

## Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Globally Harmonized  
System of Classification and Labelling of Chemicals

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Work on the Globally Harmonized System of Classification  
and Labelling of Chemicals: Other matters

## Use of “should”, “shall”, “may” and “must” in the GHS

Transmitted by the expert from the United States of America

### I. Background

1. Informal paper INF.20 (44th session), introduced at the July 2023 Sub-Committee meeting, noted that three informal working groups had recently recognized issues in the use of the above-entitled words in the GHS. For example, one informal working group recognized the need to use the words “shall” or “must” to indicate that certain action is required or mandatory, and not merely suggested or recommended as indicated by the words “should” or “may”.

2. As the GHS is a set of non-binding recommendations rather than model regulations (such as the Model Regulations on the Transport of Dangerous Goods (TDG)), the framers of the GHS text agreed, at the time the GHS was developed, to a convention of using “should” or “may” in GHS text as this provided flexibility in implementing the GHS into national/regional laws. INF.20 recognized that the use of these words is not merely editorial. The paper noted, for example, that the GHS includes guidance, explanatory text and other information (e.g., references and quotations from other texts) along with criteria. As such, the paper noted the text in GHS Part 3 (Health hazards), Part 4 (Environmental hazards) and the annexes cannot be copied into legally binding text without significant changes. Moreover, the paper noted that, in the absence of guidance, the meaning of the words in the context of the GHS may be subject to interpretation when translated into other languages or transposed into legally binding instruments for implementation. It was also noted that Part 2 (Physical hazards) uses the phrases ‘must’ and ‘shall’ as these chapters have specific test requirements to classify those physical hazards. The health and environmental hazard chapters strive to be test method neutral and do not require specific test methods to classify those hazards.

### II. Discussion

3. The potential future work described in INF.20 included the development of a statement to clarify the intended meaning of the words “should”, “shall”, “may” and “must” to help ensure consistency in the GHS.

4. The potential future work described in INF.20 also included drafting a proposal to include text for the GHS to clarify the matter for future reference.

5. As a first step, this paper suggests that there is a need to identify instances of these terms in the GHS and how these terms are currently used. To that end, the

expert from the United States of America has assembled a draft, in table format below, of in-context instances of some of the terms as used in GHS Rev.10. Please note that the table in annex I to this document is intended to identify instances of the words “must” and “shall”. The table includes some occurrences of the word “should” in proximity to the occurrences of “must” and “shall”. The word “may” in the GHS is so common that a more refined word-search will be needed. Some instances of the words, notably of “may” and “should”, could fall outside of the intended scope of this review project because their use does not intend to signal action regarding the GHS. For context, annex II to this document provides a table of some instances of ‘shall’ and ‘must’ in Part 2 (Physical hazards) as specific test methods are required for many physical hazards.

6. The tables below are working drafts.

### **Action requested**

7. The Sub-Committee is invited to provide feedback during plenary at the December 2023 session with recommendations and insights on the process described in paragraph 5, as implemented in the draft tables of the annexes. Agreement during plenary on the overall goals and this suggested first step will allow interested parties to begin a detailed analysis of the data summarized in the annexes. The expert from the United States of America respectfully requests parties interested in participating on this review project to respond by e-mail so that this review project may further proceed by virtual meetings and written feedback via e-mail.

## Annex I

**Table: Instances of ‘must’ and ‘shall’ in GHS Part 1, Part 3, Part 4, and annexes**

GHS Rev.10	Excerpt/Context
TOC	Harmonization will also have benefits in terms of facilitating international trade, by promoting greater consistency in the national requirements for chemical hazard classification and communication that companies engaged in international trade <b>must</b> meet
1.2 Definitions	<b>Liquid</b> means a substance or mixture which at 50°C has a vapour pressure of not more than 300 kPa (3 bar), which is not completely gaseous at 20 °C and at a standard pressure of 101.3 kPa, and which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101.3 kPa. A viscous substance or mixture for which a specific melting point cannot be determined <b>shall</b> be subjected to the ASTM D 4359-90 test; or to the test for determining fluidity (penetrometer test) prescribed in section 2.3.4 of Annex A of the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR);
1.1	... companies wishing to be involved in international trade <b>must</b> have large staffs of experts who can follow the changes in these laws and regulations ...
	... Workplace requirements <b>may</b> also be applied to employees involved in the administration of some drugs, or clean-up of spills and other types of potential exposures in health care settings. SDS's and training <b>must</b> be available for these employees under some systems. It is anticipated that the GHS would be applied to pharmaceuticals in a similar fashion.
1.3.2.4.9.3	... Where evidence is available from both sources and there is a conflict between the findings, the quality and reliability of the evidence from both sources <b>must</b> be assessed in order to resolve the question of classification. ...
1.3.3.1.1	... If a reaction occurs during manufacture and a new product results, a new hazard evaluation and classification <b>must</b> take place to apply the GHS to the new product. ...
1.3.3.3	When performing an assessment in accordance with the GHS requirements, the evaluator <b>must</b> take into account all available information about the potential occurrence of synergistic effects among the ingredients of the mixture.
Scope 2.1.1.2.1	(b) Explosive articles, except devices containing explosive substances or mixtures in such quantity or of such a character that their inadvertent or accidental ignition or initiation <b>shall</b> not cause any effect external to the device either by projection, fire, smoke, heat or loud noise; ***
3.2.3.3.4	Particular care <b>must</b> be taken when classifying mixtures containing certain types of substances such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in 3.2.3.3.1 and 3.2.3.3.2 might not work given that many substances are corrosive or irritant at concentrations < 1 %. For mixtures containing strong acids or bases the pH <b>should</b> be used as classification criterion (see 3.2.3.1.3) since extreme pH will be a better indicator of corrosion than the concentration limits in table 3.2.3. A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach shown in table 3.2.3, due to chemical characteristics that make this approach unworkable, <b>should</b> be classified as skin corrosion Category 1 if it contains ≥ 1 % of a corrosive ingredient and as skin irritation Category 2 or Category 3 when it contains ≥ 3 % of an irritant ingredient. ...
3.2.5.3.5.2.4	In skin sensitization studies in guinea pigs (e.g. OECD Test Guideline 406), severely irritating and corrosive exposure <b>must</b> be avoided.
3.3.3.3.4	Particular care <b>must</b> be taken when classifying mixtures containing certain types of substances such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in 3.3.3.3.1 and 3.3.3.3.2 might not work given that many such substances are seriously damaging to the eye/eye irritating at concentrations < 1 %.

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3.3.5.3.6.2	Existing data from the LVET test <b>could</b> be considered for the purpose of classification and labelling but must be carefully evaluated. The differences between the LVET and OECD Test Guideline 405 <b>may</b> result in a classification in a lower category (or no classification) based on LVET data than if the classification was based on data derived from the standard in vivo test (OECD Test Guideline 405). ...
3.4.2.1.1.1.	Respiratory sensitizers <b>shall</b> be classified in Category 1 where subcategorization is not required by a competent authority or where data are not sufficient for subcategorization.
3.4.2.2.1.1	Skin sensitizers <b>shall</b> be classified in Category 1 where subcategorization is not required by a competent authority or where data are not sufficient for subcategorization.
3.4.2.2.7.3	Tier 2 - Classification based on inconclusive data from tier 1, non stand-alone <i>in chemico</i> /in vitro methods or non-test methods. In case a definitive conclusion on classification, including subcategorization where required by a competent authority, cannot be derived from tier 1, additional lines of evidence <b>shall</b> be considered in a weight of evidence assessment in tier 2. These may include: ***
3.4.5.3.3.4	EC values are normally obtained by interpolation between adjacent test concentrations, i.e. between the highest test concentration causing an SI below, and the lowest test concentration causing an SI above the critical value. However, care <b>must</b> be taken when the EC value falls below the lowest concentration tested and can therefore only be estimated by extrapolation, which is associated with additional uncertainty. ...
3.5.3.1	<i>Classification of mixtures when data are available for the mixture itself</i> Classification of mixtures <b>will be</b> based on the available test data for the individual ingredients of the mixture using cut-off values/concentration limits for the ingredients classified as germ cell mutagens. The classifications <b>may</b> be modified on a case-by-case basis based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole <b>must</b> be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g. statistical analysis, test sensitivity) of germ cell mutagenicity test systems. Adequate documentation supporting the classification <b>should</b> be retained and made available for review upon request.
3.5.5.1.2 Decision logic 3.5.2 for mixtures footnote 2	<i>If data on another mixture are used in the application of bridging principles, the data on that mixture <b>must</b> be conclusive in accordance with 3.5.3.2.</i>
3.6.3.1	<i>Classification of mixtures when data are available for the complete mixture</i> Classification of mixtures <b>will be</b> based on the available test data of the individual ingredients of the mixture using cut-off values/concentration limits for those ingredients. The classification <b>may</b> be modified on a case-by-case basis based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole <b>must</b> be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g. statistical analysis, test sensitivity) of carcinogenicity test systems. Adequate documentation supporting the classification <b>should</b> be retained and made available for review upon request.
3.6.5.2 Decision logic 3.6.2 for mixtures footnote 2	<i>If data of another mixture are used in the application of bridging principles, the data on that mixture <b>must</b> be conclusive in accordance with 3.6.3.2.</i>
3.6.5.3.2.1	The various international documents on carcinogen assessment all note that mode of action in and of itself, or consideration of comparative metabolism, <b>should</b> be evaluated on a case-by-case basis and are part of an analytic evaluative approach. One <b>must</b> look closely at any mode of action in animal experiments taking into consideration comparative toxicokinetics/toxicodynamics between the animal test species and humans to determine the relevance of the results of humans. ... Only if a mode of action of tumour development

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	is conclusively determined not to be operative in humans <b>may</b> the carcinogenic evidence for that tumour be discounted. However, a weight of evidence assessment for a substance <b>calls for</b> any other tumorigenic activity to be evaluation as well.
3.6.5.3.2.4	... However, such determinations <b>must</b> be evaluated carefully in justifying the carcinogenic potential for humans; any occurrence of other tumours at distant sites <b>must</b> also be considered.
3.6.5.3.2.5	... certain tumour types in animals <b>may</b> be associated with toxicokinetics or toxicodynamics that are unique to the animal species tested and <b>may</b> not be predictive of carcinogenicity in humans.
3.6.5.3.2.5	... Even when a particular tumour type may be discounted, expert judgment <b>must</b> be used in assessing the total tumour profile in any animal experiment.
3.7.2.2.3	For human evidence to provide the primary basis for a Category 1A classification there <b>must</b> be reliable evidence of an adverse effect on reproduction in humans. Evidence used for classification <b>should</b> ideally be from well conducted epidemiological studies which include the use of appropriate controls, balanced assessment, and due consideration of bias or confounding factors. Less rigorous data from studies in humans <b>should</b> be supplemented with adequate data from studies in experimental animals and classification in Category 1B <b>should</b> be considered.
3.7.2.5.4	Evidence from in vitro assays, or non-mammalian tests, and from analogous substances using structure-activity relationship (SAR), can contribute to the procedure for classification. In all cases of this nature, expert judgment <b>must</b> be used to assess the adequacy of the data. Inadequate data <b>should</b> not be used as a primary support for classification.
3.7.2.5.6	Studies involving routes of administration such as intravenous or intraperitoneal injection, which <b>may</b> result in exposure of the reproductive organs to unrealistically high levels of the test substance, or elicit local damage to the reproductive organs, e.g. by irritation, <b>must</b> be interpreted with extreme caution and on their own would not normally be the basis for classification.
3.7.3.1	<i>Classification of mixtures when data are available for the complete mixture</i> Classification of mixtures <b>will be</b> based on the available test data of the individual constituents of the mixture using cut-off values/concentration limits for the ingredients of the mixture. The classification <b>may</b> be modified on a case-by-case basis based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole <b>must</b> be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g. statistical analysis, test sensitivity) of reproduction test systems. Adequate documentation supporting the classification <b>should</b> be retained and made available for review upon request.
3.7.5.1.2 Decision logic 3.7.2 for mixtures Footnote 3.	<i>If data on another mixture are used in the application of bridging principles, the data on that mixture <b>must</b> be conclusive in accordance with 3.7.3.2.</i>
3.7.5.2.2 Decision logic 3.7.4 for mixtures Footnote 3.	<i>If data on another mixture are used in the application of bridging principles, the data on that mixture <b>must</b> be conclusive in accordance with 3.7.3.2.</i>

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3.8.2.1.7.3	Evidence from appropriate studies in experimental animals can furnish much more detail, in the form of clinical observations, and macroscopic and microscopic pathological examination and this can often reveal hazards that may not be life-threatening but could indicate functional impairment. Consequently, all available evidence, and relevance to human health, <b>must</b> be taken into consideration in the classification process.
3.9.2.7.3	Evidence from appropriate studies in experimental animals can furnish much more detail, in the form of clinical observations, haematology, clinical chemistry, macroscopic and microscopic pathological examination and this can often reveal hazards that may not be life-threatening but could indicate functional impairment. Consequently, all available evidence, and relevance to human health, <b>must</b> be taken into consideration in the classification process.
3.10.1.5.2	While a methodology for determination of aspiration hazard in animals has been utilized, it has not been standardized. Positive experimental evidence with animals can only serve as a guide to possible aspiration toxicity in humans. Particular care <b>must</b> be taken in evaluating animal data for aspiration hazards.
4.1.2.11.2	It <b>must</b> be recognized that environmental degradation <b>may</b> be biotic or abiotic (e.g. hydrolysis) and <b>the criteria used to reflect this fact</b> . Equally, it <b>must</b> be recognized that failing the ready biodegradability criteria in the OECD tests does not mean that the substance will not be degraded rapidly in the real environment. Thus, where such rapid degradation can be shown, the substance <b>should</b> be considered as rapidly degradable. Hydrolysis <b>can be</b> considered if the hydrolysis products do not fulfil the criteria for classification as hazardous to the aquatic environment. A specific definition of rapid degradability is shown below. Other evidence of rapid degradation in the environment <b>may</b> also be considered and <b>may</b> be of particular importance where the substances are inhibitory to microbial activity at the concentration levels used in standard testing. The range of available data and guidance on its interpretation are provided in the guidance document of annex 9.
4.1.2.11.3	... These levels of biodegradation <b>must</b> be achieved within 10 days of the start of degradation which point is taken as the time when 10 % of the substance has been degraded, unless the substance is identified as a complex, multi-component substance with structurally similar constituents. In this case, and where there is sufficient justification, the 10-day window condition <b>may</b> be waived and the pass level applied at 28 days as explained in annex 9 (A9.4.2.2.3).
4.1.2.12.2	Poorly soluble inorganic compounds and metals may be acutely or chronically toxic in the aquatic environment depending on the intrinsic toxicity of the bioavailable inorganic species and the rate and amount of this species which may enter solution. A protocol for testing these poorly soluble materials is included in annex 10. All evidence <b>must</b> be weighed in a classification decision. This would be especially true for metals showing borderline results in the Transformation/Dissolution Protocol.
4.2.2 Classification criteria	A substance or mixture shall be classified as Category 1 according to the following table: ***
Annex 1	*** <b>NOTE 2:</b> <i>To provide clarity, assist labelling practitioners and enable comparison between equivalent classification and labelling systems under the GHS and the UN Model Regulations, transport hazard classes, divisions and pictograms are included in tables A1.1 to A1.30. However, it should be noted that in these tables the UN Model Regulations classification and labelling entries are provided for indicative purposes only. For transport purposes, the classification and labelling provisions prescribed by the UN Model Regulations <b>shall</b> be used (see also chapter 1.4, section 1.4.10 of the GHS).</i> <b>NOTE 3:</b> <i>GHS hazard pictograms are displayed in the shape of a square set at a point with a black symbol on a white background with a red frame. The transport pictograms (commonly referred to as labels in the UN Model Regulations) shall be displayed on a background of contrasting colour or, where appropriate, <b>shall</b> have either a dotted or solid boundary line as provided in chapter 5.2, section 5.2.2.2 of the UN Model Regulations and in tables A1.1 to A1.30 below. For some hazard categories, the symbol,</i>

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	<p><i>number and border line of the transport pictogram may be shown in white instead of black. Where such an alternative is available it is shown in the relevant tables below (see tables A1.2, A1.3, A1.5, A1.6, A1.12, A1.15 and A1.17).</i></p> <p>***</p>
A1.8 Self-reactive substances and mixtures	<p>Note a to table</p> <p><i>Under the UN Model Regulations, where a Type B substance or mixture has an explosive subsidiary hazard, then the transport pictogram for Divisions 1.1, 1.2 or 1.3 shall also be used without the indication of the division number or the compatibility group. For a substance or mixture of hazard category Type B, special provision 181 may apply (Exemption of explosive label with competent authority approval. See chapter 3.3 of the UN Model Regulations for more details).</i></p>
A1.15 Organic peroxides note a to table	<p><i>Under the UN Model Regulations, where a Type B substance or mixture has an explosive subsidiary hazard, then the transport pictogram for Divisions 1.1, 1.2 or 1.3 shall also be used without the indication of the division number or the compatibility group. For a substance or mixture of hazard category Type B, special provision 181 may apply (Exemption of explosive label with competent authority approval. See chapter 3.3 of the UN Model Regulations for more details).</i></p>
A1.29(a) note to table	<p><i>Under the UN Model Regulations, for category Acute 1, environmentally hazardous substances are classified under Class 9 and shall bear both the Class 9 transport pictogram and the environmentally hazardous substance transport mark (see chapter 5.2, section 5.2.1.6 and chapter 5.3, section 5.3.2.3, of the UN Model Regulations). However, if the environmentally hazardous substance presents any other hazards covered by UN Model Regulations, the Class 9 transport pictogram shall be replaced by the transport pictogram(s) applicable to the hazard(s) present and the environmentally hazardous substance pictogram is not required.</i></p>
A1.29(b) note to table	<p><sup>a</sup> <i>Under the UN Model Regulations, for categories Chronic 1 and 2, environmentally hazardous substances are classified under Class 9 and shall bear both the Class 9 transport pictogram and the environmentally hazardous substance transport mark (see chapter 5.2, section 5.2.1.6 and chapter 5.3, section 5.3.2.3, of the UN Model Regulations). However, if the environmentally hazardous substance presents any other hazards covered by UN Model Regulations, the Class 9 transport pictogram shall be replaced by the transport pictogram(s) applicable to the hazard(s) present and the environmentally hazardous substance pictogram is not required.</i></p>
A3.1.2.4	<p>All assigned hazard statements should appear on the label unless otherwise specified in 1.4.10.5.3.3. The competent authority may specify the order in which they appear. Also, where a combined hazard statement is permitted for two or more hazard statements (see A3.1.2.5), the competent authority may specify whether the combined hazard statement or the corresponding individual statements should appear on the label or may leave the choice to the manufacturer/supplier.</p>
A3.1.2.5	<p>In addition to the combinations found in table A3.1.2, it is also permitted to combine more than one health hazard statement of equivalent severity if, for example, there is insufficient space on the label. When hazard statements are combined, all hazards must be clearly conveyed and only the repetitive text may be deleted. Statements can be combined by using the work “and”, additional punctuation, and changing the case of the initial letter of the word at the beginning of a statement. For example, H317 “<b>May cause an allergic skin reaction</b>” + H340 “<b>May cause genetic defects</b>” + H350 “<b>May cause cancer</b>” may all be combined because they are all for Category 1 health hazards (i.e. health hazard statements of equivalent severity) and have repetitive elements of the hazard statement (i.e. the statements begin with “may cause”). These statements may be combined to “<b>May cause an allergic skin reaction, genetic defects, and cancer</b>”. The competent authority may limit the types of combinations permitted to ensure compatibility (e.g. limit the number of hazard statements that can be combined).</p>
A4.2.2.1	<p>The writer of the SDS needs to keep in mind that an SDS must inform its audience of the hazards of a substance or a mixture and provide information on the safe storage, handling and disposal of the substance or a mixture.</p> <p>An SDS contains information on the potential health effects of exposure and how to work safely with the substance or mixture. It also contains hazard information derived from physicochemical properties or environmental effects, on the use, storage, handling and emergency response measures related to that substance or mixture. The purpose of this guidance is to ensure consistency and accuracy in the content of each of the mandatory headings required under GHS, so that the resulting safety data sheets will enable users to take the necessary measures relating to protection of health and safety at the workplace,</p>

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	and the protection of the environment. The information in the SDS shall be written in a clear and concise manner. The SDS shall be prepared by a competent person who shall take into account the specific needs of the user audience, as far as it is known. Persons placing substances and mixtures on the market shall ensure that refresher courses and training on the preparation of SDS be regularly attended by the competent persons.
A4.2.2.3	Language used in the SDS should be simple, clear and precise, avoiding jargon, acronyms and abbreviations. Vague and misleading expressions should not be used. Phrases such as “may be dangerous”, “no health effects”, “safe under most conditions of use”, or “harmless” are also not recommended. It may be that information on certain properties is of no significance or that it is technically impossible to provide; if so, the reasons for this must be clearly stated under each heading. If it is stated that a particular hazard does not exist, the safety data sheet should clearly differentiate between cases where no information is available to the classifier, and cases where negative test results are available.
A4.3.12.1	The information that shall be provided in this section is to enable evaluation of the environmental impact of the substance or mixture if it were released to the environment. This information can assist in handling spills, and evaluating waste treatment practices, control of release, accidental release measures, and transport.
A4.3.12.6	... Test results relevant to assess persistence and degradability should be given where available. If degradation half-lives are quoted it must be indicated whether these half-lives refer to mineralization or to primary degradation. The potential of the substance or certain constituents (see also A4.3.12.8) of a mixture to degrade in sewage treatment plants should also be mentioned.
A5.2.2.6	... A substance or product under evaluation for chronic hazard labelling for consumer use in the US must satisfy a two-part test. First, it must present one of the chronic hazards covered, i.e. be classified as a chronic hazard based on specific criteria. Second, a risk assessment must be carried out to establish whether it has the potential to cause substantial illness or injury during or as a result of “reasonably foreseeable handling or use or from ingestion by children”. If the result of the risk assessment indicates the risk is very low, the substance or product need not be labelled for chronic hazard. ...
A6.3.4	Use of annex 6 and of the testing instrument ... Labels and SDS’s used in testing must as far as possible reflect the typical local usage patterns. Therefore, although sample labels and SDS’s are provided with this manual, users are encouraged to adapt the test materials within the limits of the experimental design requirements so that the materials appear as authentic as possible to local subjects.
A6.5.1	<b>Questionnaire and experimental design</b> ... Modules 2 and 10 must be completed by all participants as indicated.
A6.5.2	... it may be necessary for logistic reasons to break up the instrument by having different subjects complete only some of the modules. In this way, more participants are recruiting to the study but they complete only some parts of the evaluation. If this is the case, remember that all subjects must complete modules 2 and 10, ...
A6.5.11.1	Interviews and focus groups must be set up at a convenient time for both the interviewee and their employer (when this applies). ... If workers agree to participate during lunch break, the time must be adequate and suitable recompense provided (time back, lunch provided, etc).
Example 7 (a)	Where transport and other GHS information appear on a single packaging (e.g. a 200 l drum), consideration must be given to ensure that the label elements are placed in a manner that addresses the needs of the different sectors; ...
Example 7 (b)	Transport pictograms must convey information immediately in an emergency situation. They must be able to be seen from a distance, as well as in conditions that are smoky or otherwise partially obscure the package.
A9.1.3	Although limited in scope, it is widely accepted that this compartment is both vulnerable, in that it is the final receiving environment for many harmful substances, and the organisms that live there are sensitive. It is also complex since any system that seeks to identify hazards to the environment must seek to define those effects in terms of wider

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	effects on ecosystems rather than on individuals within a species or population. As will be described in detail in the subsequent sections, a limited set of specific properties of substances have been selected through which the hazard can be best described: acute aquatic toxicity; chronic aquatic toxicity; lack of degradability; and potential or actual bioaccumulation. The rationale for the selection of these data as the means to define the aquatic hazard will be described in more detail in section A9.2.
A9.1.6	It is clearly the objective of a globally harmonized system that, having agreed on a common set of criteria, a common dataset <b>should</b> also be used so that once classified, the classification is globally accepted. For this to occur, there must first be a common understanding of the type of data that can be used in applying the criteria, both in type and quality, and subsequently a common interpretation of the data when measured against the criteria. For that reason, it has been felt necessary to develop a transparent guidance document that would seek to expand and explain the criteria in such a way that a common understanding of their rationale and a common approach to data interpretation may be achieved. This is of particular importance since any harmonized system applied to the “universe of chemicals” will rely heavily on self-classification by manufacturers and suppliers, classifications that must be accepted across national boundaries without always receiving regulatory scrutiny. This guidance document, therefore, seeks to inform the reader, in a number of key areas, and as a result lead to classification in a consistent manner, thus ensuring a truly harmonized and self-operating system.
A9.1.12	A wide range of degradation data are available that <b>must</b> be interpreted according to the criteria for rapid degradability. Guidance is thus needed on how to use these data obtained by employing non-standard test methods, including the use of half-lives where these are available, of primary degradation, of soil degradation rates and their suitability for extrapolation to aquatic degradation and of environmental degradation rates. A short description of estimation techniques for evaluating degradability in relation to the classification criteria is also included. This guidance will be provided in section A9.4.
A9.1.16	While the guidance document provides useful advice on how to apply the criteria to a wide variety of situations, it remains a guidance only. It cannot hope to cover all situations that arise in classification. It <b>should</b> therefore be seen as a living document that in part describes the fundamental principles of the system, e.g. hazard based rather than risk based, and the fixed criteria. It <b>must</b> also, in part, be a repository for the accumulated experience in using the scheme to include the interpretations which allow the apparently fixed criteria to be applied in a wide variety of non-standard situations.
A9.2.3.2	The principal hazard classes defined by the criteria relate largely to the potential for long-term (chronic) hazard. This reflects the overriding concern with respect to chemicals in the environment, namely that the effects caused are usually sub-lethal, e.g. effects on reproduction, and caused by longer-term exposure. While recognizing that the long-term (chronic) hazard represents the principal concern, particularly for packaged goods where environmental release would be limited in scope, it must also be recognized that chronic toxicity data are expensive to generate and generally not readily available for most substances. On the other hand, acute toxicity data are frequently readily available, or can be generated to highly standardised protocols. It is this acute toxicity which has therefore been used as the core property in defining both the acute and the long-term (chronic) hazard if no adequate chronic test data are available. Nevertheless, it has been recognized that chronic toxicity data, if available <b>should</b> be preferred in defining the long-term (chronic) hazard category.
A9.3.3.2.3	Since chronic toxicity data are less common in certain sectors than acute data, for classification schemes, the potential for chronic toxicity is, in absence of adequate chronic toxicity data, identified by appropriate combinations of acute toxicity, lack of degradability and/or the potential or actual bioaccumulation. However, where adequate chronic toxicity data exist, this <b>shall</b> be used in preference over the classification based on the combination of acute toxicity with degradability and/or bioaccumulation. In this context, the following general approach <b>should</b> be used: .... (b) If adequate chronic toxicity data are available for one or two trophic levels, it <b>should</b>

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	<p>be examined if acute toxicity data are available for the other trophic level(s). A potential classification is made for the trophic level(s) with chronic data and compared with that made using the acute toxicity data for the other trophic level(s). The final classification <b>shall</b> be made according to the most stringent outcome;</p> <p>(c) In order to remove or lower a chronic classification, using chronic toxicity data, it must be demonstrated that the NOEC(s) (or equivalent ECx) used would be suitable to remove or lower the concern for all taxa which resulted in classification based on acute data in combination with degradability, and/or bioaccumulation. This can often be achieved by using a long-term NOEC for the most sensitive species identified by the acute toxicity. Thus, if a classification has been based on a fish acute LC<sub>50</sub>, it would generally not be possible to remove or lower this classification using a long-term NOEC from an invertebrate toxicity test. In this case, the NOEC would normally <b>need to be</b> derived from a long-term fish test of the same species or one of equivalent or greater sensitivity. Equally, if classification has resulted from the acute toxicity to more than one taxa, it is likely that NOECs from each taxa <b>will be</b> needed. In case of classification of a substance as Chronic 4, sufficient evidence <b>should</b> be provided that the NOEC or equivalent ECx for each taxa is greater than 1 mg/l or greater than the water solubility of the substances under consideration.</p>
A9.3.4.2	<p>Where multiple studies for a taxonomic group are available, a decision on what is the most sensitive and highest quality <b>must</b> be made. A judgement <b>has to be made</b> on a case by case basis whether a non-GLP study with a more sensitive observation is used in lieu of a GLP study. It would appear that results that indicate high toxicity from tests performed according to non-standard or non-GLP guidelines <b>should</b> be able to be used for classification, whereas studies, which demonstrate negligible toxicity, <b>would require</b> more careful consideration. Substances, which are difficult to test, may yield apparent results that are more or less severe than the true toxicity. Expert judgement <b>would also be needed</b> for classification in these cases.</p>
A9.3.4.3	<p>Where more than one acceptable test is available for the same taxonomic group, the most sensitive (the one with the lowest L(E)C<sub>50</sub> or NOEC) is generally used for classification. However, this <b>must</b> be dealt with on a case-by-case basis. When larger data sets (4 or more values) are available for the same species, the geometric mean of toxicity values <b>may</b> be used as the representative toxicity value for that species. In estimating a mean value, it is <b>not advisable</b> to combine tests of different species within a taxa group or in different life stages or tested under different conditions or duration.</p>
A9.3.5.2	<p>Nevertheless, much test data exist that may have used testing methodologies which, while not in conformity with what might be considered best practice today, can still yield information suitable for application of the classification criteria. Such data require special guidance on interpretation, although ultimately, expert judgement <b>must</b> be used in determining data validity. Such difficult to test substances may be poorly soluble, volatile, or subject to rapid degradation due to such processes as phototransformation, hydrolysis, oxidation, or biotic degradation. When testing algae, coloured materials may interfere with the test endpoint by attenuating the light needed for cell growth. In a similar manner, substances tested as cloudy dispersions above solubility may give rise to false toxicity measurements. Loading of the water column with test material can be an issue for particulates or solids such as metals. Petroleum distillate fractions can also pose loading problems, as well as difficult interpretational problems when deciding on the appropriate concentrations for determining L(E)C<sub>50</sub> values. The draft Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures describes the more common properties of many types of substances which are likely to pose testing difficulties.</p>
A9.3.5.2	<p>(a) <b>Stability:</b> If test chemical concentrations are expected to fall below 80 % of nominal, testing, in order to be valid, may require exposure regimes which provide for renewal of the test material. Semi-static or flow-through conditions are preferred. Special problems arise, therefore, with respect to testing on algae, where the standard guidelines generally include static tests to be conducted. While alternative exposure regimes are possible for crustacea and fish, these tests are frequently conducted on static conditions as included in the internationally agreed guidelines. In these tests, a certain level of degradation as well as other relevant factors have to be tolerated and appropriate account <b>must</b> be taken in calculations of toxic concentrations. Some approaches on how this can be dealt with are covered in A9.3.5.6.</p>

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	Where degradation occurs, it is also important to consider the influence of the toxicity of the degradation products on the recorded toxicity in the test. Expert judgement will need to be exercised when deciding if the data can be used for classification;
A9.3.5.3	For classification of organic compounds, <b>it is desirable</b> to have stabilized and analytically measured test concentrations. Although measured concentrations <b>are preferred</b> , classification may be based on nominal concentration studies when these are the only valid data available under certain circumstances. If the material is likely to substantially degrade or otherwise be lost from the water column, care <b>must</b> be taken in data interpretation and classification <b>should</b> be done taking the loss of the toxicant during the test into account, if relevant and possible. Additionally, metals present their own set of difficulties and are discussed separately. table A9.3.1 lists several properties of difficult to test substances and their relevance for classification.
A9.3.5.5	The following paragraphs provide some detailed guidance on some of these interpretational problems. In doing so it should be remembered that this is <b>guidance</b> and hard and fast rules cannot be applied. The nature of many of the difficulties mean that expert judgement <b>must</b> always be applied both in determining whether there is sufficient information in a test for a judgement to be made on its validity, and also whether a toxicity level can be determined suitable for use in applying the classification criteria.
A9.3.5.6.2	Where instability is a factor in determining the level of exposure during the test, an <b>essential prerequisite</b> for data interpretation is the existence of measured exposure concentrations at suitable time points throughout the test. In the absence of analytically measured concentrations at least at the start and end of test, no valid interpretation can be made and the test <b>should</b> be considered as invalid for classification purposes. Where measured data are available, a number of practical rules <b>can be</b> considered by way of guidance in interpretation: (a) where measured data are available for the start and end of test (as is normal for the acute Daphnia and algal tests), the L(E)C <sub>50</sub> , for classification purposes, <b>may</b> be calculated based on the geometric mean of the start and end of test concentrations. Where the end of test concentrations are below the analytical detection limit, such concentrations <b>shall</b> be considered to be half that detection limit; ***
A9.3.5.7.1	These substances, usually taken to be those with a solubility in water < 1 mg/l, are frequently difficult to dissolve in the test media, and the dissolved concentrations will often prove difficult to measure at the low concentrations anticipated. For many substances, the true solubility in the test media will be unknown and will often be recorded as < detection limit in purified water. Nevertheless, such substances can show toxicity, and where no toxicity is found, <b>judgement must be applied</b> to whether the result can be considered valid for classification. Judgement <b>should</b> err on the side of caution and should not underestimate the hazard.
A9.3.5.7.2 (d)	where chronic toxicity data are available, the same general rules should apply. Again, where these data cannot be validated by consideration of measured concentrations, the techniques used to achieve the maximum dissolved concentrations <b>must</b> be considered as appropriate.
Table A9.3.1	Classification of difficult test substances: Note: Relevance for classification column uses “should” “requires” “must” Example: Classification <b>must</b> distinguish toxic effects from reduced growth due to light attenuation
A9.4.2.4.1	Rapid degradation in the aquatic environment <b>may</b> be demonstrated by other data than referred to in chapter 4.1, paragraph 4.1.2.11.3 (a) and (b). These may be data on biotic and/or abiotic degradation. Data on primary degradation can only be used where it is demonstrated that the degradation products <b>shall</b> not be classified as hazardous to the aquatic environment, i.e. that they do not fulfil the classification criteria.
A9.4.3.3.2	These criteria are proposed in order to ensure that rapid mineralization did occur, although the test was ended before 28 days and before the pass level was attained. Interpretation of test data that do not comply with the prescribed pass levels <b>must</b> be made with great caution. It is mandatory to consider whether a biodegradability below the pass level was

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	due to a partial degradation of the substance and not a complete mineralization. If partial degradation is the probable explanation for the observed biodegradability, the substance <b>should</b> be considered not readily biodegradable.
A9.4.3.5.3	The suitability of the inoculum for degrading the test substance depends on the presence and amount of competent degraders. When the inoculum is obtained from an environment that has previously been exposed to the test substance, the inoculum <b>may</b> be adapted as evidenced by a degradation capacity, which is greater than that of an inoculum from a non-exposed environment. As far as possible the inoculum <b>must</b> be sampled from an unexposed environment, but for substances that are used ubiquitously in high volumes and released widespread or more or less continuously, this may be difficult or impossible. When conflicting results are obtained, the origin of the inoculum <b>should</b> be checked in order to clarify whether or not differences in the adaptation of the microbial community may be the reason.
A9.4.4	<i>Decision scheme</i> A substance <b>is considered to be</b> not rapidly degradable unless at least one of the following is fulfilled: (a) the substance is demonstrated to be readily biodegradable in a 28-day test for ready biodegradability. The pass level of the test (70 % DOC removal or 60 % theoretical oxygen demand) <b>must</b> be achieved within 10 days from the onset of biodegradation, if it is possible to evaluate this according to the available test data. If this is not possible, then the pass level <b>should</b> be evaluated within a 14 days time window if possible, or after the end of the test; or ...
A9.5.2.3.4	High quality data are defined as data where the validity criteria for the test method applied are fulfilled and described, e.g. maintenance of constant exposure concentration; oxygen and temperature variations, and documentation that steady-state conditions have been reached, etc. The experiment will be regarded as a high-quality study, if a proper description is provided (e.g. by Good Laboratory Practice (GLP)) allowing verification that validity criteria are fulfilled. In addition, an appropriate analytical method <b>must</b> be used to quantify the chemical and its toxic metabolites in the water and fish tissue (see section 1, appendix III for further details).
A9.6.3.3	What ultimately governs the validity of such predictions is the degree to which the compounds used to derive the QSAR for a specific biological endpoint, are acting by a common molecular mechanism. In many and perhaps most cases, a QSAR does not represent such a mechanistic model, but merely a correlative one. A truly valid mechanistic model <b>must</b> be derived from a series of chemicals all acting by a common molecular mechanism and fit to an equation using one or more parameters that relate directly to one or more steps of the mechanism in question. Such parameters or properties are more generally known as molecular descriptors. It is also important to keep in mind that many such molecular descriptors in common use may not have a direct physical interpretation. For a correlative model, the statistical fit of the data are likely to be poorer than a mechanistic one given these limitations. Mechanisms are not necessarily completely understood, but enough information may be known to provide confidence in this approach. For correlative models, the predictive reliability increases with the narrowness with which each is defined, e.g. categories of electrophiles, such as acrylates, in which the degree of reactivity may be similar and toxicity can be estimated for a “new” chemical using a model based solely on the log $K_{ow}$ parameter.
A9.6.4.5	One approach being proposed “...where this is scientifically justifiable ... is to consider closely related chemicals as a group, or category, rather than test them as individual chemicals. In the category approach, not every chemical <b>needs to be</b> tested for every SIDS endpoint”. Such limited testing could be justified providing that the “...final data set <b>must</b> allow one to assess the untested endpoints, ideally by interpolation between and among the category members.” The process for defining such categories and in the development of such data are described in the proposal.
A9.6.4.10.1	<i>Bioconcentration factor BCF</i> If experimentally determined BCF values are available, these values <b>should be used</b> for classification. Bioconcentration measurements <b>must be performed</b> using pure samples at

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	<p>test concentrations within water solubility, and for an adequate test duration to achieve steady state equilibrium between the aqueous concentration and that in the fish tissue. Moreover, with bioconcentration tests of extended duration, the correlation with log <math>K_{ow}</math> levels off and ultimately decreases. Under environmental conditions, bioconcentration of highly lipophilic chemicals takes place by a combination of uptake from food and water, with the switch to food taking place at log <math>K_{ow} \approx 6</math>. Otherwise log <math>K_{ow}</math> values <b>can be used</b> with a QSAR model as a predictor of the bioaccumulation potential of organic compounds. Deviations from these QSARs tend to reflect differences in the extent to which the chemicals undergo metabolism in the fish. Thus, some chemicals, such as phthalate, can bioconcentrate significantly less than predicted for this reason. Also, <b>caution should be applied</b> in comparing predicted BCF values with those using radiolabeled compounds, where the tissue concentration thus detected may represent a mix of parent compound and metabolites or even covalently bound parent or metabolite.</p>
A9.6.4.10.2	<p>Experimental log <math>K_{ow}</math> values are to be used preferentially. However, older shake flask values above 5.5 are not reliable and in many cases, it is better to use some average of calculated values or to have these remeasured using the slow stirring method (Bruijn et al., 1989). If there is reasonable doubt about the accuracy of the measured data, calculated log <math>K_{ow}</math> values <b>shall</b> be used.</p>
A9.7.1.1	<p><i>(Classification of metals and metal compounds)</i></p> <p>The harmonized system for classifying substances is a hazard-based system, and the basis of the identification of hazard is the aquatic toxicity of the substances, and information on the degradation and bioaccumulation behaviour (OECD 1998). Since this document deals only with the hazards associated with a given substance when the substance is dissolved in the water column, exposure from this source is limited by the solubility of the substance in water and bioavailability of the substance in species in the aquatic environment. Thus, the hazard classification schemes for metals and metal compounds are limited to the hazards posed by metals and metal compounds when they are available (i.e. exist as dissolved metal ions, for example, as <math>M^+</math> when present as <math>M-NO_3</math>), and do not take into account exposures to metals and metal compounds that are not dissolved in the water column but may still be bioavailable, such as metals in foods. This section does not take into account the non-metallic ion (e.g. <math>CN^-</math>) of metal compounds which may be toxic. For such metal compounds the hazards of the non-metallic ions <b>must</b> also be considered.</p>
A9.7.1.3	<p>Generally speaking, the rate at which a substance dissolves <b>is not considered</b> relevant to the determination of its intrinsic toxicity. However, for metals and many poorly soluble inorganic metal compounds, the difficulties in achieving dissolution through normal solubilization techniques is so severe that the two processes of solubilization and transformation become indistinguishable. Thus, where the compound is sufficiently poorly soluble that the levels dissolved following normal attempts at solubilization do not exceed the available <math>L(E)C_{50}</math>, it is the rate and extent of transformation, <b>which must be considered</b>. The transformation will be affected by a number of factors, not least of which will be the properties of the media with respect to pH, water hardness, temperature etc. In addition to these properties, other factors such as the size and specific surface area of the particles which have been tested, the length of time over which exposure to the media takes place and, of course the mass or surface area loading of the substance in the media <b>will all play a part in determining</b> the level of dissolved metal ions in the water. <b>Transformation data can generally, therefore, only be considered as reliable for the purposes of classification if conducted according to the standard protocol in annex 10.</b></p>
A9.7.3.2	<p><i>(Re: Assessment of environmental transformation)</i></p> <p>Such assessments are very difficult to give <b>guidance</b> for and will normally be addressed on a case by case approach. However, the following <b>may</b> be taken into account:</p> <p>(a) Changes in speciation if they are to non-available forms, however, the potential for the reverse change to occur <b>must</b> also be considered;</p> <p>(b) Changes to a metal compound which is considerably less soluble than that of the metal compound being considered.</p> <p><b>Some caution is recommended</b>, see A9.7.1.5 and A9.7.1.6.</p>

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A9.7.5.2.1.3	Where the acute ERV of the dissolved metal ions is less than or equal to 100 mg/l, <b>consideration must be given</b> to the data available on the rate and extent to which these ions can be generated from the metal. Such data, to be valid and useable, should have been generated using the Transformation/Dissolution Protocol (annex 10).
A9.7.5.2.2.1.2	Where the chronic ERV of the dissolved metal ion is less than or equal to 1 mg/l, <b>consideration must be given</b> to the available data on the rate and extent to which these ions can be generated from the metal. To be valid and useable, such data <b>should have been generated or calculated using</b> the Transformation/Dissolution Protocol (annex 10) for 28 days (see A9.7.2.2.4). If such data are unavailable, the surrogate approach should be used (see A9.7.5.2.2.2). ...
A9.7.5.3.2.1.3	Where the chronic ERV of the dissolved metal ion is less than or equal to 1 mg/l, <b>consideration must be given to</b> the available data on the rate and extent to which these ions can be generated from the metal. To be valid and useable, such data <b>should have been generated or calculated using</b> the Transformation/Dissolution Protocol (annex 10) for 28 days (see A9.7.2.2.4). If such data are unavailable, the surrogate approach <b>should be used</b> (see A9.7.5.2.2.2). ...
Annex 9 Appendix III 1.2.4	Where the chronic ERV of the dissolved metal ion is less than or equal to 1 mg/l, <b>consideration must</b> be given to the available data on the rate and extent to which these ions can be generated from the metal. To be valid and useable, such data <b>should have been generated or calculated using</b> the Transformation/Dissolution Protocol (annex 10) for 28 days (see A9.7.2.2.4). If such data are unavailable, the surrogate approach <b>should be used</b> (see A9.7.5.2.2.2). ...
2.2.2	<i>Shake-flask method</i> The basic principle of the method is to measure the dissolution of the substance in two different phases, water and <i>n</i> -octanol. In order to determine the partition coefficient, equilibrium between all interacting components of the system <b>must be achieved</b> after which the concentration of the substances dissolved in the two phases is determined. The shake-flask method is applicable when the log $K_{ow}$ value falls within the range from -2 to 4 (OECD 107, 1995). The shake-flask method applies only to essential pure substances soluble in water and <i>n</i> -octanol and <b>should</b> be performed at a constant temperature ( $\pm 1^\circ\text{C}$ ) in the range 20-25 °C.
A10.2.3.2	As pH has a significant influence on transformation/dissolution both the screening test and the full test should in principle be carried out at a pH that maximizes the concentration of the dissolved metal ions in solution. With reference to the conditions generally found in the environment a pH range of 6 to 8.5 <b>must</b> be used, except for the 28-day full test where the pH range of 5.5 to 8.5 is recommended if technically feasible to take into consideration possible long term effects on acidic lakes.
A10.5.1.2	All glass test vessels <b>must</b> be carefully cleaned by standard laboratory practices, acid-cleaned (e.g. HCl or aqua regia) and subsequently rinsed with de-ionized water. Specific attention to the type of glassware <b>is required</b> for metals that can be released from the glass. The test vessel volume and configuration (e.g. one- or two-litre reaction kettles) <b>should</b> be sufficient to hold 1 or 2 l of aqueous medium without overflow during the agitation specified. If air buffering is used (tests carried out at pH 8), it <b>is advised to</b> increase the air buffering capacity of the medium by increasing the headspace/liquid ratio (e.g. 1 l medium in 2.8 l flasks).
A10.5.1.6	The transformation/dissolution tests <b>are to be</b> carried out at a pH that maximizes the concentration of the dissolved metal ions in solution within the prescribed pH range. A pH-range of 6 to 8.5 <b>must</b> be used for the screening test and the 7-day full test, and a range of 5.5 to 8.5 for the 28 day full test (A10.2.3.2).
A10.5.4.4	To reduce chemical and biological contamination as well as evaporation, the transformation/dissolution kinetics <b>must</b> be performed in closed vessels and in the dark, whenever possible.

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3.5.5.1.2 Decision logic 3.5.2 for mixtures footnote 2	<i>If data on another mixture are used in the application of bridging principles, the data on that mixture <b>must</b> be conclusive in accordance with 3.5.3.2.</i>
3.6.5.2 Decision logic 3.6.2 for mixtures footnote 2	<i>If data of another mixture are used in the application of bridging principles, the data on that mixture <b>must</b> be conclusive in accordance with 3.6.3.2.</i>
3.7.5.1.2 Decision logic 3.7.2 for mixtures Footnote 3	<i>If data on another mixture are used in the application of bridging principles, the data on that mixture <b>must</b> be conclusive in accordance with 3.7.3.2.</i>
3.7.5.2.2 Decision logic 3.7.4 for mixtures	<i>If data on another mixture are used in the application of bridging principles, the data on that mixture <b>must</b> be conclusive in accordance with 3.7.3.2.</i>
A9.4.2.4.8 Inherent biodegradability tests Footnote 2	<p><i>In relation to interpretation of degradation data equivalent with the harmonised OECD criteria for Chronic 4, the standing EU working group for environmental hazard classification of substances is discussing whether certain types of data from inherent biodegradability tests <b>may</b> be used in a case by case evaluation as a basis for not classifying substances otherwise fulfilling this classification criterion.</i></p> <p><i>The inherent biodegradability tests concerned are the Zahn Wellens test (OECD TG 302 B) and the MITI II test (OECD TG 302 C). The conditions for use in this regard are:</i></p> <p><i>(a) The methods <b>must</b> not employ pre-exposed (pre-adapted) micro-organisms;</i></p> <p><i>(b) The time for adaptation within each test <b>should</b> be limited, the test endpoint <b>should</b> refer to the mineralization only and the pass level and time for reaching these <b>should</b> be, respectively:</i></p> <p><i>(i) MITI II pass level &gt; 60 % within 14 days</i></p> <p><i>(ii) Zahn Wellens Test &gt; 70 % within 7 days.</i></p>

## Annex II

Table: instances of ‘must’ and ‘shall’ in Part 2 of the GHS

GHS Rev.10	Excerpt/Context
2.1.2.2 Note 3	For classification tests on explosive substances or mixtures, the tests <b>should</b> be performed on the substance or mixture as presented. If for example, for the purposes of supply or transport, the same substance or mixture is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance or mixture <b>must</b> also be tested in the new form.
2.1.2.2 (d)	Division 1.4: Substances, mixtures and articles which present no significant hazard: substances, mixtures and articles which present only a small hazard in the event of ignition or initiation. The effects are largely confined to the package and no projection of fragments of appreciable size or range is to be expected. An external fire <b>shall</b> not cause virtually instantaneous explosion of almost the entire contents of the package;
Table 2.7.1 Note 1	For classification tests on solid substances or mixtures, the tests <b>should</b> be performed on the substance or mixture as presented. If for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance <b>must</b> also be tested in the new form.
2.7.2 Classification criteria	2.7.2.1 Powdered, granular or pasty substances or mixtures <b>shall</b> be classified as readily combustible solids when the time of burning of one or more of the test runs, performed in accordance with the test method described in the <i>Manual of Tests and Criteria</i> , Part III, subsection 33.2, is less than 45 s or the rate of burning is more than 2.2 mm/s. 2.7.2.2 Metal powders <b>shall</b> be classified as flammable solids when they can be ignited and the reaction spreads over the whole length of the sample (100 mm) in 10 min or less. 2.7.2.3 Solids which may cause fire through friction <b>shall</b> be classified in this class by analogy with existing entries (e.g. matches) until definitive criteria are established.
2.8.2.1 Classification criteria	Any self-reactive substance or mixture <b>should</b> be considered for classification in this class unless: ... (b) They are oxidizing liquids or solids, according to the criteria of chapters 2.13 or 2.14, except that mixtures of oxidizing substances which contain 5 % or more of combustible organic substances <b>shall</b> be classified as self-reactive substances according to the procedure defined in the note below;
2.8.2.1	<b>NOTE:</b> <i>Mixtures of oxidizing substances, meeting the criteria for classification as oxidizing substances, which contain 5.0 % or more of combustible organic substances and which do not meet the criteria mentioned in (a), (c), (d) or (e) above, <b>shall</b> be subjected to the self-reactive substances classification procedure;</i> Such a mixture showing the properties of a self-reactive substance type B to F (see 2.8.2.2) <b>shall</b> be classified as a self-reactive substance.
2.8.2.3	Criteria for temperature control Self-reactive substances <b>need to be</b> subjected to temperature control if their self-accelerating decomposition temperature (SADT) is less than or equal to 55°C. Test methods for determining the SADT as well as the derivation of control and emergency temperatures are given in the <i>Manual of Tests and Criteria</i> , Part II, section 28. The test selected <b>shall</b> be conducted in a manner which is representative, both in size and material, of the package.
Table 2.10.1 Note	For classification tests on solid substances or mixtures, the tests <b>should</b> be performed on the substance or mixture as presented. If for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance <b>must</b> also be tested in the new form.

GHS Rev.10	Excerpt/Context
Table 2.11.1 Note 1	For classification tests on solid substances or mixtures, the tests <b>should</b> be performed on the substance or mixture as presented. If for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance <b>must</b> also be tested in the new form.
2.11.2.1	A substance or mixture <b>shall</b> be classified as a self-heating substance of this class, if in tests performed in accordance with the test method given in the <i>Manual of Tests and Criteria</i> , Part III, subsection 33.4.6: ...
Table 2.12.1 Note 2	For classification tests on solid substances or mixtures, the tests <b>should</b> be performed on the substance or mixture as presented. If for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance <b>must</b> also be tested in the new form.
Table 2.14.1 Note 2	For classification tests on solid substances or mixtures, the tests <b>should</b> be performed on the substance or mixture as presented. If for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance <b>must</b> also be tested in the new form.
2.15.2.1	Any organic peroxide <b>shall</b> be considered for classification in this class, unless it contains: (a) not more than 1.0 % available oxygen from the organic peroxides when containing not more than 1.0 % hydrogen peroxide; or (b) not more than 0.5 % available oxygen from the organic peroxides when containing more than 1.0 % but not more than 7.0 % hydrogen peroxide. ----- (g) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60 °C or higher for a 50 kg package), and, for liquid mixtures, a diluent having a boiling point of not less than 150°C is used for desensitization, <b>will be</b> defined as organic peroxide TYPE G. If the organic peroxide is not thermally stable or a diluent having a boiling point less than 150°C is used for desensitization, it <b>shall</b> be defined as organic peroxide TYPE F. .....
2.15.2.2	Organic peroxides <b>are</b> classified in one of the seven categories of “Types A to G” for this class, according to the following principles: ***
2.15.2.3	Criteria for temperature control *** Test methods for determining the SADT as well as the derivation of control and emergency temperatures are given in the Manual of Tests and Criteria, Part II, section 28. The test selected <b>shall</b> be conducted in a manner which is representative, both in size and material, of the package.
2.15.4.2.3	Mixtures of organic peroxides <b>may</b> be classified as the same type of organic peroxide as that of the most dangerous ingredient. However, as two stable ingredients can form a thermally less stable mixture, the self-accelerating decomposition temperature (SADT) of the mixture <b>shall</b> be determined.
2.17.2.4	Desensitized explosives <b>shall</b> be classified as packaged for supply and use in one of the four categories of this class depending on the corrected burning rate (Ac) determined using the burning rate (external fire) test described in Part V, subsection 51.4 of the <i>Manual of Tests and Criteria</i> , according to table 2.17.1: