety Report; or
- prepare his own chemical safety report DU CSR; or
- change the supplier of a substance/mixture who will provide an exposure scenario covering his use.

These obligation (implementation of risk control measures listed in the safety data sheet and taking alternative actions) must be performed by the DU within 12 months of receipt of the safety data sheet for the registered substance.

3. To verify own role in the supply chain

If the supplier of a substance or mixture is established in the EU, his substances should already be pre registered by their producer. In this case the formulator is considered DU and is not required to register substances, but must fulfill all other DU obligations.

If the supplier of the substance or mixture is established outside the EU and does not have an "only representative" in the EU, the formulator is considered an importer and must meet the requirements of importers and register the substances used (either on its own or in a mixture).

4. To verify whether his use and the use of his recipients have been included in the safety data sheet and exposure scenarios of suppliers and to forward this information to suppliers

DU is required to verify if his own uses have been included in the safety data sheet and exposure scenarios (in case of extended SDS). If they are not included, DU must take one of the following alternative action:

- may ask his supplier (preferably through industry organizations) to include his (and/or his recipients) use in the registration dossier/CSR as an identified use. This option is beneficial for DU, as the manufacturer or importer who registers the substance carries out an assessment of the risks associated with the use;
- if DU decides not to disclose his use, he/she may develop his own chemical safety report (DU CSR) regarding his own uses (and provide recommendations on conditions of safe use). However, he/she must be aware that the development of such a report is very complicated and expensive. DU will not be required to submit it to ECHA, but will be required to make it available in case of any control and upon request;
- he/she may also adapt his activities to the conditions of identified uses specified in the exposure scenarios;

- or he may look for another supplier who will provide the exposure scenario covering his use.

5. To comply with regulatory requirements

Some substances posing a risk are subject to regulatory risk management measures, for example authorisations, restrictions or a harmonised classification. DU is obliged to act in accordance with the above mentioned legal regulations. It is recommended that DU constantly check information on regulatory activities so that they know their responsibilities. It is recommended that DU participate in social consultations during which they will be able to provide the information necessary for decision-making by regulatory authorities.

6. To comply with the conditions of authorisation

DU should regularly check the latest version of Annex XIV (List of substances subject to the authorisation procedure), in particular if his substance meets the criteria of Article 57 REACH, to ensure that a substance has not been included in Annex XIV in the meantime and therefore does not need to apply for authorisation to place it on the market or to use it.

OBLIGATION TO APPLY FOR Authorisation FOR AN IDENTYFIED USE

If the DU uses a substance from the list of substances subject to the authorisation procedure (Annex XIV of REACH), he/she should try to replace it with a safer alternative substance. If he/she wants to continue using it (e.g. the substance is of key importance to his activity), he/she must apply for authorisation. Earlier however, he/she should contact his suppliers of substances included in Annex XIV to ensure that his supplier does not apply for an authorisation covering this use.

NOTE

Applications for authorisation, in addition to producers and importers, may be submitted by DU, if their use is not covered by the authorisation granted to the manufacturer. Applications for authorisation covering one or more uses for the same substance may be submitted individually or together (Article 62 (3) REACH).

OBLIGATION TO COMPLY WITH Authorisation CONDITIONS

This obligation applies to those DU who use substances from the list of substances subject to the authorisation (Annex XIV of REACH).

- If an entity located at an earlier stage of the supply chain (e.g. a manufacturer, importer) has been authorised for a given substance, a DU that is at a later stage of the supply chain is required to comply with the conditions set out in that authorisation and notify ECHA within 3 months of the first delivery of the substance.
- If the manufacturer/importer submits an application for the use of his DU, but there is still a formulator between him and the DU, the application must also take into account the use of the substance in the formulation.

OBLIGATION TO PROVIDE INFORMATION ON Authorisation
IN SDS OR IN OTHER WAYS

The supplier must provide information in the safety data sheet in section 15 whether the substance he/she supplies is subject to authorisation or not. If YES, the supplier must immediately update the safety data sheet or provide this information in a different way (Article 32 REACH).

OBLIGATION TO PLACING REGISTRATION NUMBER
OF Authorisation ON THE LABEL

Each authorisation shall have a reference number which the manufacturer or downstream user must put on the label of the substance or the label of the mixture containing that substance, before placing it on the market.

OBLIGATION REGARDING SR&D SUBSTANCES

SR&D substances are exempted from authorisation and restrictions if their production, use or placing on the market falls within the definition of scientific research (Article 56 (3) REACH).

OBLIGATION REGARDING PPORD SUBSTANCES

PPORD substances are subject to the authorisation provisions if they are listed in Annex XIV, unless they are exempted for this type of use (see column „exempted uses (categories)" Annex XIV).

7. To comply with the restrictions conditions

The obligation applies to DU, who use substances from the list of substances subject to restrictions (Annex XVII of REACH). DU should regularly check the current version of Annex XVII to find out if the substance they have used has in the meantime been included on the list of Annex XVII and whether such a new entry does not contain bans or other conditions or restrictions on the manufacture, placing on the market or use of a given substance. As the latest consolidated version of REACH contains the status of the current list as of the date of its publication, to check whether the substance is subject to restrictions, it is recommended to check the list on the ECHA website, where the list is constantly updated. If the substance used is subject to restrictions, he may continue to use it only if he meets the conditions of the restriction.

Information on restrictions must be provided in section 15 of the safety data sheet. If a restriction is imposed, the supplier must immediately provide an updated safety data sheet or provide this information in a different way (Article 32 REACH).

If the restriction is in the form of a ban, the substance should be gradually phased out by the date specified in Annex XVII of REACH. If the restriction is in a form different from the ban of using, then the restriction conditions are included in Annex XVII of REACH and they must be forwarded down the supply chain in a safety data sheet or in other way. The downstream user should compare the conditions of the restrictions listed in Annex XVII with his own conditions of use and risk management measures to be sure that his conditions of use are in line with the guidelines of Annex XVII.

In the case of a DU acting as a formulator that adds a restricted substance to a mixture that he has placed on the market, he must provide his recipients with information on the substance restrictions in a safety data sheet or other form.

REMEMBER

If the substance used is restricted, DU may continue to use it only if he meets the restriction conditions (Annex XVII REACH).

OBLIGATION CONCERNING PPORD SUBSTANCES

Compliance with the restriction conditions also applies to the use of PPORD substances, unless they have been explicitly exempted in the text of Annex XVII.

8. To update the safety data sheet

The obligation to update the SDS applies to the supplier, and therefore also to the downstream user (except for the end user) when (Article 31 (9) of REACH):

- when only new information will appear that may affect risk management measures, or new information on hazards;
- if an authorisation is granted or refused;
- if a restriction is applied

REMEMBER

Downstream users who become newly aware of significant information regarding chemical hazards should:

- revise the labels for the chemical within 3 months;
- revise the SDS for the chemical within 3 months.

9. To storage the information

The REACH Regulation obliges manufacturers, importers, DU and D to keep for 10 years, from the date of the last production, import, delivery or use of a substance or mixture, the necessary information to fulfill the obligations imposed by REACH (Article 36 REACH).

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OBLIGATIONS IN RELATION TO RECIPIENTS

1. To communicate with other entities in a supply chain using safety data sheets (if SDS are required) or in other way if SDS is not required

DU supplying hazardous substances/mixtures must provide his recipients (DU and distributors) with safety data sheet on the date of first delivery, if SDS is required (Article 31 REACH), or in another alternative manner (Article 32 REACH), if the safety data sheet is not required.

When developing own safety data sheets, downstream users must take into account relevant exposure information obtained from suppliers.

REMEMBER

If SDS is not required, DU must provide the following information to his recipients in a different form:

- registration numbers;
- details related to each grant or refusal of authorisation in a given supply chain;
- details of each application of the restriction in production, placing on the market and use of a substance, mixture, article (Annex XVII REACH);
- information necessary to identify and implement appropriate risk control measures;
- any other available and relevant information about the substance.

NOTE

REACH does not specify the format in which hazard information is to be provided if a safety data sheet is not required. The supplier must consider which format will be the most appropriate for each recipient.

PROPOSED ALTERNATIVE WAYS OF PROVIDING INFORMATION IN THE SUPPLY CHAIN (Article 32 REACH):

- optional in the form of a safety data sheet;
- in a separate section of the Technical Data Sheet;
- in the form of an information leaflet;
- in other formats.

2. To provide the information on registration numbers

If a safety data sheet is required,

- the information shall be provided in section 1 (substances) or in section 3 (mixtures).

If the safety data sheet is not required,

- the registration number should be provided in a different way.

3. Resulting from placing the substance on the Candidate List

Placing substances on the Candidate List immediately imposes certain obligations on suppliers of substances, including:

- providing an updated safety data sheet or develop new SDS if it has not yet been required;
- informing on safe use;
- answering consumer questions within 45 days.

Substances

Each supplier of a substance from the Candidate List (supplier from the EU or the EEA) must immediately provide recipients with an updated safety data sheet or develop new SDS if it has not yet been required.

Mixtures

Each supplier (from EU and EEA) of mixtures that are not classified as hazardous, containing at least one substance from the Candidate List in a concentration ≥0.1% w/w for non-gaseous mixtures and ≥0.2% vol. for gas mixtures, must provide his recipients with SDS on request.

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Articles

Each supplier (from EU or EEA) of articles containing a substance from the Candidate List in a concentration >0.1% w/w must provide the recipients of the articles with sufficient information or make the information available free of charge at the consumer's request within 45 days of receipt of the request (Article 59 (1) REACH). This information should contain instructions for the safe use of the article, or at least the name of the substance (Article 33 REACH).

4. To provide the details related to each grant or refusal of authorisation in a given supply chain

If the entity is a DU, it is his obligation to inform his recipients of each grant or refusal of authorisation in a given supply chain in a safety data sheet or in another alternative way if a safety data sheet is not required.

5. To provide the details of any use of a restriction on production, placing on the market and use of substances, mixtures and articles

If the entity is a DU, it is his duty to provide details of each use of restriction in production, placing on the market and use of substances, mixtures and articles (Annex XVII REACH) in a safety data sheet or in another alternative way if a safety data sheet is not required.

6. To provide the information necessary to identify and implement appropriate risk control measures

DU is required to provide the recipient with the information necessary to identify and implement appropriate risk control measures in a safety data sheet or in another alternative way if a safety data sheet is not required.

OBLIGATIONS IN RELATION TO SUPPLIERS

1. To check the safety data sheet received from suppliers

It is necessary to ensure that the safety data sheet provided by the supplier is correctly prepared, in the appropriate national language and contains information required by national legislation, e.g. regarding health and safety or disposal of waste.

In the case of a FORMULATOR, the formulator is responsible for the content of all documentation transferred in the supply chain.

2. To verify whether own use and the use of recipients are included in the safety data sheet and exposure scenarios of suppliers

If DU uses are not included in the registration dossier, then he must take one of the following action:

- he may ask his supplier (preferably through industry organizations) to include his (or his recipients') use in the CSR as an identified use (Article 37 REACH). It is convenient situation for DU because, the risk assessment for a given use and the determination of the conditions of safe use are carried out by the manufacturer or importer registering the substance;
- or he take other alternative actions (see unidentified uses).

3. To promptly inform suppliers if the risk management measures recommended in the safety data sheet are inadequate

Information that might contest the appropriateness of the risk management measures recommended in any exposure scenario received, should be provided to the supplier without delay.

4. To inform suppliers if new information about hazards was obtained

The DU must notify the supplier if new hazard or classification information is available. These actions must be taken immediately (Article 34 REACH).

REMEMBER

Each DU is obliged to inform suppliers:

- about unidentified uses (not included in the safety data sheet or exposure scenarios) of his (or his recipients), within 12 months;
- if the recommended risk management measures are not adequate, immediately;
- when he/she has new information about hazards, immediately.

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OBLIGATIONS IN RELATION TO ECHA

1. To notify ECHA about the not included use

The DU must notify ECHA of his uses (Article 38 (1) REACH) not included in the safety data sheet and exposure scenarios provided by the supplier within 6 months of receiving from the supplier the extended safety data sheet for a registered substance if:

- DU prepares a downstream user chemical safety report (DU CSR), and a specific use refers to amount 1 t/a or more;
- DU is exempted from the obligation to prepare a DU CSR, because he/she uses a substance or mixture in a total quantity 1 t/a or less;
- DU is exempted from the obligation to prepare DU CSR, because he/she uses the substance to PPORD. It should be remembered that notification to ECHA is not required for use in PPORD, if the use is less than 1 t/a (Article 38 (5) REACH).
- The notification should contain a concise general description of the use of the DU and the conditions of use. It should also include an application if testing on vertebrate animals is considered necessary.

2. To notify the ECHA of a classification that differs from the classification of all suppliers

DU must notify ECHA if his classification of the substance/mixture differs from the classification of all his suppliers (Article 38 (4) REACH). The notification must be made within 6 months of receipt of the safety data sheet for the registered substance.

ECHA notification is not required if DU uses a substance or mixture in a total quantity of less than 1 t/a, in accordance with Article 38 (5) REACH.

3. To notify the ECHA of uses covered by the authorisation

DU that uses a substance from the list of substances subject to the authorisation for which use, an authorisation has been granted must notify ECHA of this use within 3 months of the first supply of the substance (Article 66 REACH).

4. To notify the ECHA about an article containing SVHC

Placing substances on the Candidate List immediately imposes an obligation to notify ECHA if the article supplied contains SVHC in amounts exceeding 1 t/a on the manufacturer/importer, and if the concentration of the substance exceeds 0.1% w/w. Notification to ECHA is free of charge and should be made within 6 months of placing the substance on the Candidate List of substances subject to authorisation.

OBLIGATIONS IN THE LIGHT OF CLP REGULATION

1. To classify substances and mixtures placed on the market

It is obligatory to classify, label and package substances and mixtures in accordance with the CLP rules before placing them on the market (Article 4 CLP). However, it is also possible to use the classification for a given substance or mixture already established, in accordance with Title II of CLP, by another actor in the supply chain, if the chemical composition of the substance or mixture is not altered.

REMEMBER

The obligation to classify, label and package (Article 4 CLP) applies irrespective of the amount of the substance produced, imported, used.

2. Regarding the new classification

If a change in the chemical composition of a substance or mixture that is placed on the market is made, a classification must be done in accordance with Title II of CLP (Article 5-14 CLP).

3. Concerning information affecting the classification

All appropriate measures should be taken to obtain new scientific or technical information that may affect the classification of substances or mixtures placed on the market. In the event of obtaining information that can be considered relevant and reliable, a new assessment of the appropriate classification should be made without undue delay (Article 15 CLP).

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4. To label substances and mixtures

Substances/mixtures must be labelled in accordance with Title III CLP (Article 17-33 CLP).

5. To package substances and mixtures

Substances/mixtures must be packaged in accordance with Title IV CLP (Article 35 CLP).

In the supply chain, it may be necessary to repackage a substance or mixture and the labelling may change with the size of the packaging or the addition of subsequent layers. In such cases, the supplier takes responsibility for repackaging and relabelling the substance or mixture and should include his contact details on the label. He/she can also replace his supplier's data with his. If the supplier changes the language of the label, he/she should add his contact details to it, as he/she is responsible for the translation.

6. To update the label

The label should be updated after any change in the classification and labelling of the substance or mixture, in some cases without undue delay (Article 30 CLP). If DU becomes newly aware of significant information regarding chemical hazard, should revise the chemical labels within 3 months.

7. To submit a proposal for amendment to the harmonised classification and labelling of substances

If new information is available that may lead to a change in the harmonised classification and labelling of a substance, an application should be submitted to the competent authority in one of the Member States where the substance is on the market (Article 37 (6) CLP).

8. To storage of information

DU has the obligation to collect and store all information required for classification and labelling for a period of at least 10 years after the last delivery of the substance/mixture. This information should be kept with other information required under the REACH and CLP Regulations (Article 36 REACH)(Article 49 CLP).

9. To provide information

Importers and DU that place mixtures on the market should be ready to provide certain information on mixtures to Member States' authorities who are responsible for receiving such information in order to determine preventive and medical measures, especially in emergencies (Article 49 CLP).

10. Regarding SR&D substances

CLP does not apply to substances and mixtures falling within the SR&D category, if they are used under controlled conditions in accordance with current Community legislation (Article 1 (2) lit. D CLP).

However, if substances for research and development start to be imported or delivered to third parties (for example, by sending samples to another research centre or importing such samples), then such activity is considered as „placing on the market" (Article 2 (18) CLP). In this situation, CLP requires that the supplier or importer prepare an appropriate classification in accordance with available information and label and package hazardous substances or mixtures according to the CLP criteria. Therefore, importers must classify and label imported substances, even if they serve only for their own use.

REMEMBER

It should be noted that the obligation to classify, label and package (Article 4 CLP) applies irrespective of the amount of the substance. The obligation to classify, label and package (Article 4 CLP) also applies to small quantities of substances or mixtures supplied to a test facility or laboratory.

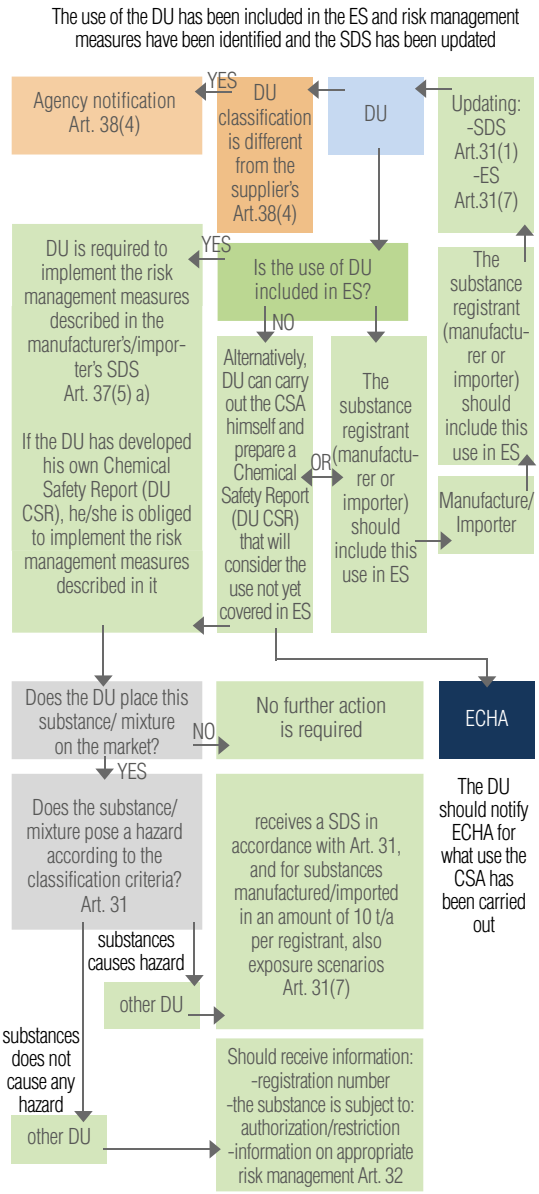
11. Regarding PPORD substances

Classification, labelling and packaging according to CLP are required for substances used for PPORD or mixtures containing such substances, irrespective of whether such substances or mixtures are made available to buyers or not.

OTHER OBLIGATIONS OF DU AND D RESULTING FROM REACH AND CLP

- Duty to provide employees with access to information: the employer provides employees and their representatives with access to information about substances or mixtures that they use in their work or are exposed to at work.
- Obligation to store information and make it available at the request of ECHA or the competent authority of a Member State: This obligation refers to any downstream user and distributor. All information required from him to fulfill his obligations under REACH should be kept for at least 10 years from the last date of delivery or the use of a substance or mixture.
- Suppliers of substances or mixtures, including DU and D chemicals, are recommended:
  - » to prepare the list of substances and mixtures (including substances contained in the mixtures) and list of substances contained in the articles, as well as list of suppliers and customers and the uses of the substance and mixtures;
  - » to assess the training needs;
  - » to monitor the information on the website of the national competent authority and ECHA in order to have up-to--date information on changes in regulations and related guidelines;
  - » to seek advice from industry organizations as part of their support.

Picture 4. Obligations of downstream user (Source: ECHA)



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10. COMMUNICATION FLOW IN THE SUPPLY CHAIN

10. COMMUNICATION FLOW IN THE SUPPLY CHAIN

REACH REGULATIONS

TITLE IV	INFORMATION IN THE SUPPLY CHAIN
Article 31	Requirements for safety data sheets
Article 32	Duty to communicate information down the supply chain for substances on their own or in mixtures for which a safety data sheet is not required
Article 33	Duty to communicate information on substances in articles
Article 34	Duty to communicate information on substances and mixtures up the supply chain
Article 35	Access to information for workers
Article 36	Obligation to keep information

The successful implementation of the REACH and CLP processes depends on the efficient and effective flow of information in all directions of the supply chain. The purpose of these regulations is to ensure a high level of protection of human health and the environment. These regulations clearly impose on producers and importers of chemicals as well as other actors in the supply chain the responsibility for managing risks associated with chemicals and obligation to provide chemical safety information to other participants in the supply chain.

Registrants prepare registration dossiers, and for substances that are manufactured or imported above 10 t/a, also chemical safety report (CSR). Registrants are required to assess the uses of the substance throughout the life cycle of the substance. That is why they need to collect information on the uses of their substance in the supply chain, for example from their customers. The registration dossier and chemical safety report (CSR), define the conditions of safe use for specific uses or groups of uses, and exposure scenarios that are part of the chemical safety report. CSR remains in ECHA, while a safety data sheet, which should

contain information consistent with CSR, is a tool for providing information on the conditions of safe use of substances down the supply chain. Safety data sheets contain exposure scenarios for substances produced or imported above 10 t/a. The exposure scenarios attached to the SDS are simpler than the exposure scenarios submitted to the ECHA Agency in the registration dossier and should clearly set out the operational conditions and risk management measures to ensure the safe use of the substance.

Upstream communication flow (right/obligation) mainly concerns the flow of information on unidentified uses, information on new hazards caused by the substance and on inappropriate risk management measures recommended in the safety data sheet to the registrant. This information can be provided directly by each participant in the supply chain (end user, DU or formulator), or through a sector organization. Depending on the supply chain, information may also flow from the DU to the formulator and further to the registrant, and may also include distributors. The formulator, providing suppliers with information on how mixtures are used in practice in the supply chain, helps registrants take into account the actual conditions of use in their chemical safety reports.

Downstream communication flow (obligation) concerns the flow of information, from the registrant, to the relevant entity down supply chain, in the safety data sheets and exposure scenarios in which appropriate risk control measures are defined. The formulator (preparing the mixtures) is responsible for the classification, labelling and packaging of mixtures that it places on the market. He/she must therefore know and provide information on the hazards of the mixture and provide this information along the supply chain. Mixtures must be classified, labelled and packaged in accordance with the Regulation on classification, labelling and packaging of substances and mixtures (CLP) (Regulation (EC) No 1272/2008).

10.1. PROVIDING INFORMATION ON HAZARDS AND PRECAUTIONS USING SAFETY DATA SHEETS

The safety data sheet (SDS or MSDS - material safety data sheet) provides a source of comprehensive information in the supply chain on the physical, health and environmental hazards posed by the chemical substance or mixture and the recommended precautions.

Each supplier of a substance or mixture is legally required (Article 31 (1) REACH) to provide a safety data sheet to all DU and distributors of substances or mixtures, prepared in accordance with Annex II of REACH if the substance falls into one of the following categories:

- meets the criteria for classification as hazardous in accordance with the CLP Regulation; or
- is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in accordance with the criteria in Annex XIII of REACH; or
- is on the Candidate List of substances that may be subject to the authorisation procedure (Annex XIV of REACH).

In addition, Article 31 (3) REACH specifies the conditions under which a safety data sheet for the mixture must be provided on request. This applies to mixtures that do not meet the criteria for classification as hazardous in accordance with the CLP Regulation, but contain substances (ingredients):
a) in concentration of ≥1% w/w for non-gaseous mixtures and ≥0.2% by volume for gaseous mixtures - at least one substance posing human health or environmental hazards; or
b) in concentration of ≥0.1% w/w for non-gaseous mixtures - at least one substance that is carcinogenic, category 2 or toxic to reproduction, category 1A, 1B and 2, skin sensitiser, category 1, respiratory sensitiser, category 1, or has effects on or via lactation or is persistent, bioaccumulative and toxic (PBT) in accordance with the criteria set out in Annex XIII or very persistent and very bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII or has been included for reasons other than those

referred to in point (a) in the list established in accordance with Article 59(1) REACH; or
c) a substance for which there are Community workplace exposure limits.

In the light of the above, it is strongly recommended that each supplier of the mixture referred to in Article 31 (3) REACH has developed a safety data sheet for such a mixture in order to be made available on request. If the substance is supplied on its own, a safety data sheet for this substance must be prepared, if the substance is supplied as part of a mixture, a safety data sheet for the mixture should be prepared.

NOTE

The use of hazardous substances and mixtures without the required SDS is not allowed in the professional activity.

The content and format of the safety data sheet within the European Economic Area are set out in Annex II to REACH. The safety data sheet consists of 16 sections and must be available in the official language of the Member State where the substance or mixture was placed on the market.

The safety data sheet is usually made first by the manufacturer, importer or only representative (or by persons acting on their behalf), but the REACH requirements for the supply of the safety data sheet apply to every stage of the supply chain. A supplier of a substance or mixture that meets certain criteria must provide a safety data sheet for them, regardless of his position in the supply chain.

Both the downstream user and the distributor forward the safety data sheet down the supply chain (to their recipients), checking its suitability and completing it to meet the specific needs of their clients. They must check whether their uses have been included in the exposure scenarios received from the supplier.

Suppliers of a substance or mixture for which SDS is required shall in any case be responsible for its content, even if they have not made the SDS themselves.

The safety data sheet must be provided free of charge, no later than when the substance or mixture is delivered on the day of the first delivery. It can be delivered in paper or electronic form.
In any case, it is the responsibility of the supplier to actually deliver the safety data sheet to the recipient. This means, for example, that making it available on a website is not enough.

There is no need to provide additional copies of the safety data sheet with subsequent deliveries to the same recipient, unless the safety data sheet has been updated.

Safety data sheets do not have to be provided for articles, although the format of the safety data sheet may be used for certain articles to provide safety information down the supply chain.

UPDATING OF THE SAFETY DATA SHEET:

Safety data sheets do not have an expiration date and there is no obligation to update them at specified intervals, however, there is a legal obligation to update the SDS (Article 31(9) REACH):

- when only new information will appear that may affect risk management measures, or new information on hazards;
- in the case of granting or refusing authorisation;
- if a restriction has been imposed.

The supplier may at any time voluntarily issue the update for other reasons. The update should also be provided to all recipients to whom the substance or mixture has been supplied in the last 12 months.

It is also necessary to follow the status of substances included in the mixture in order to be able to react early e.g. to planned changes in classification.

Table 5. Structure of the safety data sheet according to Annex II of REACH.

Section			Subsections
1	Identification of the substance/mixture and of the company/ undertaking		1.1. Product identifier 1.2. Relevant identified uses of the substance or mixture and uses advised against 1.3. Details of the supplier of the safety data sheet 1.4. Emergency telephone number
2	Hazards identification		2.1. Classification of the substance or mixture 2.2. Label elements 2.3. Other hazards
3	Composition/information on ingredients		3.1. Substances 3.2. Mixtures
4	First aid measures		4.1. Description of first aid measures 4.2. Most important symptoms and effects, both acute and delayed 4.3. Indication of any immediate medical attention and special treatment needed
5	Firefighting measures		5.1. Extinguishing media 5.2. Special hazards arising from the substance or mixture 5.3. Advice for firefighters
6	Accidental release measures		6.1. Personal precautions, protective equipment and emergency procedures 6.2. Environmental precautions 6.3. Methods and material for containment and cleaning up 6.4. Reference to other sections
7	Handling and storage		7.1. Precautions for safe handling 7.2. Conditions for safe storage, including any incompatibilities 7.3. Specific end use(s)
8	Exposure controls/personal protection		8.1. Control parameters 8.2. Exposure controls

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Section			Subsections
9	Physical and chemical properties		9.1. Information on basic physical and chemical properties • Appearance (physical state, colour) • Odour • Odour threshold • pH • Melting point/freezing point • Initial boiling point and boiling range • Flash point • Evaporation rate • Flammability (solid, gas) • Upper/lower flammability or explosive limits • Vapour pressure • Vapour density • Relative density • Solubility(ies) • Partition coefficient: n-octanol/water • Auto-ignition temperature • Decomposition temperature • Viscosity • Explosive properties • Oxidising properties 9.2. Other information
10	Stability and reactivity		10.1. Reactivity 10.2. Chemical stability 10.3. Possibility of hazardous reactions 10.4. Conditions to avoid 10.5. Incompatible materials 10.6. Hazardous decomposition products

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Section			Subsections
11	Toxicological information		11.1. Information on toxicological effects • Acute toxicity • Skin corrosion/irritation • Serious eye damage/irritation • Respiratory or skin sensitization • Germ cell mutagenicity • Carcinogenicity • Reproductive toxicity • Specific target organ toxicity (STOT)-single exposure • Specific target organ toxicity (STOT)-repeated exposure • Aspiration hazard
12	Ecological information		12.1. Toxicity 12.2. Persistence and degradability 12.3. Bioaccumulative potential 12.4. Mobility in soil 12.5. Results of PBT and vPvB assessment 12.6. Other adverse effects
13	Disposal considerations		13.1. Waste treatment methods
14	Transport information		14.1. UN number 14.2. UN proper shipping name 14.3. Transport hazard class(es) 14.4. Packing group 14.5. Environmental hazards 14.6. Special precautions for user 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code
15	Regulatory information		15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture 15.2. Chemical safety assessment

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Section			Subsections
16	Other information		This section of the safety data sheet contains other information that has not been included in sections 1-15, including: • In the case of an update of the safety data sheet, clear information is provided where changes have been made compared to the previous version of the safety data sheet, unless this information is provided elsewhere in the safety data sheet, including explanations of changes where necessary. The supplier of the substance or mixture must be able to explain the changes upon request; • Explanation of abbreviations and acronyms used in the safety data sheet; • References to key literature and data sources; • In the case of mixtures, an indication which of the information assessment methods, referred to in Article 9 of CLP Regulation, was used to classify; • List of appropriate hazard statements or precautionary statements. The full text of any statements is provided, which are not given in full in Sections 2-15; • Recommendations regarding any indicated employee training, in order to guarantee the protection of human health and the environment.

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10.1.1. EXTENDED SAFETY DATA SHEET

When using hazardous chemicals as part of industrial or professional activities, suppliers are required to provide an extended SDS, extended with exposure scenarios, if the hazardous substance is registered in an amount of at least 10 t/a per registrant. The obligation to develop exposure scenarios concerns manufacturers and importers of substances and in specific cases downstream users. Exposure scenarios are part of the chemical safety report/ registration dossier, and are then attached to the safety data sheet.

The extended safety data sheet for chemical mixture may contain:

1. exposure scenario for the mixture;
2. several exposure scenarios, each of which refers to one of the hazardous substances contained in the mixture;
3. both the exposure scenario for the mixture and several scenarios for specific hazardous substances.

Exposure scenarios

Exposure scenarios (ES) are prepared for hazardous substances and reported in a chemical safety report (CSR). ES describe how to control human and the environment exposure to certain substances and mixtures to determine their safe use.

When a substance for which a CSR has been prepared is supplied to DU, the relevant ES have to be included as an annex to SDS. This commonly referred to as extended SDS. Exposure scenarios relate to all identified uses (this information is provided in section 1.2 of SDS), from manufacturing to the waste stage, including:

- uses within a given company;
- the use of the recipients in their processes or products, e.g. in mixtures or articles;
- the use of companies down this supply chain, supplied with this substance.

If the use or conditions of use of a given DU are not included in the exposure scenarios, DU should ask his supplier to include

those uses in his CSR and to provide a revised exposure scenario, in which safe conditions for this use will be determined (it is one of the alternative ways).

The exposure scenario contains „conditions of use" that determine the level of exposure. The conditions of use are divided into two types of parameters: operational conditions and risk management (control) measures. Operating conditions describe how a given process or activity is implemented. An example of such information is the quantity, duration and frequency of use of a substance or mixture, temperature, pressure, pH, and e.g. whether the substance is used in a closed vessel or used outdoors. In general, the operational conditions of use determine the emission of substances in the process.

Risk control measures (risk management measures) means measures and procedures that reduce the risk of exposure to chemical substances / mixtures to an acceptable level. Examples of risk management measures may be local exhaust ventilation, air filters, wastewater treatment plants or personal protective equipment such as gloves, gas masks and safety goggles. Information on ambient parameters in which chemicals are used may also form part of the exposure scenario. For example, you may need information about the degree of dilution of the substance in surface water or the volume of air in the workplace to which the substance was emitted.

After receiving ES, it should be determined whether the identified use and conditions of the use are covered by the scenario. If they are not included, the following actions should be considered:

- enquire if the supplier can provide an appropriate exposure scenario;
- adjust the planned activity (use) to the received exposure scenario;
- substitute the substance/mixture or process for another included in the received exposure scenario;
- change the supplier to one that will provide the required exposure scenario;
- develop own downstream user chemical safety report (DU CSR) together with exposure scenarios;
- if necessary, send information to ECHA.

From the date of receipt of the extended SDS a downstream user has 12 months to:

- implement the extended safety data sheet and update the delivered cards (if the use and conditions of use of the substance or mixture are included in the received exposure scenario);
- develop own chemical safety report and implement the exposure scenarios contained therein (if the use or conditions of safe use are not covered by the exposure scenario obtained).

The format and content of ES are not specified in the REACH Regulation, but ECHA, with the involvement of stakeholders, agreed on its uniform format and content.

The agreed format of ES consists of the following 4 sections:

Section 1: Title section

In this section you will find a description of the identified use(s) of a substance, using 'descriptors' from the use descriptor system (UDS) as defined in the ECHA guidance R12. The purpose of the UDS is to facilitate communication in the supply chain. A meaningful description may often need a combination of a maximum of five individual descriptors, namely: the sector of use category (SU), the chemical product category (PC), the process category (PROC), the environmental release category (ERC/SPERC) and the article category (AC). Please note that some of the use descriptors are important input parameters in specific Tier 1 exposure estimation tools.

Based on section 1, you should be able to initially decide whether the ES you are reading includes your use(s).

Section 2: Conditions of use affecting exposure

The ES is intended to prescribe conditions under which a substance can be handled safely. This means addressing all factors that could potentially (under realistic assumptions) modify the emission into the workplace atmosphere as relevant for inhalation exposure, or modify the dermal exposure potential. Modifying factors for occupational exposure may be grouped in (i) substance (or material) intrinsic, (ii) process intrinsic or (iii) emission/exposure reduction measures (such as local exhaust ventilation). Additionally, personal protective equipment may be worn by workers to reduce personal exposure.

Section 3. Exposure estimation and reference to its source

This section will communicate the information related to exposure estimation and risk characterisation. Such information can be reported as numerical data (e.g. calculated exposure level and/or risk characterisation ratio (RCR)), or as a reference to where these data can be found (e.g. web-link, reference to specific subsections and/or appendices of the CSR). You should also find information on which methods and/or tools the supplier has been using for generating the exposure estimates when he/she has had no measured data. This section is sometimes shortened to one sentence in the eSDS stating e.g. the assessment method, the DNEL, the calculated RCR < 1 and that safe use is demonstrated.

Section 4: Guidance to DU to evaluate whether he/she is working inside the boundaries set by the ES

For more information please see Practical guide 13:How downstream users can handle exposure scenarios

https://echa.europa.eu/documents/10162/13655/du_practical_guide_13_en.pdf

Practical examples of exposure scenarios on ECHA websites:

https://echa.europa.eu/de/support/practical-examples-of-exposure-scenarios

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10.2. PROVIDING INFORMATION ON HAZARDS AND PRECAUTIONS USING LABELS

CLP REGULATION

TITLE III	**HAZARD COMMUNICATION IN THE FORM OF LABELLING**
Chapter 1	**Content of the label**
Article 17	General rules
Article 18	Product identifiers
Article 19	Hazard pictograms
Article 20	Signal words
Article 21	Hazard statements
Article 22	Precautionary statements
Article 23	Derogations from labelling requirements for special cases
Article 24	Request for use of an alternative chemical name
Article 25	Supplemental information on the label
Article 26	Principles of precedence for hazard pictograms
Article 27	Principles of precedence for hazard statements
Article 28	Principles of precedence for precautionary statements
Article 29	Exemptions from labelling and packaging requirements
Article 30	Updating information on labels
Chapter 2	**Application of labels**
Article 31	General rules for the application of labels
Article 32	Location of information on the label
Article 33	Specific rules for labelling of outer packaging, inner packaging and single packaging
Article 34	Report on communication on safe use of chemicals

Manufacturers, importers, downstream users and distributors, as well as producers and importers of specific items, must inform other actors in the supply chain, including consumers, of identified risks. This is done by labelling the substance or mixture in accordance with CLP before placing it on the market when:

- the substance or mixture is classified as hazardous;
- a mixture contains one or more substances classified as hazardous above a certain threshold;
- the article has explosive properties.

CLP sets out general labelling requirements to ensure the safe use and delivery of hazardous substances and mixtures.

CLP defines the content of the label and the organisation of the various label elements. See chapters 13.2, 15, 16 and Annex 1.

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11. NOTIFICATION TO ECHA

11. NOTIFICATION TO ECHA

There are situations, in which downstream user must notify ECHA. The obligations include:

NOTIFICATION about the use not included in the safety data sheet and exposure scenarios provided by the supplier

The DU must notify ECHA of his uses (Article 38 (1) REACH) not included in the safety data sheet and exposure scenarios provided by the supplier within 6 months of receiving from the supplier the extended safety data sheet for a registered substance if:

- DU prepares a downstream user chemical safety report (DU CSR), and a specific use refers to amount 1 t/a or more;
- DU is exempted from the obligation to prepare a DU CSR, because he/she uses a substance or mixture in a total quantity 1 t/a or less;
- DU is exempted from the obligation to prepare DU CSR, because he/she uses the substance to PPORD. It should be remembered that notification to ECHA is not required for use in PPORD, if the use is less than 1 t/a (Article 38 (5) REACH).

The notification should contain a concise general description of the use of the DU and the conditions of use. It should also include an application if testing on vertebrate animals is considered necessary.

NOTIFICATION of a classification that differs from the classification of all suppliers

DU must notify ECHA if his classification of the substance/mixture differs from the classification of all his suppliers (Article 38 (4) REACH). The notification must be made within 6 months of receipt of the safety data sheet for the registered substance.

ECHA notification is not required if DU uses a substance or mixture in a total quantity of less than 1 t/a, in accordance with Article 38 (5) REACH.

NOTIFICATION of uses covered by the authorisation

DU that uses a substance from the list of substances subject to the authorisation for which use, an authorisation has been granted must notify ECHA of this use within 3 months of the first supply of the substance (Article 66 REACH).

NOTIFICATION about an article containing SVHC

Placing substances on the Candidate List immediately imposes an obligation to notify ECHA if the article supplied contains SVHC in amounts exceeding 1 t/a on the manufacturer/importer, and if the concentration of the substance exceeds 0.1% w/w.

12. PUBLIC CONSULTATIONS

12. PUBLIC CONSULTATIONS

Public consultation is an opportunity for all interested parties including downstream users to influence ECHA's decisions. Consultations concern selected REACH and CLP processes, including authorisation, restrictions and adoption of a harmonised classification and labelling.

12.1. PUBLIC CONSULTATION IN AUTHORISATION PROCEDURE

The authorisation process aims to ensure that substances of very high concern (SVHCs) are progressively replaced by less hazardous substances or technologies where technically and economically feasible alternatives are available.

The authorisation process involves three steps, in each of which the public is consulted and interested parties are encouraged to get involved and give their views. The steps are:

- Identification of SVHCs

The purpose is to identify which substances will be included in the Candidate List. The public consultations take place twice a year (45 days in March-April and September-October).

- Recommendation for inclusion in the Authorisation List

The purpose is to define in which order substances from the Candidate List are included in the Authorisation List (Annex XIV). The public consultations take place once a year (90 days in September-December).

- Applications for authorisation

The purpose is to assess whether the use of the substance (as applied for by the applicant) can continue after the sunset date. The public consultations take place quarterly (eight weeks starting mid-February, mid-May, mid-August and mid-November).

12.2. PUBLIC CONSULTATIONS IN RESTRICTION PROCEDURE

A Member State, or ECHA, at the request of the European Commission, can start the restriction procedure when they are concerned that a certain substance poses an unacceptable risk to human health or the environment. ECHA can also propose a restriction on articles containing substances that are on the Authorisation List (Annex XIV).

The intention to prepare a restriction proposal is made public in the registry of intentions. The dossier proposing the restriction needs to be prepared according to the REACH Regulation (Annex XV) and has to be submitted to ECHA within 12 months of the publication of the intention.

Upon receiving the dossier ECHA's committees check whether the proposal conforms to the requirements of Annex XV. If it does, the dossier will be made publicly available for consultation for six months (excluding any commercially confidential information).

Within 9 months of that same publication date, ECHA's Committee for Risk Assessment (RAC) will give its opinion on whether the suggested restriction is appropriate in reducing the risk to human health or the environment based on the dossier and the comments received during the public consultation.

At the same time, the Committee for Socio-economic Analysis (SEAC) prepares an opinion about the socio-economic impacts of the suggested restrictions, taking into account the comments received. Interested parties have 60 days from the date of the publication of the draft opinion for the second public consultation. SEAC will then adopt its final opinion, taking the comments into account, within 12 months of the start of the first public consultation on the restriction proposal.

The two opinions of ECHA's committees contribute to the decision of the European Commission, which will then take a balanced view of the identified risks and of the benefits and costs of the proposed restriction. Within three months of receiving two committees' opinions, the Commission will provide a draft amendment to the list of restrictions in Annex XVII to REACH.

12.3. PUBLIC CONSULTATIONS IN HARMONISED CLASSIFICATION AND LABELLING (CLH)

So as to ensure an adequate risk management, for hazards of highest concern (carcinogenicity, mutagenicity, reproductive toxicity (CMR) and respiratory sensitisers) and for other substances on a case-by-case basis, classification and labelling is harmonised throughout the EU.

For substances for which harmonised classification and labelling has been established at Community level, see Annex VI to the CLP Regulation. In Part 3 of Annex VI to the CLP Regulation, Table 3.1 lists the substances having a harmonised classification and labelling in line with the requirements of the CLP Regulation.

Once the proposal for the harmonised classification and labelling is submitted to ECHA, all parties concerned (e.g. industry, Member States, other stakeholders and the general public) will be given the opportunity to comment on it in public consultation. The opportunity to comment will be provided via the ECHA website, in a specified commenting form, where comments can be introduced by a specified deadline, within 45 days. All hazard classes for which the dossier submitter has provided an appropriate information basis, and which have been assessed against the classification criteria, will be open for comments during the public consultation on CLH dossier.

The comments received will be collected by ECHA and sent to the dossier submitter who will be asked to provide, within a set deadline (normally 42 days), a response to the comments (RCOM). The RCOM must then be returned to ECHA. No revisions must be made to the original CLH dossier, but the response to all comments, including any corrections and/or revisions to the CLH dossier, should instead be addressed in the RCOM. ECHA will then forward the CLH dossier and RCOM to the Committee for Risk Assessment (RAC), which has eighteen months (Article 37(4) CLP) to form an opinion on the proposal.

The Agency will then forward this opinion to the European Commission, which considers whether the harmonisation is appropriate, taking the RAC opinion into account. Should the Commission find that the proposal and justification are appropriate, it will propose to include the substance in Table 3 of Part 3 of Annex VI to CLP, together with the relevant classification and labelling elements and, where appropriate, the SCLs, M-factors and ATEs.

13. MAIN PROCEDURES OF THE CLP REGULATION

13. MAIN PROCEDURES OF THE CLP REGULATION

The CLP Regulation is legally binding for all Member States and applies to all industries. It is the implementation of the Globally Harmonised System of Classification and Labelling of Chemicals GHS, developed by the United Nations in 2002, but additionally includes some features and procedures from the previous EU classification and labelling system, DSD and DPD, which are not part of the UN GHS. That is why the CLP Regulation is similar but not identical to the UN GHS. The purpose of both classification and labelling systems is to identify the hazardous properties of a substance or mixture by applying specific classification criteria to the available hazard data, and then to provide adequate hazard labelling and information on safety measures.

The CLP system contains criteria for classification of dangerous substances/mixtures by hazard class and category, some of which are not present in the UN GHS. Hazard class means the nature of a physical, health or environmental hazard (Article 2 (1) CLP) and the hazard category means the degree of hazard in each hazard class according to specific criteria, with category 1 being the highest hazard (Article 2 (1) CLP).

The primary purpose of introducing the CLP Regulation was to self-classify the substance/mixture by the manufacturer, importer or downstream user (Article 4 (3) CLP), including hazard identification and subsequent classification based on the criteria set out in Annex I CLP, part 2-5. The CLP Regulation allows the industry to self-classify chemicals and provides appropriate information on the risks of target groups potentially handling the substance or mixture or being exposed to it. For substances of very high concern (carcinogens, mutagens, substances toxic for reproduction (CMR) and respiratory sensitizers) or for other substances for which action is needed at EU level, CLP defines a system of formal harmonisation of classifications at EU level (harmonised classification and labelling) listed in Table 3 of Annex VI CLP.

NOTE

Hazardous substance or mixture is a substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in Parts 2 to 5 of Annex I CLP, which shall be classified in relation to the respective hazard classes provided for in that Annex. Where, in Annex I, hazard classes are differentiated on the basis of the route of exposure or the nature of the effects, the substance or mixture shall be classified in accordance with such differentiation (Article 3 CLP).

NOTE

The CLP Regulation does not apply to:

- radioactive substances and mixtures;
- substances and mixtures subject to customs supervision, provided that they are not processed and that they are temporarily stored, or are in a free zone or in a free warehouse and are to be re-exported or in transit;
- non-isolated intermediates;
- substances and mixtures for research and development purposes that are not placed on the market, provided that they are used under controlled conditions in accordance with Community provisions on working and environmental conditions.

In addition, the Regulation does not apply to substances or mixtures in the following forms, in a finished state and intended for the end user:

- medicinal products;
- veterinary medicinal products;
- cosmetic products;
- medical devices that are invasive or used in direct physical contact with the human body;
- food or feed, used:
  - » as food additives,
  - » as a flavouring in foodstuffs,
  - » as a feed additive,

The European Chemicals Agency (ECHA) manages the CLP related tasks - such as harmonised classification and labelling, handling requests for alternative names and maintaining the Classification & Labelling Inventory (C&L) - to ensure consistent implementation in the EU. The obligations for industry depend on their role in the supply chain. Manufacturers and importers have to notify to ECHA the identity and classification and labelling of substances within one month of placing them on the market either on their own or in a mixture, and regardless of the quantity.

13.1. CLASSIFICATION

CLP REGULATION

TITLE II HAZARD CLASSIFICATION

Chapter 1 Identification and examination of information

Article 5 Identification and examination of available information on substances

Article 6 Identification and examination of available information on mixtures

Article 7 Animal and human testing

Article 8 Generating new information for substances and mixtures

Chapter 2 Evaluation of hazard information and decision on classification

Article 9 Evaluation of hazard information for substances and mixtures

Article 10 Concentration limits and M-factors for classification of substances and mixtures

Article 11 Cut-off values

Article 12 Specific cases requiring further evaluation

Article 13 Decision to classify substances and mixtures

Article 14 Specific rules for the classification of mixtures

Article 15 Review of classification for substances and mixtures

Article 16 Classification of substances included in the classification and labelling inventory

CLP ANNEXES

Annex I Classification and labelling requirements for hazardous substances and mixtures

Annex VI Harmonised classification and labelling for certain hazardous substances

CLASSIFICATION is the starting point for hazard communication. The classification and labelling procedure has been harmonised to ensure harmonised risk management across the European Union. The CLP Regulation introduces the criteria of the UN Globally Harmonised System of Classification and Labelling (UN GHS) in the EU.

According to the CLP Regulation, a manufacturer, importer or downstream user is required to self-classify a substance if the substance has no harmonised classification and has hazardous properties (harmonised classification is shown in Annex VI of CLP, table 3). Hazardous substance or mixture is defined (Article 3 CLP).To make self-classification, the classifier must first collect all available information and evaluate this information in accordance with the classification criteria and then decide on the appropriate classification. Classification of the mixture can be made on the basis of data on the mixture, on similar mixtures or on individual components of the mixture. For substances of particular concern (carcinogens, mutagens, substances toxic for reproduction (CMRs) and respiratory sensitisers) or for other substances where EU-wide action is needed, CLP sets out a system for formal harmonisation of classifications at EU level (Annex VI of CLP, table 3).

For substances for which there is a harmonised classification (Annex VI of CLP, Table 3), the harmonised classification is legally valid for the classes and types of hazards included in this entry. Hazards not included in the entry should be assessed and self-classified.

The classification and labeling inventory maintained by ECHA is a database that contains information on the classification and labeling of notified and registered substances received from manufacturers and importers. It also contains a list of harmonised classifications (Tables 3.1 of Annex VI to the CLP Regulation).

Companies have to provide this information in their C&L notifications or registration dossiers. ECHA maintains the C&L Inventory, but does not review or verify the accuracy of the information.

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NOTE

Elements of CLASSIFICATION, listed in Table 3.1, Part 3, Annex VI, CLP:

- Hazard Class and Category Code(s) (e.g. Flam. Gas 1, Press. Gas)
- Hazard statement Code(s) (e.g. H220)

13.2. LABELLING

CLP REGULATIONS

TITLE III	**HAZARD COMMUNICATION IN THE FORM OF LABELLING**
Chapter 1	**Content of the label**
Article 17	General rules
Article 18	Product identifiers
Article 19	Hazard pictograms
Article 20	Signal words
Article 21	Hazard statements
Article 22	Precautionary statements
Article 23	Derogations from labelling requirements for special cases
Article 24	Request for use of an alternative chemical name
Article 25	Supplemental information on the label
Article 26	Principles of precedence for hazard pictograms
Article 27	Principles of precedence for hazard statements
Article 28	Principles of precedence for precautionary statements
Article 29	Exemptions from labelling and packaging requirements
Article 30	Updating information on labels
Chapter 2	**Application of labels**
Article 31	General rules for the application of labels
Article 32	Location of information on the label
Article 33	Specific rules for labelling of outer packaging, inner packaging and single packaging
Article 34	Report on communication on safe use of chemicals

CLP ANNEXES

Annex I	Classification and labelling requirements for hazardous substances and mixtures
Annex II	Special rules for labelling and packaging of certain substances and mixtures

Annex III	List of hazard statements, supplemental hazard information and supplemental label elements
Annex IV	List of precautionary statements
Annex V	Hazard pictograms
Annex VI	Harmonised classification and labelling for certain hazardous substances

LABELLING means the manner of informing the participants of the supply chain, including manufacturers, importers, DU, D, manufacturers and importers of certain articles as well as consumers about identified hazards.

NOTE

Elements of LABELLING listed in Table 3, Part 3, Annex VI, CLP:

- Pictogram Code(s) set out in Annex V (GHS01, GHS02, GHS03, GHS04, GHS05, GHS06, GHS07, GHS08, GHS09), according to the principles of precedence set out in Article 26 CLP;
- Signal Word Code(s): "Dgr" for "Danger" (signal word for higher risk category) and "Wng" for "Warning" (signal word for lower risk category), according to the principles of precedence set out in Article 20 (3) CLP;
- Hazard statement Code(s) (H-phrases) specified in Annex III of CLP, according to the classification;
- Suppl. Hazard statement Code(s) (EUH-phrases) in accordance with Article 25 (1) CLP and the provisions of Annex II, Part 1, CLP.

The substance or mixture contained in the packaging should be labelled, taking into account the elements of labelling specified in Article 17 CLP. Containers and vessels used for storing substances or mixtures classified, according to the CLP provisions, as posing a hazard due to health hazards or due to physical properties and containers used to work with these substances or mixtures, visible pipelines containing such substances or mixtures or for transporting them shall be marked with hazard pictograms in accordance with Annex V to CLP Regulation.

Labelling may be omitted for containers and tanks used to store hazardous substances or mixtures present in the production process for a short time or when the content of the container or tank changes frequently. Alternative security measures should then be provided:

- training ensuring an equivalent level of protection;
- set out detailed procedures for filling, using and emptying these containers and tanks.

13.3. PACKAGING

CLP REGULATIONS

TITLE IV **PACKAGING**
Article 35 Packaging

CLP ANNEXES

Annex II Special rules for labelling and packaging of certain substances and mixtures

PACKAGING containing hazardous substances or mixtures must comply with the following requirements:

- the packaging of hazardous chemicals must be designed, constructed and closed in such a way that its content could not get outside in any case.;
- the packaging material must be strong and durable and resistant to damage by its contents, and equipped with a sealed closing device;
- in some cases, child-resistant fastening and a tactile warning of danger are required;
- the packaging of a chemical substance supplied to the general public can not arouse interest or curiosity in children or mislead consumers;
- in terms of appearance or design, the package must not be similar to foodstuff packaging, animal feed or medicinal or cosmetic products;
- for detailed guidance on labelling and packaging requirements, it is recommended to read the Guidance on Labelling and Packaging in accordance with the CLP Regulation available on ECHA website.

14. CLASSIFICATION OF CHEMICAL SUBSTANCES AND MIXTURES

14. CLASSIFICATION OF CHEMICAL SUBSTANCES AND MIXTURES

Elements of CLASSIFICATION listed in Table 3, Part 3, Annex VI, CLP:

Classification elements:
- Hazard Class and Category Code(s)
- Hazard statement Code(s)

From 1 June 2017, chemicals and their mixtures must be classified and labelled in accordance with the CLP Regulation throughout the EU.

Substances and mixtures, according to CLP, are subject to a harmonised classification and labelling if they meet the criteria set out in Annex VI to CLP. The classification requirement refers to manufacturer, distributor and downstream user if there is no harmonised classification for this substance (Annex I CLP).

The CLP classification system divides hazards into 28 classes depending on the type of the hazard: 16 classes of physical hazards, 10 classes of hazards to human health and 1 class of hazards to the environment (with an additional class for substances harmful to the ozone layer).

Hazard class means the nature of a physical hazard, a human health hazard or an environmental hazard (Article 2 (1) CLP), and the category means the degree of hazard in each hazard class (Article 2 (1) CLP) according to the criteria contained in Annex I to CLP, where category 1 means the highest hazard.

The criteria for the classification of a substance / mixture for a specific hazard class and category are given in Annex I to CLP.

The classification of the substance or mixture which results from the application of the CLP classification criteria should be given in section 2 of the safety data sheet. If the substance or mixture does not meet the CLP criteria, this should be clearly indicated in this section of the safety data sheet.

14.1.HAZARD CLASSES

HAZARD CLASSES FOR PHYSICAL HAZARDS (ANNEX I, PART 2 CLP):

1. Explosives (unstable explosives, divisions 1.1, 1.2, 1.3, 1.4, 1.5 and 1.6).
2. Flammable gases, including chemically unstable gases:
   - for flammable gases (category 1 and 2);
   - for chemically unstable gases (category A and B).
3. Aerosols (category 1, 2 and 3).
4. Oxidising gases (category 1).
5. Gases under pressure (compressed gas, liquefied gas, refrigerated liquefied gas, dissolved gas).
6. Flammable liquids (category 1, 2 and 3).
7. Flammable solids (category 1 and 2).
8. Self-reactive substances and mixtures (type A, B, C, D, E, F and G).
9. Pyrophoric liquids (category 1).
10. Pyrophoric solids (category 1).
11. Self-heating substances and mixtures (category 1 and 2).
12. Substances and mixtures which in contact with water emit flammable gases (category 1, 2 and 3).
13. Oxidising liquids (category 1, 2 and 3).
14. Oxidising solids (category 1, 2 and 3).
15. Organic peroxides (type A, B, C, D, E, F and G).
16. Corrosive to metals (category 1).

HAZARD CLASSES FOR HEALTH HAZARDS (ANNEX I, PART 3 CLP):

1. Acute toxicity (category 1, 2, 3 and 4).
2. Skin corrosion/irritation (category 1 consisting of subcategories 1A, 1B, 1C and category 2).
3. Serious eye damage/eye irritation (category 1 and 2).
4. Respiratory or skin sensitisation:
   - Respiratory sensitisation (category 1 and subcategories 1A, 1B);
   - Skin sensitisation (category 1 and subcategories 1A, 1B).
5. Germ cell mutagenicity (category 1 consisting of subcategories 1A, 1B and category 2).
6. Carcinogenicity (category 1 consisting of subcategories 1A, 1B and category 2).
7. Reproductive toxicity (category 1 consisting of subcategories 1A, 1B, category 2 and additional category for effects on or via lactation).
8. Specific target organ toxicity - single exposure (category 1, 2 and 3; category 3 includes narcotic effects and respiratory tract irritation).
9. Specific target organ toxicity - repeated exposure (category 1 and 2).
10. Aspiration hazard (category 1).

HAZARD CLASSES FOR ENVIRONMENTAL HAZARDS (ANNEX I, PART 4 CLP):

1. Hazardous to the aquatic environment:
   - Acute (short-term) aquatic hazard – acute category 1;
   - Chronic (long-term) aquatic hazard – chronic category 1, 2, 3 and 4.

HAZARD CLASSES FOR ADDITIONAL HAZARDS (ANNEX I, PART 5 CLP):

1. Hazardous to the ozone layer (category 1).

Table 6. Hazard class and category codes used for each of the hazard categories/divisions/types included in a class.

Hazard Class	Hazard Class and Category Code(s) (use always as below, in English)		Subclasses, Categories, Types of Hazard
Explosives	Unst. Expl. Expl. 1.1 Expl. 1.2 Expl. 1.3 Expl. 1.4 Expl. 1.5 Expl. 1.6		Unstable explosives or explosives Divisions: 1.1 to 1.6
Flammable gases (including chemically unstable gases)	Flam. Gas 1 Flam. Gas 2 Chem. Unst. Gas A Chem. Unst. Gas B		Flammable gases, categories: 1, 2 Chemically unstable gases, categories: A, B
Aerosols	Aerosol 1 Aerosol 2 Aerosol 3		Categories: 1, 2, 3
Oxidising gases	Ox. Gas 1		Category: 1
Gases under pressure	Press. Gas (Comp.) Press. Gas (Liq.) Press. Gas (Ref. Liq.) Press. Gas (Diss.)		Groups: Compressed gas Liquefied gas Refrigerated liquefied gas Dissolved gas
Flammable liquids	Flam. Liq. 1 Flam. Liq. 2 Flam. Liq. 3		Categories: 1, 2, 3
Flammable solids	Flam. Sol. 1 Flam. Sol. 2		Categories: 1, 2

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Hazard Class	Hazard Class and Category Code(s) (use always as below, in English)		Subclasses, Categories, Types of Hazard
Self-reactive substances and mixtures	Self-react. A Self-react. B Self-react. CD Self-react. EF Self-react. G		Types: A to G
Pyrophoric liquids	Pyr. Liq. 1		Category: 1
Pyrophoric solids	Pyr. Sol. 1		Category: 1
Self-heating substances and mixtures	Self-heat. 1 Self-heat. 2		Categories: 1, 2
Substances and mixtures which in contact with water emit flammable gases	Water-react. 1 Water-react. 2 Water-react. 3		Categories: 1, 2, 3
Oxidising liquids	Ox. Liq. 1 Ox. Liq. 2 Ox. Liq. 3		Categories: 1, 2, 3
Oxidising solids	Ox. Sol. 1 Ox. Sol. 2 Ox. Sol. 3		Categories: 1, 2, 3
Organic peroxides	Org. Perox. A Org. Perox. B Org. Perox. CD Org. Perox. EF Org. Perox. G		Types: A to G
Substances and mixtures corrosive to metals	Met. Corr. 1		Category: 1

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Hazard Class	Hazard Class and Category Code(s) (use always as below, in English)		Subclasses, Categories, Types of Hazard
Acute toxicity	Acute Tox. 1 Acute Tox. 2 Acute Tox. 3 Acute Tox. 4		Categories: 1, 2, 3, 4
Skin corrosion/irritation	Skin Corr. 1A Skin Corr. 1B Skin Corr. 1C Skin Irrit. 2		Category 1 (subcategories: 1A, 1B, 1C) Category 2
Serious eye damage/eye irritation	Eye Dam. 1 Eye Irrit. 2		Categories: 1, 2
Respiratory or skin sensitisation	Resp. Sens. 1 Resp. Sens. 1A Resp. Sens. 1B Skin Sens. 1 Skin Sens. 1A Skin Sens. 1B		Respiratory sensitisation, category: 1 (subcategories: 1A, 1B) Skin sensitisation, category: 1 (subcategories: 1A, 1B)
Germ cell mutagenicity	Muta. 1A Muta. 1B Muta. 2		Categories: 1A, 1B Category 2
Carcinogenicity	Carc. 1A Carc. 1B Carc. 2		Categories: 1A, 1B Category 2
Reproductive toxicity	Repr. 1A Repr. 1B Repr. 2 Lact.		Categories: 1A, 1B Category 2 Additional category: Effects on or via lactation
Specific target organ toxicity-single exposure STOT-single exposure	STOT SE 1 STOT SE 2 STOT SE 3		Categories: 1, 2, 3 (Category 3 includes narcotic effects and respiratory tract irritation)

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Hazard Class	Hazard Class and Category Code(s) (use always as below, in English)		Subclasses, Categories, Types of Hazard
Specific target organ toxicity-repeated exposure STOT-repeated exposure	STOT RE 1 STOT RE 2		Categories: 1, 2
Aspiration hazard	Asp. Tox. 1		Category 1
Hazardous to the aquatic environment	Aquatic Acute 1 Aquatic Chronic 1 Aquatic Chronic 2 Aquatic Chronic 3 Aquatic Chronic 4		Acute (short-term) aquatic hazard, category 1; Chronic (long-term) aquatic hazard, Categories: 1, 2, 3, 4
Hazardous to the ozone layer	Ozone 1		Category 1

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14.2. HAZARD STATEMENTS

Hazard statements describe the nature and severity of the hazards of a substance or mixture and are assigned to specific hazard classes and categories (Part 2-5, Annex I, CLP). Full list of hazard statements (H-phrases) is provided in Annex III CLP, Part 1.
In this document in Annex 2.

RECORD OF CLASSIFICATION

The classification is presented in the form of a hazard class and category code.

NOTE

Proper classification record: Skin Irrit. 2 H315

Explanation:

- Hazard class: Skin corrosion/irritation
- Hazard category (expressing the degree of danger): 2
- Hazard statement (assigned to this hazard class and hazard category): H315 (Causes skin irritation)

14.3. METHODS OF CHEMICAL MIXTURES CLASSIFICATION

Mixtures, according to CLP, will be subject to the classification and labelling according to criteria set out in Annex I to CLP.

According to the CLP Regulation, the classification of mixtures should be carried out taking into account the following data:

- data from physical, toxicological and ecotoxicological tests;
- epidemiological data, from workplaces or toxicological centers;
- data obtained on the basis of important qualitative and quantitative models of the structure-activity (Q) SAR relationship;
- data obtained on the basis of appropriate in vitro methods;
- data obtained through the use of substance grouping and read-across;
- data from scientific literature.

The classification methods for mixtures together with examples are described in Guidance on the Application of the CLP Criteria, available at:

https://echa.europa.eu/documents/10162/23036412/clp_en.pdf

Classification of mixtures in terms of physical hazards

When classifying mixtures for physical hazards, appropriate test methods are used or in some cases a calculation method may be used, e.g. for flammable liquids. When classifying mixtures in terms of physical hazards, no bridging rules apply.

Classification of mixtures in terms of health and environmental hazards

The classification of mixtures in terms of health hazards and aquatic environment hazards shall be carried out depending on the type of information available on the mixture and its components by the following methods:

1. based on testing the mixture;
2. based on bridging principles;
3. based on calculation methods.

Bridging methods (bridging principles) are methods for classification of mixtures due to risks to human health or the environment, where the mixtures have not been tested, but there is sufficient data on similar tested mixtures and individual hazardous substance components (section 1. 1. 3 and each section of parts 3 and 4 of Annex I of the CLP). Bridging rules are not used to classify mixtures due to physical hazards. There are the following bridging principles: "Dilution, Batching, Concentration of highly hazardous mixtures, Interpolation within one hazard category, Substantially similar mixtures, Review of classification where the composition of a mixture has changed, Aerosols".

Calculation methods are methods for classifying mixtures that take into account the content of all substances classified as hazardous, their classification and their concentration limits (general and specific concentration limits) for individual hazard classes/categories. Calculation methods are used for classification for human health or the environment and in some cases physical hazards, e.g. in the case of flammable liquids (Annex I CLP).

The generic concentration limits are specified in Parts 3-5 of Annex I CLP. For classification purposes, a specific concentration limit, if established for a given substance, takes precedence over the generic concentration limit for a given hazard class and category. (See table 2).

Specific concentration limits are given in part 3 of Annex VI CLP (Table 3, column „Specific concentration limits and coefficients M and ATE").

REMEMBER

For classification purposes, specific concentration limits take precedence over generic concentration limits, even when the specific concentration limit is higher than the generic for a given hazard class/category. See table 2, chapter 7 in this document.

Index No	International Chemical Identification	EC No	CAS No	Classification			Labelling			Specific Conc. Limits, M factors, ATE
				Hazard Class and Category Code(s)	Hazard statement Code(s)		Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code	
011-002-00-6	Sodium hydroxide; caustic soda	215-185-5	1310-73-2	Skin Corr. 1A	H314		GHS05 Dgr	H314		Skin Corr. 1A; H314: C ≥ 5% Skin Corr. 1B; H314: 2% ≤ C < 5% Skin Irrit. 2; H315: 0.5% ≤ C < 2% Eye Irrit. 2; H319: 0.5% ≤ C < 2%

Table 7. Example of the specific concentration limit listed in part 3 of Annex VI CLP (Table 3) for sodium hydroxide.

The specific concentration limits (SCL) for the aquatic environment are calculated by dividing the total limit concentration for acute or chronic hazard by the factor „M" mentioned in Table 3, Part 3 of Annex VI CLP. Applies only to category 1 acute toxicity and category 1 chronic toxicity to the aquatic environment.

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Table 8. Examples of the factor M listed in part 3 of Annex VI CLP (Table 3) for cobalt sulphide and copper(II) oxide.

Index No	International Chemical Identification	EC No	CAS No	Classification			Labelling			Specific Conc. Limits, M factors, ATE
				Hazard Class and Category Code(s)	Hazard statement Code(s)		Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code	
027-003-00-X	cobalt sulfide	215-273-3	1317-42-6	Skin Sen. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410		GHS07 GHS09 Wng	H317 H410		M=10
029-016-00-6	copper(II) oxide	215-269-1	1317-38-0	Aquatic Acute 1 Aquatic Chronic 1	H400 H410		GHS09 Wng	H410		M=100

The additivity rule is a calculation method that assumes that each component classified into a given hazard class contributes to the overall properties of the mixture in proportion to its potency and concentration.

Table 9. The hazard classes for human health for which the additivity formula applies.

Hazard classes for human health		Application of additivity formula
Acute toxicity		YES
Skin corrosion/irritation		YES /NO
Serious damage to eyes/eye irritation		YES
Respiratory/skin sensitisation		NO
Germ cell mutagenicity		NO
Carcinogenicity		NO
Reproductive toxicity		NO
Specific target organ toxicity (STOT) - single exposure		cat. 1 i 2: NO; cat. 3: YES
Specific target organ toxicity (STOT-RE) - repeated exposure		NO

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In case of classification of the mixture due to the corrosive/irritant effects on the skin and eyes, the additivity formula is not used for mixtures containing strong acids or bases. The pH criterion is then used as a classification criterion because the pH is a better indicator of irritant activity than the concentration limit. The mixture is considered to be corrosive to the skin (category 1) or/and corrosive to eyes (category 1) if its pH is 2 or less or 11. 5 or more.

The summation method of classified components is a calculation method used for the classification of mixtures in terms of risks to the aquatic environment - acute and chronic toxicity of mixture. The sum of all substances classified as hazardous to the aquatic environment (acute toxicity, cat. 1, chronic toxicity, cat. 1, 2, 3, 4) present in the mixture above the respective limit values is taken into account.

Table 10. Classification of mixtures in terms of hazards to the aquatic environment based on summation of classified components.

The sum of ingredients classified as:		Classification of mixture
acute hazards		
Acute category 1 × M ≥ 25%		Acute category 1
chronic hazards		
Chronic category 1 × M ≥ 25%		Chronic category 1
(M × 10 × chronic category 1) + chronic category 2 ≥ 25%		Chronic category 2
(M × 100 × chronic category 1) + (10 × chronic category 2) + chronic category 3 ≥ 25%		Chronic category 3
Chronic category 1 + chronic category 2 + chronic category 3 + chronic category 4 ≥ 25%		Chronic category 4

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15. LABELLING OF CHEMICAL SUBSTANCES AND MIXTURES

15. LABELLING OF CHEMICAL SUBSTANCES AND MIXTURES

All suppliers of substances / mixtures, including:

- manufacturers and importers of substances;
- importers of mixtures;
- DU of substances and mixtures, including formulators;
- distributors of substances and mixtures, including entities conducting retail trade,

must ensure the labelling and packaging of their substances and mixtures in accordance with the provisions of the CLP Regulation before they are placed on the EU market.

NOTE

Labelling elements listed in Table 3, Part 3, Annex VI, CLP

- Hazard pictograms Code(s);
- Signal Word Code(s);
- Hazards statement Code(s);
- Suppl. Hazard statement Code(s).

HAZARD PICTOGRAMS

Hazard pictogram is a graphical representation for the purpose of providing information on a given hazard. According to Article 19 CLP, classification of the substance or mixture determines the type of pictogram used on the label. Annex V CLP assigns appropriate pictograms to individual hazard classes and categories.

Currently nine types of pictograms are distinguished.

Hazard pictograms must be in the shape of a square set at a point (a diamond) and include a black hazard symbol on a white background with a red frame that is wide enough to be clearly visible. The specific shade of red has not been determined. Each picto-

gram should occupy at least one fifteenth of the label's surface, its size may not be less than 1 cm^2. The minimum dimensions of labels and pictograms are given in Table 1.3 in Annex I of the CLP.

Table 11. PICTOGRAM CODES (Article 19 CLP, Annex V CLP)

GHS01 Exploding bomb	GHS02 Flame	GHS03 Flame over circle	GHS04 Gas cylinder	GHS05 Corrosion
				
GHS06 Skull and crossbones	GHS07 Exclama-tion mark	GHS08 Health hazard	GHS09 Environ-ment	
				

SIGNAL WORDS

The signal word concerns the severity of the hazard and results from the classification of the substance/mixture. The signal word „Danger" is used for higher risks, and the signal word "Warning" - for lower risks (Article 20 CLP).

The signal words assigned to a given classification are included in Annex I of CLP. On the label of a substance or mixture classified for more than one hazard, only one signal word can be used.

In this case, the signal word „Danger" takes precedence and then the signal word „Warning" is not placed.

SIGNAL WORD CODES (Article 20 CLP)

- "Dgr" for "danger" (used in the case of a higher risk)
- "Wng" for "warning" (used in the case of a lower risk)

The label should contain the appropriate signal word according to the classification of the substance or mixture causing the risk.

HAZARD STATEMENTS (listed in Annex 2 to the Pocket Guide)

Hazard statements describe the nature and severity of the hazards of a substance or mixture and are assigned to specific hazard classes and categories (Part 2-5, Annex I, CLP). Annex III CLP contains the hazard statements in different languages and in the wording in which they should be placed on the labels. Hazard statements in one language should be grouped on a label with precautionary statements in the same language. Some hazard statements require additional information, such as route of exposure or target organ.

If the substance classification is harmonised (Part 3, Annex VI CLP, Table 3), the corresponding hazard statements must be provided on the label. The harmonised classifications marked with an asterisk are the minimum classifications that may require the classification of a higher rank and the corresponding phrase. This means that the substance can therefore be more hazardous than suggested by the harmonised classification.

Annex III to CLP contains permitted combinations of hazard statements for acute toxicity that relate to different routes of exposure, but in the same category. These phrase combinations can be included on the label and in the safety data sheet.

SUPPLEMENTAL HAZARD STATEMENTS (listed in Annex 2 to the Pocket Guide)

These are risk phrases transferred from DSD and DPD,
but not yet included in the UN GHS. Thay are codified as EUH;
(EU Hazard Phrases);
EUH Phrases and indications for their use are listed in Annex II

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to CLP, part 1 and 2.

The wording of EUH Phrases in the national languages of the European Union can be found in Annex III to CLP, parts 2 and 3.

Do not forget about these properties when assessingthe hazard.

List of hazard statements (H phrases) and EU hazard statements (EUH phrases) are listed in Annex 2 to this document.

CODES OF HAZARD STATEMENTS (H-PHRASES) AND SUPPLEMENTAL HAZARD STATEMENTS (EUH-PHRASES)

Each hazard statement is identified by a code beginning with the letter H (hazard) followed by three numbers (see bellow).

- H (HAZARD STATEMENT)
  - NUMBERS IN HAZARD STATEMENTS:
  - » H200-299 - H-phrases for physical hazard
  - » H300-399 - H-phrases for health hazard
  - » H400-499 - H-phrases for environmental hazard

- EUH-hazard statements (supplemental hazard statement) transferred to CLP from DSD and DPD, but not included in the GHS.
  - numbers in EU hazard statements:
  - » EUH 001,006,014,018,019,044 - EUH-phrases for physical hazards
  - » EUH 029,031,032,066,070,071 - EUH-phrases for health hazards
  - » EUH 059 - EUH-phrases for environmental hazards
  - » EUH 201/201A,202,203,204,205,206,207,208,209/209A,210 AND EUH 401 - EUH-phrases containing supplemental information on certain substances and mixtures

16. LABEL OF CHEMICAL SUBSTANCES AND MIXTURES

16. LABEL OF CHEMICAL SUBSTANCES AND MIXTURES

CLP REGULATION

TITLE III HAZARD COMMUNICATION IN THE FORM OF LABELLING

Chapter 1 Content of the label

Article 17 General rules
Article 18 Product identifiers
Article 19 Hazard pictograms
Article 20 Signal words
Article 21 Hazard statements
Article 22 Precautionary statements
Article 23 Derogations from labelling requirements for special cases
Article 24 Request for use of an alternative chemical name
Article 25 Supplemental information on the label
Article 26 Principles of precedence for hazard pictograms
Article 27 Principles of precedence for hazard statements
Article 28 Principles of precedence for precautionary statements
Article 29 Exemptions from labelling and packaging requirements
Article 30 Updating information on labels

Chapter 2 Application of labels

Article 31 General rules for the application of labels
Article 32 Location of information on the label
Article 33 Specific rules for labelling of outer packaging, inner packaging and single packaging
Article 34 Report on communication on safe use of chemicals

CLP ANNEXES

Annex I Classification and labelling requirements for hazardous substances and mixtures

The CLP Regulation defines the content of the label and the location of individual elements on it. The sizes of labels (and pictograms) are indicated in section 1.2.1. Annex I CLP. Information of the label can be provided on the packaging itself instead of on the label. Labels shall be drawn up in the official language (s) of the country in which the substance or mixture is placed on the market. Labels can be organized in a way that is deemed appropriate. However, the pictograms, signal word, hazard statements and precautionary statements should be put on the label together. The order of phrases is arbitrary. When more than one language is used on the label, phrases in the same language should be grouped on the label. The label should be securely attached to the packaging in one or several places and must contain the following data:

- supplier's contact details (the name, address and telephone number of the supplier or suppliers);
- product identifier;
- nominal quantity (only for substances and mixtures intended for the general public);
- hazardous ingredients (in the case of mixtures);
- hazard pictograms;
- signal word;
- hazard statements, indicating the nature and degree of the risks posed by the product;
- precautionary statements (usually no more than six, unless they are necessary to reflect the nature and severity of the hazard), indicating how the product should be handled to minimize risks to the user (as well as to other people and the general environment);
- where appropriate, supplementary information (Article 25 of CLP).

SUPPLIER'S CONTACT DETAILS

According to Article 17 CLP on the label should be given details of one or several suppliers. Article 17 does not specify whether all suppliers should be provided, or whether any of them have priority. According to Article 4 (4) CLP the supplier of hazardous substances or mixtures must ensure their appropriate labelling and packaging in accordance with Title III and Title IV of CLP before placing them on the market. In the supply chain, it may be necessary to repackage a substance or mixture and the labelling may change with the size of the packaging or the addition of subsequent layers. In such cases, the supplier takes responsibility for repackaging and relabelling the substance or mixture and should include his contact details on the label. He/she can also replace his provider's data with his. If the supplier changes the language of the label, he/she should add his contact details to it, as he/she is responsible for the translation.

PRODUCT IDENTIFIERS

Product identifiers should meet the requirements of Article 18 (2) CLP (for substances) and Article 18 (3) CLP (for mixtures). The same product identifiers should be included on the label as in the safety data sheet.

Identifiers for a substance:

- if the substance is listed in Part 3 of Annex VI to CLP, please provide: name and identification number specified in Part 3 of Annex VI to CLP;
- if the substance is not listed in Part 3 of Annex VI to CLP, but is listed in the C&L inventory on the ECHA website, please provide: name and the identification number assigned to it in the C&L list;
- if the substance is not listed in Part 3 of Annex VI to CLP, nor is it listed in the C&L inventory on the ECHA website, please provide: CAS number with IUPAC name or CAS number along with another international chemical names
- if the CAS number is not available and if none of the above points apply, please provide: IUPAC or another international chemical name.

Identifiers of a mixture:

The product identifier (mixture) must contain two elements:

- the trade name or designation of the mixture; and
- data identifying all substances in the mixture that determine its classification in terms of health hazards.

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If the name of the substance is shorter than other names available to the user or better recognized in the language of the country in which the mixture is placed on the market, this name should be used. Often, this applies to common or basic ingredients.
If a translated name is given in Annex VI CLP or in the classification and labelling inventory, it should be given priority. If the trade name or designation of the mixture contains the name of the substance that determines its classification, this name does not need to be repeated. To limit the number of substance names on the mixture label, a maximum of four chemical names should be given on it, unless this is necessary due to the nature and severity of the hazards. If the supplier wants to keep the chemical names of the mixture confidential, he/she may apply to ECHA for authorisation to use an alternative chemical name in accordance with Article 24 CLP. As an alternative name, a more generic name should be used for the most important functional groups or an alternative designation.

HAZARD PICTOGRAMS Annex V CLP

See also previous chapter.

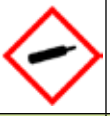
Hazard pictogram is a graphical representation for the purpose of providing information on a given hazard.

For the various package sizes the following minimum sizes of the individual pictograms (edge x edge of the red square) are prescribed:

- for package sizes up to 3 litres: at least 10 x 10 mm, if possible 16 x 16 mm,
- for package sizes >3 to 50 litres: at least 23 x 23 mm,
- for package sizes >50 to 500 litres: at least 32 x 32 mm,
- for package sizes >500 litres: at least 46 x 46 mm.

When more than one pictogram should be placed on the label, check whether the principles of precedence apply (Article 26 CLP). The general rule is that the pictograms should be placed on the label which correspond to the highest hazard category in each hazard class.

Table.11. PICTOGRAM CODES (Article 19 CLP, Annex V CLP)

GHS01 Exploding bomb	GHS02 Flame	GHS03 Flame over circle	GHS04 Gas cylinder	GHS05 Corrosion
				
GHS06 Skull and crossbones	GHS07 Exclamation mark	GHS08 Health hazard	GHS09 Environment	
				

Pictograms indicate the type of hazards. The colour and layout of the label should be selected in such a way that the pictogram and its background are clearly visible.

Principles of precedence:

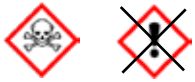
- for physical hazards: If the pictogram GHS01 (exploding bomb) is on the label, then the pictograms GHS02 (flame) and GHS03 (flame over circle) are optional, except when several pictograms are mandatory, i.e. self reactive substances type B and organic peroxides type B;

MANDATORY OPTIONAL OPTIONAL

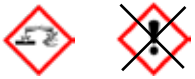
- for physical and health hazards: If the pictogram GHS02 (flame) or GHS06 (skull and crossbones) is on the label, the GHS04 pictogram (gas cylinder) is optional;

MANDATORY or MANDATORY OPTIONAL

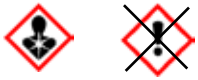
- for health hazards: If the GHS06 pictogram (skull and cross-bones) is on the label, the placement of the GHS07 pictogram (exclamation mark) is prohibited;



- for health hazards: If the pictogram GHS05 (corrosion) is on the label, then the GHS07 pictogram (exclamation mark) can not be used for skin and eye irritation, but must be used for other hazards;



- for health hazards: If the pictogram GHS08 (health hazard) relating to respiratory sensitization is on the label, then the GHS07 pictogram (exclamation mark) can not be used for skin sensitization or irritation to the skin or eyes, but must be used in case of other hazards.



If EUH071 is used for the substance or mixture, then the GHS05 pictogram (corrosion) may be used. In this case, the GHS07 pictogram (exclamation mark) for STOT-SE (Specific Target Organ Toxicity – Single Exposure), category 3, and the phrase H335 should be removed from the label.

In the case of substances and mixtures marked in accordance with the regulations on the transport of dangerous goods, CLP pictograms may be omitted if they relate to the same type of hazard as the transport regulations.

When printing labels, you may find that there are more empty spaces for pictograms than you need. Such places should be blackened. Leaving the red borders and the white background is not prohibited in the regulation, but it can create the impression of a print error and can be confusing.

SIGNAL WORDS (see also previous chapter)
The signal word concerns the severity of the hazard and results from the classification of the substance or mixture, with the signal word „Danger" for higher risks, and the signal word "Warning" for lower risks (Article 20 CLP).

HAZARD STATEMENTS
(List of H phrases: Annex 2 of the Pocket Guide)
The wording of H phrases in the national languages of the European Union can be found in Annex III CLP, part 1.
The full set of criteria when specific H phrases should be used for each hazard class and category (for substances and mixtures) is given in part 2-5 of Annex I to CLP. If the substance classification is harmonised (part 3 of Annex VI CLP), the corresponding hazard phrases must be provided on the label. For more information on H-phrases, see also chapter 15 of this document.

SUPPLEMENTAL HAZARD STATEMENTS
(List of EUH phrases: Annex 2 of the Pocket Guide)

For the indications when to use the EUH phrases, see Annex II to CLP (special rules for labelling and packaging of certain substances and mixtures), part 1 (supplemental hazard information) and 2 (special rules for supplemental label elements for certain mixtures). The wording of all EUH phrases in the national languages of the European Union can be found in Annex III CLP, part 2 and 3, for more information on euh-phrases, see chapter 15 of the pocket guide)

PRECAUTIONARY STATEMENTS
(List of P phrases: Annex 3 of the Pocket Guide)

The wording of P phrases in the national languages of the European Union can be found in Annex IV to CLP, part 2.

These phrases provide information on measures to prevent adverse effects or to minimize adverse effects on human health or the environment (Article 22 CLP). The full set of precautionary statements that are appropriate for each hazard class and category

are given in Parts 2-5 in Annex I to CLP. Precautionary statements should be chosen in accordance with the provisions of Article 22 and Article 28 and Part 1 of Annex IV to CLP. As a general rule, there should not be more than six precautionary statements on the label, unless more phrases are needed to convey the nature and severity of the risks. Part 2 of Annex IV CLP contains precautionary statements in various languages and in the wording in which they should be included on the labels. In the case of differences in translations, the translation of the national version of the CLP Regulation is usually the most appropriate.

The precautionary statements are not given in Annex VI. Everyone preparing the safety data sheets must select one of the P-statements given in Parts 2,3,4, and 5 of Annex I to CLP Regulation for the relevant hazard class and category.

CODES OF P-PHRASES:

P (precautionary statement)

- numbers in precautionary statements
  - » P101-199 General
  - » P201-299 Prevention
  - » P301-399 Reaction
  - » P401-499 Storage
  - » P501-599 Disposal

Changes in P statements

In accordance with Commission Regulation (EU) 2016/918 of February 1, 2018 some statements P have been changed and must be obligatorily used in the wording given in the Regulation (P statements are listed below).

Substances and mixtures placed on the market before 1 February 2018 need not be re-labeled and re-packaged before 1 February 2020 in accordance with this Regulation. However, the company that place the product on the market may decide to switch to the modified P statements earlier.

To ensure consistency between labeling and safety data sheets, it is also important to update the safety data sheet when the labeling is changed!

SUPPLEMENTAL INFORMATION ON THE LABEL

a. Mandatory supplementary information

- » EUH-phrases (complementary phrases indicating the type of hazard resulting from physical and chemical properties, health effects and composition of mixtures);
- » the labelling provisions laid down in Directive 75/324/EEC applicable to aerosol products;
- » supplementary first aid instructions placed in brackets in precautionary statements e.g. P320 – Specific treatment is urgent (see ... on this label), P321 - Specific treatment (see... on this label);
- » in the case of mixtures containing ingredient (s) with unknown acute toxicity at a concentration of 1% or more, the phrase „x% of the mixture is ingredient (s) of unknown toxicity" (also included in the safety data sheet);
- » in the case of a mixture for which there is no information available on the risk to the aquatic environment due to acute or long-term toxicity of one or more relevant constituents, the phrase „contains x% ingredients with an unknown hazard for the aquatic environment" (also included in safety data sheet);
- » the authorisation reference number required under the REACH Regulation;
- » list of surface-active substances and fragrances in accordance with Regulation (EC) No. 648/2004 on detergents, as amended;
- » reference number of the authorisation of a biocidal product in accordance with Regulation (EU) No 528/2012 on biocidal products;
- » flammability mark in accordance with Directive 75/324/EEC on aerosol dispensers, as amended;
- » content of volatile organic compounds in accordance with Directive 2004/42/EC;
- » list of specified ingredients required by Regulation (EC) No. 648/2004 on detergents, as amended.

b. Optional supplementary information

- » detailed product information;
- » basic instructions for use;
- » precautionary statements that do not result directly from the

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classification of the product e.g. Read the label before use;
» additional label elements originating from the UN GHS, which have not been included in the CLP Regulation.

The supplementary information on the label must be in accordance with the classification of the substance or mixture. This means that it can not contain phrases such as „non-toxic", „non-polluting", „ecological", „harmless", „safe".

Hazard pictograms, signal word, hazard statements and precautionary statements are placed together on the label (Article 32 CLP).

The table below presents nine hazard pictograms in GHS/CLP that correspond to the respective physical, health and environmental risks caused by chemicals, as well as hazard classes, categories and H phrases assigned to particular pictograms and the examples of their use.

Table 12. Hazard pictograms, types of hazards that pictograms represent, the corresponding hazard classes, categories and h-phrases, as well as examples of the pictogram applications

GHS/CLP pictograms and types of hazards they represent	Corresponding hazard classes and categories		Corresponding H phrases	Application examples
Physical hazards				
GHS01 Symbol: Exploding bomb  Explosion, blast or projection hazard	Unstable explosives		H200 Unstable explosives.	Fireworks, ammunitions.
	Explosives, divisions 1.1, 1.2, 1.3, 1.4		H201 Explosive; mass explosion hazard (division 1.1) H202 Explosive; severe projection haz-ard (division 1.2) H203 Explosive; fire, blast or projection hazard (division 1.3) H204 Fire or projection hazard (division 1.4)	
	Self-reactive substances and mixtures, type A, B		H240 Heating may cause an explosion (type A) H241 Heating may cause a fire or explosion (type B)	
	Organic peroxides, type A, B		H240 Heating may cause an explosion (type A) H241 Heating may cause a fire or explosion (type B)	

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GHS/CLP pictograms and types of hazards they represent	Corresponding hazard classes and categories		Corresponding H phrases	Application examples
GHS02 Symbol: Flame  Flammable liquids, solids and gases; including self heating and self igniting substances	Flammable gases, cat. 1		H220 Extremely flammable gas (cat. 1)	Lamp oil, petrol, nail polish remover, hand sanitiser, glue
	Flammable aerosols, cat. 1, 2		H222 Extremely flammable aerosol (cat. 1) H223 Flammable aerosol (cat. 2) H229 Pressurised container: May burst if heated (cat. 1, 2)	
	Flammable liquids, cat. 1, 2, 3		H224 Extremely flammable liquid and vapour (cat. 1) H225 Highly flammable liquid and vapour (cat. 2) H226 Flammable liquid and vapour (cat. 3)	
	Flammable solids, cat. 1, 2		H228 Flammable solid (cat. 1, 2)	
	Self-reactive substances and mixtures, type B, C, D, E, F		H241 Heating may cause a fire or explosion (type B) H242 Heating may cause a fire (type C, D, E, F)	
	Pyrophoric liquids, cat. 1		H250 Catches fire spontaneously if exposed to air (cat. 1)	
	Pyrophoric solids, cat. 1		H250 Catches fire spontaneously if exposed to air (cat. 1)	
	Self-heating substances and mixtures, cat. 1, 2		H251 Self-heating: may catch fire (cat. 1) H252 Self-heating in large quantities; may catch fire (cat. 2)	
	Substances and mixtures which in contact with water emit flammable gases, cat. 1, 2, 3		H260 In contact with water releases flammable gases which may ignite spontaneously (cat. 1) H261 In contact with water releases flammable gases (cat. 2, 3)	
	Organic peroxides, type B, C, D, E, F		H241 Heating may cause a fire or explosion (type B) H242 Heating may cause a fire (type C, D, E, F)	

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GHS/CLP pictograms and types of hazards they represent	Corresponding hazard classes and categories		Corresponding H phrases	Application examples
GHS03 Symbol: Flame over circle  Oxidising liquids, solids and gases, may cause or intensify fire	Oxidising gases, cat. 1		H270 May cause or intensify fire; oxidizer (cat. 1)	Bleach, oxygen
	Oxidising liquids, cat. 1, 2, 3		H271 May cause fire or explosion; strong oxidizer (cat. 1) H272 May intensify fire; oxidizer (cat. 2, 3)	
	Oxidising solids, cat. 1, 2, 3		H271 May cause fire or explosion; strong oxidizer (cat. 1) H272 May intensify fire; oxidizer (cat. 2, 3)	
GHS04 Symbol: Gas cylinder  Gases under pressure	Gases under pressure: • Compressed gas • Liquefied gas • Refrigerated liquefied gas • Dissolved gas		H280 Contains gas under pressure; may explode if heated (compressed, liquefied, dissolved gas) H281 Contains refrigerated gas; may cause cryogenic burns or injury (refrigerated liquefied gas)	Containers or bottles with gas
GHS05 Symbol: Corrosion  Corrosive chemicals, may be corrosive to metals	Corrosive to metals, cat. 1		H290 May be corrosive to metals (cat. 1)	Drain cleaners, acids, bases, ammonia, BBQ cleaner
Health hazards				
GHS06 Symbol: Skull and Crossbones  Fatal or toxic if swallowed, inhaled or in contact with skin	Acute toxicity (by alimentary tract, after application to the skin, after inhalation exposure), cat. 1, 2, 3.		H300 Fatal if swallowed (cat. 1, 2) H301 Toxic if swallowed (cat. 3) H310 Fatal in contact with skin (cat. 1, 2) H311 Toxic in contact with skin (cat. 3) H330 Fatal if inhaled (cat. 1, 2) H331 Toxic if inhaled (cat. 3)	Insecticides, nicotine refills for e-cigarettes

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GHS/CLP pictograms and types of hazards they represent	Corresponding hazard classes and categories		Corresponding H phrases	Application examples
GHS05 Symbol: Corrosion  Corrosive chemicals, may cause severe skin and eye damage	Skin corrosion, cat. 1A, 1B, 1C		H314 Causes severe skin burns and eye damage (cat. 1A, 1B, 1C)	Drain cleaners, acids, bases, ammonia, BBQ cleaner
	Serious eye damage, cat. 1		H318 Causes serious eye damage (cat. 1)	
GHS07 Symbol: Exclamation mark  Low level toxicity. This includes respiratory, skin, and eye irritation, skin sensitisers and chemicals harmful if swallowed, inhaled or in contact with skin.	Acute toxicity (by alimentary tract, after application to the skin, after inhalation exposure), cat. 4		H302 Harmful if swallowed (cat. 4) H312 Harmful in contact with skin (cat. 4) H332 Harmful if inhaled (cat. 4)	Washing detergents, toilet cleaner, anti freeze, window cleaning fluid, silicone, super glue, varnish
	Skin irritation, cat. 2		H315 Causes skin irritation (cat. 2)	
	Eye irritation, cat. 2		H319 Causes serious eye irritation (cat. 2)	
	Skin sensitization, cat. 1, 1A, 1B		H317 May cause an allergic skin reaction (cat. 1, 1A, 1B)	
	Specific target organ toxicity – single exposure, cat. 3 (Respiratory irritation, Narcotic effects)		H335 May cause respiratory irritation (cat. 3); H336 May cause drowsiness or dizziness (cat. 3)	

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GHS/CLP pictograms and types of hazards they represent	Corresponding hazard classes and categories		Corresponding H phrases	Application examples
GHS08 Symbol: Health Hazard  Chronic health hazards; this includes aspiratory and respiratory hazards, carcinogenicity, mutagenicity and reproductive toxicity	Respiratory sensitization, cat. 1, 1A, 1B		H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled (cat. 1, 1A, 1B)	Turpentine, petrol, lamp oil
	Germ cell mutagenicity, cat. 1A, 1B, 2		H340 May cause genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard> (cat. 1A, 1B) H341 Suspected of causing genetic defects <. . .> (cat. 2)	
	Carcinogenicity, cat. 1A, 1B, 2		H350 May cause cancer <. . .> (cat. 1A, 1B) H351 Suspected of causing cancer <. . .> (cat. 2)	
	Reproductive toxicity, cat. 1A, 1B, 2		H360 May damage fertility or the unborn child <state specific effect if known> <. . .> (cat. 1A, 1B) H361 Suspected of damaging fertility or the unborn child <state specific effect if known> <. . .> (cat. 2)	
	Specific target organ toxicity – single exposure, cat. 1, 2		H370 Causes damage to organs <or state all organs affected, if known> <. . .> (cat. 1) H371 May cause damage to organs <or state all organs affected, if known> <. . .> (cat. 2)	
	Specific target organ toxicity – repeated exposure, cat. 1, 2		H372 Causes damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <. . .> (cat. 1) H373 May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <. . .> (cat. 2)	
	Aspiration hazard, cat. 1		H304 May be fatal if swallowed and enters airways (cat. 1)	
No pictogram	Reproductive toxicity – additional category for effects on or via lactation		H362 May cause harm to breast-fed children.	

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GHS/CLP pictograms and types of hazards they represent	Corresponding hazard classes and categories		Corresponding H phrases	Application examples
Environmental hazards				
GHS09 Symbol: Environment  Hazardous to aquatic life	Hazardous to the aquatic environment Acute toxicity, cat. 1		H400 Very toxic to aquatic life (cat. 1)	Herbicides, turpentine, petrol, varnish
	Chronic toxicity, cat. 1, 2		H410 Very toxic to aquatic life with long lasting effects (cat. 1) H411 Toxic to aquatic life with long last-ing effects (cat. 2)	
No pictogram	Hazardous to the aquatic environment – chronic toxicity, cat. 3, 4		H412 Harmful to aquatic life with long lasting effects (cat. 3) H413 May cause long lasting harmful effects to aquatic life (cat. 4	Some detergents
Additional hazards				
GHS07 Symbol: Exclamation mark  Hazardous to the ozone layer	Hazardous to the ozone layer, cat. 1		H420 Harms public health and the environ-ment by destroying ozone in the Upper atmosphere (cat. 1)	Cooling factors

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Arrangement of information on the label (Article 32 CLP)

Hazard pictograms, signal words, hazard statements and precautionary statements are placed together on the label. The supplier can determine the order in which the hazard statements are placed on the label - but all hazard statements are grouped on the label by language.

The supplier of the substance or mixture can determine the order in which the precautionary statements are placed on the label - but all precautionary statements are grouped on the label by language.

Groups of hazard statements and groups of precautionary statements shall also appear on the label together by language.

The minimum size of the labels according to the CLP Regulation

The minimum size of the labels is also determined according to the section 1.2.1 of Annex I of the Regulation (EU) No 286/2011, in function of the package size:

- for package sizes up to 3 litres: at least 52 x 74 mm,
- for package sizes >3 to 50 litres: at least 74 x 105 mm,
- for package sizes >50 to 500 litres: at least 105 x 148 mm,
- for package sizes >500 litres: at least 148 x 210 mm.

The minimum text size

The minimum text size on the label is recommended to be about 1.8 mm (like that of Arial 7).

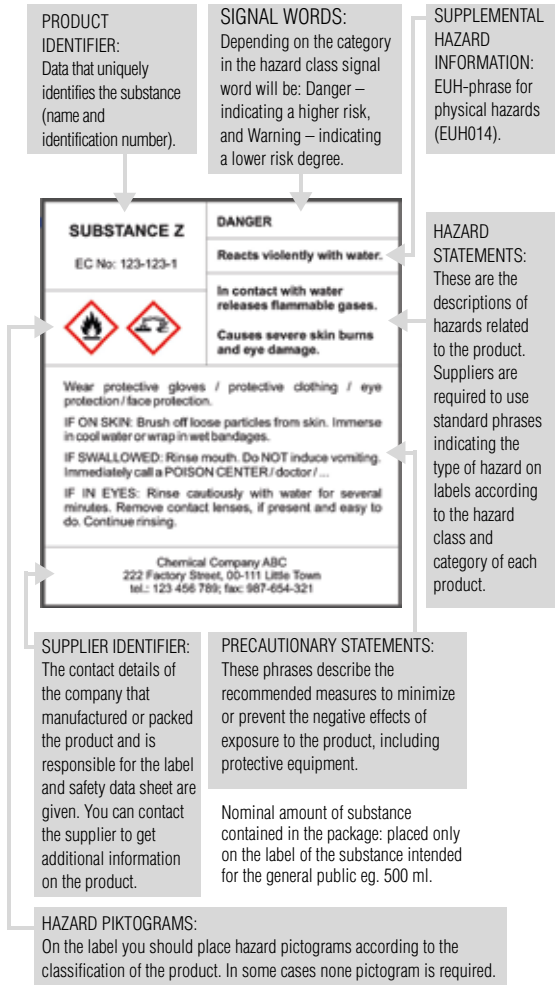
NOTE

The label elements indicated in section 2.2 of the safety data sheet and the content of the label on the product must be compatible with each other.

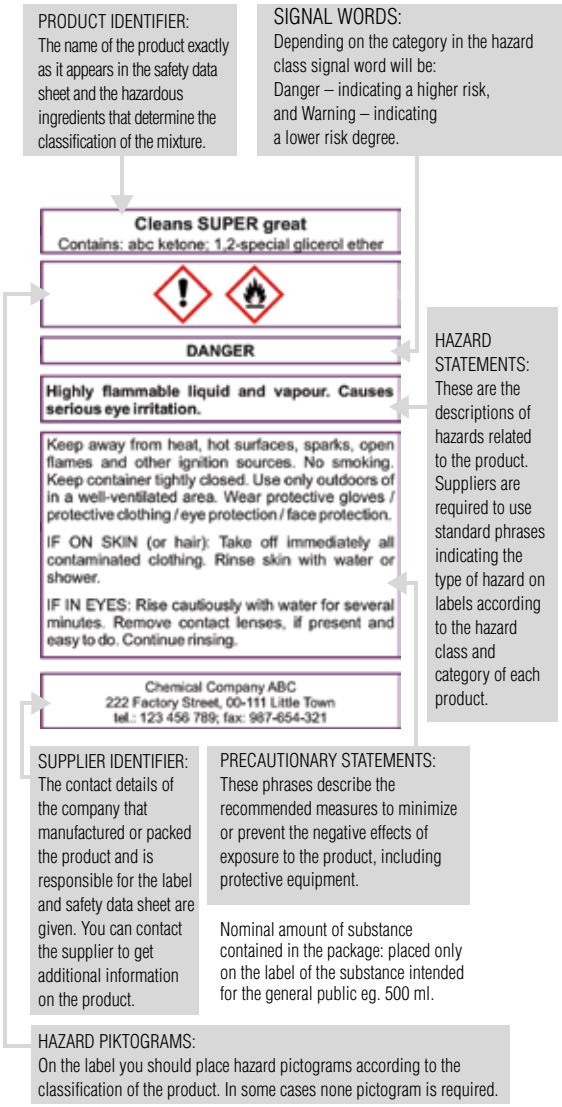
ANNEX 1. EXAMPLES OF LABELS

ANNEX 1. EXAMPLES OF LABELS

An example of a monolingual label for a substance (not intended for the general public).



An example of a monolingual label for a mixture (not intended for the general public).



For mixtures that are not classified as hazardous under the CLP Regulation and are not intended for the general public, but contain certain specific classified ingredients above certain limits for which an SDS must be provided on demand, the label on the packaging must contain information on the availability of the SDS. The text required to determine availability reads as follows: „Safety data sheet available on request"(Annex II CLP, point 2.10, EUH210).

ANNEX 2.
LIST OF HAZARD STATEMENTS (H PHRASES) AND EU HAZARD STATEMENTS (EUH PHRASES)

ANNEX 2. LIST OF HAZARD STATEMENTS (H PHRASES) (Annex III CLP, Part 1)

H-PHRASES FOR PHYSICAL HAZARDS (Annex III CLP, Part 1, Table 1.1)

H200 Unstable explosives.
H201 Explosive; mass explosion hazard.
H202 Explosive; severe projection hazard.
H203 Explosive; fire, blast or projection hazard.
H204 Fire or projection hazard.
H205 May mass explode in fire.
H220 Extremely flammable gas.
H221 Flammable gas.
H222 Extremely flammable aerosol.
H223 Flammable aerosol.
H224 Extremely flammable liquid and vapour.
H225 Highly flammable liquid and vapour.
H226 Flammable liquid and vapour.
H227 Combustible liquid. (cat. 4 in hazard class: "Flammable liquids" according to GHS)
H228 Flammable solid.
H229 Pressurised container: May burst if heated.
H230 May react explosively even in the absence of air.
H231 May react explosively even in the absence of air at elevated pressure and/or temperature.
H240 Heating may cause an explosion.
H241 Heating may cause a fire or explosion.
H242 Heating may cause a fire.
H250 Catches fire spontaneously if exposed to air.
H251 Self-heating: may catch fire.
H252 Self-heating in large quantities; may catch fire.
H260 In contact with water releases flammable gases which may ignite spontaneously.
H261 In contact with water releases flammable gases.
H270 May cause or intensify fire; oxidizer.
H271 May cause fire or explosion; strong oxidizer.
H272 May intensify fire; oxidizer.

H280 Contains gas under pressure; may explode if heated.
H281 Contains refrigerated gas; may cause cryogenic burns or injury.
H290 May be corrosive to metals.

H-PHRASES FOR HEALTH HAZARDS (Annex III CLP, Part 1, Table 1.2)

H300 Fatal if swallowed.
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H303 May be harmful if swallowed. (cat. 5 in hazard class: "Acute toxicity" statement use in GHS, does not exist in CLP)
H304 May be fatal if swallowed and enters airways.
H305 May be harmful if swallowed and enters airways. (cat. 2 in hazard class: "Aspiration hazard" statement use in GHS, does not exist in CLP)
H310 Fatal in contact with skin.
H311 Toxic in contact with skin.
H312 Harmful in contact with skin.
H313 May be harmful in contact with skin. (cat. 5 in hazard class: "Acute toxicity" statement use in GHS, does not exist in CLP)
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H316 Causes mild skin irritation. (cat. 3 in hazard class: "Skin corrosion/irritation", statement use in GHS, does not exist in CLP)
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H320 Causes eye irritation. (cat. 2B in hazard class: "Serious eye damage/eye irritation", statement use in GHS, does not exist in CLP)
H330 Fatal if inhaled.
H331 Toxic if inhaled.
H332 Harmful if inhaled.
H333 May be harmful if inhaled. (cat. 5 in hazard class: "Acute toxicity", statement use in GHS, does not exist in CLP)
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
H340 May cause genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H341 Suspected of causing genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H350 May cause cancer <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H351 Suspected of causing cancer <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H360 May damage fertility or the unborn child <state specific effect if known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H360F May damage fertility.
H360FD May damage fertility. May damage the unborn child.
H360D May damage the unborn child.
H360Fd May damage fertility. Suspected of damaging the unborn child.
H360Df May damage the unborn child. Suspected of damaging fertility.
H361 Suspected of damaging fertility or the unborn child <state specific effect if known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

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H361f	Suspected of damaging fertility.
H361d	Suspected of damaging the unborn child.
H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
H362	May cause harm to breast-fed children.
H370	Causes damage to organs <or state all organs affected, if known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H371	May cause damage to organs <or state all organs affected, if known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H372	Causes damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H373	May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H300+H310	Fatal if swallowed or in contact with skin.
H300+H330	Fatal if swallowed or if inhaled.
H310+H330	Fatal in contact with skin or if inhaled.
H300+H310+ +H330	Fatal if swallowed, in contact with skin or if inhaled.
H301+H311	Toxic if swallowed or in contact with skin.
H301+H331	Toxic if swallowed or if inhaled.
H311+H331	Toxic in contact with skin or if inhaled.
H301+H311+ +H331	Toxic if swallowed, in contact with skin or if inhaled.
H302+H312	Harmful if swallowed or in contact with skin.
H302+H332	Harmful if swallowed or if inhaled.
H312+H332	Harmful in contact with skin or if inhaled.
H302+H312+ +H332	Harmful if swallowed, in contact with skin or if inhaled.

H-PHRASES FOR ENVIRONMENTAL HAZARDS (Annex III CLP, Part 1, Table 1.3)

H400	Very toxic to aquatic life.
H401	Toxic to aquatic life. (cat. 2 in hazard class: "Hazardous to the aquatic environment/acute aquatic hazard" - statement use in GHS, does not exist in CLP)
H402	Harmful to aquatic life. (cat. 3 in hazard class: "Hazardous to the aquatic environment/acute aquatic hazard" - statement use in GHS, does not exist in CLP)
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.
H420	Harms public health and the environment by destroying ozone in the upper atmosphere.

LIST OF EU HAZARD STATEMENTS (EUH PHRASES, FOR EU COUNTRIES) – SUPPLEMENTAL HAZARD INFORMATION (Annex III CLP, Part 2, Table 2)

EUH-PHRASES FOR PHYSICAL HAZARDS (Annex III CLP, Part 2, Table 2.1)

EUH 001	Explosive when dry.
EUH 006	Explosive with or without contact with air.
EUH 014	Reacts violently with water.
EUH 018	In use may form flammable/explosive vapour air mixture.
EUH 019	May form explosive peroxides.
EUH 044	Risk of explosion if heated under confinement.

EUH-PHRASES FOR HEALTH HAZARDS (Annex III CLP, Part 2, Table 2.2)

EUH 029 Contact with water liberates toxic gas.
EUH 031 Contact with acids liberates toxic gas.
EUH 032 Contact with acids liberates very toxic gas.
EUH 066 Repeated exposure may cause skin dryness or cracking.
EUH 070 Toxic by eye contact.
EUH 071 Corrosive to the respiratory tract.

EUH-PHRASES FOR ENVIRONMENTAL HAZARDS

EUH 059 Hazardous to the ozone layer.

EUH-PHRASES CONTAINING SUPPLEMENTAL INFORMATION ON CERTAIN SUBSTANCES AND MIXTURES (Annex III CLP, Part 3)

EUH 201/201A Contains lead. Should not be used on surfaces liable to be chewed or sucked by children. Warning! Contains lead.
EUH 202 Cyanoacrylate. Danger. Bonds skin and eyes in seconds. Keep out of the reach of children.
EUH 203 Contains chromium(VI). May produce an allergic reaction.
EUH 204 Contains isocyanates. May produce an allergic reaction.
EUH 205 Contains epoxy constituents. May produce an allergic reaction.
EUH 206 Warning! Do not use together with other products. May release dangerous gases (chlorine).
EUH 207 Warning! Contains cadmium. Dangerous fumes are formed during use. See information supplied by the manufacturer. Comply with the safety instructions.
EUH 208 Contains <name of sensitising substance>. May produce an allergic reaction.
EUH 209/209A Can become highly flammable in use. Can become flammable in use.
EUH 210 Safety data sheet available on request.
EUH 401 To avoid risks to human health and the environment, comply with the instructions for use.

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ANNEX 3.
LIST OF PRECAUTIONARY STATEMENTS (P PHRASES)

ANNEX 3. LIST OF PRECAUTIONARY STATEMENTS (P PHRASES)

GENERAL PRECAUTIONARY STATEMENTS (Annex IV CLP Table 6.1)

P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.
P103 Read label before use.

PREVENTION PRECAUTIONARY STATEMENTS (Annex IV CLP Table 6.2)

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P211 Do not spray on an open flame or other ignition source.
P220 Keep away from clothing and other combustible materials.
P222 Do not allow contact with air.
P223 Do not allow contact with water.
P230 Keep wetted with…
P231 Handle and store contents under inert gas/....
P232 Protect from moisture.
P233 Keep container tightly closed.
P234 Keep only in original packaging.
P235 Keep cool.
P240 Ground and bond container and receiving equipment.
P241 Use explosion-proof [electrical/ventilating/lighting/…] equipment.
P242 Use non-sparking tools.
P243 ake action to prevent static discharges.
P244 Keep valves and fittings free from oil and grease.
P250 Do not subject to grinding/shock/friction/....
P251 Do not pierce or burn, even after use.

P260 Do not breathe dust/fume/gas/mist/vapours/ spray.
P261 Avoid breathing dust/fume/gas/mist/vapours/ spray.
P262 Do not get in eyes, on skin, or on clothing.
P263 Avoid contact during pregnancy and while nursing.
P264 Wash … thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P282 Wear cold insulating gloves and either face shield or eye protection.
P283 Wear fire resistant or flame retardant clothing.
P284 [In case of inadequate ventilation] wear respiratory protection.
P231 + P232 Handle and store contents under inert gas/.... Protect from moisture.

RESPONSE PRECAUTIONARY STATEMENTS (Annex IV CLP Table 6.3)

P301 IF SWALLOWED:
P302 F ON SKIN:
P303 IF ON SKIN (or hair):
P304 IF INHALED:
P305 IF IN EYES:
P306 IF ON CLOTHING:
P308 IF exposed or concerned:
P310 Immediately call a POISON CENTER/doctor/ …
P311 Call a POISON CENTER/doctor/…
P312 Call a POISON CENTER/doctor/…if you feel unwell.
P313 Get medical advice/attention.
P314 Get medical advice/attention if you feel unwell.
P315 Get immediate medical advice/attention.
P320 Specific treatment is urgent (see … on this label).
P321 Specific treatment (see … on this label).
P330 Rinse mouth.
P331 Do NOT induce vomiting.
P332 If skin irritation occurs:
P333 If skin irritation or rash occurs:
P334 Immerse in cool water [or wrap in wet bandages].
P335 Brush off loose particles from skin.
P336 Thaw frosted parts with lukewarm water. Do no rub affected area.
P337 If eye irritation persists:
P338 Remove contact lenses, if present and easy to do. Continue rinsing.
P340 Remove person to fresh air and keep comfortable for breathing.
P342 If experiencing respiratory symptoms:
P351 Rinse cautiously with water for several minutes.
P352 Wash with plenty of water/…
P353 Rinse skin with water [or shower].
P360 Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.
P361 Take off immediately all contaminated clothing.
P362 Take off contaminated clothing.
P363 Wash contaminated clothing before reuse.
P364 And wash it before reuse.
P370 In case of fire:
P371 In case of major fire and large quantities:
P372 Explosion risk.
P373 DO NOT fight fire when fire reaches explosives.
P375 Fight fire remotely due to the risk of explosion.
P376 Stop leak if safe to do so.
P377 Leaking gas fire: Do not extinguish, unless leak can be stopped safely.
P378 Use… to extinguish.
P380 Evacuate area.
P381 In case of leakage, eliminate all ignition sources.
P390 Absorb spillage to prevent material damage.
P391 Collect spillage.
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor/…

P301 + P312	IF SWALLOWED: Call a POISON CENTER/ doctor/…if you feel unwell.
P302 + P334	IF ON SKIN: Immerse in cool water or wrap in wet bandages.
P302 + P352	IF ON SKIN: Wash with plenty of water/…
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P306 + P360	IF ON CLOTHING: rinse immediately contaminated clothing and skin with plenty of water before removing clothes.
P308 + P311	IF exposed or concerned: Call a POISON CENTER/doctor/…
P308 + P313	IF exposed or concerned: Get medical advice/ attention.
P332 + P313	If skin irritation occurs: Get medical advice/ attention.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P336 + P315	Thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/ attention.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor/…
P361 + P364	Take off immediately all contaminated clothing and wash it before reuse.
P362 + P364	Take off contaminated clothing and wash it before reuse.
P370 + P376	In case of fire: Stop leak if safe to do so.
P370 + P378	In case of fire: Use… to extinguish.
P301 + P330 + + P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P302 + P335 + + P334	IF ON SKIN: Brush off loose particles from skin. Immerse in cool water [or wrap in wet bandages].
P303 + P361 + + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305 + P351+ + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P370 + P380+ + P375	In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.
P371 + P380 + + P375	In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.
P370 + P372 + +P380 + P373	In case of fire: Explosion risk. Evacuate area. DO NOT fight fire when fire reaches explosives.
P370 + P380 + + P375 + P378	In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion. [Use... to extinguish].

STORAGE PRECAUTIONARY STATEMENTS (Annex IV CLP Table 6.4)

P401	Store in accordance with...
P402	Store in a dry place.
P403	Store in a well-ventilated place.
P404	Store in a closed container.
P405	Store locked up.
P406	Store in a corrosion-resistant/… container with a resistant inner liner.
P407	Maintain air gap between stacks or pallets.
P410	Protect from sunlight.
P411	Store at temperatures not exceeding …°C/ …°F.
P412	Do not expose to temperatures exceeding 50 °C/ 122 °F.
P413	Store bulk masses greater than … kg/… lbs at temperatures not exceeding …°C/…°F.
P420	Store separately.
P402 + P404	Store in a dry place. Store in a closed container.
P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P403 + P235	Store in a well-ventilated place. Keep cool.
P410 + P403	Protect from sunlight. Store in a well-ventilated place.
P410 + P412	Protect from sunlight. Do no expose to temperatures exceeding 50 °C/ 122 °F.

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DISPOSAL PRECAUTIONARY STATEMENTS (Annex IV CLP Table 6.5)

P501 Dispose of contents/container to …

P502 Refer to manufacturer or supplier for information on recovery or recycling.

P503 Refer to manufacturer/supplier...for information on disposal/recovery/recycling (statement use in GHS, does not exist in CLP).

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