How to submit a CLH dossier

June 2022

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DOCUMENT HISTORY

Version	Comment	Date
1.0	First edition	May 2021
2.0	Changes to include the feed-back from the survey. Editorial changes	

Practical guide: How to submit a CLH dossier

Reference: ECHA-21-G-04-EN
ISBN: 978-92-9481-908-6
Cat. Number: ED-09-21-131-EN-N
DOI: 10.2823/21614
Publ.date: May 2021
Language: EN

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List of Abbreviations

Standard term / Abbreviation	Explanation
AR	Assessment Report
ATE	Acute Toxicity Estimate
ATP	Adaptation to Technical Progress (to the CLP Regulation)
BCF	Bioconcentration factor
BPR	Biocidal Products Regulation: Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products
bw	Body weight
C&L	Classification and Labelling
CAR	Competent Authority Report (for active substances in biocidal products)
CAS No	Chemical Abstract Service No
CLH	Harmonised Classification
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenicity, Mutagenicity and Reproductive toxicity
COM	European Commission
DAR	Draft Assessment Report (for active substances in plant protection products)
DS	Dossier Submitter
eCA	Evaluating Competent Authority
ECHA	European Chemicals Agency
EC No	The EC Number is the numerical identifier for substances in the EC Inventory
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
HC	Hazard Class
ISO	International Organisation for Standardization
IUCLID	International Uniform Chemical Information Database
M-factor	Multiplying factor
MSCA	Member State Competent Authority
LLNA	Local Lymph Node Assay
Log Kow	Octanol/water partition coefficient (Kow)
N(L)OAEL	No(low) Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NTP	National Toxicology Program (US)

Standard term / Abbreviation	Explanation
OECD	Organisation for Economic Co-operation and Development
OECD TG	OECD Test Guideline All Test Guidelines are available at the OECD homepage: http://www.oecd.org/document/40/0,3343,en_2649_34377_37051368_1_1_1_1,00.html
PPP	Plant Protection Products Regulation
(Q)SAR	(Quantitative) Structure Activity Relationship
RAAF	Read Across Assessment Framework
RAC	Committee for Risk Assessment
RAR	Renewal Assessment Report
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals1
RMS	Rapporteur Member State
RoI	Registry of Intentions
SCL	Specific Concentration Limit
SID	Substance Identification
SSD	Species Sensitivity Distribution
STOT RE	Specific Target Organ Toxicity - Repeated Exposure
STOT SE	Specific Target Organ Toxicity - Single Exposure
UN RTDG MTC	United Nation Recommendation on the Transport of Dangerous Goods, Manual of Tests and Criteria
UN RTDG MR	United Nation Recommendation on the Transport of Dangerous Goods, Model Regulation
USEPA	US Environmental Protection Agency
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials

1. Introduction

Practical Guides are written by ECHA to provide “hands on” information on REACH, CLP and Biocidal Products Regulation (BPR) requirements and to highlight best practice on how to fulfil them. They do not replace the formal Guidance documents which provide the principles and interpretations needed for a thorough understanding of the requirements of the CLP Regulation. The aim of a practical guide is to provide support in a ”hands on” way, in order to help the reader comply with their obligations under the CLP.

1.1. The purpose of this document

This Practical Guide on ‘How to submit a CLH dossiers’ aims to provide practical tips and advice to help the Dossier Submitter (DS) in the preparation of a good quality dossier. This guide takes into account the CLP Regulation, the best regulatory practices, and ECHA’s Committee for Risk Assessment (RAC) needs to be able to make conclusions on the hazard classifications proposed: all of this helps to pass the so called ‘accordance check’ performed by ECHA. This check is to ensure that the CLH dossier complies with the CLP Regulation Article 36 for submitting a CLH dossier. This practical guide also takes into account the experience gained from the numerous dossiers processed through the harmonised classification process and assessed by RAC.

This document should be used in combination with other ECHA guidance documents, particularly the “Guidance on the preparation of dossiers for harmonised classification and labelling” (see section 1.3 for links) which explains more ‘administrative’ aspects, for example who can submit a CLH dossier, the differences between ‘REACH chemicals’ and ‘active substances’ under either the Biocidal Products Regulation (BPR) or the Plant Protection Products (PPP) Regulation. In addition, the “Guidance on the Application of the CLP Criteria” (CLP guidance) provides information on the interpretation of the criteria for each hazard class (HC) and incorporates examples of classifications based on the available data and the ECHA Practical Guide “How to report robust study summaries” lays out the minimum details to be included in the reporting of a study for it to be considered a ‘robust study summary’.

This practical guide aims to bring together information from the CLP Regulation, the ECHA guidance, other relevant documentation and experience from RAC, to facilitate the task of the DS. However, readers are reminded that the text of the CLP Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice.

1.2. CLH process

This practical guide focuses on the first steps in the CLH process, namely the CLH intention and the dossier submission and then what happens at accordance check:

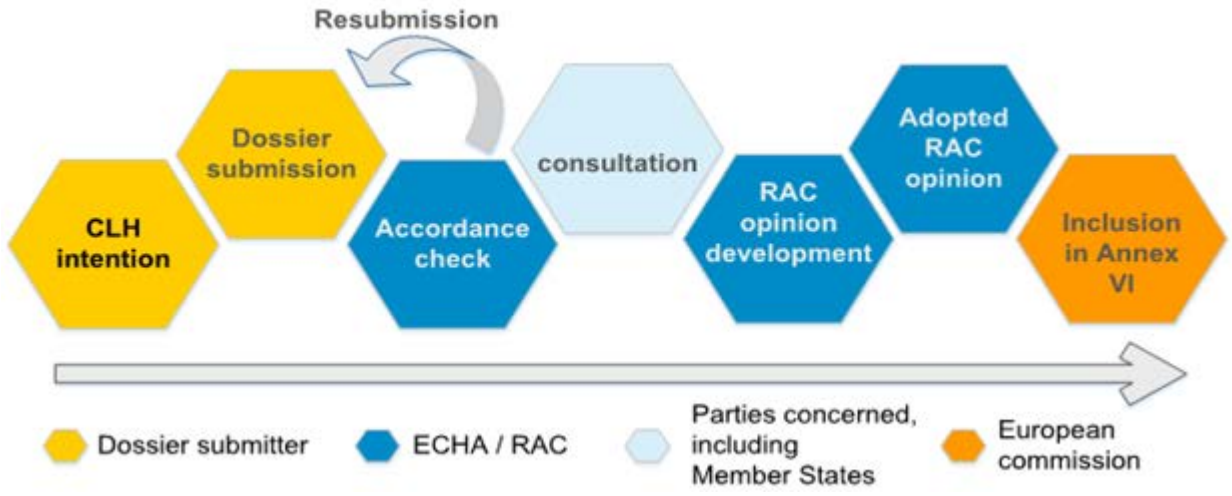

Figure 1: CLH process

See ECHA website Harmonised classification and labelling (CLH) - ECHA (europa.eu) and Submission of CLH dossiers - ECHA (europa.eu) for an overview.

1.3. Links

Links to the online material have been included for convenience. However, these documents will undergo periodical updates; hence, the latest version should always be referred to.

- CLP Regulation: Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures, available at https://echa.europa.eu/regulations/clp/legislation
- Introductory Guidance on the CLP Regulation, available at https://echa.europa.eu/documents/10162/23036412/clp_introductory_en.pdf
- CLP guidance: Guidance on the Application of the CLP Criteria, available at https://www.echa.europa.eu/documents/10162/23036412/clp_en.pdf
- Guidance on the preparation of dossiers for harmonised classification and labelling, available at https://echa.europa.eu/documents/10162/23036412/clh_en.pdf
- REACH guidance: Guidance on Information Requirements and Chemical Safety Assessment, available at https://www.echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
- ECHA practical guidance: How to report robust study summaries, available at https://echa.europa.eu/documents/10162/13643/pg_report_robust_study_summaries_en.pdf

2. General

2.1. Registry of Intentions (RoI)

The first action a DS can take when considering submitting a CLH dossier is to submit an intention in the Registry of Intentions (RoI). The RoI lists the intentions and proposals received by ECHA for a new or revised harmonised classification and labelling of a substance. The proposals are submitted by Member State Competent Authorities (MSCAs), manufacturers, importers or downstream users.

An intention should precede a submission in order to duly plan work and commitments, not only for the DS, but also interested parties who can follow the progress of a proposal through the CLH process, from the notification of the intention to the adoption of the opinion of the RAC. The RoI lists CLH submissions from intention until outcome.

Changes in (re)submission times or eventual withdrawals should be communicated on a timely basis, as advance notice enables interested parties to plan and prepare for commenting later on, or to be aware of any changes in intention. Anyone with relevant information on the identity or hazard properties of a substance is encouraged to provide this information to the DS during the early stages of the process, or at the latest during the consultation.

For more information see ECHA website: Registry of CLH intentions until outcome - ECHA (europa.eu).

2.2. CLH proposal, Annex I and the Confidential Annex

The DS for a new CLH dossier can be a MSCA, or a manufacturer, importer and downstream user of a substance. The DS can submit a CLH proposal in the following three situations:

- Where a substance is either Carcinogenic, Mutagenic or Reprotoxic (CMR) or a respiratory sensitiser,
- When it is justified that a classification for a substance at EU level is needed for other HCs,
- To add one or more new HCs to an existing entry (under the conditions above).

Only MSCAs may propose:

- A revision of an existing harmonised entry, for any substance that is under the scope of the CLP Regulation,
- When a substance is an active substance in biocidal or plant protection products.

The DS must undertake a transparent, adequately documented and independent evaluation of the reliability and scientific quality of studies reported in the CLH dossier. This evaluation needs to be consistent with the CLP guidance and REACH Technical Guidance Documents as well as the respective OECD Test Guidelines / test protocols.

This evaluation is submitted in a “CLH proposal” document which is supported by an Annex I for very detailed or additional information and Confidential Annex for any confidential information.

The CLH report should contain enough information to be a stand-alone document that will be published on ECHA’s website during the consultation. Confidential information should not be included in the CLH report but submitted in the Confidential Annex (see also section 2.8).

The CLH proposal and its Annex I should be prepared using the appropriate templates available on ECHA website: https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats.

Specific templates should be used if the proposal is also an active substance in:

- Plant Protection Products (PPP, Regulation EC 1107/2009) see page 30),
- Biocidal Products (BPR, Regulation (EU) 528/2012, see page 30).

The information included in this document follows the order of the headings in the CLH dossier report, where possible.

2.3. Classification table

The classification table provides, at a quick glance in the CLH dossier, what the DS proposal is. This table is used also in other stages of the CLH process, making it important to write it in a consistent format. Please see below a few tips on how to fill in the classification table. It is filled in slightly differently depending on the presence of an existing classification or not. If the substance has no existing classification, the row 'Current Annex VI entry' is empty and the DS proposal is added on the row 'Dossier submitter's proposal' without the clarifying words "**Add**", "**Retain**", "**Modify**" and "**Remove**". These are included in this latter row to improve the clarity of the DS proposal if an existing classification is present in Annex VI. The example below is for an imaginary substance with an existing entry because these entries are where additional attention is needed.

Table 1: Example of classification table when the substance has an existing Annex VI entry

	Index No	Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	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)		
Current Annex VI entry	WWW-XXX-YY-Z	substance name: ISO name; EC name/IUPAC name	AAA-BBB-C	DDD-EE-F	Acute Tox. 4* Acute Tox. 4* Eye Irrit. 2 Skin Irrit. 2 Aquatic Chronic 3	H332 H302 H319 H315 H412	GHS08 GHS07 Wng	H332 H302 H319 H315 H412			
Dossier submitter's proposal	WWW-XXX-YY-Z	substance name: ISO name; EC name/IUPAC name	AAA-BBB-C	DDD-EE-F	**Retain** Aquatic Chronic 3 **Add** STOT RE 2 Aquatic Acute 1 **Modify** Acute Tox. 2 Acute Tox. 4 **Remove** Skin Irrit. 2	**Retain** H412 **Add** H373 (blood system)(oral) H400 **Modify** H330 H302 **Remove** H315	**Retain** GHS08 **Add** GHS06 GHS09 **Remove** GHS07	**Add** H373 (blood system)(oral) **Modify** H330 H302 H410 **Remove** H315 H412		**Add** inhalation: ATE = 0,27 mg/L (dusts or mists) oral: ATE = 500 mg/kg bw M = 10	
Resulting entry in Annex VI if adopted by RAC and agreed by Commission	WWW-XXX-YY-Z	substance name: ISO name; EC name/IUPAC name	AAA-BBB-C	DDD-EE-F	Acute Tox. 2 Acute Tox. 4 STOT RE 2 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 3	H330 H302 H373 (blood system)(oral) H319 H400 H412	GHS06 GHS08 GHS09 Wng	H330 H302 H373 (blood system)(oral) H319 H410		inhalation: ATE = 0,27 mg/L (dusts or mists) oral: ATE = 500 mg/kg bw M = 10	

The first row includes the current classification in Annex VI.

The second row lists all the HCs which are evaluated in the CLH dossier and for which the data fulfil the classification criteria. All changes to the existing classification should be labelled using the words below based on the DS proposal:

- "**Retain**" when the hazard class is reassessed by the DS, and no changes to the current classification are proposed
- "**Add**" to include an additional HC to the current classification,
- "**Modify**" to change the hazard class (sub)Category, e.g. Acute Tox. 3 to Acute Tox. 4.
- "**Remove**" to delete an existing HC from the current classification,

Please note that "**Retain**" should only be used when the hazard class is reassessed by the DS, and no changes to the current classification are proposed. If no reassessment of the hazard is included in the CLH dossier the HC should not be listed under "**Retain**". It will however be listed under the first row "Current Annex VI entry" and the last row "Resulting entry in Annex VI if adopted by RAC and agreed by Commission" - see example of "Eye Irrit. 2" above.

Please note: the revaluation of the minimum classification goes under "**Modify**" even if no change in classification is proposed, for example if Acute Tox. 4* is modified to Acute Tox. 4; hence, only removing the minimum classification without revising the Category (H302 or H332 in the table above).

The third row contains the resulting classification if the DS proposal is adopted by RAC and agreed by the Commission (COM) without changes.

In the example above, the CLH dossier contains data, their comparison with the criteria and a classification proposal for at least these HCs: acute toxicity via the oral and inhalation route, specific target organ toxicity by repeated exposure (STOT RE), skin irritation and toxicity to aquatic environment. No data or assessment of the HC eye damage / irritation is included.

The next subsections address the most frequent issues found in the CLH dossiers, grouped by the table column.

2.3.1. Chemical identification

The substance name should start with small letter (non-capital).

2.3.2. Classification / Hazard Class and Category Code(s)

The HCs should be listed in a specific order in the classification table as follows:

- Physical hazards listed in the same order as in the CLP Regulation Annex I, section 2
- Carc. 1A, 1B or 2
- Muta. 1A, 1B or 2
- Repr. 1A, 1B or 2
- Lact.
- Acute Tox. 1, 2, 3 or 4 [inhalation route]
- Acute Tox. 1, 2, 3 or 4 [dermal route]
- Acute Tox. 1, 2, 3 or 4 [oral route]
- Asp. Tox. 1
- STOT SE 3
- STOT SE 1 or 2 (target organ)(route)
- STOT RE 1 or 2 (target organ)(route)
- Skin Corr. 1A or 1B / Skin Irrit. 2
- Eye Dam. 1 / Eye Irrit. 2
- Resp. Sens. 1, 1A, 1B or 2
- Skin Sens. 1, 1A, 1B or 2

- Aquatic Acute 1
- Aquatic Chronic 1, 2, 3 or 4
- Ozone 1

2.3.3. Labelling / Hazard statement Code(s)

In this column, the hazard statement codes should be in the same order as the corresponding HC and the Category codes. However, this is not always possible since some hazard statement codes can be omitted from the label in case of evident duplication or redundancy (see CLP Regulation Article 27). One classical example is for substances classified as Aquatic Acute and Aquatic Chronic, see CLP guidance, Table 4.1 and below:

Table 2: Example of omitted hazard statement code from the labelling column

Classification		Labelling
Hazard Class and Category Code(s)	**Hazard statement Code(s)**	**Hazard statement Code(s)**
Aquatic Acute 1	H400	H410
Aquatic Chronic 3	H412	

In addition, consider the principles of precedence for hazard pictograms stated in the CLP Regulation Article 26(1). The hazard pictograms should be in the same order as the classification and hazard statement codes that triggers them. As a consequence, GHS09 will always be the last one, before Wng or Dgr.

2.3.4. Specific Concentration Limits, Multiplying factors and Acute Toxicity Estimate

The order of the elements in the column title in the classification table (specific concentration limits (SCL), then M-factors, followed by Acute Toxicity Estimate (ATE)) reflects the current header in the CLP Regulation Annex VI; however, it does not correspond to the order in which these three elements should be listed in the classification table. The correct order is ATEs, SCLs and M-factors. An example of the correct order and format for each element is the following:

- inhalation: ATE = 0,05 mg/L (dusts or mists)
- dermal: ATE = 300 mg/kg bw
- oral: ATE = 500 mg/kg bw
- STOT RE 1; H372 (liver): C ≥ 20 %
- M = 10

Please note that spaces are used before and after the equal sign for ATE and M-factors, the use of commas as decimal separator in both ATE and SCL, and the non-capital letter of inhalation, dermal and oral ATEs. In the accordance check, required changes apply only when elements are missing, e.g. the inhalation ATE value without the indication of gases / vapours / dusts or mists, and not for format related differences, e.g. a missing space or the use of a dot instead of a coma.

2.4. Table: Reason for not proposing harmonised classification and status under consultation

The ‘reason for no classification’, the data provided on the specific HC, and indication if this HC is open for consultation must match. Note that each sentence included in the second column (header: reason for no classification) has a slightly different meaning; hence, the selected text

should be chosen carefully. It is important that the 'reason' matches the assessment of the specific HC section in the CLH dossier.

The HC should be open for consultation (please choose 'Yes' in the last column), when the text in the column 'reason for no classification' is one of the following:

- 'data conclusive but not sufficient for classification', or
- 'harmonised classification proposed',

The HC should not be open for consultation (please choose 'No' in the last column), when the reason for no classification is one of the following:

- hazard class not assessed in this dossier, or
- hazard class not applicable

If these two reasons are indicated, it is understood that the DS did not evaluate this HC; hence, it should not be open for consultation. If the DS included data under a HC as supporting information for another HC, e.g. germ cell mutagenicity data to provide additional background data for the carcinogenicity assessment, the correct choice is 'hazard class not assessed in this dossier' and not open for consultation for the HC germ cell mutagenicity. Please note, 'hazard class not applicable' strictly speaking is only appropriate when the substance has a different physical state[1], e.g. oxidising liquids when the substance is a solid, or for organic peroxides. In the latter case, the HC is not applicable (no need to compare the data with the criteria), if the chemical does not include the peroxide functional group (-O-O-) i.e., it is outside this HC definition, see CLP Regulation, Annex I, 2.15.1.1.

The DS can choose if the HC should be open for consultation or not when the text in the column 'reason for no classification' is one of the following:

- 'data lacking', or
- 'data inconclusive'

Regardless of which of the above reasons is chosen, it is assumed that the DS gathered and assessed the available data and concluded on them. Please note that the conclusion 'data lacking / data inconclusive' implies that the DS sought (and assessed) the existing data, even if they considered the data to be 'lacking' or 'inconclusive'. If the available data do not enable a conclusion on classification to be drawn, 'data inconclusive' should be used to justify no classification.

Please note that one of the scopes of the CLH consultation is to collect additional data. Therefore, if the DS considers that a HC should be evaluated by RAC and could not find conclusive data, the appropriate option is to choose 'data lacking / data inconclusive' and 'open for consultation'. Please be aware, that if additional data would be submitted during the consultation, the DS in the reply to the comment(s) may propose a classification. In this event, depending on how the new information was submitted, it might undergo a second, so-called 'ad hoc consultation'.

2.5. Justification that action is needed at community level

According to Article 36(3) of the CLP Regulation, a justification demonstrating the need for action at EU level needs to be provided with proposals for harmonised classification and labelling for HCs / differentiations other than carcinogenicity, mutagenicity, reproductive toxicity (CMR) and respiratory sensitisation. However, for active substances covered by the BPR and PPP Regulation, no justification is needed as according to Article 36(2) of the CLP Regulation they shall normally be subject to harmonised classification and labelling, and hence,

[1] When not clearly stated in the hazard class name, check the CLP Regulation to know which hazard classes are applicable as the same hazard class could be applicable to, e.g., both solid and liquid substances (e.g. explosives, aspiration hazards).

the CLH dossier is a requirement under these two regulations. Please note the Regulation (EU) 2020/103 (and subsequently transferred to Regulation (EU) 2020/1740) introduced modifications of the HCs to be evaluated by the DS for plant protection active substances.

Therefore, for a REACH chemical, if the CLH dossier evaluates more than the four HCs mentioned above, a justification will be needed for the additional HCs. For example, if the DS is proposing classification for one or more of the CMR HCs and at the same time evaluating other HCs (e.g. revising an existing minimum classification for acute toxicity), they need to include a justification demonstrating the need for proposing harmonised classification for these additional HCs.

Examples of acceptable justifications are provided in Section 4.2 “Justification demonstrating the need for action at EU level” in the ‘Guidance on the preparation of dossiers for harmonised classification and labelling’.

2.6. Substance identity (SID)

Every substance needs to be unequivocally identified, in terms of EC / CAS numbers (where available) and names, identification of constituents, etc. Particular attention should be paid when identifying substances containing isomers. Individual isomers are regarded as constituents of a substance and their individual concentration levels need to be taken into account when deriving the name of a substance. Substances consisting of more than one individual isomer as main constituent are regarded as multi-constituent substances.

The name of a substance should be derived following the ECHA and CLP Guidance on substance identification and naming, see https://www.echa.europa.eu/documents/10162/23036412/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d. Section 1.1 of Annex VI of CLP includes additional information related to the use of identifiers.

List numbers with the format 6XX-XXX-X, 7XX-XXX-X, 8XX-XXX-X and 9XX-XXX-X should not be used as substance identifiers in a CLH dossier since they are numerical identifiers automatically assigned by ECHA when an EC number is not available. They do not have any legal significance and they are not published in the Official Journal of the European Union. A link explaining the difference between a List number and an EC number can be found at https://echa.europa.eu/information-on-chemicals/registered-substances/information. See also https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/143.

Because of the challenges that may be encountered in substance identification, it is strongly recommended to communicate to ECHA the intention to submit a CLH dossier in advance of the submission. This enables resolving upfront possible issues concerning name(s) and numerical identifiers.

Table 4: Tips on how to fill-in the tables describing the substance identity and composition

Name and other identifiers of the substance	
Name(s) in the IUPAC nomenclature or other international chemical name(s)	
Other names (usual name, trade name, abbreviation)	Include here names describing the proposed substance as such. Names describing the individual constituents of the proposed substance should not be reported in this table.
ISO common name (if available and appropriate)	
EC number (if available and appropriate)	

EC name (if available and appropriate)	Include the EC name when an EC entry is available
CAS number (if available)	
Other identity code (if available)	
Molecular formula	
Structural formula	If the substance includes stereoisomers, please reflect the information in the structural formula
SMILES notation (if available)	If the substance includes stereoisomers, please reflect the information in the SMILES notation
Molecular weight or molecular weight range	
Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)	
Description of the manufacturing process and identity of the source (for UVCB substances only)	
Degree of purity (%) (if relevant for the entry in Annex VI)	For UVCB substances the degree of purity information is not relevant, a value of 100% should be reported for these substances

Confidential information related to the composition of the substance should be reported in a Confidential Annex to the CLH report.

2.7. Data availability

All available, relevant data needs to be included in the CLH report and taken into account in the derivation of the appropriate hazard classification. This includes information from all relevant Regulatory processes, for example from REACH Registration dossiers, Competent Authority Reports (CARs) for biocidal-active substances, Draft Assessment Reports (DARs) or Renewal Assessment Report (RARs) for pesticidal-active substances, as well as information generated under the National Toxicology Program (NTP), the United States Environmental Protection Agency (USEPA) and any other national Regulatory programs. Relevant literature studies could also be included when they provide additional information on hazardous properties of the substance.

In all cases, the CLH report should contain enough information and details to work as a stand-alone document in order to (i) provide adequate details on the key studies to evaluate the study quality, (ii) to enable meaningful comments during the consultation, (iii) to facilitate the RAC opinion-making process. Omission of relevant information needs to be explicitly justified. See section 2.10 below.

2.8. Data confidentiality

To understand data confidentiality, refer to REACH Article 119 for additional information on the rules.

2.8.1. Redacting / replacing authors names

Authors of unpublished studies are considered as confidential information, and as such the authors' names must be redacted; please see the ECHA website on the "Personal data protection" section: Personal data protection (https://echa.europa.eu/about-us/the-way-we-work/personal-data-protection) and the document "Policy for the publication of study author's names" under "related" at the bottom of the page.

Authors' names should be redacted / replaced by an anonymous reference in all CLH related documents that will be published. This also includes any annexes the DS includes in the submission to provide additional information, if not flagged as confidential. The classical way to write an anonymous reference is Anonymous, YYYY; if more than one study conducted in the same year is included in the report, for clarity a unique reference can be included, e.g. Anonymous, 2021a or Anonymous 1, 2021.

2.8.2. Impurities

Impurities or constituents are normally considered confidential unless they contribute significantly to the classification of the substance, CLP Regulation Annex VI, 1.1.1.4. For further guidance, refer to "Impurities and (degree of) purity in CLP and in the CLH process" on ECHA website:

https://echa.europa.eu/documents/10162/13626/clh_impurities_purity_en.pdf/cc0406ba-2e6c-4ee0-3082-2b2b3f123ee4.

2.8.3. Confidential Annex

The confidential information should be submitted in a confidential annex of the CLH report.

2.9. Comparison with the CLP criteria

The study results must be compared with the criteria of the hazard Category for which the classification is proposed, as well for the categories which would result in a more or less stringent classification or categorisation. Copy pasting the whole CLP criteria relevant to the HC may on some occasions decrease the readability of the text. As an example, the numerical criteria for skin corrosion / irritation improve the understanding of the DS's conclusion. On the other hand, the full text of lengthy criteria, such as those for reproductive toxicity could hinder the readability.

However, merely copy and pasting of the criteria is not sufficient, as a proper comparison of the data against the criteria is needed. Even where no classification is proposed, the study results must be compared with the criteria for the HC. Under the heading "Comparison with criteria" one must not state "not relevant", as the comparison with the criteria is always relevant[2]. Instead, a statement, such as the following one, should be included: "The substance does not meet the criteria for classification for [hazard class] because [reason]".

It is recommended that for all the hazard classes considered in the CLH report, the CLP Regulation is the primary reference for the classification criteria instead of referring to the CLP guidance. Please note that the text in the green boxes in the CLP guidance is from the CLP Regulation.

2.10. Scientific details needed

To serve as a stand-alone document, it is recommended that the CLH report contains sufficient details on all studies (both negative and positive results) to allow an independent assessment by RAC for the HC, without any need to go back to the robust study summaries or full study reports.

For clarity, it is recommended to use additional tables where needed, ideally not embedded within the study summary table.

Study summaries should report basic information, such as:

- test material: the identity of the test material (name, impurities, other substance

[2] Unless the HC is not relevant due to different physical state, or the data were included for information in support for the evaluation of another HC, e.g. germ cell mutagen data to support the assessment of carcinogenicity data. In this event, it is suggested that a statement such as the following is included instead "not under the scope of this dossier".

identification information) needs to be clearly reported;

- test guideline: test guideline(s) used to conduct the study needs to be clearly identified. Updated versions of OECD TG are always accepted, whereas the validity of other guidelines should be verified by the DS. More information on the acceptability of test guidelines is available in the ECHA CLP guidance and in the ECHA Guidance on Information Requirements and Chemical Safety Assessment (R.7);
- experimental conditions: conditions described in the test guideline(s) should be verified by the DS and summarised in the CLH dossier (e.g. year, study duration, test organism (species / strains), doses, exposure route, number of animals / replicates / individual per replicate as appropriate, temperature, pH, light intensity...);
- deviations from test guideline: any deviation from the guideline used to conduct the test should be described and assessed for impacts on the test reliability;
- validity criteria: the fulfilment of validity criteria described in used test guideline(s) should be verified, referring to the updated versions of these;
- exposure (where relevant): information on exposure of organisms should be reported. Where possible, table format is preferred;
- results: effects on observed parameters should be reported, preferably in table format (including information on incidences and severities of findings, extent of changes relative to controls, and whether the differences are statistically significant compared to controls etc.);
- conclusion: the final proposal ((eco)toxicological endpoint, physico-chemical characteristic) derived from results should be clearly stated.

For additional information, please refer to ECHA practical guidance 'How to report robust study summaries'.

2.11. Evaluation of the study results

In the CLH process, the evaluation of the findings relevant for classification for each hazard class relies on the description of the effects (incidence, severity, statistical significance, etc.). Hence, in order to enable an independent assessment by RAC, the detailed observed effects for each dose should be included in the tables and/or the text, in addition to any N(L)OAEL and qualitative assessment (such as limited, slightly, moderate) that might also be available. Where possible, the findings should be quantitated, using numeric values, e.g. slight body weight decrease (-8%), should also be included.

Furthermore, the statement "no treatment related effects were observed" is considered ambiguous as it implies an assessment of the observed effects, i.e. effects were observed and were considered not treatment related by the DS. Consequently, it is recommended to distinguish between "no effects were observed", and "effects were observed but were not considered treatment related". Therefore, for transparency, if there are effects, it is recommended that effects are described, even if the DS considers them not related to the treatment. Please bear in mind that RAC should have all information to form an independent opinion, which might differ from the DS's assessment.

2.12. Weight of evidence, (Q)SAR models and grouping of substances and read across

ECHA website (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/weight-of-evidence) includes specific information and specific guidance documents on how to use weight of evidence, (Q)SAR models and grouping of substances as well as read-across approaches. It is advised to comply as far as possible with the requirements described in the guidance documents, to improve the CLH dossier quality and consistency of the assessments. In the CLH dossier, all information to support the validity of the provided result should be given, e.g. if the substance is within the applicability domain when using a (Q)SAR

prediction. Another example: for some *in vitro / ex vivo* studies, the result could fall within the 'no prediction can be made' interval, and this should be reported accordingly, but it is not equivalent to classification in a Category or no classification.

2.12.1. Read-across - additional considerations

The use of data from one substance (source) to support the classification of another (target) in the CLH dossier needs to be adequately justified.

Justification must be adequately substantiated in terms of hypothesis / use of analogue substance(s), properly documented and clearly reported, preferably on an endpoint-by-endpoint basis. The substantiation does not only refer to structural and other chemical similarities, but also to environmental fate and ecotoxicological similarities, common patterns / trends, and mode of action information.

ECHA Read-Across Assessment Framework (RAAF,) structures the scientific evaluation of grouping and read-across approaches under REACH. For additional information refer to the following documents which are available from the ECHA website: https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across and related guidance, available at https://echa.europa.eu/documents/10162/13628/raaf_en.pdf/614e5d61-891d-4154-8a47-87efebd1851a.

In addition, for the HCs where criteria are expressed in mg/kg bw (e.g. acute toxicity), it is important to consider the difference in molecular weight between the target and the source substance when calculating the dose at which toxic effects are expected to be observed for the target substance. If the ratio between the two molecular weights is close to one, it needs to be stated; in this case it is acceptable not to calculate the 'corrected target doses' as the difference would be small. However, if the ratio is not close to one, the corrected target doses have to be included in the CLH dossier and it is important to clearly distinguish between the 'source doses' and the 'corrected target doses', to avoid confusion.

3. Physical hazards

It is assumed that the assessor is aware of the physical state of the substance as per CLP Annex I section 1.0, and that only the hazard classes relevant for that physical state are assessed.

Note 1: The Commission Regulation (EU) 2019/521 (12th ATP, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0521&from=EN), which entered into force on 17 Oct 2020, has introduced a few changes on the criteria for classification as physical hazards and a new hazard class, desensitised explosives.

Note 2: Generally, results from EU methods A.10 to A.17 and A.21 listed in Council Regulation (EC) 440/2008 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02008R0440-20170518) do not provide sufficient information to conclusively assess the relative physical hazard. Exceptions will be listed below as appropriate.

Links to the online material have been included for convenience. However, they will undergo periodical updates, and hence the latest version should always be the one referred to.

- UNECE webpage with links to the revised seventh edition of the UN Recommendation on the Transport of Dangerous Goods, Manual of Test and Criteria, its amendment and Corrigendum (https://unece.org/transport/dangerous-goods/rev7-files)
- UN Recommendations on the Transport of Dangerous Goods - Model Regulations (https://unece.org/transport/dangerous-goods/un-model-regulations-rev-22)
- (https://unece.org/transport/dangerous-goods/rev7-files):
- Test method ISO 10156 (https://www.sis.se/api/document/preview/922143).

For all physical hazard classes, please check if the substance is listed in the GHS transport

classification which can provide useful information for classification as explained in the CLP guidance, Annex VII.

3.1. Explosives

The substance shall not be considered for classification as explosive if it is an organic peroxide or a self-reactive substance. If the substance is proposed / classified as explosive, it should not be considered for classification in any other physical hazard class.

The hazard class is assessed by a screening procedure, followed, if needed, by the classification procedure.

Data needed:

- For the screening procedure (2.1.4.3):
    - Chemical structure and Table A6.1 in Appendix 6 of the UN RTDG MTC
    - Oxygen balance
    - Decomposition energy and decomposition onset temperature
- The classification and further allocation to a division is a very complex procedure. The classification process is divided into two stages, the acceptance procedure, and the assignment procedure. In the acceptance procedure, intrinsic explosive properties are determined through tests of its sensitivity, stability, and explosion effects. If the substance, mixture, or article is not characterised as unstable explosive and is provisionally accepted into the class of explosives, it is then necessary to ascertain the correct division (6 divisions in total) by applying the assignment procedure.
    - UN Test series 1 to 8 in Part I of the UN RTDG MTC.

When assessing this hazard class, please consider the following EU hazard statements:

EUH044 - Risk of explosion if heated under confinement

Note: Test method EU A.14 does not provide sufficient information to conclusively assess the explosive properties of the substance.

3.2. Flammable gases (including chemically unstable gases)

The substance shall not be considered for classification in this hazard class if it is an aerosol.

Data needed:

- Flammability: Test method ISO 10156 as amended or clause 4.2 of EN 1839 as amended.
- Pyrophoricity: Test method IEC 60079-20-1 ed1.0 (2010-01) or DIN 51794
- Information on experience in production or handling up to 54°C
- Chemical instability (if flammable): Test methods in Part III of the UN RTDG MTC

Note: Test method EU A.11 does not provide sufficient information to conclusively assess this hazard class.

3.3. Oxidising gases

Oxidising gases do not need to be classified in any other physical hazard class apart from ‘Gases under pressure’ where appropriate.

Data needed:

- Test methods ISO 10156 as amended.

3.4. Flammable liquids

The substance shall not be considered for classification as flammable liquid if it is (will be) classified as explosive or inorganic oxidising liquid. A flammable liquid is classified in one of the four categories for this class according to the flash point and the initial boiling point.

Data needed:

- Flash point
- Initial boiling point

Possible test methods for determining the flash point or the initial boiling point are listed in Tables 2.6.3 and 2.6.4 (CLP Annex I). Please note that the substance viscosity drives the choice of the method.

When assessing this hazard class please consider the following EU hazard statements:

EUH018 - In use, may form flammable / explosive vapour-air mixture

EUH209 - Can become highly flammable in use

EUH209A - Can become flammable in use

Note: Test method EU A.9 does not provide sufficient information to conclusively assess this hazard class.

3.5. Flammable solids

The substance shall not be considered for classification as flammable solid, if it is (will be) classified as explosive, organic peroxide, self-reactive substance, pyrophoric, oxidising solids, or an inorganic oxidising solid.

Data needed:

- Results of test method N.1, see Part III of the UN RTDG MTC[3]

Note: The result 'not highly flammable' from test method EU A.10 can be used conclusively for 'no classification'. However, for any other result than 'not highly flammable', additional testing using method UN Test N.1 is needed to determine the influence of the wetted zone, see REACH guidance R.7.1.10.3.

Note: A burning index up to 3 from Burning Behaviour test (VDI 2263, part 1) can be used conclusively for 'no classification'. If the burning index is above 3, additional testing using method UN Test N.1 is needed.

3.6. Self-reactive substances and mixtures

The substance shall not be considered for classification as 'self-reactive', if it is (will be) classified as explosive, oxidising liquid or solid or organic peroxide.

The hazard class is assessed by a screening procedure, followed, if needed, by the classification procedure. Data needed:

- For the screening procedure (2.8.4.2):
    - Chemical structure and Tables A6.1 and A6.3[4] in Appendix 6 of the UN RTDG MTC
    - Estimated self-accelerating decomposition temperature (SADT), see Part II,

[3] CLP guidance, section 2.7.4.2 and Figure 2.4, refers to a 'screening procedure', which is part of the test method N.1. Therefore, it is part of the results of N.1 method and will not be considerate separately.
[4] Annex I 2.8.4.2(a) refers to Tables A6.1 and A6.2 in Appendix 6 of the UN RTDG MTC, however on the sixth revision of the UN RTDG MTC, Table A6.2 was renamed as Table A6.3.

section 28 of the UN RTDG MTC

- Exothermic decomposition energy, see Part II, section 20 of the UN RTDG MTC

- For the classification procedure:
  - UN Test series A to H in Part II of the UN RTDG MTC.

3.7. Pyrophoric liquids

The substance shall not be considered for classification as 'pyrophoric liquid', if it is (will be) classified as explosive or inorganic oxidising liquid.

Data needed:

- Results of test method N.3, see Part III of the UN RTDG MTC
- Information on experience in production or handling (2.9.4.1)

Note: Test method EU A.13 is considered equivalent to test method N.3; thus, it can provide sufficient information to conclusively assess this hazard class, see REACH guidance R.7.1.10.5.

3.8. Pyrophoric solids

The substance shall not be considered for classification as 'pyrophoric solid' if it is an inorganic oxidising solid.

Data needed:

- Results of test method N.2, see Part III of the UN RTDG MTC
- Information on experience in production or handling (2.10.4.1)

Note: Test method EU A.13 is considered equivalent to test method N.2; thus, it can provide sufficient information to conclusively assess this hazard class, see REACH guidance R.7.1.10.6.

3.9. Self-heating substances and mixtures

The substance shall not be considered for classification as 'self-heating' if it is (will be) classified as pyrophoric liquids or solids.

The hazard class is assessed by a screening procedure, followed, if needed, by the classification procedure.

Data needed:

- For the screening procedure (2.11.4.2):
  - Melting point (CLP guidance 2.11.4.2)
  - Examples of tests:
    - Grewer Oven Test
    - Bulk Powder Screening Test
- For the classification procedure:
  - Results of test method N.4 in Part III of the UN RTDG MTC

Note: Test method EU A.16 is generally inappropriate for a sound assessment and the findings are not sufficient to conclusively assess this hazard class.

3.10. Substances and mixture which in contact with water emits flammable gases

The hazard class is assessed by a screening procedure, followed, if needed, by the classification procedure. Data needed:

- For the screening procedure (2.12.4.1):
    - Chemical structure
    - Experience in production or handling
    - Water solubility
- For the classification procedure:
    - Results of test method N.5 in Part III of the UN RTDG MTC

Note: Test method EU A.12 does not provide sufficient information to conclusively assess this hazard class.

When assessing this hazard class, please consider the following EU hazard statements:

EUH014 - Reacts violently with water

EUH029 - Contact with water liberates toxic gas.

3.11. Oxidising liquids

Existing "transport" classification: substances classified in Division 5.1 in the modal transport regulations (ADR, RID, ADN and IMDG Code, ICAO TI) shall normally be classified in this hazard class. Packing Groups I, II and III of the transport regulations correspond directly to Categories 1, 2 and 3 of the CLP, respectively.

The substance shall not be considered for classification as 'oxidising liquid', if it is (will be) classified as explosive, organic peroxide.

The hazard class is assessed by a screening procedure, followed, if needed, by the classification procedure. Data needed:

- For the screening procedure (2.13.4.1 and 2.13.4.2):
    - Chemical structure
- For the classification procedure:
    - Results of test method O.2, see Part III of the UN RTDG MTC

Note: Test method EU A.21, if negative, can be used to conclusively conclude on 'no classification'. A positive result cannot be used for classification, as A.21 does not lead to a discrete classification category. If the latter is the case, UN test O.2 results need to be present in the CLH dossier..

3.12. Oxidising solids

Existing classification: substances classified in Division 5.1 in the modal transport regulations (ADR, RID, ADN and IMDG Code, ICAO TI) shall normally be classified in this hazard class. Packing Groups I, II and III of the transport regulations correspond directly to Categories 1, 2 and 3 of the CLP, respectively.

The substance shall not be considered for classification as 'oxidising solid' if it is (will be) classified as organic peroxide.

The hazard class is assessed by a screening procedure, followed, if needed, by the classification procedure.

Data needed:

- For the screening procedure (2.14.4.1 and 2.14.4.2):
    - Chemical structure
- For the classification procedure:
    - Results of test method O.1 or O.3, see Part III of the UN RTDG MTC

- Information on experience in handling (2.14.4.3)

Note: Test method EU A.17 does not provide sufficient information to conclusively assess this hazard class.

3.13. Organic peroxides

For classification as organic peroxide under CLP, the substance must contain the bivalent –O-O- structure (2.15.1.1).

Data needed:

- For the screening procedure for organic peroxides:
  - Available oxygen content calculated using formula in 2.15.2.1
- For the classification procedure:
  - UN Test series A to H, see Part II of the UN RTDG MTC
  - SADT, see Part II, section 28 of the UN RTDG MTC

3.14. Corrosive to metal

The hazard class 'corrosive to metal' is assessed by a screening procedure, followed, if needed, by the classification procedure.

Data needed:

- For the screening procedure (CLP guidance 2.16.4.1):
  - Melting point for solids
  - Chemical nature of the substance
  - pH value for liquids
- For the classification procedure:
  - UN Test C.1, see Part III of the UN RTDG MTC

4. Human health hazards

4.1. General consideration applicable to several hazard classes

4.1.1. Route of Exposure

Generally, a route of exposure can be specified when the data conclusively show that no classification is warranted by the remaining routes. A negative study, or other conclusive evidence can be considered as conclusive evidence. On the contrary, absence of information on one or more routes of exposure is generally not sufficient to exclude these routes of exposures.

4.1.2. Specific concentration limits

Proposal for specific concentration limits (SCL) should be included whenever relevant. If considered not appropriate, for clarity, a statement specifying that the SCLs have been considered, but concluded not to be necessary, may be added at the end of the relevant HCs. For further guidance on how to set the SCLs, refer to the CLP guidance. For additional information, see CLP guidance 1.5.1 and Table 1.1

4.1.3. Historical control data

Usually, the most relevant comparison of effects is with the concurrent control. However, sometimes information from historical controls may be available. If the DS decides to include

them in their assessment, the time range, a brief evaluation of the appropriateness and relevance must be provided, as well as information on the laboratory and test animals (strain), breeder, mean, confidence interval, quartiles etc.. For additional information on the general principles for the use of historical control data, please refer to the CLP guidance 3.6.2.3.2. It is noted that the text was specifically written for carcinogenicity; however, the general principles are applicable also when used for other hazard classes. Furthermore, Commission Regulation (EU) No 283/2013 provides additional guidance on the information to be included when using the historical control data, see https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02013R0283-20141117.

4.2. Acute toxicity

The rationale for the Acute Toxicity Estimate (ATE) should be included in the "Comparison with the criteria", even in the case of a default value, according to Table 3.1.2 in the CLP Regulation. Please include the proposed ATE along with the proposed classification, in section "Conclusion on classification and labelling for acute […] toxicity" (and in the classification table).

If the substance has an existing classification (even if it is a minimum classification), consider including a reassessment of the available data to update the classification and propose an ATE. This allows for a more efficient use of the available resources by limiting the likelihood of submitting a second CLH dossier to update the minimum classification.

4.3. Skin corrosion / irritation

The criteria are based on the average irritation score over time for each animal. In some cases, average irritation scores for animals at a specific time point or the overall average irritation score, i.e. over time and animals, have been included in a CLH report. These do not allow a comparison with the criteria; hence, ECHA will require the average over time for each animal. If these values are not available, please specify this in the CLH dossier.

As an example, if 3 animals were used and the irritation score were reported as in the table below, the averages to be included in the CLH dossier are: 0.33, 1, 0.66.

Table 5: Example of irritation scores for an animal study

Skin Irritation scores				
	Irritation score at 24h	Irritation score at 48h	Irritation score at 72h	Average over time
Animal 1	1	0	0	0.33
Animal 2	2	1	0	1
Animal 3	2	0	0	0.66

Irritation scores of 1.66, 0.33, 0 (average at each time point) or 0.66 (overall average) do not allow a comparison with the criteria.

4.4. Serious eye damage / eye irritation

The criteria are based on the same principles as for the skin corrosion / irritation; hence, the instruction above applies also for this hazard class.

The classification as Eye Dam. 1 is "automatic" for a substance classified as Skin Corr. 1 and its sub-categories (1A, 1B or 1C). Despite this, in the presence of data, including and assessing them is recommended to avoid the situation that a future change in the skin

corrosion classification would automatically result in the eye damage classification being lost.

4.5. Respiratory or skin sensitisation

Skin sensitisation is a hazard class with three main *in vivo* OECD test guideline studies available (local lymph node assay (LLNA), Buhler test and Guinea pig maximisation test (GPMT) with well-defined methods and classification criteria. In addition, there are *in vitro / in chemico* assays that are now the first choice to fulfil the REACH requirements. These have not yet been included in the CLP Regulation.

Regarding respiratory sensitisation, currently there are no formally recognised *in vitro* or animal tests. Many CLH dossiers have based classification for respiratory sensitisation on occupational exposure reports and epidemiological studies. However, as it may be difficult to assess the frequency of occurrence of the pathology based on the available data (insufficient number of cases, the fraction of which are affected and how many were actually reported, etc.) often no subcategory is applied to the classification. Another commonly used approach to assess the hazard is to apply a weight of evidence approach, where the use of read-across and identification of structural alerts for respiratory sensitisation can be supported by positive results in the LLNA skin sensitisation test since non-protein substances known to cause respiratory allergy and occupational asthma have been shown to test positive in the LLNA.

4.6. Germ cell mutagenicity

Mutagenicity has two potential adverse effects on human health: carcinogenicity and transfer of mutations to offspring. As the CLP regulation already has a hazard class for carcinogenicity, the main concern for germ cell mutagenicity relates to transfer of mutations to offspring, but the relevance for carcinogenicity should not be neglected.

In vivo data from the substance itself, or in case of read across from a similar substance, is required for classification. It should be noted, however, that *in vitro* data may be valuable supportive data. It is questionable if there is any point to open the germ cell mutagenicity hazard class if there is no *in vivo* data available and no read-across is proposed. However, including mutagenicity data in the CLH dossier is always useful in case of assessment of carcinogenicity. Note that a database, which has only *in vitro* data, may raise concern for a genotoxic mode of action for carcinogenicity, even if not decisive.

Please consider the following:

- for *in vitro* data, include information on cytotoxicity and precipitation as the evaluation is difficult without this data,
- data from studies on yeast and *Drosophila* according to test guidelines that have been removed by OECD are of questionable value. The existence of such studies can be acknowledged but there is normally no point to include the data in the CLH dossier,
- *in vivo* studies with non-physiological routes of exposure, e.g. intravenous, are considered less informative than these using physiological routes of exposure, , e.g. oral,
- assays such as sister chromatid exchange, for which the mechanism is unknown, carries less weight, but it is recommended to include such studies in the CLH dossier,
- a negative study in e.g. bone marrow should be evaluated with care if there is no data indicating exposure to the target organ,
- lack of positive controls and counting of too few cells affect the reliability of a negative result more than a positive result.

4.7. Carcinogenicity

All observed neoplastic lesions are considered relevant to humans by default, and therefore, classification can only be avoided if non-relevance to humans is demonstrated. A dose-response relationship and statistical significance are often taken into account in the evaluation of the neoplastic lesions. These are strongly influenced by other factors, such as dose spacing, top dose, possible internal dose plateau and tumour background incidence. Therefore, in the absence of a dose-response relationship, the observation should be supported by the discussion of the factors affecting it where relevant. e.g. rare tumours rarely show a dose dependence relationship.

A mutagenic substance is considered as potentially carcinogenic and, in some circumstances, mutagenicity data can be used to propose classification as Carc. 2, see CLP guidance, 3.6.2.3.3.

4.8. Reproductive toxicity

Reproductive effects consist of 1) adverse effects on sexual function and fertility, 2) adverse effects on development of the offspring and 3) adverse effects on or via lactation, and these differentiations of reproductive toxicity should be assessed separately. If effects relevant to some or all of these endpoints are present in one study, they should be discussed in the applicable subsections under the heading of reproductive toxicity. For example, two-generation studies and extended one-generation studies include parameters on sexual function and fertility as well as on development and lactation, and these should be assessed under the appropriate headings of the CLH report (please see the CLH report template with instructions for further support). If there are reproductive toxic effects that cannot be clearly assigned to either adverse effects on sexual function and fertility or to developmental toxicity, please discuss this in the text. Reproductive toxicity effects that cannot be clearly assigned to either adverse effects on sexual function and fertility or to developmental toxicity must be classified as reproductive toxicants (i.e. Repr. 1A; H360, Repr. 1B; H360 or Repr. 2; H361) without specifying the differentiation (F/f and or D/d) in the hazard statement (CLP Regulation, Annex I, 3.7.1.1). Please note that adverse effects on onset of puberty (vaginal opening and preputial separation) should be assessed under sexual function and fertility and not under developmental toxicity although they occur in the developing offspring (CLP Regulation, Annex I, 3.7.1.3).

The CLP Regulation and CLP guidance provide instructions / guidance on how other toxicity such as maternal toxicity must be considered in classification for reproductive toxicity. In particular, please ensure that Annex I, Sections 3.7.2.3.4-5, 3.7.2.4.2-4 and 3.7.2.5.8 of the CLP Regulation and Section 3.7.2.2.1 of the CLP guidance have been adequately taken into account. All findings on reproductive toxicity should be considered for classification purposes even if they are seen in the presence of parental toxicity. Parental toxicity that is less than marked should not influence the classification for reproductive toxicity. A comparison between the severity of the effects on reproduction and the severity of other toxicological findings must then be performed. Other toxicity must not be used to negate findings on reproduction unless it can be clearly demonstrated that the reproductive effects are only secondary, non-specific effects. When a substance is so toxic that maternal death or severe inanition results, or the dams are prostrate and incapable of nursing the pups, it is reasonable to assume that developmental toxicity is produced solely as a secondary (non-specific) consequence of maternal toxicity and discount the developmental effects. Maternal mortality greater than 10% is considered excessive and the data for that dose level must not normally be considered for further evaluation. When considering the maternal body weight as the indicator of maternal toxicity, please consider the corrected body weight (body weight minus the gravid uterine weight) rather than the actual body weight at the end of pregnancy, to differentiate the maternal effect from an intrauterine effect. Please also note that in rabbits, the body weight gain may not be a useful indicator of maternal toxicity, because of normal fluctuations in body weight during pregnancy.

Please note data from other studies may be relevant for the assessment of reproductive effects

and should be discussed in this section. An example is sperm data observed in repeated dose toxicity studies which must be included and evaluated under adverse effects on sexual function and fertility.

4.9. Specific target organ toxicity, single exposure (STOT SE)

For most substances, the data to assess this HC are the same used to assess the acute toxicity, with the possible addition of some early effects from repeated dose studies. If acute toxicity data have been included in the CLH dossier, the DS is encouraged to include the assessment of this hazard class in the CLH dossier for overall efficiency when the CLH proposal is in any case prepared.

STOT SE includes three categories, and therefore a separate comparison with the CLP criteria for STOT SE 1/2 and 3 needs to be included, as Category 1/2 and 3 concern different endpoints. Categories 1 and 2 are assigned for non-lethal 'significant and/or severe toxic effects', reflecting the dose level required to cause the toxic effect occurring in a specific target organ, while Category 3 covers 'transient effects' occurring after single exposure, specifically respiratory tract irritation and narcotic effects (see Sections 3.8.2.4.3 and 3.8.2.4.2 of the CLP guidance).

Adverse effects observed in repeated dose toxicity studies immediately after dosing, or within the first days of dosing, should be included in the assessment of this HC (see CLP Regulation Annex I, 3.9.1.6, and CLP guidance section 3.9.1).

When assessing the effects against the guidance values, please consider that these are intended to assist in the decision, not as strict demarcation values (see CLP Regulation, Annex I, Note a. below table 3.8.2).

4.10. Specific target organ toxicity, repeated exposure (STOT RE)

The effects observed in all studies where the animals are dosed repeatedly should be included in the assessment of this HC. Consequently, effects observed in e.g. carcinogenicity and reproductive toxicity studies should be included in the assessment.

When assessing the effects against the guidance values, please consider that these are intended to assist in the decision and not as strict demarcation values (see CLP Regulation, Annex I, 3.9.2.9.8). This should be taken into account especially after applying Haber's rule. In addition, note the pragmatic approach to be used for studies of duration up to 9 days when using Haber's rule (see CLP guidance section 3.9.2.2, and table 3.16).

4.10.1. Specific target organs: organ or system names

Specific target organs for both STOT SE and STOT RE are included in the safety data sheets. To improve the general understanding, some target organs or systems are included with a general name instead of the specific name. For example, thymus is replaced by immune system, and blood system is used as default when effects on blood are observed unless it can be established that the observed effect is only on blood and not on any of the organs involved in blood cell generation or removal. In such cases "blood" could be used (e.g. anticoagulants).

5. Environment hazards

5.1. Degradation

A concrete conclusion on rapid degradability for CLP purposes needs to be drawn at the end of the respective section of the CLH dossier. This needs to be evaluated against the criteria in 4.1.2.9. of the CLP Regulation. As stipulated in section 4.1.2.9, for a robust conclusion on rapid degradability, all relevant and reliable information from both abiotic (for example hydrolysis) and biotic (both ready and higher-tier simulation) degradation testing should be taken into account and assessed against the CLP criteria. In other words, the results from screening / ready biodegradability studies can be used for the conclusion on ready

biodegradability, but the conclusion on rapid degradability needs to take into account all relevant reliable information on degradation in the environment (e.g. simulation test etc). Photolysis is of uncertain relevance as a route of degradation in typical European aquatic environments and, given the available data, there is often insufficient information to evaluate photodegradation in terms of mineralisation or transformation to non-classifiable substances, in general. Therefore, aquatic photolysis is not considered further in relation to meeting the criteria for rapid degradation.

If a substance is concluded to be rapidly degradable via the primary degradation route, a discussion on whether the degradation products fulfil the criteria for classification as hazardous to the aquatic environment also needs to take place following CLP Regulation, Annex I 4.1.2.9.3 and 4.1.2.9.4. The assessment and reporting of the experimental information needs to follow the principles described earlier on (for example, sections 2.7-2.12). Additionally, a conclusion on the suitability of the reported test protocols relating to the physicochemical and partitioning properties of each substance needs to take place. This point is particularly relevant for “difficult to test” substances such as poorly water soluble, surface-active, very adsorptive, polar, etc.

5.2. Bioaccumulation

A concrete conclusion on bioaccumulation for CLP purposes needs to be drawn at the end of the respective section of the CLH dossier. All relevant information, including experimental studies, QSARs, information on octanol-water partition coefficient, etc. needs to be included and assessed against the criteria stipulated in the CLP guidance section 4.1.2.8. In the presence of a good quality bioaccumulation study deriving a bioconcentration factor (BCF), the conclusion can be that the substance may (or not) be bioaccumulative. In the absence of such an experimental study and only Log Kow data being available, a better-suited conclusion is that the substance has a high or low potential for bioaccumulation. In very exceptional cases (for example when there is contradictory data, high variability between species, low confidence on study quality, complete absence of information, etc.) a conclusion as “inconclusive” may be drawn.

5.3. Aquatic toxicity

Attention should be given that the appropriate test protocol is followed, and its provisions carefully met and recorded, especially the fulfilment of the test validity criteria. In case of “difficult” substances (surfactants, poorly water soluble, very adsorptive, volatile, etc.) the OECD Guidance on Difficult Substances and Mixtures should be consulted (https://www.oecd.org/env/guidance-document-on-aquatic-toxicity-testing-of-difficult-substances-and-mixtures-0ed2f88e-en.htm). In chronic toxicity studies, it has to be noted that, according to the Guidance on Information Requirements and Chemical Safety Assessment (Chapter R.7b: Endpoint specific guidance Version 3.0, February 2016), “*tests performed according to OECD TG 204 or similar guidelines cannot be considered suitable long-term tests. They are, in effect, prolonged acute studies with fish mortality as the major endpoint examined*”.

Information on all three trophic levels, if available, needs to be weighted in order to come to a conclusion on which classification is warranted. If adequate chronic toxicity data is not available for all three trophic levels, the so-called "surrogate approach" should be used following Table 4.1.0(b)(iii) of the CLP Regulation. In these cases, a comparison needs to take place between the classification outcomes derived by the criteria stipulated in Table 4.1.0(b)(i) or (ii) **and** those of Table 4.1.0(b)(iii). The chronic classification would, then, be derived according to the most stringent outcome from this comparison.

The same is the case if aquatic acute classification is derived using data for a species for which there is no chronic data available. As above, a comparison needs to take place between the classification outcomes derived by the criteria stipulated in Table 4.1.0(b)(i) or (ii) **and** those of Table 4.1.0(b)(iii). The chronic classification would, then, be derived according to the most

stringent outcome from this comparison.

In the case of very data-rich substances, consideration should be given as to whether statistical approaches such as the Species Sensitivity Distribution (SSD) could also be applicable. A consideration of the impact of any presumed species sensitivity from the acute aquatic database on the chronic one should be given. If chronic data for the most sensitive species from the acute dataset is not available, an elaboration and detailed discussion on the potential applicability of the "surrogate approach" should be included.

An explicit statement should be provided in case of test concentrations above the limit of the water solubility. In case of no effects in aquatic testing, an explicit statement should be included on whether the lack of effects corresponds merely to the highest tested (exposure) concentrations where no effects were seen and not the limit of water solubility. Note that if effects are seen above the water solubility limit of the test, the classification can be based on the water solubility determined by an appropriate test guideline (CLP guidance section 4.2).

Additionally, the reported results from chronic studies need to establish that they refer to "true" NOECs, especially when this argument leads to no environmental classification. The CLP Regulation states that "'*no observed effect concentration (NOEC)' means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect. The NOEC has no statistically significant adverse effect compared to the control*". Finally, in the presence of both EC_{10} and NOEC values within the same study, EC_{10} values are generally preferred over NOEC, as regression-based estimates are less influenced by dose selection and make full use of the dose response curve.

As stipulated in the CLP Regulation, the conclusion on chronic classification (including the M-factors and hazard statement codes) should include the final assessment and conclusion on rapid degradability, bioaccumulation and the aquatic ecotoxicological information, preferably in that order.

6. Plant Protection Products: common Assessment Report and CLH dossiers

Active substances used in PPP are required to have a harmonised classification[5].

For PPP active substances, a common template which incorporates the CLH proposal and Volume 1 of the Assessment Report (AR) is available on https://ec.europa.eu/food/plant/pesticides/approval_active_substances/application_report_en See also the EC guidelines webpage.

Additional information on the PPP procedures and recent changes in the legislation can be found on the commission website: https://ec.europa.eu/food/plant/pesticides_en, and on the EFSA website: https://www.efsa.europa.eu/en/applications/pesticides In particular, see New rules on transparency and/or EFSA's Practical Arrangements.

The common AR and CLH template is intended to be used for compiling the CLH proposal and the assessment report (DAR or RAR). The aim is to avoid duplication of work resulting from the need to present the same information in two different formats. With the use of the combined template, the information needed for both processes will be in one document. This is to ensure consolidated views, transparency and efficiency, and to facilitate the alignment of the active substance approval process undertaken by EFSA in the framework of Regulation (EC) No 1107/2009 with the CLH procedure undertaken by ECHA under the CLP Regulation. The template aligns the structure of the assessment report with the dossier.

Whilst the template should fit for both PPP and CLH processes, some information included in the template may only be relevant for one of the processes. For example, all studies on

[5] CLP Regulation, Article 36(2), and the PPP Implementing Regulation (EU) 2020/1740, Articles 11(9)

efficacy are not relevant for the CLH process but need to be included for the PPP process and equally, classification is based on all existing data, therefore, all studies / data should be included in the common template even if they are not relevant for the PPP approval process.

In order to improve the accordance check phase in the CLH process, it is recommended to submit Volume 3 chapters relevant for classification purposes together with the Volume 1 of the PPP dossier, namely:

- Vol. 3 CA B-1 (identity of the active substance),
- Vol. 3 CA B-2 (physical and chemical properties of the active substance),
- Vol. 3 CA B-6 (toxicology and metabolism data),
- Vol. 3 CA B-8 (environmental fate and behaviour),
- Vol. 3 CA B-9 (ecotoxicology data).

6.1.1. Alignment of the processes

The submission of a joint template will trigger an aligned process, and it is envisaged to be the default case for all renewal substances[6]. This alignment is for the early steps in the processes for submission and accordance check and the parallel consultations conducted on the EFSA and ECHA websites.

When submitting a combined AR and CLH report, the document should be submitted to both ECHA and EFSA so alignment can be guaranteed. Indeed, with the use of the combined template the aim is that the same level of information is made available to both EFSA and ECHA in order to ensure consistency in the data set for the two processes and to present more transparent classification proposals. Following submission of the combined report, an accordance check will be undertaken by both EFSA and ECHA at the same time, with the same general purpose. Once ECHA and EFSA consider that the documents are in accordance, a joint consultation will be conducted in parallel on both websites, for a common duration of 60 days. The aim is to launch the consultation and thereby the peer review on the AR only when the complete accordance check (including re-evaluation of the updated document following resubmission) has been finalised. Sanitisation of the common AR and CLH report will be carried out by EFSA on the amended final document after the accordance check, before the consultations start.

For substances in the renewal process, the Rapporteur Member State (RMS) must submit a CLH proposal to ECHA at the latest at the same time of submitting the draft RAR to EFSA. The RMS must address all the required hazard classes[7], either confirming the existing classification or propose reclassification of the active substance. Where the RMS considers that there is no need to change the existing classification, it should duly justify why the existing classification remains valid.

MSCAs should keep both EFSA and ECHA informed on the progress and planned submission dates of the combined AR and CLH dossier.

When an MSCA submits an AR and CLH dossier (in combined template or separate documents) to one Agency, either ECHA or EFSA, they should at the same time inform the other Agency: for ECHA this is done via the CLH WebForm (https://comments.echa.europa.eu/comments_cms/DossierIntentionCLHAuthority2010.aspx) and for EFSA via the pesticides peer-review functional mailbox (pesticides.peerreview@efsa.europa.eu) and APDESK functional mailbox (Apdesk.applications@efsa.europa.eu).

[6] Implementing Regulation 2020/1740
[7] Article 11(9) of Commission Implementing Regulation (EU) 2020/1740

7. Biocidal Products: combined Competent Authority Report and CLH dossiers

Active substances used in biocidal products shall normally be subjected to harmonised classification[8].

For biocidal active substances, a common template which incorporates the CLH proposal and CAR is available on ECHA website: https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats/formats-for-the-authorities.

There are specific instructions for the common template, which should be considered when preparing a common CAR and CLH dossier. A CAR consists of the following parts, i.e. for a CAR, all parts should be included:

- Summary
- Part A
- Part B
- Part C
- Part D (Appendices)

However, the CLH report consists of:

- Summary
- Part A
- Appendix V of Part D (which includes References)
- Appendix VII of Part D (which includes study summaries)

The parts used for CLH should be made non-confidential, except for personal data (see section 2.8). There is also a legal requirement to include additional information in the CLH report, since based on the CLP regulation, a weight of evidence approach should be used. In the weight of evidence, all available relevant data from REACH registration dossier(s), the RMS assessment report(s) submitted for the EU peer review of active substances used in PPP (DAR) and relevant and reliable key data from public sources should be considered.

7.1. Options how to include details of study results

To enable an independent assessment of the data, it may be necessary to add important / detailed information from robust study summaries or full study reports of key endpoints, such as CMR (e.g. historical control incidences of tumour findings, findings from individual animals if differences are seen between animals in same study and dose group). This information, needed for an independent and transparent assessment, should be included either

- in Part A under each endpoint, or
- in Part D Appendix VII (e.g. by extracting from IUCLID for new active substances in BPR, please see the instructions for extracting study summaries from IUCLID in Appendix VII of Part D). In the link below, the template of Annex I to the CLH report (https://echa.europa.eu/documents/10162/13563/clh_report_template_ai_en.doc/8ab5af56-a04a-44e8-98a7-816aa4e5787c) shows an example on how Appendix VII could be compiled and how each study could be presented individually under its own subchapter, including the study reference, detailed study summary and results.

The format of the detailed study summary of an individual study is flexible, as long as the summary is clearly reported and under the correct hazard class (either in Part A or in in Part D

[8] CLP Regulation, Article 36(2).

Appendix VII).

7.2. Timelines and obligation for submitting a CLH report on biocidal active substances

Harmonised classification is a key element in the approval of a biocidal active substance, and ideally the RAC opinion on the active substance should be available before the final approval decision. This is particularly of importance for substances which are proposed for classification as a CMR in Category 1A or 1B, and will meet the exclusion criteria under BPR with impact on the active substance approval / non-approval decision.

In the absence of a RAC opinion on the classification of the active substance, it is difficult for the Biocidal Products Committee to adopt its opinion and therefore has an impact on the process. Therefore, it is highly recommended, that a CLH dossier of a biocidal active substance is submitted as early as possible in the active substance evaluation process, preferably when the hazard assessment part of the evaluation is finalised by the evaluating Competent Authority (eCA), before evaluating the risk assessment part.

Further information on the obligations to submit a CLH dossier on biocides active substance, based on the Regulation 1062/2014 (the Review Programme Regulation) and as agreed at the Biocides Competent Authority meeting on 13 September 2013, can be found in the Working Procedure for active substance approval https://echa.europa.eu/documents/10162/4221979/bpc_working_procedure_active_substance_en.pdf. The same principles are applied to non-review programme active substances.

According to the Working procedure, the timelines / obligations to submit a CLH dossier are as follows:

- If the CMR-based exclusion criteria are met, the RAC opinion on harmonised C&L should be available at the time of submitting the CAR.
- If the substitution criteria are met because of CMR properties, it is highly preferable and therefore strongly recommended that the RAC opinion on harmonised C&L is available at the time of submitting the CAR. In any case, a CLH dossier needs to have been submitted by the time of submitting the CAR.
- If the substitution criteria are not met, a CLH dossier needs to have been submitted by the time of submitting the CAR when changes are proposed to an already existing harmonised classification, or no harmonised classification is available for the active substance. However, if the eCA proposes Muta. 2 classification, the RAC opinion on CLH needs to be available at the time of submitting the CAR, because the risk characterisation may be very restrictive as exposure would need to be minimised without an identifiable threshold of safety.

For preparation of a CLH dossier, a close collaboration between biocides and CLP competent authorities is recommended.

Further information on the BPR process can be found on ECHA website: https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr

Appendix 1. Checklist before submitting your dossier

A CLH dossier that passes ECHA accordance check, is a finalised document ready to undergo the consultation. Please check your dossier against the elements in the table below.

Table A1: Final check before submission

Elements to be removed from the CLH dossier
Residual text from the template: *[usually in italic within square brackets: common examples include the note on confidential information, instructions on what to include in the tables]*
Highlighted text
The 'draft' watermark
Tracked changes, comments, broken cross-references etc.
Confidential information, see 2.8 above
Check the CLH dossier for the following
Check for consistency between proposed HCs open for consultation (see 2.4 above) and the conclusion on the corresponding HC
Check consistency between your proposal and the classification table, e.g. ATEs, SCLs (see 2.3 above)
Check that all studies are identified by a unique reference
Run an English (UK) spelling check
Always submit a word and pdf version of the report and the annexe(s) if present
The submitter email address is published on the Registry of Intention; therefore, a functional mailbox email address is preferable. Personal email addresses should be avoided

Appendix 2. Accordance check – what is checked?

Table A2: Accordance check checklist

General
Correctness of the classification table
Comparison with the criteria is adequate
CLH proposal should be clearly stated also in the conclusion of each HC, even when the proposal is no classification
SCLs, M-factors, and ATEs are part of the proposal and should be included in the HC conclusion and in the classification table
Hazard classes open for consultation should be clearly stated and in line with the content of the rest of the report
If justification for submitting the dossier is required, it is included
Substance identity is clear
Read across is robustly justified
All data from other processes (REACH, BPR, PPP) are considered in the CLH dossier, if available
Sufficient information is included in order for the CLH report to serve as a stand-alone document
Physical hazards
Addressed for BPR ad PPP substances
Some physical hazard classes are relevant for one (or more) physical states (e.g. solid substances), consequently only the hazard classes relevant for that physical state should be assessed.
Assessment is based on criteria and methods listed in Annex I of the CLP Regulation
Human health hazards
Unpublished studies have authors names redacted and appropriate referencing
Study summaries include basic information (see section 2.10)
If present, historical control data are included with relevant information (see section 4.1.3)
Data relevant for one HC generated under studies normally considered indicative for another HC are included on the assessment of the latter HC. E.g. sperm data observed in repeated dose toxicity studies are included and evaluated under reproductive toxicity, adverse effects sexual function and fertility
Environmental hazards
Unpublished studies have authors names redacted and appropriate referencing
Appropriate test protocols used for Aquatic Toxicity
Study summaries include basic information (see section 2.10)
Clear conclusion on substance properties (rapid degradability, bioaccumulation, ecotoxicity values)

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