Labelling of small packagings

Transmitted by the European Chemical Industry Council (CEFIC) on behalf of the informal correspondence group

Introduction

1. Building on the experience gained during biennium 2010-2012, at its 24th session the Sub-Committee asked the correspondence group to focus its work on the development of one or two examples illustrating the general principles applicable to the labelling of small packagings and addressing, to the extent possible, the following issues:

   (a) General issue of the redundancy of precautionary statements which requires first the consideration of the outcome of the informal correspondence group on annexes 1, 2 and 3.

   (b) Possible standardization of hazard information provided on inner labels for small packages.

   (c) Appropriateness of the inclusion of provisions regarding the minimum size of pictograms or text to ensure the readability of the information shown on the labels.

   (d) Difficulty to accommodate the labelling requirements and the need to give instructions for use which may be important for safety.

   (e) Lay out of the pictograms: contiguous (sharing the red border) or separate?

   (f) Possibility to include in the GHS provisions like those that exist in TDG regulations: creation of a simple generic symbol that would be more legible and could replace several - too small - symbols on very small packagings.

   (g) Possibility to define minimum label elements required on a label where it is impossible to include a full label even by using tie-on or fold-out labels.

   (h) Possibility to define precedence of hazard pictograms (similar to current TDG regulations for precedence of hazard characteristics) in the case where two or more hazard pictograms are required on a label for a very small packaging.

   (i) Possibility to define requirements for use of fold-out labels e.g. what label elements must go on the front page and what elements could appear on the internal fold-out page(s).
Development of a first example

2. As a first step, example 1 of informal document INF.21 (24th session) has been reworked in order to be more explicit on the available options and their applicability. It is proposed for consideration by the correspondence group and the sub-committee. Open questions have been left for discussion.

Example:

Small immediate container in a container which can display the entire information required on the label

Immediate container that cannot be labelled based on shape/size and restrictions relating to the method of use: Cardboard box containing 5 ampoules

(i) Substance:
   5 ampoules of blahzenic acid supplied in a cardboard box

(ii) Use:
   Laboratory reagent – professional use

(iii) Classification
   Acute toxicity oral Cat 2
   Acute toxicity dermal Cat 1
   Acute toxicity inhalation Cat 2
   Skin corrosion Cat 1B

(iv) Full labelling information
   • Pictograms:
     ![Pictograms]
   • Signal word:
     Danger
   • Hazard statements:
     H300+H310+H330 Fatal if swallowed, in contact with skin or if inhaled
     H314 Causes severe skin burns and eye damage
• Precautionary statements

(as assigned to the respective hazard categories in GHS Annex 3, Section 3 taking into account use/application, the number of precautionary statements required on the actual label may be reduced by excluding redundant/similar statements):

Prevention:
P264  Wash...thoroughly after handling
P270  Do not eat, drink or smoke when using this product
P262  Do not get in eyes, on skin or on clothing
P280  Wear protective gloves/protective clothing/eye protection/face protection
P260  Do not breathe dust/fume/gas/mist/vapours/spray
P271  Use only outdoors or in a well-ventilated area
P284  Wear respiratory protection

Response:
P301+P310: IF SWALLOWED: Immediately call a POISON CENTER / doctor/…
P321  Specific treatment (see … on this label)
P330  Rinse mouth;
P302+P352: IF ON SKIN: Gently wash with plenty of water /…
P310  Immediately call a POISON CENTER/doctor/…;
P361+ P364: Take off immediately all contaminated clothing and wash it before reuse.
P363  Wash contaminated clothing before reuse
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing
P320  Specific treatment is urgent (see … on this label)
P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting;
P303+P361+P353: IF ON SKIN (or hair): Take off all contaminated clothing. Rinse skin with water/shower
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Storage:
P405  Store locked up
P403+P233  Store in a well-ventilated place; Keep container tightly closed.

Disposal:
P501  Dispose of contents/container to…
(v) Packaging description and size
Cardboard box containing 5 glass ampoules. Each ampoule contains 0.5 grams blahzenic acid.

(vi) Labelling problems encountered
The working solution of this reagent is prepared by removing the top of the ampoule and placing the bottom half (containing the substance) in the required amount of deionized water. Consequently, labels cannot be applied to the actual ampoules as they may contaminate the working solution, which may affect subsequent reactions. It is impossible to put all applicable GHS label elements on the immediate container (i.e. the glass ampoule) due to its size and shape.

The area available on the outer cardboard box is large enough to carry a legible version of the required GHS label elements in a single language. Legibility is reduced if labelling in more than one official language is required. Legibility is also a concern in any labelling for the glass ampoule.

(vii) Possible options to address labelling problems encountered

GHS definition of “Label” (GHS chapter 1.2):
“Label means an appropriate group of written, printed or graphic elements concerning a hazardous product, selected as relevant to the target sector(s), that is affixed to, printed on, or attached to the immediate container of a hazardous product, or to the outside packaging of a hazardous product.”

General principles that should underpin labelling of small packaging (GHS 1.4.10.4.4):
(a) All the applicable GHS label elements should appear on the immediate container of a hazardous substance or mixture where possible;
(b) Where it is impossible to put all the applicable label elements on the immediate container itself, other methods of providing the full hazard information should be used in accordance with the definition of “Label” in the GHS. Factors influencing this include inter alia:
   (i) the shape, form or size of the immediate container;
(ii) the number of label elements to be included, particularly where the substance or mixture meets the classification criteria for multiple hazard classes;

(iii) the need for label elements to appear in more than one official language.

(c) Where the volume of a hazardous substance or mixture is so low and the supplier has data demonstrating, and the competent authority has determined, that there is no likelihood of harm to human health and/or the environment, then the label elements may be omitted from the immediate container;

(d) Competent authorities may allow certain label elements to be omitted from the immediate container for certain hazard classes/categories where the volume of the substance or mixture is below a certain amount;

(e) Some labelling elements on the immediate container may need to be accessible throughout the life of the product, e.g. for continuous use by workers or consumers.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Potential options</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label cannot be applied directly to or printed on the immediate container (i.e. the glass ampoule) as it may contaminate the working solution, which may affect subsequent reactions</td>
<td>Provide label elements in a fold-out label</td>
<td>Not practical as fold-out label cannot be directly affixed to the glass ampoule (to avoid potential contamination of the working solution)</td>
</tr>
<tr>
<td>Provide label elements on a tie-on tag</td>
<td></td>
<td>Not practical as tie-on tag cannot be directly affixed to the glass ampoule (to avoid potential contamination of the working solution)</td>
</tr>
<tr>
<td>Provide label elements on an outer packaging</td>
<td></td>
<td>Not acceptable to only provide label elements on outer packaging - general principles requires all applicable label elements to appear on immediate container where possible; also some label elements on the immediate container may need to be accessible to users throughout life of product</td>
</tr>
<tr>
<td>Not possible to put all applicable GHS label elements on the immediate container (i.e. the glass ampoule) due to its size and shape</td>
<td>Seal the unlabelled ampoule in a polythene sleeve with an end tag for a label - ampoule is not removed from the polythene sleeve until the point of intended use, i.e. preparation of the working solution.</td>
<td></td>
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<tr>
<td>Area available for a label on polythene sleeve end tag is not sufficient to include all required label elements</td>
<td>Label on the polythene sleeve end tag (using both sides of the end tag if needed) should contain at least hazard pictograms, product identifier and name/telephone of the supplier; all required label elements should appear on the outside packaging</td>
<td>Could use both sides of the end tag if needed Increasing the size of the end tag is not practical (i.e. need to avoid using larger packaging) Language requirements (e.g. country where product is placed on the market)</td>
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<td>has more than one official language) may limit amount of labelling</td>
<td></td>
<td>Issues to be discussed:</td>
</tr>
<tr>
<td>information that can be fitted on the end tag</td>
<td></td>
<td>- minimum label elements required on a label where it is impossible to include a full label even by using fold-out labels</td>
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<td></td>
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<td>- minimum size of pictograms or text to ensure the readability of the information</td>
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<td></td>
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<td>- layout of the pictograms (contiguous or separate)</td>
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<td>- possibility of a simple generic symbol or precedence of hazard pictograms</td>
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<td></td>
<td>Affix a fold-out label to the polythene sleeve end tag</td>
<td>Issues to be discussed; provisions for fold-out labels e.g. what label elements must go on the front page and what elements could appear on the internal fold-out page(s)</td>
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<tr>
<td>All required label elements appear on the outside packaging.</td>
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<td>However, it may not be possible to produce a legible label for the</td>
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<td>outside packaging where the country in which the product is used has</td>
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<td>more than one official language,</td>
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<td>If labelling is required in more than one official language, a fold-out label</td>
<td>Avoids using larger packaging (sustainability)</td>
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<td>could be securely attached to the outer cardboard box</td>
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<td>Issues to be discussed: provisions for fold-out labels e.g. what label elements must go on the front page and what elements could appear on the internal fold-out page(s)</td>
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<td></td>
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<td>For example, the hazard pictograms, signal word, hazard statements (in the required official languages) and supplier details appear on the front of the folded label whilst the precautionary statements and other supplemental information appear in the fold-out part. The fold-out label is produced in a way such that the front part cannot be detached from the reminder of the label or the outside packaging.</td>
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(viii) Proposed/suggested solution

Immediate container

The area available for a label on the end tag is not sufficient to include all required label elements. The proposed solution would be to include at least the hazard pictograms, product identifier and name plus telephone number of the supplier. This would ensure that the user is aware of the substance identity (enables identification of the associated substance SDS), its hazards (indicates that the substance is hazardous and needs to be handled/stored appropriately) and the name/contact details of the supplier (if needed in an emergency situation). All required label elements (including hazard and precautionary statements plus signal word) would appear on the outside packaging.
Outside packaging

BLAHZENIC ACID  CAS No. xxx-xx-xx

DANGER

Fatal if swallowed, in contact with skin or if inhaled
Causes severe skin burns and eye damage

Wear protective gloves/clothing and eye/face protection.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a POISON CENTER or doctor
IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor
Wash contaminated clothing before reuse.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Store locked up
Dispose of contents/container to a hazardous waste disposal site

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