SLOVENSKI STANDARD
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Embalaža - Elementi za prepoznavanje proizvodov (nevarnih preparatov) v nujnih primerih s pomočjo označb

Elements for the identification of products in emergency enquiries

Elemente zur Produktidentifikation bei Notfallanfragen

Eléments pour l'identification des produits lors des appels d'urgence

Ta slovenski standard je istoveten z: **EN 15178:2007**

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55.020	Pakiranje in distribucija blaga na splošno	Packaging and distribution of goods in general

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EUROPEAN STANDARD

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English Version

Elements for the identification of products in emergency enquiries

Eléments pour l'identification des produits lors des appels d'urgence

Elemente zur Produktidentifikation bei Notfallanfragen

This European Standard was approved by CEN on 13 July 2007.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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Foreword

This document (EN 15178:2007) has been prepared by CEN/BT/TF/154 “Product identification”, the secretariat of which is held by DIN.

This document shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2008 and conflicting national standards shall be withdrawn at the latest by February 2008.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

After an accident or inappropriate use of products such as intake by ingestion, inhalation, aspiration or skin contact, the poison information centres give immediate information about any potential danger and make suggestions regarding treatment.

To give the best advice, poison information centres need to be able to identify unambiguously products that have been involved by accident or inappropriate use. However, in practice product, packaging contains a lot of information which can complicate clear product identification. This European Standard improves product identification by introducing a product identification field on the packaging, marked by a symbol, and where at least one clear identification element is present.

Provided that the packaging of the relevant product is still available to the caller after an accident or inappropriate use, the identification element(s) can help the poison information centres to identify quickly the exact product. With the product information available in a structured – preferably electronic – form, the poison information centres will be able to give adequate advice for treatment.

This European Standard should be understood as a possible component in trying to make improvements in product safety and it does not replace the need for responsible care when dealing with products in the broader sense.

1 Scope

This European Standard specifies requirements for an area on the packaging – the product identification field – marked by a symbol, where clear product identification element(s) is (are) present. This European Standard applies to products that are the subject of emergency enquiries to the poison information centres.

This European Standard does not apply to medicinal products (human and veterinary drugs) (see [2], [3]) and medical devices (see [4], [5]), as information requirements are already covered.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
poison information centre
institution that provides information about all aspects of human exposure, especially in cases of accidents or inappropriate use of products

2.2
bar code
order of parallel rectangular lines and spaces that are in accordance with the rules of a particular specification of symbols and that represent data in machine-readable form

[EN 1556:1998, 3.14]

2.3
primary packaging
packaging designed to come into direct contact with the contents

2.4
secondary packaging
packaging designed to contain one or more primary packages and including any protective materials, if present

2.5
product identification field
combination of the graphical symbol and the identification element(s)

3 Requirements for the product identification field

3.1 General

Products shall be clearly and easily identifiable.

3.2 Identification elements and their arrangement

At least one identification element, sufficient for unique product and formulation identification, shall be placed on the primary packaging of the product. If this is not feasible, the product identification field shall be placed on the secondary packaging of the product. The identification element shall be changed if there is a relevant alteration to the formula of the product, affecting its physico-chemical and/or toxicological properties (see Annex A).

Suitable identification elements should include at least one of the following pieces of information, e.g.:

— clear product/trade name (long product names may be abbreviated);

— accompanying article number;

— registration number;

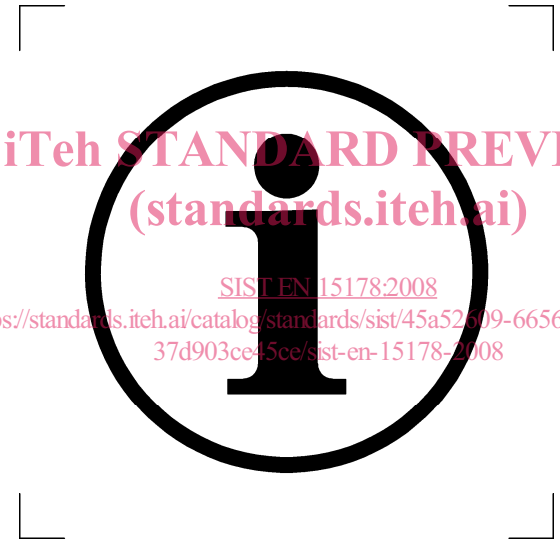
— authorization number.

For examples, see Annex B.

NOTE Wherever practical, it is recommended to use the first 128 characters of the ASCII character set. This will facilitate electronic identification and data exchange. Phonetic data transfer from the caller to the poison information centres and processing in databases without special characters is more effective.

3.3 Design and arrangement of the product identification field

The following symbol shall be placed before the identification element.



NOTE In cases of dark backgrounds the symbol may be reproduced inversely (e.g. white on a black background).

Figure 1 — Graphic symbol "Product information" [ISO 7000]

The symbol and the identification element(s) shall be legible and indelible. The letter "i" in the symbol shall be at least the same font size as the identification element.

The product identification field consisting of the graphic symbol and the product identification element(s) (see 3.2) should be adjacent to the bar code, if available. The address of the party responsible for placing of the product on the market should be placed in close proximity to the product identification field, if possible.

The product identification field shall not be rendered unrecognisable when opening the packaging in the recommended way.

Annex A
(informative)

Rationale

A.1 General

The following explanations should be considered as examples for certain categories of products to decide as to when the identification element shall be changed due to relevant altering in the formula of the product that affects its physico-chemical and/or toxicological properties according to 3.2.

A.2 Dangerous preparations/substances

A relevant alteration is any change in preparation that leads to a change in classification according to the Dangerous Preparations/Substances Directives (see [6], [7]). The Dangerous Preparation Directive [7] states in article 4 and article 5 when a change in a preparation leads to a new evaluation of the physico-chemical and/or toxicological properties.

The Biocidal Products Directive [8] states that biocides should be classified according to the Dangerous Preparation Directive (article 20).

A.3 Other preparations (not classified as dangerous)

A relevant alteration in preparations that are not classified as dangerous can be identified by:

— changes in the pH-value of preparations by more than 1 pH if the pH is ≤ 3 or ≥ 11,5;

— changes in the number of ingredients, or changes of ± 20 % in the relative concentration of an ingredient.

EXAMPLE

Ingredient: Sodium chloride in a concentration of 4 %; change needs to be notified if the ingredient has a share of under 3,2 % or over 4,8 % in the changed formulation.

A.4 Cosmetic products

In several European countries a frame formulation system according to [9], [10] has been established.

In case a frame formulation system may be used, a relevant alteration is any change in the formulation of the product to be notified to poison information centres corresponding to Form 1, Form 2 and Form 3.

Form 1: Products covered by a frame formulation where no additional information about the composition of the product is required.

Form 2: Products covered by a frame formulation with additional information concerning the product composition.

Form 3: This applies to products without frame formulation. The exact formulation is required.