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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
(Second session, 12 -14 December 2001, agenda item 3)

GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Annexes 5 to 8

Transmitted by the Inter-Organization Programme for the Sound Management of Chemicals (IOMC)

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Annex 5

Consumer product labelling based on the likelihood of injury

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Introduction

1. The Globally Harmonized System of Classification and Labelling of Chemicals is based on an assessment of the intrinsic hazardous properties of the chemicals involved. However, it has been recognized that some systems provide information about chronic health hazards in consumer products only after considering additional data regarding potential exposures to consumers under normal conditions of use or foreseeable misuse. These systems thus provide information based on an assessment of risk, or the likelihood of injury occurring from exposure to these products. Where this exposure assessment and determination of likelihood of injury reveal that the potential for harm to occur as a result of the expected exposures is insignificant, chronic health hazards may not be included on the product label for consumer use. This type of system was recognized in a paper clarifying the scope of the GHS work in 1998 (IFCS/ISG3/98.32B[1]):

   The application of the components of the system may vary by type of product or stage of the life cycle. Once a chemical is classified, the likelihood of adverse effects may be considered in deciding what informational or other steps should be taken for a given product or use setting.

2. The work on the GHS has not addressed harmonisation of this type of approach. Therefore, specific procedures to apply this approach would have to be developed and applied by the competent authority. However, in recognition that it is an approach that has been used, and will continue to be used in the future, this annex is being provided to give additional guidance on how such an approach may work in practice.

3. Exposure assessments for some consumer products are used to determine what information is included on a label in this type of approach. Regulators and manufacturers obtain exposure data or generate hypothetical exposure data based on customary use or foreseeable misuse. These assumptions are then used to determine whether a chronic health hazard is included on a consumer product label, and what precautions are to be followed, under a risk-based approach. These decisions are thus made on the basis of considerations regarding the likelihood of harm occurring in the consumer exposure situations that have been identified.

4. Consumer product labels in some systems are based on a combination of hazard and risk. For example, acute and physical hazards may be indicated on the label, while chronic health effects labelling is based on risk. This may be due in part to the expectation that exposures to some consumer products are of short duration, and thus may not be sufficient to lead to the development of chronic health effects as a result of those exposures. These expectations may not be accurate where consumer products are used in a workplace, e.g., paints or adhesives used by construction workers on a regular basis

5. While hazards of a chemical can be determined for all sectors, information about exposure, and thus risk, varies significantly among the sectors covered by the GHS. The vehicle by which this information is then transmitted to the user also varies. In some cases, particularly in the consumer setting, the label is the sole source of information, while in others, especially the workplace, it is one piece of a comprehensive system, supplemented by SDSs and worker training. In transport, a label transmits the primary information, but additional information is provided by the transport documentation.

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[1] *IOMC Description and Further Clarification of the Anticipated Application of the Globally Harmonized System (GHS), IFCS/ISG3/98.32B.*

General principles

6. While the specific risk assessment approach has not been addressed or harmonized in the GHS, certain general principles are as follows:

(a) All chemicals should be classified based on GHS classification criteria

The first step in the process of classifying hazards and communicating information should always be classification of intrinsic hazards based on the GHS criteria for substances and mixtures.

(b) Risk-based labelling can only be applied by the competent authorities to the chronic health hazards of chemicals in the consumer product setting. All acute health, environmental and physical hazards should be labelled based on intrinsic hazards

The hazard classification should lead directly to labelling of acute health effects, environmental and physical hazards. The labelling approach that involves a risk assessment should only be applied to chronic health hazards, e.g., carcinogenicity, reproductive toxicity, or target organ systemic toxicity based on repeated exposure. The only chemicals it may be applied to are those in the consumer product setting where consumer exposures are generally limited in quantity and duration.

(c) Estimates of possible exposures and risks to consumers should be based on conservative, protective assumptions to minimise the possibility of underestimating exposure or risk

Exposure assessments or estimates should be based on data and/or conservative assumptions.

Assessment of the risk and the approach to extrapolating animal data to humans should also involve a conservative margin of safety through establishment of uncertainty factors.

An example of risk-based labelling used in the United States Consumer Product Safety Commission

7. In general, consumers rely on product labels for information about the effects of a chemical product. Whereas other sectors have additional sources of information (e.g., safety data sheets, shipping papers) to expand upon or refine product information and relate risk to the hazard information provided, the consumer sector generally does not.

8. As noted above, the general rule for the GHS is that the label information will be based on intrinsic properties (hazards) of the chemical in all sectors. The rationale for hazard based labelling in the GHS has been described earlier in this document, and may be applied to consumer products as well as products in other sectors.

9. In particular, the principle of the user's "right-to-know" about the intrinsic hazards of the chemical is important and widely supported by many stakeholders. Hazard information is an incentive to choose less hazardous chemicals for use. It may not be possible to accurately predict the exposures when the products are used, and consumer protective measures are less certain than those in other more structured sectors.

10. On the other hand some research has indicated [2-7] that a consumer’s attention can be diverted by too much information on a label regarding all potential hazards. It appears there is some evidence

that warnings focused on specific hazards that are likely to cause injury enhance consumer protection.

11. To ensure that consumers have the information needed to take appropriate protective measures, a risk-based labelling approach examines likely or possible exposures and communicates information related to the actual risks of exposure. Consumer exposures from use, foreseeable use and accidents can be estimated since products are designed for specific use(s).

12. The following process has not been harmonized in the GHS. It is consistent with US Consumer Product Safety Commission Guidelines[8] and with other national and international guidelines on conducting risk assessments[9-11]. 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 (see paras. 8- 0), the substance or product need not be labelled for chronic hazard. In other words, whether a given substance is labelled for a chronic effect depends not only on whether it is hazardous, but also on exposure and risk.

12. The extent of the exposure assessment would depend on the hazard. For example, for non-cancer chronic endpoints, an "acceptable daily intake" (ADI) would be calculated from the "no observed adverse effect level" (NOAEL). For a conservative estimate of exposure, one can assume that the consumer will use the entire consumer product in a day and/or assume that all of the hazardous substance/mixture that the consumer is exposed to will be absorbed. If the resulting exposure is lower than the "acceptable daily intake" no hazard communication would be required. If the exposure level is higher than the ADI, then a more refined quantitative assessment could be performed before making a final labelling decision. If refined data are not available, or a refined analysis is not done, the hazard would be communicated on the label.

13. For carcinogens, a unit risk from exposure to the carcinogen would be calculated based on linear extrapolation with the multistage model as a default model. Life time exposures can be calculated either by assuming worst case scenarios (such as all of the substance in a product is reaching the target tissue at each use, exposure is daily/weekly/monthly), or by determining actual exposures during use, or some combination of these approaches.

14. The competent authority will need to establish what level of risk is acceptable to implement such an approach to consumer product labelling for chronic effects. For example, CPSC recommends labelling for a cancer hazard if the lifetime excess risk exceeds one-in-a-million from exposure during "reasonably foreseeable handling and use."

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Annex 6

Comprehensibility testing methodology

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**IMPLEMENTATION OF HAZARD COMMUNICATION
COMPREHENSIBILITY ASSESSMENT INSTRUMENTS**

1. This instrument has been developed for the International Labour Office (ILO) Working Group on Hazard Communication as part of international efforts to promote a Global Harmonised System (GHS) for hazard communication. The tool aims to provide a methodology for the assessment of the comprehensibility of labels and Safety Data Sheets (SDS's) for chemical hazards. The tool has been developed by a multidisciplinary team at the University of Cape Town with a particular focus on addressing the needs of workers and consumers in developing countries. The emphasis of instrument development has been to provide a tool that is, as far as possible, globally applicable taking into account varied levels of literacy and differences in cultural experience.

Overview of the Instrument

2. The instrument is organized into a number of modules, directions for each of which is covered in this Annex. Broadly speaking, the instrument consists of four parts:

- Module 1: This is a focus group, whose main purpose is to ensure that the instruments used in modules 2 to 11 are sensible across diverse cultures and settings. We recommend its use in all categories of target populations (see Table 2 below) but it should be mandatory to commence with this modules in groups of workers and community members from cultures different to the settings in which labels and SDS's have been produced.
- Modules 2 to 8: These include a general questionnaire (module 2) and a set of label and Safety Data Sheet questions and exercises (modules 3 to 8). Depending on whether the subject is a worker and makes use of a Safety Data Sheet, some elements of these modules may not apply.
- Module 9: This is a simulation exercise. One version is intended for workers and is applicable to most people involved in production, while the other version (module 9a) is adapted for a consumer setting.
- Module 10: Module 10 contains a final post-test questionnaire. It is applicable to all participants in the questionnaires (modules 2 to 8) and the simulations (module 9). It is also administered to participants in the group exercise (Module 11). The questionnaire is focused on training, and past experience, and offers an opportunity for open-ended feedback and comment on the testing process.
- Module 11: This is a group exercise for workers that draws on all elements contained in previous modules and is intended to test comprehensibility in the context of group learning. It is designed to complement modules 2 to 10 but is carried out on different subjects to those in modules 1, 2 to 8, and 9.

3. It is further proposed that follow-up testing be conducted at one and twelve months after comprehensibility testing. This testing should be repeated on the same subjects who underwent initial testing. Depending on resources and logistics, it may be possible to avoid re-testing on all the modules completed at baseline. Repeat testing would be important to gain insight into retention and real benefits of exposure to hazard messages.

4. Table 1 summarizes the modules in the instrument, the main activities in the modules, and the objectives and outcomes to be derived from each module.

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5. Although the testing instrument has been designed as a self-contained package, it may be possible to make use of selective modules from the battery where there are local priorities and needs. Moreover, it is recognized that as global harmonization of hazard communication evolves, new needs for testing may arise. The instrument may be adapted to take account of new testing priorities over time by using adapted testing materials (labels and SDS's) in the same testing formats. For example, if new icons for hazard symbols are under consideration, module 4 can be amended to include new symbols.

Use of the Annex and the Testing Instruments

6. Each module is the actual test questionnaire for a specific set of comprehensibility testing objectives. The layout of the modules is such that instructions are clearly marked in the questionnaires for those administering the comprehensibility tests. Accompanying each module, but presented separately, is a set of detailed guidance notes comprising the manual for the particular module. The manuals also outline the different labels and/or SDS's to be used in each module and the outputs and time requirements of each module.

7. To avoid rendering the modules to lengthy, instructions on the modules have been kept to a minimum in the text of the modules, reserving the elaboration on instructions for the manual sections. Where key instructions are present in modules 3 to 11, they are listed in bold text within shaded boxes to improve ease of administration. Italic font is used throughout the modules for all text to be read out to the subject.

8. Some modules (Modules 3, 4, 6, 7, 8 and 9) require random selection of labels and/or SDS's. A box of cards is provided to the interviewer to expedite the selection of a random label/SDS or set of labels/SDS's. The interviewer will have a specific box of such cards marked for every relevant module.

9. Labels and Safety Data Sheets are provided but should be to conform to the normative styles and presentations existing in the countries in which the tool is to be applied. The GHS will bring a certain degree of standardization in the content and layout of hazard communication methods but a great deal of variation will still arise in relation to local traditions, styles, size and preferences. 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.

10. Notwithstanding attempts to simplify the relatively complex testing procedures required to measure hazard communication comprehensibility, the test instruments require careful administration and quality control. Training of interviewers is therefore critical. This is dealt with in more detail in the manuals for modules 1 and 2.

Table 1. Comprehensibility Testing: Objectives and Outcomes by Module

Module	Contents	Objectives	Outcome
Module 1	**Focus Groups**	To shape research tool to the context, language, and cultural interpretations of the specific target group. To identify cultural specific definitions of words. To test whether ranking, the use of colour for attributing hazard, and the quantitative estimation of ambiguous variables are culturally transferable. Testing strategies used in subsequent modules are piloted for face validity and identify alternatives. To identify potential biases in the testing situation arising from cultural use of items.	Culturally consistent explanations for difficult words. Appropriate use of colour in local context. Account of cultural factors that would bias comprehensibility tests. Validation of colour blindness test methods. Interpretability of psychometric scales for non-Western populations. Contextual testing. Instruments to capture workers' experience. "Dummy" symbols.
Module 2	**General Interview**	To ascertain demographic and other data as a basis for analysis of comprehensibility. To clarify competence in colour and visual acuity necessary for some of the subsequent tests. To collect data on work experience, critical to interpretation of comprehensibility assessments.	Relevant demographic and other data for linking to study results and analysis. Colour and visual acuity assessed. Role work experience plays in comprehensibility.
Module 3	**Recall, reading, and comprehensi-bility of labels and SDS's**	To evaluate subjects' familiarity with a label and a SDS. To test subjects' recall of label elements. To evaluate the sequence used to look at label elements. To test the comprehensibility of signal words, colours, symbols and hazard statements. To assess the impact of the label on the subjects': - Ranking of hazard, both to self and to spouse or child - Intention to use, store and dispose of the chemical Whether ranking and reporting change after questions on comprehensibility Can subjects correctly identify the appropriate SDS? Can subjects correctly identify information on chemical name, health hazard, physical hazard and use of protective clothing?	Identify a priori familiarity with labels and SDS's. An assessment of the impact of different label fonts. Identification of poorly understood elements terms. Identify statements with highest comprehensibility. Hazard ranking, and intention to behave as a result of the label The effect of detailed questions on comprehensibility on subjects' perceptions of hazard as a proxy for training. The impact of the Hawthorne effect will be gauged. Comparison of ranking of hazard to self differs from ranking of hazard to a close relative. Identifying whether subjects can link data from a label to an appropriate SDS in a meaningful way.

Table 1. Comprehensibility Testing: Objectives and Outcomes by Module

Module	Contents	Objectives	Outcome
Module 4	**Rating and understanding of hazards:** **Signal words, Colours, and Symbols**	To test subjects' relative ranking for severity of hazard for: - Signal words, colours and symbols. - combinations of symbols and multiple symbols - selected combinations of symbols, colour and signal words To test understanding of signal words, colours, and symbols. To test opinion on the ability of signal words, colours, and symbols to attract attention. To test whether subjects' perception of the label will influence their reported intention to use, store or dispose of the chemical. To explore subjects' views as to why hazard elements are present on a label.	Signal words, Colours and Symbols will be rated for ability to denote level of hazard, and for comprehension both separately, and for selected combinations of elements. Quality control assessment of face validity of ranking. Ability of label elements to attract attention. Label rated highest for attracting attention will be explored for its ability to: Prompt the subject to identify further information, particularly health hazard information. Influence reported intention to behave in safe ways.
Module 5	**Comprehension of hazard symbols with and without text**	To test subjects' understanding of symbols representing hazard classes. To test subjects' understanding of concepts of hazard classes. To identify whether adding text words improves understanding of selected symbols representing hazard classes: reproductive, carcinogenic, and mutagenic. To identify whether adding signal words improve understanding of symbols representing classes.	Ability to identify the correct symbol for a hazard class. Identification of hazard classes for which symbols perform poorly; and of symbols which perform poorly as indicators of a hazard class. Identify symbols with ambiguous interpretations. The effectiveness of adding text to symbols for reproductive, carcinogenic and mutagenic hazards. The effectiveness of adding signal words to symbols denoting hazard class.
Module 6	**Size, Placement, Background colour and Border of symbols /Pictograms**	To test the impact of varying symbol size, border and placement. To test the impact of varying background colour and varying icon size in a pictogram relative to border.	Impact of the symbol size, border and placement: - ability to identify chemical name - perception of risk - recall of symbol as proxy for attention to symbol - recall of hazard statement as proxy for attention to hazard statement - reported intention to behave - sequence of reading Comparison of whether ranking of hazard to self differs from ranking of hazard to a close relative.

Table 1. Comprehensibility Testing: Objectives and Outcomes by Module			
Module	**Contents**	**Objectives**	**Outcome**
Module 7	**Pictogram comprehension - Additional testing (Pesticides)**	To test subjects' ability to identify information: - chemical name - health hazards To assess subjects' rating of hazard To test subjects' understanding of pictograms To assess subjects' sequence of reading	Comprehensibility of pictograms: understanding, ranking of hazard, attention, access to key information Comparison of whether ranking of hazard to self differs from ranking of hazard to a close relative.
Module 8	**Comprehensibility of safety data sheets (SDS's) by organisation of data**	To test subjects' ability to identify safety information from a SDS. To test the understanding of hazard information on a SDS. To evaluate what the subject reads on a SDS and the sequence in which subjects report reading the elements of the SDS To assess what information is useful, appropriate and understandable. To assess whether SDS information is related to intention to behave in safe ways. To evaluate the impact of different organisation of SDS information on the above.	Comprehension of SDS hazard information assessed from different aspects: 1) Interpretation of health hazard information; 2) Self-assessment of understandability to others; 3) Scoring of how the subject explains a hazard statement to a third party; 4) Reported intention to behave Agreement between these four measures of understanding will be estimated. The impact of different ways to organise SDS information will be estimated. Subjective assessment of the usefulness and appropriateness of sub-elements to identify areas for further review of SDS development.

Table 1. Comprehensibility Testing: Objectives and Outcomes by Module			
Module	**Contents**	**Objectives**	**Outcome**
Module 9	**Simulation Exercise: Impact of the use of labels and SDS's, and of symbols and signal words on labels on safe chemical practices**	To assess safety practices in relation to a simulated exercise in which a chemical is handled. To evaluate whether safety practices are improved by the presence of the Signal Word 'Danger' and/or by the size of the Hazard Symbol (Skull and Crossbones). To identify whether past experience in relation to chemicals plays a significant role in both safety practices, and in the impact of Signal Words and Symbols on safety practices.	Measures of actual behaviour observed and related to use of labels, SDS's prior to, and during the task. Safety behaviours include use of PPE and other preventive hygiene practices. The impact of varying label elements (with or without 'Danger'; with different size Hazard Symbol) and SDS layout (explicit heath hazard heading versus health hazard data under regulatory information). Relationship between understanding, practice and experimental conditions to be explored.
Module 10	**Post interview/ Post stimulation interview**	To ascertain past history of contact with chemicals and training. To test the effect of a brief explanation of symbols, signal words, colours and hazard statements on ranking for severity of hazard, and comprehension. To identify chemical information needs from subjects.	Variables derived from training and past experience for stratified analysis of responses to modules 3 to 9. Results will help to indicate whether training should be the subject of more detailed evaluation in the long term. Responses to questions on needs for chemical information can be useful to GHS efforts on chemical safety.
Module 11	**Group exercise - comprehension**	To test whether learning about hazard communication happens differently in a group context than with individuals. To test whether subjects working as a group come up with significantly different answers than when individual subjects are asked a questionnaire.	A quality control assessment on the affect of group versus individual learning. Groups coming up with significantly different responses from individuals indicate that the testing model needs to be revised. Implications for how training should be addressed in future as an element of hazard communication.

General Concerns

Consent

11. Before conducting any of the modules in this instrument, participants should first give informed consent. To do so, the purpose of the exercises should be explained to them as well as the procedures that will be asked of them. Participants should not be coerced into participating and should know that they have the right to withdraw their participation at any time. The nature of the information provided in the consent procedure is sufficiently generic so as not to give away the explicit hypotheses being tested.

12. Consent procedures are outlined in the opening sections of modules 1 (focus group), 2 (commencement of interviews) and 10 (simulation exercises). Irrespective of whether the same subjects complete all modules or not, all three consent procedure should be applied when required. The consent procedure for the simulation is by necessity more of an explanation to obviate the obvious bias to be introduced by alerting the subject to the purpose of the exercise.

Policy on rewards or compensation to participants

13. Each participating respondent in this study is to be given some form of compensation or incentive for participating in the study. Participating respondents should be told in consenting to the testing that at the end of the study some form of compensation will be presented to them. Compensation may vary from country to country depending on what is culturally appropriate and locally available. Some suggestions (based on other studies) are food (lunch), hats/caps, mugs, food (sugar, rice, mealie meal), certificates, etc. It is up to the countries applying the tool to develop an appropriate policy on compensation for participants.

Sampling

Target populations

14. Target populations are outlined in Table 2 below. These are largely adult working populations, typical of groups who use, distribute or manage chemicals, either directly or indirectly. Children are another important potential audience. However, although the ability to provide understandable safety messages to children is recognised as critically important, it has not been possible to address this area in this manual because of the specialised methods required for evaluation. Further development at some future point may be able to extend the comprehensibility testing to methods suitable for children.

15. Proposed methods for attaining representative samples are outlined in the Manual sections for Modules 1 and 2. University students should not be used as they have been extensively used in previous hazard communication studies and are not considered representative of the target populations identified in this study.

Focus Groups

16. Given the aim of the focus groups to ensure that the instruments used in modules 2 to 11 are sensible across diverse cultures and settings, participants for focus groups should be as far as possible typical of the target groups to be evaluated. We recommend that emphasis be placed on targeting groups of workers and community members from cultures different to the settings in

which labels and SDS's have been produced. This will mainly apply to farm workers, non-agricultural workers and community / residents / consumer groups, both literate and non-literate, groups whose cultural and linguistic backgrounds may make hazard communication complex. Categories for focus groups are recommended in the Table 2 below.

17. At least 2 focus groups are recommended per category. However, where results from a FG in one category (e.g. non-literate farm workers) appear highly similar to an analogous group (e.g. non-literate non-agricultural workers), it may be possible to dispense with further groups. This should only be done if the testers are confident that no different results would be anticipated from additional testing. In general, once findings from different FGs are consistent, it is recommended to proceed directly to the main evaluation (modules 2 onward). Where findings appear vastly discrepant, or where inadequate information to inform the rest of the instrument has been obtained, it is recommended to continue assembling FGs until such information is obtained. Under such circumstances, testing until results are consistent or clarity is achieved may require more groups than the 2 per category recommended.

18. Focus group participants should preferably not be the same workers included in the testing under modules 2 to 11 as some learning will take place through the focus group itself. Groups should aim, wherever possible, to be homogenous for language, inasmuch as all participants should be able to communicate in at least one common language.

Questionnaire and experimental design

19. Different sub-populations of working and non-working people will have different experiences that influence their comprehension of hazard communication messages. Modules 2 to 8, and module 10 will test comprehension under different experimental conditions. Sample size calculations combined with considerations of logistical ease suggest that the minimum numbers of subjects to be tested are those contained in the Table 2 below. Modules 6 (effect of label font and layout on comprehensibility) and 9 (simulation test) include comparisons of different label types (8 and 11 strata respectively). Thus, larger numbers are needed for these modules to generate sufficient cases within each stratum. The other interview modules (3, 4, 5, 7 and 8) have fewer strata (vary from one to four maximum) and thus can be managed with fewer subjects. Users of this instrument may choose to apply all the modules to all participants, in which case the minimum number of participants recommended is as for modules 6 and 9 in the table below. Modules 2 and 10 must be completed by all participants as indicated.

20. In view of the length of the full battery of tests (see Table 3), 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, irrespective of how many of the other modules they complete. For example, the battery of modules could be sub-divided into sets consisting of a) Modules, 2, 3, 8 and 10; b) Modules 2, 4 and 10; c) Modules 2, 5, 6, 7 and 10; d) Modules 2 and 11; e) Modules 9, 2 and 10. However, it is preferable that, if possible, participants are given the full battery of tests contained in the instrument, and are adequately compensated for their effort.

Table 2. Sample Size - recommended numbers					
Category	**Sub-category**		**Focus Group Module 1**	**Interviews: Modules 2, 6 & 10; Simulation Module 9**	**Interviews Modules 3, 5, 7, 8.**
Target Group 1: Workplace a) Management	**Population 1**: Production Managers, engineering, technical		Optional	30-50*	25
	Population 2: Supervisory Managers in industry, agriculture		Optional	30-50*	25
b) Workers	Population: Farm workers	**3**. Literate	At least one group	100	50
		4. Non-literate	At least one group	100*	50
	Population: Workers other than in agriculture	**5**. Literate	At least one group	100	50
		6. Non-literate	At least one group	100*	50
Target Group 2: Transport	**Population 7**. Transport workers		Optional	30-50	25
Target Group 3: Community Residents/ Consumers/general public	**Population 8**: Literate		At least one group	100	50
	Population 9: Non-literate		At least one group	100*	50
	Population 10: Retailers and distributors		Optional	30-50*	25
Target Group 4: Emergency Responders	**Population 11**: Health Professionals, Technical Extension staff and Emergency Responders		Optional	30-50*	25
Target Group 5: Other	**Population 12**: Enforcement / Regulatory		Optional	30-50*	25

* *Recognising the practical difficulties in organising a simulation test, it is suggested that in these groups simulation testing only be carried out where resources are available and where practically feasible.*

21. As far as possible, the selection of sub-groups should be done an as representative a sample as possible, using random selection of the population for participation. This is critical for generalisability of the results. Even where different participants are chosen from the same sub-group to complete different parts of the instrument, for reasons of length of the battery, selection of participants should emphasise representivity. However, it is recognised that random selection may be very difficult to achieve in practice. Nonetheless, it should be borne in mind that whatever, selection is used, it should seek to generate a sample as representative as possible.

22. Note that within the modules, randomisation of subjects within the groups is essential and cannot be compromised on. Randomisation is necessary for internal validity of the comparisons and is not the same as random selection of the sample, which is needed for generalisability of the study results.

Simulation studies

23. Because simulations studies are relatively resource intensive exercises, it is proposed that the simulations only be conducted with limited target populations - workers, both agricultural and non-agricultural, transporters, and consumers. However, where resources permit, these simulations can easily be applied to other strata as desired.

Contamination and Co-intervention

24. The testing design requires control circumstances. For this reason, the situation should be avoided where a participant is able to see or be told of the experimental materials of another participant. This will invalidate the comparisons being made where manipulation of the independent variable is key to the evaluation. Such events occurring in an experimental set up are called contamination.

25. To avoid contamination, participants should avoid contact with each other whilst testing is being conducted. This may require considerable effort on the part of the testing team to ensure that chance meetings of subjects does not occur. Although difficult, every effort should be made to minimise the probability of contamination.

26. A distinct but related problem is co-intervention, where both experimental groups are subjected to an intervention occurring independent of the experimental situation. This would occur when, for example, every worker in factory received detailed hazard safety training in the week before the testing was done. It may result in a masking of the effect of the different hazard communication elements and may lead to an under-estimation of the effect of different formulations of the label and SDS. Where this is not preventable, note should be taken of the possibility that co-intervention took place.

Group Learning

27. Module 11 is included to test comprehensibility in the context of group learning. It is applied only to workers (populations 3 to 6 in Table 2 above) and will need a sample separate from workers completing Modules 2 to 8. Ten groups should be tested in total including 5 groups of factory workers and 5 groups of farm workers. Groups should aim to be homogenous for literacy level and approximately equal numbers literate and non-literate groups. Each group should not be larger than 10 and not smaller than 6.

Context

28. The context under which comprehensibility testing is carried out is crucial to the accurate evaluation of meaning and understanding. This is particularly so amongst workers with little formal education who use contextual cues to improve their understanding of hazard messages. For this reason, the bulk of testing in this instrument makes use of complete labels rather than elements of a label or SDS. While well-educated subjects may find it conceptually easier to respond to the isolated elements, the interpretation of such elements may have little bearing to real world learning situations. For this reason, all testing is to be conducted using realistic labels and SDS's.

29. To maximise realism, we propose using an in-site label attached to a container. To attach a different label to each container may pose an unnecessary burden on the tester, so it is proposed that the label be attached to a standard container, and removed after testing. This procedure may require an assistant to the interviewer if overly burdensome for the interviewer. It is important that every visual cue be offered to subjects to maximise their possibilities of comprehension,

particularly for workers with low levels of formal education who rely on contextual information to a greater degree. Therefore, the labels should be presented attached to container at all times. A Velcro strip attached to the container may make the procedure relatively simple.

30. To standardise opportunities for comprehension, the actual chemicals identified in the labels will be spurious chemicals, although made to look as if they could be genuine agents. This aims to retain context, while not disadvantaging those unfamiliar with a particular chemical.

31. As indicated above, 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 so as to maximise context.

Sample sizes for sub-studies

32. Sample sizes for the sub-studies have been calculated based on a two-sided alpha error of 0.1 and a power of 0.8, but have also been tempered by considerations of logistical feasibility. Preliminary piloting of the instrument confirms these estimates. In particular, the simulation exercise has been considered relatively selectively for a smaller number of subjects and target groups, largely because of anticipated logistical constraints.

Translations

33. Language is key to much hazard communication. Although the instrument seeks to take account as far as possible of language differences, poor and unstandardised translation may introduce considerable error into the testing. For this reason, careful attention needs to be paid to accurate translation. We recommend the following procedure to be followed:

- Two persons fluent in English (the language of the current instrument) independently translate the questionnaire into the index language (the language of the target group).
- Both translations are then translated back into English by a further pair of translators independent of each other and of the original translators.

34. Back-translations should aim to achieve less than 5% errors on first round. Clarification of the errors in the translation should be conducted to correct ambiguities. Where possible, a combined translation should try to include all elements correctly translated and back translated from either questionnaire.

35. If the latter is not possible, the translation with the lower rate of errors should be taken as the translation of preference. A second round of back translation will be necessary if errors exceed 5%.

Timing of Interviews and Focus Groups

36. Interviews and focus groups must be set up at a convenient time for both the interviewee and their employer (when this applies). Farm workers should not be requested to attend an interview during a crucial and busy period for farmers (e.g., planting, ploughing, spraying, or harvest). Workers should be interviewed during working time and should not suffer financial loss for their participation. It is not recommended that workers participate in their own time (lunch or after hours) without adequate compensation. If workers agree to participate during lunch break, the time must be adequate and suitable recompense provided (time back, lunch provided, etc).

37. Table 3 gives the estimated time needed for completion of individual modules based on preliminary piloting with two South African factories. Depending on the module and how skilled the administrators of the modules are, total testing time could vary from 20 minutes to 2 hours. Testing times will be prolonged with non-literature workforces.

Table 3. Approximate testing times for Hazard Communication Comprehensibility testing

Module	Time (minutes)
1	60 – 120
2	30 – 45
3	45 – 75
4	75 – 105
5	20 – 30
6	20 –30
7	20 –30
8	45 – 75
9	30
10	30 - 45
11	120 – 180

Rating and Coding of responses

38. Rating of responses to comprehensibility testing requires expert judgement as to the correctness of the response. Previous experience in Zimbabwe has shown that content analysis of open-ended responses may be feasible where observers are carefully standardised in their approach.

39. This instrument requires the presence of a set of experts to conduct the rating required for comprehension. The panel of experts should be identified before commencing the study in a process outlined below:

a) Select a panel with a range of experience, including (one or more) employees, employers and practitioners, as well as researchers skilled in the field of coding and rating;

b) Convene a workshop with the panel to review the nature of potential responses to questions in each of the modules listed. Review the documentation of the IOMC and ILO GHS process and aim to arrive at consensus as to what responses would constitute the following categories:

- Correct: Meaning is identical, or fully consistent with intention of the GHS construct. This includes responses which are not 100% the same as the GHS meaning but would suffice as the basis for a safety action or precaution;

- Partly correct: Some element of the meaning is correct but it would be insufficient to ensure adequate safety action or precaution;
- Incorrect: Meaning given is either completely wrong, or has very poor relation to the GHS intended meaning;
- Opposite meaning (critical confusions): Meaning given is not only incorrect but indicates an understanding opposite of the intention of the GHS system. Such a critical confusion may result in a dangerous behaviour or action;
- Cannot answer / doesn't know;

c) Pilot the questionnaire amongst 5 or 10 subjects. Review the results in relation to the criteria selected;

d) If the results show significant discrepancy, iterate the process above until agreement reached about criteria.

40. Further coding of responses to questions in the different modules is discussed under each module, where appropriate.

Analyses

41. Analyses proposed for these modules are simple computations of proportions and means in relation to different strata. More complex analyses may be undertaken and are indicated in the different modules. An overall estimate for comprehensibility may be attempted by combining results from subjects in the different strata, but should be adjusted for weightings by stratum and by other demographic factors known to affect comprehensibility.

Feedback and follow up

42. All subjects should be offered the opportunity of seeing the results of the comprehensibility evaluations, and to give feedback on the interview and testing procedures.

Follow up evaluation

43. Subjects participating in these evaluations should be re-interviewed after 1 month and 1 year to assess retention and the medium and long-term benefits of exposure to the GHS hazard messages. Depending on resources and logistics, it may be possible to avoid re-testing on all the modules completed at baseline.

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Annex 7
Examples of arrangements of the GHS label elements

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Example 1

The product is a liquid substance:

- classified under GHS as skin corrosive category 1B and flammable liquid category 3.
- UN RTDG classification is corrosive liquid, flammable, N.O.S., - UN 2920.

1. Label for large container (200 litre drum) for transport, emergency response and workplace audiences

UN 2920

Corrosive liquid, flammable, N.O.S.

(2-methyl tetramethylenexxxxx)

2-methyl tetramethylenexxxxx

Danger

Causes severe skin burns and eye damage
Highly flammable liquid and vapour
Avoid contact with skin and eyes
Keep away from heat and ignition sources

First aid:

For skin contact, remove contaminated clothing and wash affected area thoroughly with water. If irritation develops, seek medical attention.

For eye contact, immediately flush eyes with flowing water for at least 15 minutes and seek medical attention.

GHS Example Company, Akron, NWT, Canada. Telephone (888) 888-8888

2. Label for small workplace container (10 litre) packaged inside an outer shipping container – for workplace audience

2-methyl tetramethylenexxxxx

Danger

Causes severe skin burns and eye damage
Highly flammable liquid and vapour
Avoid contact with skin and eyes
Keep away from heat and ignition sources

First aid:

For skin contact, remove contaminated clothing and wash affected area thoroughly with water. If irritation develops, seek medical attention.

For eye contact, immediately flush eyes with flowing water for at least 15 minutes and seek medical attention.

GHS Example Company, Akron, NWT, Canada Telephone (888) 888-8888

3. Outer shipping container has UN transport markings and labels only – for transport and emergency response audiences.

UN 2920

Corrosive liquid, flammable, N.O.S.

(2-methyl tetramethylenexxxxx)

Example 2

The product is a liquid mixture:

- classified under GHS as toxic to reproduction, category 1B and flammable liquid, category 3.
- UN RTDG classification is flammable liquid - UN 1263.

1. Label for large container (200 litre drum) for transport, emergency response and workplace audiences

ZZZ Red Paint

Danger

UN 1263

Paint

May damage fertility or the unborn child

Highly flammable liquid and vapour

** Contains lead pigments and cellosolve acetate

Keep away from heat and ignition sources

Keep away from food and drink

Avoid contact with skin and eyes and inhalation of vapour

Wash hands thoroughly after use and before eating

First aid:

For skin contact, remove contaminated clothing and wash affected area thoroughly with water. If irritation develops, seek medical attention.

For eye contact, immediately flush eyes with flowing water for at least 15 minutes and seek medical attention.

GHS Example plc, Leeds, England. Telephone 44 999 999 9999

** *Note that competent authorities may choose to not require disclosure of ingredient identities on the label of products intended for workplace use only – See Part I, chapter 4, paragraph 42.*

2. Label for small workplace container (10 litre) packaged inside an outer shipping container – for workplace audience

ZZZ Red Paint

DANGER

May damage fertility or the unborn child

Highly flammable liquid and vapour

** Contains lead pigments and cellosolve acetate

Keep away from heat and ignition sources
Keep away from food and drink
Avoid contact with skin and eyes and inhalation of vapour

Wash hands thoroughly after use and before eating

First aid:

For skin contact, remove contaminated clothing and wash affected area thoroughly with water. If irritation develops, seek medical attention.

For eye contact, immediately flush eyes with flowing water for at least 15 minutes and seek medical attention.

GHS Example plc, Leeds, England. Telephone 44 999 999 9999

** *Note that competent authorities may choose to not require disclosure of ingredient identities on the label of products intended for workplace use only.*

3. Outer shipping container has UN transport markings and label only – for transport and emergency response audiences.

UN 1263
Paint

Annex 8
An example of classification in the Globally Harmonized System

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NOTE: Under Review

CLASSIFICATION PROPOSAL: GHS1

The following classification proposal draws on the GHS criteria. The document includes both brief statements about the proposal for each health hazard endpoint and details of all the available scientific evidence.

Classification is proposed for both the acute toxicity and the corrosivity of this substance based on standard and non-standard animal studies. It should be noted that the current absence of GHS criteria for respiratory tract irritation is an issue for this substance.

Proposed classification	GHS:	Acute oral toxicity Category 4 Acute dermal toxicity Category 3 Skin irritation/corrosion Category 1C Eye irritation/corrosion Category 1 Flammable liquid Category 4

1. IDENTIFICATION OF THE SUBSTANCE

1.1 EINECS Name If not in EINECS IUPAC Name	Globalene Hazexyl Systemol
	CAS No. 999-99-9 EINECS No. 222-222-2
1.2 Synonyms (state ISO name if available)	2-Hazanol Globalethylene
1.3 Molecular formula	$C_xH_yO_z$
1.4 Structural formula	
1.5 Purity (w/w)	
1.6 Significant impurities or additives	
1.7 Known uses	*Industrial:* Solvent for surface coatings and cleaning solutions. Chemical intermediate for Globalexyl UNoxy ILOate. *General public:* Toilet cleaner

2. PHYSICO-CHEMICAL CHARACTERISTICS

Classification as a category 4 flammable liquid is proposed for the physico-chemical endpoints*

2.1	**Physical form**	Liquid
2.2	**Molecular weight**	146.2
2.3	**Melting point/range (°C)**	-45
2.4	**Initial Boiling point/ boiling range (°C)**	208.3
2.5	**Decomposition temperature**	
2.6	**Vapour pressure (Pa(°C))**	7
2.7	**Relative density (g/cm3)**	0.887 - 0.890
2.8	**Vapour density (air = 1)**	5.04
2.9	**Fat solubility (mg/kg, °C)**	
2.10	**Water solubility (mg/kg, °C)**	Slightly soluble (0.99% w/w)
2.11	**Partition coefficient (log Pow)**	
2.12	**Flammability** **flash point (°C)** **explosivity limits (%,v/v)** **auto-flammability temp. (°C)**	**closed cup:** 81.7 **open cup:** 90.6 **lower limit:** 1.2 **upper limit:** 8.4
2.13	**Explosivity**	No data available
2.14	**Oxidising properties**	
2.15	**Other physico-chemical properties**	

* *The secretariat has been advised that the content of this section should be checked carefully.*

3.1 ACUTE TOXICITY

There is no reliable information available about the potential of this substance to produce specific, non-lethal target organ/systemic toxicity arising from a single exposure. Therefore, under GHS, no classification for target organ/systemic toxicity (TOST) is proposed.

3.1.1 Oral

Classification under GHS Category 4 (300-2000 mg/kg) are justified.

Species	LD_{50} (mg/kg)	Observations and remarks	Ref.
Rat	1480	No further details were available.	2
Rat	1500 (males) 740 (females)	The LD_{50} values in mg/kg were calculated from ml/kg using the known density for EGHE of 0.89 g/cm^3.	8

3.1.2 Inhalation

There were no deaths or signs of overt toxicity in animals exposed to the saturated vapour concentration of approximately 0.5 mg/L and therefore, the available data do not support classification.

Species	LC_{50} (mg/l)	Exposure time (h)	Observations and remarks	Ref.
Rat	> 83 ppm. (approx equal to 0.5 mg/l).	4	No deaths, clinical signs or gross lesions occurred at 83 ppm (85 ppm is stated to be the saturated vapour concentration at room temperature).	3
Rat	Not stated	6	The animals were exposed to the saturated vapour concentration at room temperature (assumed to be 85 ppm). No deaths occurred and no signs of gross pathology were observed.	8
Rat	Not stated	8	No deaths occurred with exposure to the “saturated vapour concentration” at room temperature (assumed to be 85 ppm).	2

3.1.3 Dermal

Classification under GHS Category 3 (200-1000 mg/kg) is justified.

Species	LD_{50} (mg/kg)	Observations and remarks	Ref.
Rat	790	No further details were available.	2
Rabbit (5/sex/ group)	720 (males) 830 (females)	Animals were exposed to up to 3560 mg/kg for 24 hours. All but 2 of the animals that died did so during the application period. Following the exposure period, local toxicity (erythema, oedema, necrosis and ecchymoses) was reported in an unstated number of animals, and persisted throughout the 14 day post-application observation period. Ulceration was also noted in an unstated number of animals at the end of the observation period.	8

3.2 SKIN IRRITATION/CORROSION

There are conflicting reports concerning the irritant nature of this substance. In a dedicated skin irritation study reported in the same paper as the acute dermal study, the author states that “necrosis” was observed in 3 of 6 treated rabbits which was still present on the last day of observation (day 7), along with mild to moderate erythema. Mild to marked oedema was also observed during the course of the study but had resolved within the 7-day observation period. Given that one animal showed no evidence of any skin response in this study and that only slight to moderate skin irritation was observed in the other animals the observation of “necrosis” in three of the animals is somewhat surprising. An acute dermal toxicity study in rabbits also reported signs of dermal irritation including the description 'necrosis' and ulceration but did not quantify the number of animals affected. In contrast to these findings, an old and briefly reported study indicated that there was little or no indication of skin irritation in rabbits.

Similarly mixed skin irritation findings have been observed with a closely related substance, for which both necrosis and no skin irritation has been reported. In addition a secondary source indicates that some other similar substances cause 'moderate' skin irritation, and that prolonged exposure to these group of substances may cause burns. However, much shorter chain similar substances are not considered to be skin irritants.

We consider that the reported necrosis in both the acute dermal and skin irritation studies cannot be dismissed and, taken together with the findings seen with structurally similar substances, this justifies classification. There are 3 Categories under the GHS for classification as corrosive. The data do not match the criteria readily, but we propose that Category 1C is appropriate since the necrotic lesions observed occurred after an exposure period of 4 hours. There is no evidence to suggest that significantly shorter exposures would produce skin corrosion.

Species	No. of animals	Exposure time (h)	Conc. (w/w)	Dressing: (occlusive, semi-occlusive, open)	Observations and remarks (specify degree and nature of irritation and reversibility)	Ref.
Rabbit	6	4	0.5 ml of 100%	Occlusive	No signs of irritation was observed in one animal, and only slight erythema (grade 1) in another on day 1, which had resolved by day 7. Four animals showed a mild to moderate erythema (grade 1-2) and a mild to marked oedema (grade 1-3) after removal of the dressing. The oedema had resolved by day 7 post-exposure. "Necrosis" at the application site was reported in 3/6 rabbits from day 1 until the end of the observation period on day 7. Desquamation was observed in 4/6 rabbits on day 7.	8
Rabbit (albino)	5	24	100% (volume not stated)	Not stated	Little or no signs of skin irritation were found in this poorly reported study.	2

3.3 SEVERE DAMAGE TO EYES/ EYE IRRITATION

The only available study involved exposure of rabbits to considerably lower amounts of the test substance than the standard protocols for this endpoint recommend. Relatively severe (eg. conjunctival redness grade 3) but reversible effects were seen. We predict that under standard test conditions, the effects on the eye would be very severe and propose that GHS Category 1 (irreversible effects on the eye) is justified.

Species	No. of animals	Conc. (w/w)	Observations and remarks (specify degree and nature if irritation, any serious lesions, reversibility)	Ref.
Rabbit	6	0.005 ml of 100%	One hour post-instillation conjunctival redness (grade 3) and discharge (grade 2.8) observed. The mean scores for the 24, 48 and 72 hour readings for corneal opacity, iris, conjunctival redness, chemosis and discharge were all approx 0.5. All lesions had resolved by day 7. This study did not conform to the EU Annex V protocol in that only a very small amount of substance was used in the test.	8
Rabbit	60	1 and 5%.	A report in the secondary literature of severe eye injury observed in rabbits associated with instillation of an unstated amount of 5%, could not be substantiated as the information was not found in the reference stated.	1

3.4 IRRITATION OF THE RESPIRATORY TRACT

It is noted that irritant effects on the upper respiratory tract have not been reported in either single and repeat exposure studies in rats exposed to saturated vapour concentrations of the substance.

3.5 SKIN AND RESPIRATORY SENSITISATION

No data are available. There are no additional grounds for concern (eg. structure activity relationships) and no classification proposed.

3.6 TOXICITY FOLLOWING REPEATED EXPOSURE

3.6.1 Oral

No oral repeat dose studies are available and therefore no classification is proposed.

3.6.2 Inhalation

There was no evidence of adverse toxicity in a 13-week rat inhalation study at 0.43 mg/l (approx. 72 ppm), an exposure level close to the saturated vapour concentration. No classification is justified according to GHS criteria.

Species	conc. mg/l	Exposure time (h)	Duration of treatment	Observations and remarks (specify group size, NOEL, effects of major toxicological significance)	Ref.
Rat (F344) 20/sex / group (plus 10/ sex/group - 4 week recovery groups)	0.12, 0.24 & 0.425	6	5 d/wk for 13 weeks	No deaths occurred. Decreased weight gain was observed in high dose animals of both sexes and medium dose females. There were no toxicologically significant changes in haematological or urinalysis parameters. High dose females showed an increase in alkaline phosphatase. High and medium dose males showed a statistically significant increase in absolute and relative kidney weight. A small increase in absolute liver weight (12%) was observed in high dose females. However, there were no gross or histopathological changes in any organs examined.	3

3.6.3 Dermal

Unquantified haematological changes were reported in rabbits exposed to 444 mg/kg dermally for 11 days. However, due to the limited information provided, no conclusions can be drawn from this study and no classification is proposed.

Species	Dose mg/kg	Exposure time (h)	Duration of treatment	Observations and remarks (specify group size, NOEL, effects of major toxicological significance)	Ref.
Rabbit	0, 44, 222 & 444	6	9 doses applied over 11 days	This is an unpublished study reported in the secondary literature. Unquantified decreases in haematological parameters were noted in top dose animals. No description of local effects was provided.	1

3.7 CARCINOGENICITY (INCLUDING CHRONIC TOXICITY STUDIES)

No data available – no classification proposed.

3.8 MUTATIONS IN GERM CELLS

Negative results have been reported *in vitro* from Ames, cytogenetics, and gene mutation tests reported in the secondary literature. There are no *in vivo* data available. These data do not support classification.

3.8.1 *In vitro* studies

Test	Cell type	Conc. range	Observations and remarks	Ref.
Ames	Salmonella (strains unstated)	0.3-15 mg/plate	**Negative**, in the presence and absence of metabolic activation. This is an unpublished study described in a secondary source and no further information is available.	5
IVC	CHO	0.1-0.8 mg/ml (-S9), 0.08-0.4 mg/ml (+S9)	**Negative**, in the presence and absence of metabolic activation. This is an unpublished study described in a secondary source and no further information is available.	6
Gene mutation	CHO	Not stated	**Negative**. This is an unpublished study described in a secondary source and no further information is available.	7
SCE	CHO	Not stated	**Negative**. This is an unpublished study described in a secondary source and no further information is available.	7

3.9 REPRODUCTIVE TOXICITY - FERTILITY

No data available – no classification proposed.

3.10 REPRODUCTIVE TOXICITY - DEVELOPMENTAL TOXICITY

There was no evidence of developmental toxicity in rats or rabbits following inhalation exposure to levels inducing slight maternal toxicity. It is noted that although shorter chain related substances are classified for developmental toxicity, this toxicity decreases with increasing chain length such that there is no evidence of this hazar. No classification is proposed.

Species	Route	Dose	Exposure	Observations and remarks	Ref.
Rat	Inhalation	21, 41 & 80 ppm (0.12, 0.24 & 0.48 mg/L)	days 6-15 of gestation	The substance was tested up to approximately the saturated vapour concentration. Decreases in dam body weight gain, associated with decreases in food consumption, were observed in the medium and high dose groups during the exposure period. There was no evidence of developmental toxicity.	4
Rabbit	Inhalation	21, 41 & 80 ppm (0.12, 0.24 & 0.48 mg/L)	days 6-18 of gestation	The substance was tested up to approximately the saturated vapour concentration. Decrease in absolute body weight during the exposure period was observed in the high dose animals. There was no evidence of developmental toxicity.	4

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5. Etc.

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