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European foreword

This document (EN 71-13:2021) has been prepared by Technical Committee CEN/TC 52 “Safety of toys”, the secretariat of which is held by DS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2021, and conflicting national standards shall be withdrawn at the latest by April 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 71-13:2014.

This document has been prepared under a standardization request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive 2009/48/EC, see informative Annex ZA, which is an integral part of this document.

Additional information on the rationale for various requirements is given in Annex A.

The significant changes from the previous edition of this standard are detailed in Annex D.

This document constitutes the thirteenth part of the EN 71 series of standards on safety of toys.

EN 71, *Safety of toys* consists of the following parts:

- *Part 1: Mechanical and physical properties;*
- *Part 2: Flammability;*
- *Part 3: Migration of certain elements;*
- *Part 4: Experimental sets for chemistry and related activities;*
- *Part 5: Chemical toys (sets) other than experimental sets;*
- *Part 7: Finger paints — Requirements and test methods;*
- *Part 8: Activity toys for domestic use;*
- *Part 9: Organic chemical compounds — Requirements;*
- *Part 10: Organic chemical compounds — Sample preparation and extraction;*
- *Part 11: Organic chemical compounds — Methods of analysis;*
- *Part 12: N-nitrosamines and N-nitrosatable substances;*
- *Part 13: Olfactory board games, cosmetic kits and gustative games;*
- *Part 14: Trampolines for domestic use.*

It is up to the user of the standard to determine whether or not a toy is included in the scope of several of the above parts of the EN 71-series, and to apply each applicable standard accordingly. Normative references from one part of the EN 71-series to another, are therefore normally not provided in the individual parts.

NOTE 1 In addition to the above parts of EN 71, the following technical reports have been published:

- CEN/TR 15071, *Safety of toys — National translations of warnings and instructions for use in EN 71*, and
- CEN/TR 15371 (parts 1 and 2), *Safety of toys — Interpretations*;
- CEN/TR 16918, *Safety of toys — Children's mouthing behaviour in contact with toys*;
- CEN ISO/TR 8124-8, *Safety of toys — Part 8: Age determination guidelines*.

NOTE 2 Words in *italics* (apart from document titles) are defined in Clause 3 (Terms and definitions).

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

Introduction

This document EN 71-13 is intended to reduce the risks and health hazards to a child when *olfactory board games*, *cosmetic kits* and *gustative games* are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

During use of these toys, the hazards should be kept to a minimum by the provision of appropriate information to make the play safe and controllable. Therefore, this document specifies warning phrases and instructions for use for these toys.

As a general rule, toys are designed and manufactured for particular ages of children. Their characteristics are related to the age and stage of development of the children, and their use presupposes certain aptitudes. Therefore, age requirements are given.

The requirements of this document do not release parents or carers from their responsibility of watching over the child while he or she is playing. On the contrary, the use of these sets requires close supervision by adults.

1 Scope

This document applies to *olfactory board games, cosmetic kits, gustative games* and *supplementary sets*. It specifies requirements on the use of substances and mixtures and in some cases on their amount and concentration in *olfactory board games, cosmetic kits, gustative games* and *supplementary sets* to such games or kits.

These substances and mixtures are:

- those classified as hazardous by the EC-legislation applying to hazardous substances [13] and hazardous mixtures [13];
- substances and mixtures which in excessive amounts could harm the health of the children using them and which are not classified as hazardous by the above-mentioned legislation; and
- any other chemical substance(s) and mixture(s) delivered with the set.

Furthermore, this document specifies allergenic fragrances which are prohibited in toys, marking requirements, in particular regarding allergenic fragrances, and requirements on a contents list, instructions for use, the equipment intended to be used during the activity and the use of highly flammable liquids.

This document does not apply to cosmetic toys such as play cosmetics for dolls.

NOTE The terms “substance” and “mixture” are defined in the REACH regulation (EC) No. 1907/2006 [14] and in the CLP regulation (EC) No. 1272/2008 [13].

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 71-1:2014+A1:2018, *Safety of toys - Part 1: Mechanical and physical properties*

EN ISO 8317:2015, *Child-resistant packaging - Requirements and testing procedures for reclosable packages (ISO 8317:2015)*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1

olfactory board game

toy, the purpose of which is to assist a child to learn to recognize different odours or flavours

Note 1 to entry: *Olfactory board games* include activities of smelling and/or tasting as olfactive recognition can be done by retro-olfaction.

3.2

cosmetic kit

toy, the purpose of which is to assist a child to learn to make products such as fragrances, soaps, creams, shampoos, bath foams, glosses, lipsticks, other make-up, toothpaste and conditioners

3.3

gustative game

toy, the purpose of which is to allow children to make sweets or dishes which involve the use of food ingredients such as sweets, liquids, powders and aromas

Note 1 to entry: Commonly used terms for *gustative game* are “gustative kit” and “food kit”.

3.4

supplementary set

incomplete *olfactory board game*, *cosmetic kit* or *gustative game* which is intended to be used with a complete game or kit

3.5

packaging

material accompanying the toy when purchased but having no intended play function

4 Requirements (see A.4)

4.1 Olfactory board games

4.1.1 General

Olfactory board games shall be supplied with instructions for use (see Clause 7) and first aid information if applicable (see Clause 8).

4.1.2 Substances and mixtures

4.1.2.1 Olfactory board games using substances and mixtures recognized as food flavours or food ingredients

Only substances and mixtures recognized as food flavours and food ingredients shall be used.

NOTE Food flavours and other food ingredients are subject to the relevant food legislation, e.g. Regulation (EC) No 178/2002 [7] (“general food law”), Regulation (EC) No 1334/2008 [6] (flavours), and Regulation (EC) No 1333/2008 [5] and Commission Regulation (EU) No 231/2012 [19] (food additives) and Regulation (EU) No 1169/2011 [8] (food information to consumers).

4.1.2.2 Olfactory board games using not only substances and mixtures recognized as food flavours or food ingredients

NOTE 1 With regard to the following requirements it is important to consider Regulation (EC) No. 1272/2008 [13].

Besides substances and mixtures recognized as food flavours and food ingredients also substances or mixtures which have been assessed to pose no risk under normal conditions of use taking into account the behaviour of children may be used.

NOTE 2 As an example, a substance classified as skin sensitizing which cannot come into contact with the skin may be acceptable.

NOTE 3 Food ingredients are subject to the relevant food legislation, e.g. Regulation (EC) No 178/2002 [7] (“general food law”), Regulation (EC) No 1334/2008 [6] (flavours), Regulation (EC) No 1333/2008 [5] and Commission Regulation (EU) No 231/2012 [19] (food additives) and Regulation (EU) No 1169/2011 [8] (food information to consumers).

4.1.2.3 Further requirements for all types of olfactory board games

Only preservatives which under intended and foreseeable use conditions have been assessed as having no risk taking into account the behaviour of children shall be used in *olfactory board games* and *supplementary sets for olfactory board games*.

NOTE 1 Regulation (EC) No 1223/2009 [2] and Regulation (EC) No 1333/2008 [5] contain requirements on the use of preservatives. It is important to consider these requirements in the assessment.

Olfactory board games and *supplementary sets for olfactory board games* for children below 36 months shall not contain any fragrance listed in Table 1. Other *olfactory board games* and *supplementary sets for olfactory board games* may contain the fragrances listed in Table 1. *Olfactory board games* and *supplementary sets for olfactory board games* involving tasting shall only contain substances allowed by food legislation, taking into account all legal requirements, especially specific limits given there.

NOTE 2 Certain substances, e.g. “coumarin”, are restricted/not permitted in Regulation (EC) No 1334/2008 [6].

If any of the fragrances specified in Table 1 are supplied in the *olfactory board game* or *supplementary set*, specific warning requirements apply (see 6.1 and 6.3).

Olfactory board games and *supplementary sets for olfactory board games* shall not contain the allergenic fragrances listed in Table 2. However, the presence of traces of these fragrances is permitted provided that such presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg per fragrance.

NOTE 3 The lists of allergenic fragrances in Table 1 and Table 2 originate from Directive 2009/48/EC [1] (see A.1). The lists in Directive 2009/48/EC [1] are subject to change.

Table 1 — Allergenic fragrances which require a warning

Name of the allergenic fragrance	CAS number
Amyl cinnamal	122-40-7
Amylcinnamyl alcohol	101-85-9
Benzyl alcohol	100-51-6
Benzyl salicylate	118-58-1
Cinnamyl alcohol	104-54-1
Cinnamal	104-55-2
Citral	5392-40-5
Coumarin	91-64-5
Eugenol	97-53-0
Geraniol	106-24-1
Hydroxy-citronellal	107-75-5
Hydroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4
Isoeugenol	97-54-1
Oakmoss extracts	90028-68-5
Treemoss extracts	90028-67-4
Anisyl alcohol	105-13-5
Benzyl benzoate	120-51-4
Benzyl cinnamate	103-41-3
Citronellol	106-22-9
Farnesol	4602-84-0
Hexyl cinnamaldehyde	101-86-0
Lilial	80-54-6
d-Limonene	5989-27-5
Linalool	78-70-6
Methyl heptine carbonate	111-12-6
3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5

Table 2 — Allergenic fragrances which shall not be supplied in toys covered by this document

Name of the allergenic fragrance	CAS number
Alanroot oil (<i>Inula helenium</i>)	97676-35-2
Allylthiocyanate	57-06-7
Benzyl cyanide	140-29-4
4 tert-Butylphenol	98-54-4
Chenopodium oil	8006-99-3
Cyclamen alcohol	4756-19-8
Diethyl maleate	141-05-9
Dihydrocoumarin	119-84-6
2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0
3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9
Dimethyl citraconate	617-54-9
7,11-Dimethyldodeca-4,6,10-trien-3-one	26651-96-7
6,10-Dimethylundeca-3,5,9-trien-2-one	141-10-6
Diphenylamine	122-39-4
Ethyl acrylate	140-88-5
Fig leaf, fresh and preparations	68916-52-9
trans-2-Heptenal	18829-55-5
trans-2-Hexenal diethyl acetal	67746-30-9
trans-2-Hexenal dimethyl acetal	18318-83-7
Hydroabietyl alcohol	13393-93-6
4-Ethoxy-phenol	622-62-8
6-Isopropyl-2-decahydronaphthalenol	34131-99-2
7-Methoxycoumarin	531-59-9
4-Methoxyphenol	150-76-5
4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
Methyl trans-2-butenoate	623-43-8
6-Methylcoumarin	92-48-8
7-Methylcoumarin	2445-83-2
5-Methyl-2,3-hexanedione	13706-86-0
Costus root oil (<i>Saussurea lappa</i> Clarke)	8023-88-9
7-Ethoxy-4-methylcoumarin	87-05-8

Name of the allergenic fragrance	CAS number
Hexahydrocoumarin	700-82-3
Peru balsam, crude (Exudation of <i>Myroxylon pereirae</i> (Royle) Klotzsch)	8007-00-9
2-Pentylidene-cyclohexanone	25677-40-1
3,6,10-Trimethylundeca-3,5,9-trien-2-one	1117-41-5
Verbena oil (<i>Lippia citriodora</i> Kunth)	8024-12-2
Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
4-Phenyl-3-buten-2-one	122-57-6

4.2 Cosmetic kits

4.2.1 General

Cosmetic kits (as multi-component cosmetic products) and its individual components to be mixed based on clear instructions, are for the purpose of this document considered as cosmetic products, e.g. soap chips to be mixed with a colouring mixture and a fragrance mixture, or a cream base to be mixed with a perfuming mixture.

NOTE Therefore, the European cosmetic products regulation (including marking and labelling) applies to *cosmetic kits* and individual components which are cosmetic products. See cosmetics borderline manual [20] for more information on how to address *cosmetic kits* according to the cosmetic products regulation.

Cosmetic kits shall be supplied with instructions for use (see Clause 7).

The use of denatured alcohol (ethanol) or substances that are not classified as hazardous substances or mixtures that are not classified as hazardous mixtures [13] (e.g. drinking water, salt, sugar or honey) not supplied with the *cosmetic kit* may be suggested in the instructions for use.

Cosmetic kits shall be supplied with a contents list, warnings and first aid information (see Clause 8). The first aid information and the instructions for use can be on the *packaging* and/or the instruction sheet.

Cosmetic kits shall be supplied with an ingredient list visible from outside the *packaging*. For marking requirement see Clause 6.

4.2.2 Fragrances

Cosmetic kits and *supplementary sets* for *cosmetic kits* may contain the substances listed in Table 1. If any of the fragrances specified in Table 1 are supplied in the *cosmetic kit* specific warning requirements apply (see 6.1).

The intended and possible reactions between all fragrances and other components of *cosmetic kits* shall be checked by the manufacturer in order to evaluate that no reaction products or mixtures could be formed, which could harm the health of children (including skin reaction etc.) using the kit.

Cosmetic kits and *supplementary sets* for *cosmetic kits* shall not contain any of the allergenic fragrances listed in Table 2. However, the presence of traces of these fragrances is permitted provided that such presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg per fragrance.

4.2.3 Resulting products - Cosmetic Safety Requirements (see A.2)

The resulting product(s) made by a child using a *cosmetic kit* in accordance with the instructions for use are considered as cosmetic products and therefore must comply with the relevant requirements of relevant legislation on cosmetics, i.e. Regulation (EC) No 1223/2009 [2].

4.3 Gustative games

4.3.1 General

Gustative games shall be supplied with instructions for use (see Clause 7).

Gustative games shall be supplied with a contents list, warnings and first aid information (see Clause 8). The first aid information and the instructions for use can be on the *packaging* and/or the instruction sheet.

The use of food ingredients (e.g. drinking water, salt, sugar or honey) not supplied with the *gustative game* may be suggested in the instructions for use.

Gustative games shall be supplied with an ingredient list visible from outside the *packaging*. For marking requirement see Clause 6.

4.3.2 Substances and mixtures

Substances and mixtures recognized as food flavours and other food ingredients shall be used.

NOTE Food flavours and food ingredients are subject to the relevant food legislation, e.g. Regulation (EC) No 1334/2008 [6] (flavours), Regulation (EC) No 1333/2008 [5] and Regulation (EU) No 231/2012 [19] (food additives), Regulation (EC) No 178/2002 [7] ("general food law") and Regulation (EU) No 1169/2011 [8] (food information to consumers).

The intended and possible reactions between all substances and mixtures of *gustative games* shall be assessed by the manufacturer in order to ascertain that no reaction products or mixtures could be formed that could harm the health of the children using the kit.

Besides substances and mixtures recognized as food flavours and other food ingredients, *gustative games* and *supplementary sets* for *gustative games* may only contain the substances listed in Table 1 except those substances not allowed by food legislation. If any of the fragrances specified in Table 1 are supplied in the *gustative game*, specific warning requirements apply (see 6.1 and 6.3).

Gustative games and *supplementary sets* for *gustative games* shall not contain the allergenic fragrances listed in Table 2. However, the presence of traces of these fragrances is permitted provided that such presence is technically unavoidable under good manufacturing practice, does not exceed 100 mg/kg per fragrance and still fulfil the corresponding requirements given in food legislation.

4.3.3 Resulting products

The resulting product(s) made by a child using a *gustative game* in accordance with the instructions for use must be in compliance with the relevant requirements of legislation on food. Heating as part of the activity used to obtain the resulting product, shall only be specified in the instructions for use if the manufacturer has ensured that such heating does not lead to a harm to the health of the children using the game.

NOTE Food ingredients are subject to the relevant food legislation, e.g. Regulation (EC) No 1334/2008 [6] (flavours), Regulation (EC) No 1333/2008 [5], and Commission Regulation (EU) No 231/2012 [19] (food additives), Regulation (EC) No 178/2002 [7] ("general food law") and Regulation (EU) No 1169/2011 [8] (food information to consumers).

4.3.4 Food allergens

If allergenic food ingredients are supplied with the *gustative game*, these ingredients shall be labelled visible from outside the *packaging*.

NOTE For information on the labelling of allergenic food ingredients see Regulation (EU) No 1169/2011 [8]. This Regulation's Annex II also lists commonly known food allergens.

5 Equipment

5.1 General

For the safety assessment required by Directive 2009/48/EC [1], here of *olfactory board games* and *gustative games*, special attention should be given to the material of the equipment supplied that can reasonably be expected to be brought or are already in contact with food or food ingredients.

NOTE Relevant legislation for food contact material are Regulation (EC) No 1935/2004 [3] and Regulation (EU) No 10/2011 [4]. Further guidance might be found in Resolution CM/Res(2013)9 on metals and alloys used in food contact materials and articles [21].

5.2 Containers and glassware

5.2.1 Glassware

In sets where the instructions for use include activities in which glassware is heated, all glassware intended to be heated shall be made of borosilicate glass in order to be heat resistant.

When necessary, borosilicate glass shall be identified by the test method described in Annex B.

5.2.2 Containers for fragrances, substances and mixtures

5.2.2.1 General

Containers, except if made of glass, for fragrances, substances and mixtures shall not break or crack when tested according to the drop test specified in EN 71-1:2014+A1:2018.

Containers made of glass do not have to be tested as they are covered by EN 71-1:2014+A1:2018, 4.5 a) (accessible glass may be used where its use is necessary to the function of the toy).

Containers shall differ in size and shape from laboratory glassware to avoid them being mistaken as glassware for use in the activities specified in the instructions for use.

All containers supplied in *gustative games* and all containers in *olfactory board games* which contain food ingredients must be in compliance with relevant food contact material legislation.

NOTE Relevant legislation for food contact material are Regulation (EC) No 1935/2004 [3] and Regulation (EU) No 10/2011 [4].

5.2.2.2 Maximum content of flammable liquids in cosmetic kits and gustative games

The maximum content of a container shall not exceed:

- 10 ml for liquids having a flash point < 23 °C and an initial boiling point > 35 °C;
- 30 ml for liquids having a flash point ≥ 23 °C and ≤ 60 °C.

5.2.3 Child-resistant containers

If, after the safety assessment made by the manufacturer, child-resistant containers are needed for substances and mixtures classified as hazardous by the EC-legislation applying to hazardous substances [13], [14], and hazardous mixtures [13], [14], the child-resistant containers shall comply with EN ISO 8317:2015.

NOTE 1 Regulation (EC) No. 1272/2008 [13] specifies requirements on child resistant containers.

Closures for child-resistant containers intended to be used for liquids shall not break, crack or leak when tested according to the following procedure:

- Fill the container with water. The filling volume shall be 3/4 of the container volume.
- Attach the closure.
- Drop the filled container including its closure with its closure facing downwards five times from a height of (850 ± 50) mm on to a 4 mm thick steel plate according to the steel plate specified in EN 71-1:2014+A1:2018, 8.5;
- Check visually for any breaks, cracks or leakages of the closure.

NOTE 2 Compliance with these requirements is intended to prevent younger children accessing materials contained in such containers.

5.3 Equipment for the transfer of liquid

Mouth-actuated pipettes shall not be supplied. Where the transfer of liquid is required, a mechanical means which does not permit aspiration by the mouth shall be provided (e.g. a dropper with a permanently fitted teat).

5.4 Eye protection

Eye protection shall be provided if needed according to the safety assessment made by the manufacturer.

NOTE Eye protection provided with the set is Personal Protective Equipment. It is therefore subject to the requirements of Regulation (EU) 2016/425 on personal protective equipment [15].

6 Warnings and markings (see A.4 and A.7)

6.1 General markings and warnings

Olfactory board games, gustative games, cosmetic kits, and supplementary sets shall bear the following markings:

- batch number, on the *packaging*;
- if relevant, an exhaustive list of the ingredients contained in the game or kit, including any of the allergenic fragrances listed in Table 1. As a minimum, this information shall be listed on the *packaging*;
- if relevant, the shelf life or “used by” date or a period after opening on the *packaging* which shall be clearly legible.

NOTE The cosmetic legislation and food stuff legislation lay down additional marking requirements, e.g. list of ingredients, batch numbers on individual containers for *cosmetic kits* and *gustative games*. See A.7 for cosmetics labelling.

Gustative games, cosmetic kits, and supplementary sets to such kits/games shall bear the following warnings on the *packaging*:

- “Warning. Not suitable for children under (*) years. For use under adult supervision”;
- “Read the instructions before use, follow them and keep them for reference”;
- “Keep the game/kit out of reach of children under (**) years old”.

(*) The age is to be specified by the manufacturer or authorized representative. The age shall be 3 years or older according to the assessment of the manufacturer or authorized representative.

(**) The age is to be specified by the manufacturer or authorized representative.

The *packaging of olfactory board games, cosmetic kits, gustative games and supplementary sets* to such games/kits, that contain one or more of the allergenic fragrances listed in Table 1 shall carry the following warning:

“Warning. Not suitable for children under 36 months. Contains fragrances that may cause allergies.” or
“Warning. Not suitable for children under three years. Contains fragrances that may cause allergies.”

The phrase: “Not suitable for children under 36 months” or “Not suitable for children under three years” may be substituted by the symbol as specified in Figure 1.



Figure 1 — Age-warning symbol

The details of the design shall be as follows:

- the circle and the stroke shall be red;
- the background shall be white;
- the age range and the outline of the face shall be black;
- the symbol shall have a diameter of at least 10 mm and the proportions between its different elements shall be such as those prescribed in Figure 1.

The symbol shall be used to indicate only “0 to 3” years and not for any other age-grade warning to avoid misinterpretation of the symbol

This warning shall not apply to games/kits which, on account of their function, dimensions, characteristics or properties, or on other cogent grounds, are manifestly unsuitable for children under 36 months. In this case, the *packaging of olfactory board games, cosmetic kits, gustative games and supplementary sets* to such games/kits, that contain one or more of the allergenic fragrances listed in Table 1 shall carry the following warning:

“Warning. Contains fragrances that may cause allergies”.

The *packaging* of *olfactory board games*, *cosmetic kits*, *gustative games* and *supplementary sets* to such games/kits, that contain highly flammable liquids shall carry the following warning:

“Warning. Contains highly flammable liquids. Not to be used by children under (***) years”.

(***) The age is to be specified by the manufacturer or authorized representative. The age shall be 8 years or older according to the assessment of the manufacturer or authorized representative.

6.2 Markings on individual containers and individual packaging for reagents, substances or mixtures

Individual containers and individual *packaging* shall be marked with the content (e.g. substance name, mixture name or material name or other identifying element).

Any child-resistant container shall be marked and bear warnings in accordance with the appropriate requirements.

NOTE 1 These specifications are detailed in Regulation (EC) No. 1272/2008 [13].

NOTE 2 With regard to *cosmetic kits* and its individual components see marking and labelling requirements of the European cosmetic products regulation [2] and cosmetics borderline manual [20].

6.3 Warning phrase for food allergens

The *packaging* of *gustative games*, *olfactory board games*, and *supplementary sets* to such games, that contain allergenic food ingredients shall carry the following warning:

“Warning. Contains (*) that may cause food allergy”.

(*) The name(s) of the ingredient(s) shall be given in the warning text.

NOTE For information on commonly known food allergens, see Regulation (EU) No 1169/2011 [8], Annex II.

6.4 Warning phrase when glass is used as container

When glass containers are supplied, the following warning shall be marked on the *packaging* or in the instructions for use:

“Warning. Contains glass that may break”.

7 Instructions for use

Detailed information on how to perform each activity shall be given.

Any known hazards arising from the use of the set, especially during the activity, shall be addressed in detail in the instructions for use (e.g. handling of food ingredients and handling of glassware).

If applicable, the instructions for use shall contain an indication of the shelf life of the products made according to the instructions as determined by the manufacturer.

8 Contents list and first aid information

The contents list of *cosmetic kits* and *gustative games* and *supplementary sets* shall contain the following information:

a) a list of the chemicals supplied;

b) as appropriate for the product, general first aid information such as:

“In case of eye contact: Wash out eye with plenty of water. Seek immediate medical advice if necessary”.

For *cosmetic kits*, add the following information:

“If swallowed: Wash out mouth with water and drink some fresh water. Do not induce vomiting. Seek immediate medical advice”.

The first aid information (see Clause 8) shall be on the *packaging* and/or the instructions for use.

Annex A (informative)

Rationale

A.1 Allergenic fragrances (see Clause 4, Table 1 and Table 2)

Directive 2009/48/EC [1], Annex II, III., 11. specifies particular safety requirements regarding allergenic fragrances. In particular, the first table in this part of the Directive specifies the allergenic fragrances which shall not be contained in toys, while the second table specifies those allergenic fragrances for which certain marking requirements apply.

In this document, the tables of Directive 2009/48/EC [1] have been reorganized by merging the allergenic fragrances set out in points 41 to 55 from the first table with those of the second table to the “List of allergenic fragrances which require a warning” (Table 1 of this document). This reflects Directive 2009/48/EC [1], Annex II, III., 12. which allows the use of the fragrances set out in points 41 to 55 from the first table of the Directive and the fragrances from the second table of the Directive under certain conditions (see A.4).

A.2 Safety assessment for cosmetic kits (see 4.2.3)

In addition to the safety assessment required by the Directive 2009/48/EC [1], a safety assessment of the products which can be made according to the instructions for use, should be carried out in accordance with the cosmetic legislation. This safety assessment should include one or more of the following considerations: dermatological test, eye irritation test and/or photo toxicity test. In addition, the efficiency of preservation should be tested according to the European Pharmacopeia or ISO 11930 and an additional assessment based on Annex I, Part B of Regulation (EC) No 1223/2009 [2] should also be made.

A.3 Safety procedures

Cosmetic formulations must be deposited to poison control centre or notified through European dedicated portal (CPNP), according to Regulation (EC) No 1223/2009 [2].

A.4 Requirements which need to be fulfilled when using certain fragrances (see Clause 4 and Clause 6)

Directive 2009/48/EC [1], Annex II, III., 12. sets certain conditions under which the fragrances specified in Table 1 may be used:

- “those fragrances are clearly labelled on the *packaging*, and the *packaging* contains the warning set out in point 10 of Part B of Annex V”;
- “if applicable, the resulting products made by the child in accordance with the instructions comply with the requirements of Directive 76/768/EEC” (which has been replaced by Regulation (EC) No 1223/2009 [2]);
- “if applicable, those fragrances comply with the relevant legislation on food.”;
- “such *olfactory board games*, *cosmetic kits* and *gustative games* shall not be used by children under 36 months and shall comply with point 1 of Part B of Annex V”.

These conditions have been taken into account in Clause 4 (compliance with the relevant legislation of food), 4.2.3 (compliance of resulting products made by the child in accordance with the instructions with the requirements of Directive 76/768/EEC, i.e. Regulation (EC) No 1223/2009 [2]) and 6.1 (compliance with point 1 of Part B of Annex V of Directive 2009/48/EC [1]) and 6.1 (warning set out in point 10 of Part B of Annex V of Directive 2009/48/EC [1]).

A.5 Current relevant directives and regulations on cosmetics and food stuff

Besides Directive 2009/48/EC [1] other additional relevant legislation can apply to olfactory board games, cosmetic kits and gustative games. In particular *cosmetic kits* are subject to Regulation (EC) No 1223/2009 [2] and the following legislation is relevant for *gustative games* and for *olfactory board games* with tasting activity:

- Regulation (EC) No 1935/2004 [3];
- Regulation (EU) No 10/2011 [4];
- Regulation (EC) No 1333/2008 [5];
- Regulation (EC) No 1334/2008 [6];
- Regulation (EC) No 178/2002 [7];
- Regulation (EU) No 1169/2011 [8];
- Commission Regulation (EC) No 450/2009 [16];
- Council Directive 84/500/EEC [17];
- Commission Directive 2007/42/EC [18].

A.6 Explanations of regulations relevant to this document

Some substances and mixtures used in *olfactory board games* which are not food ingredients, should be classified and labelled in accordance with Regulation (EC) No. 1272/2008 [13].

Cosmetic kits and *supplementary sets* to such kits are considered as cosmetic products and therefore Regulation (EC) No 1223/2009 [2] applies. Consequently, Regulation (EC) No. 1272/2008 [13] is not applicable.

A.7 Markings, labelling and warnings

Additional requirements on markings, labelling and warnings are given in Directive 2009/48/EC, its associated guidance documents and EN 71-1.

The precautionary classifications and labelling requirements should be reasonable for educational purposes and should ensure harmonized labelling and safety requirements.

Cosmetic kits and its individual components are considered as cosmetic products. They are, therefore, subject to the Cosmetic Regulation and must comply with the labelling requirements.

Annex B (normative)

Test method for identification of borosilicate glass

B.1 General

Several methods exist to distinguish borosilicate glass, e.g. determination of density and refractive index. A density method is given here. Alternative methods are acceptable only if it has been proven that the achieved results are equivalent to those results of the described method.

B.2 Apparatus

B.2.1 25-ml pycnometer

B.2.2 Water bath, capable of maintaining a temperature of (20 ± 1) °C

B.2.3 Deionised water

B.2.4 Analytical balance, accuracy 0,1 mg

B.3 Procedure

Weigh the pycnometer (m_0). Make sure that the fraction from the glass sample is clean. Place the fraction in the pycnometer and re-weigh the pycnometer (m_2). Then fill up the pycnometer with water and place it in a water bath until the contents equilibrate at 20 °C. Top up the pycnometer with water. Remove the pycnometer from the water bath, dry the exterior and weigh the pycnometer (m_3). Empty the pycnometer. Fill up the pycnometer with water and place it in a water bath until the contents equilibrate at 20 °C. Top up the pycnometer with water, dry the exterior and weigh the pycnometer. Record the weight (m_1).

$$\rho_{Glass} = \frac{(m_2 - m_0)}{(m_1 - m_3 + m_2 - m_0)} \cdot \rho_{Water}$$

where

ρ_{Glass} is the density of the glass sample in g/cm³;

ρ_{Water} is the density of water at 20 °C ($\rho_{Water} = 0,9882 \text{ g / cm}^3$)

m_0 is the mass of the empty pycnometer in g;

m_1 is the mass of the pycnometer filled with water in g;

m_2 is the mass of the pycnometer with the glass sample in g;

m_3 is the mass of the pycnometer with glass sample and water in g.

NOTE Reference densities for certain types of glass are:

- $(2,40 \pm 0,05)$ g/cm³ for sheet window glass;
- $(2,48 \pm 0,05)$ g/cm³ for soft soda glass;
- $(2,25 \pm 0,05)$ g/cm³ for borosilicate glass;
- $(2,21 \pm 0,05)$ g/cm³ for fused silica glass.

Annex C (informative)

Environmental considerations

Every product affects the environment in the course of its life cycle from raw material acquisition through production, distribution and use, to disposal. The environmental impacts are consequences of the consumption of energy and resources and the generation of waste as well as the emission of substances into air, water and soil. The magnitude of the environmental impacts during the various life cycle changes depends on a number of choices made in the design of the product. These relate to aspects such as choice of materials, production methods, and the possibility of maintenance and recycling. Manufacturers and distributors should consider the environmental impact of their product, for example by:

- minimizing the use of environmentally harmful substances;
- selecting the best available technology and techniques to reduce consumption of energy and materials;
- considering the use of recycled materials for product and *packaging*;
- encouraging responsible end of life disposal by the user including guidance on separation and identification of any recyclable components and *packaging*;
- using materials, components, and manufacturing facilities, which have declared documented environmental policies.

Annex D (informative)

Significant technical changes between this document and the previous version

Table D.1 — Significant technical changes between this document and the previous version

Clause/Paragraph/Table/ Figure	Change
4.1	The requirements on <i>olfactory board games</i> , in particular regarding Substances and mixtures (4.1.2), have been slightly revised.
4.2	The requirements on <i>cosmetic kits</i> , in particular the general requirements (4.2.1) and the requirements regarding Substances and mixtures (4.2.2, title changed to “Fragrances”), have been revised.
4.3	The requirements on <i>gustative games</i> , in particular regarding Substances and mixtures (4.3.2), have been slightly revised.
5	The requirements on equipment, in particular regarding containers and glassware (5.2), have been slightly revised.
5.2.3	The requirements on closures for child-resistant containers have been revised by permitting only closures in compliance with EN ISO 8317:2015.
6	The requirements on general warnings and markings (6.1) have been revised.
Annex A	Several rationales have been revised and a new rationale on markings, labelling and warnings has been added.
Former Annex C	The test method for closures of containers has been removed.
Bibliography	The bibliography has been updated, in particular in view of changes of legislation. The (informative) references in the whole document to legislation have been updated accordingly.
<p>NOTE The technical changes referred to above are the significant changes to the previous version. The list is not an exhaustive list of all modifications to the previous version.</p>	

Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive 2009/48/EC aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/445 to provide one voluntary means of conforming to essential requirements of Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

Once this standard is cited in the Official Journal of the European Union under that Directive 2009/48/EC, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 2009/48/EC

Essential Requirements of Directive 2009/48/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes
Annex II. III,11 (Particular)	4.1.2.3, 4.2.2, 4.3.2	
Annex II. III,12 (Particular)	4.1.2, 4.2.2, 4.2.3, 4.3.2, 6.1, 6.3	
Annex II, I, 1 (Particular)	5.2.2.1	
Annex II. II,2 (Particular)	5.2.2.2	
Annex V, Part B,1 (Particular)	6.1	
Annex V, Part B,4 (Particular)	6.1	
Annex V, Part B,10 (Particular)	6.3	

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

Bibliography

- [1] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, OJ L 170, 30.6.2009, p. 1–37, available from <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:170:0001:0037:EN:PDF>
- [2] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59–209, available from <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:EN:PDF>
- [3] Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338, 13.11.2004, p. 4–17, available from <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:338:0004:0017:EN:PDF>
- [4] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, OJ L 12, 15.1.2011, p. 1–89, available from <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF>
- [5] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L 354, 31.12.2008, p. 16–33, available from <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:EN:PDF>
- [6] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC, OJ L 354, 31.12.2008, p. 34–50, available from <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0034:0050:EN:PDF>
- [7] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
- [8] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004
- [9] Age determination guidelines: Relating Children’s Ages to Toy Characteristics and Play Behaviour, September 2002, CPSC Staff document
- [10] The European Commission, An explanatory guidance document (to Directive 2009/48/EC)
- [11] CEN-CENELEC Guide 11, *Product information relevant to consumers — Guidelines for standard developers*
- [12] ISO 11930, *Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product*

- [13] Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures
- [14] Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EEC and 2000/21/EC
- [15] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC
- [16] Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food
- [17] Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs
- [18] Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs
- [19] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council Text
- [20] Manual of the Working Group on Cosmetic Products (Sub-Group on Borderline Products) on the Scope of the Application of the Cosmetics Regulation (EC) NO 1223/2009 (Art. 2(1)(a)) Manual on the scope of application of the Cosmetics Regulation (EC) No 1223/2009 (Art. 2(1)(a)) (Version 5.2, September 2020), Clause 3.5.6. "Cosmetic kits" p.35
- [21] Resolution CM/Res. (2013)9 on metals and alloys used in food contact materials and articles, available at https://search.coe.int/cm/Pages/result_details.aspx?ObjectID=09000016805c8094

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