

Safety of Toys

Part 7: Finger paints — Requirements and test methods

The European Standard EN 71-7:2002 has the status of a
British Standard

ICS 97.200.50

National foreword

This British Standard is the official English language version of EN 71-7:2002. The UK participation in its preparation was entrusted to Technical Committee CW/15, Safety of toys, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 11 April 2002.

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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 Management Centre has the same status as the official versions.

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Foreword

This document EN 71-7:2002 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of an identical text or by endorsement, at the latest by February 2003, and conflicting national standards shall be withdrawn at the latest by February 2003.

This document has been prepared under a mandate 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(s), see informative annex ZA, which is an integral part of this document.

This European Standard for 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 6: Graphical symbol for age warning labelling

This standard is part 7 of the European Standard for safety of toys, EN 71.

This part should be read in conjunction with parts 1, 2 and 3, particularly the introduction and clauses 1 and 2 of EN 71-1:1998.

With this part in force, the requirements for finger paints in part 3 are superseded.

This standard contains six annexes:

- Annex A (normative) List of colourants allowed for use in finger paints
- Annex B (normative) List of preservatives allowed for use in finger paints
- Annex C (informative) Ingredients used in the manufacture of finger paints
- Annex D (normative) Method for the detection of certain azo colourants and determination of primary aromatic amines
- Annex E (informative) Rationale
- Annex ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

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

Introduction

It is recognised that finger paints when compared to other toy products present different risks: the ingestion of paint material and the possibility for prolonged skin contact. Therefore, the safety limitations expressed in other parts of EN 71 are not wholly appropriate.

In order to accommodate this risk and to reduce the risks associated with potential ingestion of paint, this part of this European Standard specifies the ingredients that may be used in the manufacture of finger paints, and specifies certain limitations on impurities, preservatives, migration of certain elements and other attributes.

It is intended to reduce the risks which may be presented to a child when finger paints are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children.

Chemical Abstract Service Registry Number (CAS), European Inventory of Existing Chemical Substances Number (EINECS) or Colour Index Number given in the tables are provided for information purposes only.

This European Standard is intended to complete the general valid safety requirements of Directive 88/378/EEC by special requirements for finger paints, to facilitate the proof of compliance with these general specifications.

1 Scope

This part of EN 71 specifies requirements for the substances and materials used in finger paints and applies to finger paints only.

Additional requirements are specified for markings, labelling and containers.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 71-3:1994, *Safety of toys - Part 3: Migration of certain elements*.

prEN 13690, *Fruit and vegetable juices - Determination of the ethanol content of fruit juices - Method using gas chromatography*.

EN ISO 787-9, *General methods of test for pigments and extenders - Part 9: Determination of pH value of aqueous suspension (ISO 787-9:1981)*.

3 Terms and definitions

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

3.1

finger paints

paste and/or jelly like, coloured preparations specially designed for children, directly applicable to suitable surfaces with the fingers and hands

NOTE In addition to water, finger paints essentially consist of colourants, extenders, binders, humectants, preservatives, surfactants and embittering agent.

3.2

colourant

colouring chemical compounds (dyes and pigments)

3.3

extender

substance consisting of insoluble particles used to increase volume, maximise some technical feature or influence optical qualities

3.4

humectant

substance that delays the drying process

3.5

binding agent

water soluble or miscible, non volatile component(s) that bind(s) the paint to the surface to which it has been applied

3.6

preservative

substance that prevents the growth of undesirable micro-organisms

3.7

surfactant

surface active substance

3.8

embittering agent

substance that gives the product a bitter taste

4 Requirements

4.1 General

Finger paints shall not contain dangerous substances or preparations in amounts which may harm the health of children using them.

The use of ingredients in annex A and annex B is considered to meet this general requirement.

NOTE 1 Directives 67/548/EEC and 99/45/EC refer (see Bibliography).

NOTE 2 Differing legal requirements may exist in non EU countries.

4.2 Colourants

4.2.1 The use of colourants listed in annex A is permitted. Annex A consists of colourants falling in one or more of the following categories:

- food colourants;
- colourants permitted for the use in cosmetics, without limitation in the field of application and which fulfil the requirements given there;
- other pigments (listed as substances 1 – 35) which meet the general requirements of 4.1.

4.2.2 Colourants which are not classified as carcinogenic, mutagenic, toxic to reproduction, very toxic, toxic, harmful, corrosive, irritant or sensitising, may also be used in finger paints.

NOTE Directive 67/548/EEC refers.

4.2.3 Finger paints shall not contain azo colourants that by cleavage of one or more azo groups can produce primary amines listed in Tables 3 and 4 when tested in accordance with 5.2.

4.3 Preservatives

Finger paints shall be preserved using only the preservatives listed in annex B, when tested in accordance with 5.3. The maximum concentrations specified in the column "maximum allowed concentration" of Table B.1 and the limitations and requirements specified in the column "Limitations and requirements" of Table B.1 shall be observed.

4.4 Limits for the migration of certain elements

The migration of elements from finger paints shall not exceed the limits given in Table 1 (after application of the analytical correction given in Table 2) when tested in accordance with EN 71-3 (see also 5.4).

Table 1 — Limits for the migration of certain elements from finger paints

Element	Sb	As	Ba	Cd	Cr	Pb	Hg	Se
Maximum migration in finger paint (mg/kg)	10	10	350	15	25	25	10	50

Table 2 — Analytical correction

Element	Sb	As	Ba	Cd	Cr	Pb	Hg	Se
Analytical correction (%)	60	60	30	30	30	30	50	60

4.5 Limits for primary aromatic amines

4.5.1 The single primary aromatic amines listed in Table 3 shall not be determinable when tested in accordance with 5.5.

Table 3 — Primary aromatic amines which shall not be determinable in finger paints

Primary aromatic amines	CAS number
Benzidine	CAS 92-87-5
2-Naphthylamine	CAS 91-59-8
4-Chloro-2-methyl-aniline (4-Chloro-o-toluidine)	CAS 95-69-2
4-Aminobiphenyl	CAS 92-67-1

4.5.2 With the exception of those amines listed in Table 3, finger paints shall not contain primary aromatic amines in a total amount exceeding 20 mg/kg, with no individual primary aromatic amine exceeding 10 mg/kg, when tested in accordance with 5.5. The limitation does not apply to aromatic aminocarboxylic acids or aminosulfonic acids.

Table 4 gives examples of other primary aromatic amines of concern.

Table 4 — Other primary aromatic amines of concern (examples)

Primary aromatic amine	CAS number
o-Aminoazotoluene (4-o-tolyazo-o-toluidine)	CAS 97-56-3
2-Amino-4-nitro-toluene (5-Nitro-o-toluidine)	CAS 99-55-8
4-Chloroaniline	CAS 106-47-8
2,4-Diaminoanisole	CAS 615-05-4
4,4'-Diaminodiphenylmethane (4,4'-Methylenedi-o-toluidine)	CAS 101-77-9
3,3'-Dichlorobenzidine	CAS 91-94-1
3,3'-Dimethoxybenzidine	CAS 119-90-4
3,3'-Dimethylbenzidine	CAS 119-93-7
3,3'-Dimethyl-4,4'-diaminodiphenylmethane	CAS 838-88-0
p-Cresidine (6-Methoxy-m-toluidine)	CAS 120-71-8
2,2'-Dichloro-4,4'-methylenedianiline (4,4'-Methylene-bis-2-chloroaniline)	CAS 101-14-4
4,4'-Oxydianiline	CAS 101-80-4
4,4'-Thiodianiline	CAS 139-65-1
o-Toluidine	CAS 95-53-4
2,4-Xylidine	CAS 95-68-1
2,6-Xylidine	CAS 87-62-7
4-Amino-3-fluorophenol	CAS 399-95-1
6-Amino-2-ethoxynaphthalene	not available
2-Methoxyaniline (o-anisidine)	CAS 90-04-0
4-Aminoazobenzene	CAS 60-09-3
4-Methyl-m-phenylenediamine (Toluene-2,4-diamine)	CAS 95-80-7
2,4,5-Trimethylaniline	CAS 137-17-7

4.6 Taste and smell

Finger paints shall not be sweetened, flavoured or fragranced. An embittering agent in accordance with the following list shall be added in order to minimise the ingestion of paint:

- sucrose octaacetate (CAS 126-14-7);
- naringin (CAS 10236-47-2);
- denatonium benzoate (CAS 3734-33-6).

NOTE The relative bitterness of these substances is approximately 1:10:3000 (naringin : sucrose octaacetate : denatonium benzoate). The following levels have been found suitable: naringin 1 %; sucrose octaacetate 0,1 %; denatorium benzoate 0,000 4 % (4 mg/kg).

For the preparation of an embittering solution, only ethanol shall be used. The concentration of ethanol in the final product shall not exceed 0,5 % when tested in accordance with 5.6.

4.7 pH-value

The pH-value of the final product shall be between 4 and 9 when tested in accordance with 5.7.

4.8 Binding agents, extenders, humectants and surfactants

Binding agents, extenders, humectants and surfactants that are classified as carcinogenic, mutagenic, toxic to reproduction, very toxic, toxic, harmful, corrosive, irritant or sensitising shall not be used. See annex C for a list of acceptable compounds.

5 Test methods

5.1 General

In order to determine whether the requirements in clause 4 are met, the following test methods shall be applied:

5.2 Colourants

The detection of azo colourants that by cleavage of one or more azo groups can produce primary aromatic amines listed in Tables 3 and 4 shall be in accordance with the test method described in annex D.

5.3 Preservatives

Test methods are in accordance with those used for cosmetic products in the relevant EU Directives, where available.

NOTE Directives 82/434/EEC, 83/514/EEC, 85/490/EEC, 90/207/EEC, 93/73/EEC, 95/32/EEC and 96/45/EEC refer.

5.4 Migration of certain elements

Test methods shall be in accordance with EN 71-3:1994, 8.9.

5.5 Primary aromatic amines

The determination of free primary aromatic amines shall be in accordance with the test method described in annex D.

5.6 Ethanol

Test method shall be in accordance with prEN 13690.

5.7 pH-value

Test method shall be in accordance with EN ISO 787-9.

6 Product information

6.1 General

Markings shall be visible, easily legible, indelible and in the national language(s) of the country of sale.

The container shall bear the manufacturer's / distributor's information and warning, as given in 6.2.2.

The other packaging information should also be included on the container.

6.2 Marking

6.2.1 Manufacturer's identification

The container shall bear the name and address, tradename and/or mark of the manufacturer, his authorised representative or the importer. The name and address may be abbreviated provided that the abbreviation enables identification of the manufacturer, his authorised representative or the importer.

6.2.2 Labelling phrases

The container shall bear the following notation:

WARNING — "Warning! Children under 3 years of age should be supervised by adults."

The container shall indicate the preservative(s) and embittering agent(s) used.

NOTE Preservatives should be identified by their chemical name, INCI (name) or E number, where available.

7 Containers

Containers which are likely to lead to or promote confusion with foodstuffs shall not be used.

Annex A

(normative)

List of colourants allowed for use in finger paints

Table A.1 — Colourants

No.	Colourant	CI number ¹⁾	Colour	Limitations, requirements and information
1	Pigment Green 8	10 006	Green	³⁾
2	Pigment Yellow 1	11 680	Yellow	⁴⁾
3	Pigment Yellow 3	11 710	Yellow	⁴⁾
4	Pigment Yellow 74	11 741	Yellow	
5	Pigment Yellow 154	11 781	Yellow	
6	Pigment Orange 38	12 367	Orange	
7	Pigment Red 188	12 467	Red	
8	Pigment Red 170	12 475	Red	
9	Pigment Brown 25	12 510	Brown	
10	Pigment Red 208	12 514	Red	
11	Pigment Violet 32	12 517	Violet	
12	Pigment Yellow 151	13 980	Yellow	
13	Pigment Yellow 12	21 090	Yellow	
14	Pigment Yellow 14	21 095	Yellow	
15	Pigment Yellow 13	21 100	Yellow	³⁾
16	Pigment Yellow 17	21 105	Yellow	
17	Pigment Orange 13	21 110	Orange	
18	Pigment Orange 34	21 115	Orange	
19	Pigment Violet 19	73 900	Violet	³⁾
20	Pigment Violet 23	51 319	Violet	³⁾
21	Pigment Yellow 138	56 300	Yellow	
22	Pigment Yellow 139	56 298	Yellow	
23	Pigment Red 168	59 300	Red	
24	Pigment Orange 43	71 105	Orange	⁴⁾
25	Pigment Red 122	73 915	Red	³⁾
26	Pigment Green 7	74 260	Green	⁵⁾
27	Pigment Green 36	74 265	Green	
28	Pigment White 19	77 005	White	
29	Pigment Brown 24	77 310	Brown	
30	Pigment Yellow 53	77 788	Yellow	
31	Pigment Yellow 155	200310	Yellow	
32	Pigment Red 214	200660	Red	
33	Pigment Red 242	20067	Red	
34	Pigment Red 48:4	15 865:4	Red	
35	Pigment White 7	77975	White	
36	Solvent Orange 1	11920	Orange	

Table A.1 (continued)

No.	Colourant	CI number ¹⁾	Colour	Limitations, requirements and information
37	Pigment Red 5	12490	Red	
38	Acid Yellow 9	13015	Yellow	E 105
39	Acid Orange 6	14270	Orange	E 103
40	Food Red 1	14700	Red	
41	Acid Red 14	14720	Red	E 122
42	Food Red 2	14815	Red	E 125
43	Pigment Red 68	15525	Red	
44	Pigment Red 51	15580	Red	
45	Pigment Red 57:1	15850:1 ²⁾	Red	
46	Pigment Red 48:2	15865:2 ²⁾	Red	
47	Pigment Red 63:1	15880:1	Red	
48	Food Orange 2	15980	Orange	E 111
49	Food Yellow 3	15985 ²⁾	Yellow	E 110
50	Food Red 17	16035	Red	
51	Acid Red 27	16185	Red	E 123
52	Acid Red 18	16255 ²⁾	Red	E 124
53	Acid Red 41	16290	Red	E 126
54	Acid Red 33	17200 ²⁾	Red	
55	Acid Yellow 17	18965	Yellow	
56	Acid Yellow 23	19140 ²⁾	Yellow	E 102
57	Food Black 2	27755	Black	E 152
58	Food Black 1	28440	Black	E 151
59	Food Orange 5	40800	Orange	
60	Food Orange 6	40820	Orange	E 160 e
61	Food Orange 7	40825	Orange	E 160 f
62	Food Orange 8	40850	Orange	E 161 g
63	Acid Blue 3	42051 ²⁾	Blue	E 131
64	Food Green 3	42053	Green	
65	Food Blue 2	42090	Blue	
66	Acid Green 50	44090	Green	E 142
67	Solvent Red 72	45370 ²⁾	Orange	Not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
68	Acid Red 87	45380 ²⁾	Red	Not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
69	Acid Red 92	45410 ²⁾	Red	Not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid

Table A.1 (continued)

No.	Colourant	CI number 1)	Colour	Limitations, requirements and information
70	Acid Red 95	45425	Red	Not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid and 3 % 2-(iodo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
71	Food Red 14	45430 ²⁾	Red	E127 Not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
72	Acid Yellow 3	47005	Yellow	E 104
73	Pigment Red 83 (:1)	58000:1	Red	
74	Solvent Violet 13	60725	Violet	
75	Solvent Green 3	61565	Green	
76	Acid Green 25	61570	Green	
77	Pigment Blue 6	69800	Blue	E 130
78	Pigment Blue 64	69825	Blue	
79	Pigment Blue 66	73000	Blue	
80	Food Blue 1	73015	Blue	E 132
81	Pigment Red 181	73360	Red	
82	Pigment Violet 36	73385	Violet	
83	Pigment Blue 15	74160	Blue	
84	Natural Yellow 6	75100	Yellow	Natural Yellow 19, Natural Red 1
85	Natural Orange 4	75120	Orange	E 160 b
86	Natural Yellow 27	75125	Yellow	E 160 d
87	Natural Yellow 26	75130	Orange	E 160 a
88	Natural Yellow 27	75135	Yellow	E 161 d
89	Natural White 1	75170	White	
90	Natural Yellow 3	75300	Yellow	E 100
91	Natural Red 4	75470	Red	E 120
92	Natural Green 3	75810	Green	E 140 and E 141
93	Pigment Metal 1	77000	White	E 173
94	Pigment White 24	77002	White	
95	Pigment White 19	77004	White	
96	Pigment Blue 29	77007	Blue	
97	Pigment Red 101 /	77491	Red	Mix
98	Pigment White 21	77120	White	
99	Pigment White 14	77163	White	
100	Pigment White 18	77220	White	E 170
101	Pigment White 25	77231	White	
102	Pigment Black 6	77266	Black	

Table A.1 (concluded)

No.	Colourant	CI number ¹⁾	Colour	Limitations, requirements and information
103	Pigment Black 9	77267	Black	
104	Food Black 3	77268:1	Black	E 153
105	Pigment Green 17	77288	Green	Free from chromate ion
106	Pigment Green 18	77289	Green	Free from chromate ion
107	Pigment Blue 28	77346	Green	
108	Pigment Metal 2	77400	Brown	
109	Pigment Metal 3	77480	Brown	E 175
110	Ferrous oxide	77489	Orange	E 172 (Mix)
111	Pigment Red 101	77491	Red	E 172
112	Pigment Yellow 42	77492	Yellow	E 172
113	Pigment Black 11	77499	Black	E 172
114	Pigment Blue 27	77510	Blue	Free from cyanide ions
115	Pigment White 18	77713	White	Magnesium carbonate
116	Pigment Violet 16	77742	Violet	
117	-	77745	Red	Manganesephosphate hydr.
118	-	77820	White	E 174 (Silver)
119	Pigment White 6	77891	White	E 171
120	Pigment White 4	77947	White	
121	Lactoflavin	-	Yellow	E 101
122	Caramel	-	Brown	E 150
123	Capsanthin, capsorubin	-	Orange	E 160 c
124	Beetroot red	-	Red	E 162
125	Anthocyanins		Red	E 163
126	Aluminium, zinc, magnesium and calcium stearates	-	White	

¹⁾ The Colour Index is published by The Society of Dyers and Colourists, PO Box 244, Perkin House 82 Grattan Road, Bradford, West Yorkshire BD1 2JB, United Kingdom.

²⁾ The insoluble barium, strontium and zirconium lakes, salts and pigments of these colourants are also permitted.

³⁾ This substance is restricted in 76/768/EEC (Cosmetics Directive) as follows: "Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin."

⁴⁾ This substance is restricted in 76/768/EEC (Cosmetics Directive) as follows: "Colouring agents allowed exclusively in cosmetic products intended not to come into contact with the mucous membranes."

⁵⁾ This substance is restricted in 76/768/EEC (Cosmetics Directive) as follows: "Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of the eyes, in particular eye make-up and eye make-up remover."

Annex B (normative)

List of preservatives allowed for use in finger paints

Table B.1 — Preservatives

Reference number	Substance	Maximum allowed concentration	Limitations and requirements
1	Benzoic acid, its salts and esters ¹⁾	0,5 % (acid)	
2	Propionic acid and its salts ¹⁾	2 % (acid)	
3	Sorbic acid (hexa-2,4-dienoic acid) and its salts ¹⁾	0,6 % (acid)	
4	Paraformaldehyde	0,1 % expressed as free formaldehyde	
5	Biphenyl-2-ol (o-Phenylphenol) and its salts ¹⁾	0,2 % expressed as the phenol	
6	Inorganic sulphites and hydrogen sulphites	0,2 % expressed as free SO ₂	
7	4-Hydroxybenzoic acid and its salts and esters ¹⁾	0,4 % (acid) for 1 ester, 0,8 % (acid) for mixtures of esters	
8	3-Acetyl-6-methylpyran-2,4-(3H)-dione (Dehydroacetic acid) and its salts ¹⁾	0,6 % (acid)	
9	Formic acid and its sodium salt ¹⁾	0,5 % (acid)	
10	3,3'-Dibromo-4,4'-hexamethylene-dioxydibenzamidine (Dibromohexamidine) and its salts (including isethionate) ¹⁾	0,1 %	
11	Undec-10-enoic acid and its salts ¹⁾	0,2 % (acid)	
12	Hexetidine (INN)	0,1 %	
13	Bronopol (INN)	0,1 %	Avoid formation of nitrosamines
14	2,4-Dichlorobenzyl alcohol	0,15 %	
15	Triclocarban (INN)	0,2 %	Purity criteria: 3,3',4,4'-Tetra-chloroazobenzene less than 1 mg/kg 3,3',4,4'-Tetra-chloroazoxybenzene less than 1 mg/kg
16	Triclosan (INN)	0,3 %	
17	4-Chloro-3,5-xlenol	0,5 %	
18	3,3'-Bis(1-hydroxymethyl-2,5-dioximidazolidin-4-yl)-1,1'-methylene-diurea (Imidazolidinyl urea)	0,6 %	

Table B.1 (continued)

Reference number	Substance	Maximum allowed concentration	Limitations and requirements
19	Poly(1-hexamethylenebiguanide hydrochloride)	0,3 %	
20	2-Phenoxyethanol	1 %	
21	Hexamethylenetetramine (Methenamine (INN))	0,15 %	
22	Methenamine 3-chloro-allylochloride (INNM) (Quaternium-15)	0,2 %	
23	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one (Climbazole (INN))	0,5 %	
24	1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (DMDM Hydantoin)	0,6 %	
25	Benzyl alcohol	1 %	
26	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-pyridon and its monoethanolamine salt	0,5 %	
27	6,6-Dibromo-4,4-dichloro-2,2'-methylenediphenol (Bromochlorophen)	0,1 %	
28	4-Isopropyl-m-cresol	0,1 %	
29	2-Benzyl-4-chlorophenol (Chlorophene)	0,2 %	
30	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride	0,3 % expressed as chlorhexidine	
31	Alkyl (C ₁₂ -C ₂₂)-trimethyl-ammonium, bromide and chloride	0,1 %	
32	4,4-Dimethyl-1,3-oxazolidine	0,1 %	The pH of the finished product shall not be lower than 6.
33	N-1,3-Bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl-N,N'-bis(hydroxymethyl)-urea (Diazolidinylurea) CAS [78491-02-8]	0,5 %	
34	Hexamidine (INN) and its salts (including isethionate and p-hydroxybenzoate) ¹⁾	0,1 %	
35	Chlorphenesin (INN)	0,3 %	
36	Sodium N-hydroxymethyl-glycinate	0,5%	

Table B.1 (*concluded*)

Reference number	Substance	Maximum allowed concentration	Limitations and requirements
37	Mixture of 5-chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate	0,001 5 % (of a mixture in the ratio 3:1 of 5-chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H) one	
¹⁾ The salts of the cations sodium, potassium, calcium, magnesium, ammonium and ethanolamines and of the anions chloride, bromide sulfate and acetate; and the esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl and phenyl of these preservatives are permitted.			

Annex C (informative)

Ingredients used in the manufacture of finger paints

In accordance with current knowledge the following ingredients are used:

a) Binding agents:

carboxymethylcellulose and its salts

dextrins

polyvinyl alcohol

cellulose ethers

starch

tragacanth

xanthan

polyvinylpyrrolidone

casein

alginates

polyacrylates

b) Extenders:

calcium carbonates (including whitening)

calcium sulfate

silicon dioxide

magnesium oxide

aluminium oxide

magnesium silicate

calcium silicate

kaolin (china clay)

bentonite

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c) Humectants:

sodium polyphosphate

fatty alcohol ethoxylates

polyalkylene glycol ethers

fatty acid taurid- sodium salt

glycerols

polyglycols

propylene glycol

capillaire syrup (commercial blends of soluble saccharides), provided they do not impart sweetness

d) Surfactants:

sodium salts of edible fatty acids

polyalkylene glycol ethers

alkylbenzene sulfonates

polywaxes

Annex D (normative)

Method for the detection of certain azo colourants and determination of primary aromatic amines

D.1 General

For the detection of certain azo colourants, the sample is treated with sodium dithionite in a citrate buffer (pH 6) at 70 °C in a sealed vessel. Upon reductive cleavage, the resultant amines are extracted with *tert*-butyl methyl ether by means of a "kieselguhr" type SPE column, e.g. Chromabond® XTR, or equivalent. The ether extract is carefully concentrated with a rotary evaporator or an equivalent sample concentrator and the residue is dissolved in acetonitrile or other suitable solvent, depending upon the detection/determination procedure to be used.

The detection/determination of the amines is performed by high performance liquid chromatography with a diode-array detector (HPLC/DAD); thin layer chromatography (TLC, HPTLC); capillary gas chromatography with a flame-ionisation detector or mass-specific detector (GC/FID or GC/MS); or by capillary electrophoresis with a diode-array detector (CE/DAD).

The amines shall be identified by at least one of the chromatographic separation techniques described in this annex. Unless an unequivocal identification is achieved (e.g. by using GC/MS and comparing retention times with known standards), confirmation of positive results shall be achieved by a suitable alternative separation technique (to avoid possible misinterpretation from, for example, isomers of the amines to be identified).

The quantification of the amines is performed by HPLC/DAD or GC/MS.

NOTE Some of the amines are cleaved under the reductive conditions in D.6.2 according to Table D.1:

Table D.1 – Amine compounds which can be cleaved under reductive conditions

Amine compound	Cleavage products
o-Aminoazotoluene	o-Toluidine, 2-Methyl-p-phenylenediamine
2-Amino-4-nitrotoluene	4-Methyl-m-phenylenediamine
4-Amino-azo-benzene	p-Phenylenediamine, Aniline

4-Aminoazobenzene is reductively cleaved to p-phenylenediamine and aniline; o-aminoazotoluene is reductively cleaved to 2-methyl-p-phenylenediamine and o-toluidine; and 5-nitro-o-toluidine is reduced to 4-methyl-m-phenylenediamine.

A prohibited azo colourant is deemed to be present in the finger paint if, on reductive cleavage, one or more of the amines listed in Tables 3 and 4 is present in a concentration exceeding 30 mg/kg.

The single primary aromatic amines listed in Table 3 are deemed to be determinable at levels exceeding 5 mg/kg.

D.2 Reagents

Reagent-grade chemicals are to be used, if nothing else is specified.

D.2.1 Methanol

D.2.2 Acetonitrile

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D.2.3 *tert*-Butyl methyl ether

D.2.4 Citrate/sodium hydroxide buffer, $c(\text{trisodium citrate}) = 0,06 \text{ mol/l}$, pH 6, preheated to 70 °C or 37 °C: Dissolve 12,6 g citric acid monohydrate and 6,4 g sodium hydroxide in 900 ml water. Adjust the volume to 1 l.

NOTE 'Ready-for-use' solution, Merck-Nr. 1.09437, has been found suitable.

D.2.5 Sodium dithionite solution, freshly dissolved in water, $\rho = 200 \text{ mg/ml}$

D.2.6 Porous, granular "kieselguhr" SPE column

NOTE Chromabond® XTR has been found suitable.

D.2.7 Amine standards, primarily those listed in Tables 3 and 4, (highest available purity)

NOTE The amines in Tables 3 and 4 are human carcinogens or cancer suspect agents (MAK-list III A1/III A2: EU C1/C2, respectively). The handling of these chemicals requires the utmost care and commensurate safety measures.

D.2.8 Internal standards for gas chromatography

D.2.8.1 IS 1: Naphthalene- d_8 , CAS No. 1146-65-2

D.2.8.2 IS 2: 2,4,5-Trichloroaniline, CAS No. 636-30-6

D.2.8.3 IS 3: 4-Amino-2-methylquinoline, CAS No. 6628-04-2

D.2.8.4 IS 4: Anthracene- d_{10} , CAS No. 1719-06-8

D.2.9 Standard solutions

D.2.9.1 Calibration solution of amines of Tables 3 and 4, $\rho = 10,0 \text{ µg/ml}$ of each amine of a suitable solvent

D.2.9.2 Internal standard solution of IS 1 to IS 4, (D.2.8.1 – D.2.8.4) $\rho = 10,0 \text{ µg/ml}$ of each required IS of a suitable solvent

D.2.9.3 Solutions of amines of Tables 3 and 4 for procedure check, $\rho = 30,0 \text{ µg/ml}$ of each amine of a suitable solvent

NOTE The solvent used will depend on the chromatographic method chosen for analysis.

The stability of the amine solutions shall be demonstrated.

D.3 Apparatus

Ordinary laboratory equipment, and

D.3.1 Reaction vessel (20 ml to 50 ml) of temperature-resistant glass with tight-fitting screw cap

D.3.2 Water bath, drying oven or heating block; all devices thermostated, capable of maintaining a temperature of $(37 \pm 2) \text{ °C}$ and $(70 \pm 2) \text{ °C}$

D.3.3 Column made from glass or polypropylene, 25 mm to 30 mm internal diameter, 140 mm to 150 mm length, filled with about 20 g porous, granular "kieselguhr" SPE material, fitted on the outlet with a glass fibre filter (or commercial SPE column).

NOTE Chromabond® XTR (Macherey-Nagel Catalogue No. 730 507) has been found suitable.

D.3.4 Vacuum rotary evaporator or equivalent low temperature sample concentration system

D.3.5 Pipettes 10 ml, 5 ml, 2 ml, 1 ml

D.4 Instrumentation

The analysis shall be performed using equipment selected from the following list

- D.4.1 Equipment for TLC and/or HPTLC, including UV-lamp
- D.4.2 HPLC with gradient-elution and DAD
- D.4.3 GC with FID or MS
- D.4.4 CE with DAD

D.5 Sampling procedure

Homogenize the sample by stirring thoroughly.

D.6 Procedure

D.6.1 Sample preparation

For both the detection of certain azo colourants, and the determination of 'free' primary aromatic amines, a representative sample of approximately 1,0 g is weighed accurately into the reaction vessel (D.3.1).

D.6.2 Reductive cleavage of azo colourants

17 ml buffer (D.2.4), preheated to $(70 \pm 2) ^\circ\text{C}$, is added to the sample. The reaction vessel is tightly closed and after brief vigorous shaking to homogenize the contents is kept at $(70 \pm 2) ^\circ\text{C}$ for 30 min.

To achieve reductive cleavage of the azo colourants 3,0 ml of sodium dithionite solution (D.2.5) is added to the reaction vessel. The vessel is immediately tightly sealed, thoroughly shaken and kept again at $(70 \pm 2) ^\circ\text{C}$ for another (30 ± 2) min, and then cooled to ambient temperature within 2 min.

D.6.3 Extraction of soluble amines

For the determination of free aromatic amines (see 4.5.2), the reductive cleavage (D.6.2) is not carried out. Instead, 20 ml of the buffer solution (D.2.4) preheated only to $(37 \pm 2) ^\circ\text{C}$ is added to the sample. The reaction vessel is tightly closed and after brief vigorous shaking to homogenize the contents is kept at $(37 \pm 2) ^\circ\text{C}$ for 30 min.

D.6.4 Solid phase extraction and concentration of amines

The solution from D.6.2 or D.6.3, as appropriate, is poured onto the SPE column without rinsing the vessel with water or buffer. The aqueous phase is left for 15 min to absorb onto the column. The amines are then extracted twice with 40 ml *tert*-butyl methyl ether as described below.

Before extracting the SPE column, the first 40 ml of *tert*-butyl methyl ether is divided into portions of 2×10 ml and 1×20 ml for rinsing the reaction vessel. 10 ml of ether is added to the vessel, it is closed and shaken vigorously. After allowing 15 min for the water phase to absorb onto the column, the *tert*-butyl methyl ether is decanted from the reaction vessel onto the column. The eluant is collected in a 100-ml round-bottom flask. This operation is repeated with the remaining 10-ml and 20-ml portions of *tert*-butyl methyl ether. Finally, the second 40 ml is poured directly onto the column. The eluate is usually clear and needs no drying.

The *tert*-butyl methyl ether extract is carefully concentrated at a maximum temperature of $25 ^\circ\text{C}$ using a rotary evaporator with vacuum, or equivalent sample concentrator, to about 1 ml (not to dryness!). If *tert*-butyl methyl ether is not the required chromatographic solvent, the remainder of the ether is carefully removed under a light flow of inert gas. If *tert*-butyl methyl ether is the required chromatographic solvent, the residue is quantitatively transferred to a small graduated tube and the volume made up to 2,0 ml with washings from the round-bottom flask.

NOTE 1 During solvent removal, considerable losses of amines may occur if the process is not closely supervised (i.e. vacuum too high, temperature too high, high inert gas flow). The solvent removal should be performed under subdued light (avoid direct sunlight and if possible, direct fluorescent lightening).

If taken to dryness, each residue is immediately dissolved in 2,0 ml of a suitable solvent, e.g. methanol in an amber glass flask, and subsequently analysed. If the analysis cannot be carried out immediately, the sample has to be stored at -20°C .

The quantification of the amines is conducted using HPLC/DAD or GC/MS. If using GC/MS, internal standards shall be used.

NOTE 2 Certain amines, e.g. 2,4-toluenediamine and 2,4-diaminoanisole, have a very low stability. If the extraction and concentration procedure is not carried out expediently, partial or total loss of amines can occur.

D.6.5 Chromatography

The following conditions have been found suitable for the detection/determination of primary aromatic amines:

D.6.5.1 Thin Layer Chromatography (TLC)

OPTION 1

Plates (HPTLC):	Silica gel 60 with fluorescent indicator F_{254} 20 cm x 10 cm;
Applied volume:	2 μl to 5 μl , applied as one spot
Mobile solvent 1:	Volume fraction (chloroform/glacial acetic acid) = 90:10

OPTION 2

Plates (TLC):	Silica gel 60
Applied volume:	10 μl , applied as line,
Mobile solvent 2:	Volume fraction (chloroform/ethyl acetate/glacial acetic acid) = 60:30:10
Mobile solvent 3:	Volume fraction (chloroform/methanol) = 95:5
Mobile solvent 4:	Volume fraction (<i>n</i> -butyl acetate/toluene) = 30:70
Development:	Saturated tank

OPTION 3

Plates (TLC):	Silica gel 60
Mobile solvent 2 and 3:	Development by solvent 3 following 2 without drying of the plate
Spray reagent 1:	Sodium nitrite, $w(\text{NaNO}_2) = 0,1\%$ in aqueous KOH ($c = 1\text{ mol/l}$)
Spray reagent 2:	α -Naphthol, $w(\text{C}_{10}\text{H}_8\text{O}) = 0,2\%$ in aqueous KOH ($c = 1\text{ mol/l}$)
Detection:	1. UV-lamp 2. Spraying with spray reagent 1 and thereafter with reagent 2; time of reaction approximately 5 min

D.6.5.2 High pressure liquid chromatography (HPLC)

Eluent 1:	Acetonitrile
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Eluent 2:	0,575 g ammonium dihydrogenphosphate + 0,7 g disodium hydrogenphosphate in 1 000 ml water, pH 6,9
Column:	HyPurity Advance 250 x 3 mm; 5 µm ThermoQuest Catalogue No. 21005-0035
Flow rate:	0,4 ml/min
Gradient:	0 min 15 % eluent 1, within 45 min linear to 75 % eluent 1
Column temperature:	40 °C (or 15 °C as an alternative temperature)
Injection volume:	5,0 µl
Detection:	DAD, full spectra
Quantification:	at 240 nm, 280 nm and 305 nm

D.6.5.3 Gas Chromatography (GC)

Capillary column:	DB-5MS, DB-35MS, SE 54 or equivalent type, length: 30 m, internal diameter: 0,25 mm, film thickness: 0,25 µm, preferably deactivated for amines
Injector:	split/splitless
Injection temperature:	260 °C
Carrier:	Helium
Temp. programme:	60 °C (2 min), 60 °C to 310 °C (15 °C/min), 310 °C (2 min)
Injection volumes:	1,0 µl, split 1:15
Detection:	MS

D.6.5.4 Capillary electrophoresis (CE)

200 µl final solution (D.6.4) is diluted with 50 µl HCl ($c = 0,01$ mol/l) and filtered through a membrane (0,2 µm). This solution is used for CE.

Capillary 1:	56 cm, uncoated, 50 µm internal diameter with extended light path (HP);
Capillary 2:	56 cm, coated with polyvinyl alcohol, 50 µm internal diameter with extended light path (HP)
Buffer:	Phosphate buffer ($c = 0,05$ mol/l), pH 2,5
Column temperature:	25 °C
Voltage:	30 KV
Injection time:	4 s
Flushing time:	5 s
Detection:	DAD at 214 nm and 254 nm, verification by comparison of spectra

D.6.6 Verification of analytical system

To check the analytical procedure, add 1,0 ml of standard solution (D.2.9.3) and 1,0 ml methanol to reaction vessel **D.3.1** containing 15 ml buffer preheated to (70 ± 2) °C. Then follow the procedure from D.6.2 (second sentence). The recovery rate of the amines should be at least 70 %, with the exception of 2,4-diaminoanisole, *o*-toluidine and 2,4-toluenediamine; the recoveries of which are expected to lie between 20 % and 50 %.

NOTE Suitable values will be made available after the peer review of this method.

D.7 Calculation

The amine concentration is calculated from the area of each amine peak and is given as mass portion w , in mg/kg, of single amine component in test material according to equation (1):

$$w = \frac{A_s \cdot C_c \cdot V_s}{A_c \cdot E_s} \quad (1)$$

where

A_s is the peak area of the amine in the sample solution in area units

A_c is the peak area of the amine in the calibration solution in area units

C_c is the concentration of the amine in the calibration solution ($\mu\text{g/ml}$)

E_s is the initial mass of sample in the end volume (g)

V_s is the volume of test solution obtained in D.6.4 used for chromatographic analysis (ml)

If an internal standard has been used, the mass portion of amine component (w) is multiplied by $A_{IS(s)} / A_{IS(c)}$

where

$A_{IS(s)}$ is the peak area of the internal standard in the sample solution in area units

$A_{IS(c)}$ is the peak area of the internal standard in the calibration solution in area units

D.8 Report

Any report of analysis shall refer to this method and include:

D.8.1 Precise sample description/identification/article number

D.8.2 Type and date of sampling

D.8.3 Date of submission and date of analysis

D.8.4 Data on procedure (separation and detection)

D.8.5 Data on quantification procedure

D.8.6 Calculated results

D.8.7 A statement as to whether or not a proscribed azo colourant has been detected (see 4.2.3)

D.8.8 A statement as to whether the requirements for primary aromatic amines have been met (see 4.5)

Annex E (informative)

Rationale

The standard on finger paints is restricted to certain compound groups which may be harmful and is open for further improvement due to technological developments. The general requirements fix this principle and give recommendations on components fulfilling these requirements.

The present annex A on **colourants** contains a single consolidated list based on special colourants for finger paints (No 1-35) and on a consolidated list of permitted food colourants and cosmetic colourants (without application limitations).

The specific list of colourants for finger paints (No 1-35) in annex A is based on a 1985 list of about 80 colourants reported to be used in finger paints by European manufacturers; prepared as a basis for voluntary agreement on manufacture and marketing of finger paints. These 35 pigments have been screened against a limited set of toxicological and fastness/solubility data. The list contains 6 organic pigments based on 3,3'-dichlorobenzidine (colourants 13-18), but neither these nor any of the other 29 pigments are restricted under the 5th amendment of the German Consumer Goods Ordinance (Bedarfsgegenstände-Verordnung).

More detailed requirements on **aromatic amines** are included in order to exclude risks which may derive from impurities in colourants.

Preservation of finger paints against microbiological spoilage is necessary. **Preservatives** suitable for finger paints are listed in annex B, and are in principle preservatives permitted for use in foodstuffs and cosmetics (without limitations).

The limits for the migration of **certain elements** in finger paints had been regulated in EN 71-3. With this part 7 of EN 71 special consideration of the requirements for certain elements according to Directive 88/378/EEC leads to a further reduction of the limits for migration of these elements due to the special exposure conditions compared to other toys.

These requirements for finger paints provide sufficient risk minimisation. But due to the easy and foreseeable availability during play the addition of **embittering agents** reduce the risk of ingestion by most children.

Annex ZA (informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 88/378/EEC.

WARNING : Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this Standard.

The following clauses of this Standard are likely to support requirements of EU Directive 88/378/EEC: Council Directive of 3 May 1988 on the approximation of the laws of the Member States concerning the Safety of toys.

Compliance with the clauses of this Standard provides one means of conforming to the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 88/378/EEC

Essential Requirements of Directive 88/378/EEC as given in annex II	Corresponding clauses / subclauses of EN 71-7
I. 1 a), b) (General)	4.1
I. 2 b); 3 (General)	6.2.2
II. 3.,1. (Particular)	4.2, 2.3, 4.4, 4.5, 4.7
II. 3.,2. (Particular)	4.4

Bibliography

This European Standard incorporates references to EU Directives. These references are cited at the appropriate place in the text and the publications are listed hereafter. Existing amendments and adaptations to the directives should be regarded.

European Parliament and Council Directive 94/34/EC of 30 June 1994 amending Directive 89/107/EEC on the approximation of the laws of Member States concerning food additives authorised for use in foodstuffs intended for human consumption

European Parliament and Council Directive 95/2/EC of 20 February 1995 concerning food additives other than colouring matters and sweeteners

European Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

European Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products

Second Commission Directive 82/434/EEC of 14 May 1982 on the approximation of the Laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products

Third Commission Directive 83/514/EEC of 27 September 1983 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products

Fourth Commission Directive 85/490/EEC of 11 October 1985 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products

Commission Directive 90/207/EEC of 4 April 1990 amending the second Directive 82/434/EEC on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products

Fifth Commission Directive 93/73/EEC of 9 September 1993 on the methods of analysis necessary for checking the composition of cosmetic products

Sixth Commission Directive 95/32/EC of 7 July 1995 on the methods of analysis necessary for checking the composition of cosmetic products

Seventh Commission Directive 96/45/EC of 2 July 1996 on the methods of analysis necessary for checking the composition of cosmetic products

European Council Directive 99/45/EC of 31 May 1999 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

Analytical method No. 212: Determination of unsulphonated primary aromatic amines in pigments and in solvent soluble dyestuffs intended for use in food packaging; Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry (ETAD)

HPLC Method for the determination of aromatic amines released from water-colours under physiological conditions; Mitt. Gebiete Lebensm. Hyg. 88, 305-320 (1997)

German regulation: Bedarfsgegenständeverordnung vom 10. April 1992 including amendments

G. Schneider, Deutsche Lebensmittel-Rundschau 93, 69-74 (1997)

EN 71-7:2002 (E)

Deutsche Forschungsgemeinschaft: MAK- und BAT-Werte-Liste 1995; Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Mitteilung 31, Abschnitt IIIA, VCH-Verlagsgesellschaft, Weinheim

Official collection of analytical procedure acc. § 35 LMBG, No. B82.02-4, January 1998; Detection of the application of certain azo dyes from polyester fibres

Official collection of analytical procedure acc. § 35 LMBG, No. B82.02-4, Proof of application of certain Azo Dyes in consumer goods.

NOTE The official method was developed by the working group "Analytik verbotener Azofarbstoffe" of the "Kommission des Bundesinstituts für gesundheitlichen Verbraucherschutz und Veterinärmedizin zur Durchführung des § 35 LMBG" and evaluated with 11 participants.

EN 71-1, *Safety of toys — Part 1: Mechanical and physical properties.*

EN 71-2, *Safety of toys — Part 2: Flammability.*

EN ISO 3696, *Water for analytical laboratory use - Specification and test methods (ISO 3696:1987).*

