

PROSAFE JOINT ACTION 2010 - CHILDREN'S FANCY DRESS

GUIDE FOR ECONOMIC OPERATORS CONCERNING THE SAFETY REQUIREMENTS FOR CHILDREN'S FANCY DRESSES (CFDs)

(Also referred to as Carnival Costumes, Disguise Costumes, Dressing Up Clothes etc.)

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1. Introduction

Children's Fancy Dresses (CFDs) that are currently being placed on the market by economic operators cover a wide range of articles for children under 14 years of age. They usually come within the scope of the Directive on the Safety of Toys (2009/48/EC). The exception to this are carnival costumes, disguise costumes, fancy dresses etc. that are designed for children in the 0-1 age range, which come under the provisions of the General Product Safety Directive (2001/95/EC).

The General Product Safety Directive acts as an 'umbrella' item of legislation. Article 3.1 places an obligation on producers to place only safe products on the market. The remaining sections of Article 3 detail the various requirements and safety standards that a producer needs to satisfy if it is to be regarded as being 'safe'.

Many CFDs are made from one or more fabrics and, as a consequence, present a range of physical and mechanical hazards, as well as chemical hazards. Some of these hazards are regulated by safety requirements that are outside the scope of the toy directive. Unfortunately the legislation and safety requirements relating to these hazards are fragmented and are often not easily accessible by economic operators.

This Guide aims to identify the relevant legislation, how it may be obtained and, where applicable, the relevant safety standards. In some cases the legislation prescribes the safety requirement relating to a particular hazardous substance, but does not identify how the product may be evaluated so as to establish whether the safety limit for the substance concerned has been exceeded. Where possible, advice is given on the methods used by test laboratories to quantify the amount of the substance present in the article.

CFDs often contain a number of fabrics, each of which may present a number of different hazards to the user. It is important to assess the hazards presented by the article as a whole, as well as those presented by the individual fabrics and other items, such as accessories and embellishments, that make up the garment. It is necessary to bear in mind that each fabric may present different flammability characteristics and may contain different dyes and other potentially hazardous substances to those in the rest of the garment.

DG Enterprise & Industry's Expert Group on Toy Safety has recently published guidance on those CFDs that are intended for children in the 0-1 age range. Their Guidance Document No.17 - On the application of the Directive on the safety of toys - Carnival Costumes (Disguise Costumes, Fancy Dress etc.) was published on 4 December 2012¹ and states:

“That babies are not even capable to dress themselves, it is impossible for them to have an idea what they are dressed as and to play this character. Carnival costumes for children aged 0-1 year clearly have no play value for the children and should therefore not be classified as toys. This is also in accordance with the age determination guidelines of the CPSC. Economic operators have to bear in mind that other EU legislation may be applicable e.g. General Product Safety Directive 2001/95/EC (GPSD).”

The principal safety standard governing these products is EN 71 - Safety of Toys. The various parts of this standard and their applicability to CFDs are discussed at 2. Other legislation and safety standards that apply to CFDs are discussed at 3.

The physical and mechanical hazards likely to be present in CFDs are discussed at 4.

¹ Published at: http://ec.europa.eu/enterprise/sectors/toys/files/guidance-documents/017-guidance-document-disguise-costumes_en.pdf

2. Toy safety standards - EN 71 - Safety of toys & EN 62115 - Electrical toys - Safety

2.1 EN 71 - Safety of toys

EN 71 has the following parts that are applicable to CFDs:

EN 71-1: 2011 - Part 1 - Mechanical & physical properties

EN 71-2: 2011 - Part 2 - Flammability

EN 71-3: 1995 - Part 3 - Specification for migration of certain elements

EN 71-9: 2005 + A1: 2007 - Part 9 - Organic chemical compounds - Requirements

EN 71-10: 2005 - Part 10 - Organic chemical compounds - Sample preparation & extraction

EN 71-11: 2005 - Part 11 - Organic chemical compounds - Methods of extraction

It is likely that EN 71-12. Safety of toys. Part 12. N-nitrosamines and N-nitrosatable substances will be published in the not too distant future as a 'draft for public comment' was published in mid 2012.

Other documents relating to EN 71 that are likely to be useful include:

PD CEN/TR 15071: 2005 - Safety of toys. National translations of warnings and instruction for use of EN 71

PD/CEN TR 15371 - Safety of toys. Replies to requests for interpretation of EN 71-1, EN 71-2 & EN 71-8

(Note: The versions of each standard cited above are those current as at April 2013. New editions or amendments to these standards will, from time to time, be approved for publication by CEN. The date of withdrawal of conflicting standards (i.e. the previous edition of the standard) is usually published in the text of the new edition.)

EN 71-1 covers a wide range of physical and mechanical hazards that may be present in toys. It is recommended that when testing CFDs that economic operators should ask test laboratories to test products in relation to those clauses that are applicable to the CFD concerned.

EN 71-2 is particularly relevant to CFDs as these garments usually contain fabrics that are highly flammable, such as net or voile. Clause 4 is particularly important as it details the safety and marking requirements for toys to be worn on the head (clause 4.2); toy disguise costumes and toys intended to be worn by a child in play (clause 4.3) and toys intended to be entered by a child (clause 4.4).

EN 71-3 is relevant for those CFDs that have metallic parts. Currently the standard covers the safety requirements & test methods concerning the migration of the following elements:

Antimony, Arsenic, Barium, Cadmium, Chromium, Lead, Mercury, Selenium

The Directive on the safety of toys provides that, for articles that are placed on the market after 20 July 2013, the following migration limits shall apply to toys or components of toys, and shall not be exceeded:

<i>Element</i>	<i>mg/kg in dry, brittle, powder-like or pliable toy material</i>	<i>mg/kg in liquid or sticky toy material</i>	<i>mg/kg in scraped-off toy material</i>
Aluminium	5 625	1 406	70 000
Antimony	45	11.3	560
Arsenic	3.8	0.9	47
Barium	4 500	1 125	56 000
Boron	1 200	300	15 000
Cadmium	1.9	0.5	23
<i>Element</i>	<i>mg/kg in dry, brittle, powder-like or pliable toy material</i>	<i>mg/kg in liquid or sticky toy material</i>	<i>mg/kg in scraped-off toy material</i>
Chromium (III)	37.5	9.4	460
Chromium (VI)	0.02	0.005	0.2
Cobalt	10.5	2.6	130
Copper	622.5	156	7 700
Lead	13.5	3.4	160
Manganese	1 200	300	15 000
Mercury	7.5	1.9	94
Nickel	75	18.8	930
Selenium	37.5	9.4	460
Strontium	4 500	1 125	56 000
Tin	15 000	3 750	180 000
Organic tin	0.9	0.2	12
Zinc	3 750	938	46 000

In mid 2013 CEN are intending to publish a draft of a new edition of EN 71-3 which is likely address the testing of those elements that are subject to the additional safety requirements imposed by Directive 2009/48/EC.

EN 71- 9 and its related parts, EN 71-10 & EN 71-11, concern the limits for a wide range of substances that may be found in toys and their accessible components. (In each case the 'Action Limit' is applicable, unless stated otherwise.) The substances that are likely to be found in CFDs include:

From Table 2A the following flame retardants:

Tri-o-cresyl phosphate CAS No 78-30-8
Tris(2-chloroethyl) phosphate CAS No 115-96-8

From Table 2B the following colourants:

Disperse Blue 1 CAS No 2475-45-8
Disperse Blue 3 CAS No 2475-46-9
Disperse Blue 106 CAS No 12223-01-7
Disperse Blue 124 CAS No 61951-51-7
Disperse Yellow 3 CAS No 2832-40-8
Disperse Orange 3 CAS No 730-40-5
Disperse Orange 37/76 CAS Nos 12223-33-5 & 13301-61-6

Disperse Red 1	CAS No 2872-52-8
Solvent Yellow 1	CAS No 60-09-3
Solvent Yellow 2	CAS No 60-11-7
Solvent Yellow 3	CAS No 97-56-3
Basic Red 9	CAS No 569-61-9
Basic Violet 1	CAS No 8004-87-3
Basic Violet 3	CAS No 548-62-9
Acid Red 26	CAS No 3761-53-3
Acid Violet 49	CAS No 1694-09-3

From Table 2C the following primary aromatic amines (see also 3.1 below):

Benzidine	CAS No 92-87-5
2-Naphthylamine	CAS No 91-59-8
4-Chloroaniline	CAS No 106-47-8
3,3'-Dichlorobenzidine	CAS No 91-94-1
3,3'-Dimethoxybenzidine	CAS No 119-90-4
3,3'-Dimethylbenzidine	CAS No 119-93-7
o-Toluidine	CAS No 95-53-4
2-Methoxyaniline (o-Anisidine)	CAS No 90-04-0
Aniline	CAS No 62-53-3

From Table 2D the following monomer:

Acrylamide	CAS No 79-06-1	
Bisphenol A	CAS No 80-05-7	Limit - 0.1 mg/l
Formaldehyde	CAS No 50-00-0	Limit - 2.5 mg/l ²
Phenol	CAS No 108-95-2	Limit - 15 mg/l
Styrene	CAS No 100-42-5	Limit - 0.75 mg/l

Note: The limits are expressed as amount of substance per litre of simulant

From Table 2I the following plasticisers:

Triphenyl phosphate	CAS No 115-86-6
Tri- <i>o</i> -cresyl phosphate	CAS No 78-30-8
Tri- <i>m</i> -cresyl phosphate	CAS No 563-04-2
Tri- <i>p</i> -cresyl phosphate	CAS No 78-32-0

Note: Limits are expressed as amount of substance per litre of simulant

2.2 EN 62115 - Electrical Toys - Safety

Increasingly CFDs include batteries that may be used to power lights on the garment, or to generate sound. EN 62115: 2005 + A11: 2012 specifies, at Clause 9, the temperature rise of accessible parts of the toy. Toys containing batteries will therefore need to be checked for this hazard.

Clause 9.9 states that:

The temperature rise of the surface of handles, knobs and other parts that are likely to be touched by hand shall not exceed the following values:

- 25 K, for parts of metal;
- 30 K, for parts of glass or porcelain;
- 35 K, for parts of plastic or wood.

² Note: In some EU Members States there is also national legislation concerning the presence of formaldehyde in textiles.

The temperature rise of other accessible parts of the toy shall not exceed the following values:

- 45 K, for parts of metal;
- 50 K, for parts of glass or porcelain;
- 55 K, for parts of other materials.

In some cases the batteries may be easily accessible by the wearer of the garment and, if swallowed, it may leak thereby giving rise to a chemical hazard. In 2012 there were 4 RAPEX notifications relating to this hazard. It is necessary therefore to ensure that batteries are an integral part of the article and are not accessible by the user of the garment.

3. Other legislation and safety standards that apply to CFDs

3.1 The key items of other legislation and safety standards that apply to CFDs

The section focuses on the most important chemical requirements that relate to the safety of the children's fancy dresses. They include:

3.1.1 Regulation (EC) 1907/2006 - REACH - Annex XVII - 27 - Nickel

The Regulation specifies that nickel shall not be used in articles that come into direct and prolonged contact with the skin if the rate of nickel release is greater than 0.5 µg/cm²/week. The relevant test methods are:

EN 1811: 2011 - Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin and/or

EN 12472: 2006 + A1: 2009 - Method for the simulation of wear and corrosion for the detection of nickel release from coated items.

Note: These requirements relate to items on the CFD that may come into direct and prolonged contact with the skin. The requirements relating to nickel that are detailed at 2 above, relate to the nickel content of any parts of the CFD that contains nickel.

3.1.2 Regulation (EC) 1907/2006 - REACH - Annex XVII - 43 - Azocolourants

Annex XVII specifies Article 43 that azo dyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8 in detectable quantities, i.e. above 30 ppm in the finished article or in the dyed parts thereof shall not be used in textiles and leather articles which may come into direct and prolonged contact with the human skin or oral cavity.

The Article also specifies that Azodyes, which are contained in Appendix 9 shall not be placed on the market or used for colouring textiles and leather articles as a substance or constituent of preparations in concentrations higher than 0.1% by mass.

The substances to which the requirement relates are listed at REACH Appendix 8 and Appendix 9.

The list at Appendix 8 includes 22 azo colourants and is more extensive than the list of primary aromatic amines given at EN 71-9 - Table 2C. (See 2.1 above.) All the substances listed at EN 71-9 - Table 2C are listed at REACH Appendix 8, with the exception of Aniline 62-53-3 - which is only listed at EN 71-9 - Table 2C.

The following aromatic amines are listed at REACH Annex XVII, Appendix 8:

No.	Substance	CAS number
1	4-aminodiphenyl	92-67-1
2	Benzidine	92-87-5
3	4-chloro-o-toluidine	95-69-2
4	2-naphthylamine	91-59-8
5 *	4-amino-2',3-dimethylazobenzene	97-56-3
6 *	2-amino-4-nitrotoluene	99-55-8
7	4-chloroaniline	106-47-8
8	2,4-diaminoanisole	615-05-4
9	4,4'-diaminodiphenylmethane	101-77-9
10	3,3'-dichlorobenzidine	91-94-1
11	3,3'-dimethoxybenzidine	119-90-4
12	3,3'-dimethylbenzidine	119-93-7
13	3,3'-dimethyl- 4,4'-diaminodiphenylmethane	838-88-0
14	4-cresidine	120-71-8
15	4,4'-methylene-bis-(2-chloroaniline)	101-14-4
16	4,4'-oxydianiline	101-80-4
17	4,4'-thiodianiline	139-65-1
18	2-aminotoluene	95-53-4
19	2,4-diaminotoluene	95-80-7
20	2,4,5-trimethylaniline	137-17-7
21	2-methoxyaniline	90-04-0
22 **	4-aminoazobenzene	60-09-3

A single restricted azo colourant is listed at Appendix 9 to REACH. This substance is referred to as a 'blue colourant' and is a mixture of a number of substances which is referenced by EC Number

405-665-4 and consists of Component 1 - CAS No 118685-33-9 - $C_{39}H_{23}ClCrN_7O_{12}S_2Na$ and Component 2 - $C_{46}H_{30}CrN_{10}O_{20}S_2 \cdot 3Na$ for which no CAS No is specified.

The standards relating to the determination of the amount of aromatic amine in a textile are:

EN 14362 - Part 1: 2012 - Textiles - Methods for the determination of certain aromatic amines derived from azo colorants - Detection of the use of certain azo colorants accessible with and without extracting the fibres;

EN 14362 - Part 3: 2012 - Textiles - Methods for the determination of certain aromatic amines derived from azo colorants - Detection of the use of certain azo colorants which may release 4-aminoazobenzene;

EN ISO 17234-1: 2010 - Leather – Chemical tests for the determination of certain azo colorants in dyed leathers - Part 1: Determination of certain aromatic amines derived from azo colorants, and

EN ISO 17234-2: 2011 - Leather – Chemical tests for the determination of certain azo colorants in dyed leathers - Part 2: Determination of 4- aminoazobenzene;

3.1.3 Regulation (EC) 1907/2006 - REACH - Annex XVII - Articles 51 & 52 - Phthalates.

This Article specifies that:

the phthalates DEHP, DBP and BBP shall not be used as substances or mixtures in concentrations greater than 0.1% by weight of the plasticised material in toys and child care articles, and

that the phthalates DINP, DIDP and DNOP shall not be used as substances or mixtures in concentrations greater than 0.1% by weight in plasticised materials in toys or child care articles which can be placed in the mouth by children.

Recently the European Chemicals Agency (ECHA) has offered guidance on the maximum amount of phthalate that a toy or child care article may contain. They state 'A toy or childcare article would not comply with the Entry 51 or Entry 52

respectively if it contains either more than 0.1% of DEHP, DBP and BBP combined or more than 0.1% of DINP, DIDP and DNOP combined. However, it would be considered compliant if it contained only 0.09% of DEHP, DBP and BBP combined and 0.09% of DINP, DIDP and DNOP combined.³

The test method for phthalates is: EN 15777: 2009 - Textiles – Test method for phthalates.

3.2 Other hazardous substances that may be present in CFDs

3.2.1 The European Chemical Agency (ECHA) includes in its 'Candidate List of Substances of Very High Concern' (SVHC)

The European Chemical Agency (ECHA) includes in its 'Candidate List of Substances of Very High Concern' (SVHC) the following hazardous fire retardants that have been found in textiles or plastics:

Hexabromocyclododecane (HBCDD) and α - HBCDD, β - HBCDD and γ - HBCDD (CAS Nos. 25637-99-4, 3194-55-6 (134237-50-6) (134237-51-7) (134237-52-8), and Tris (2-chloroethyl) phosphate (CAS No 115-96-8)

³ ECHA -Questions and Answers - Implementation of Annex XVII to REACH on the restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and Articles. July 2012. Available at: http://echa.europa.eu/documents/10162/13645/questions_and_answers_restrictions_en.pdf

The presence of these substances may be detected using Gas Chromatography-Mass Spectrometry (GC-MS) or Liquid Chromatography-Mass Spectrometry LC-MS.

3.2.2 Other substances referenced at REACH Annex XVII

The Finnish Environmental Institute⁴ has drawn attention to the hazardous substances listed below. These substances have, on occasion, been found in textile items that have been placed on the market and which are restricted under the provisions of REACH Annex XVII.

No.	Substance	Restriction on Use
4	Tris (2,3 dibromopropyl) Phosphate CAS No 126-72-7	Not to be used in textile articles intended for contact with skin
5	Benzene CAS No 71-43-2	Not permitted in toys or parts of toys where the concentration of benzene in the free state is in excess of 5mg/kg of the weight of the toy or part of the toy
7	Tris(aziridinyl) Phosphin oxide CAS No 5455-55-1	Not to be used in textile articles intended for contact with skin
8	Polybrominated biphenyls (PBB) CAS No 59536-65-1	Not to be used in textile articles intended for contact with skin. ⁵
20	Tri-substituted organotin compounds	Not be used after 1 July 2010 in articles where concentrations (w/w) is >0.1 %
20	Dibutyltin (DBT) Compounds	Not to be used after 1 Jan 2012 in articles to general public where the concentration (w/w) is >0.1 % of tin
20	Dioctyltin (DOT)	As for DBT; includes textile and footwear compounds in contact with skin
22	Pentachlorophenol	Not to be used in concentrations (w/w) > 0,1 %
23	Cadmium CAS No 7440-43-9	Not to be used in certain PVC articles (apparel/clothing; impregnated/coated fabrics; imitation leather) (see also 2.1 above)
53	Perfluorinated Sulfonates	Not to be placed on the market for textiles or other coated materials if the amount of PFOS is equal to or >1 µg/m ² of coated material

⁴ Risk Management and Governance of chemicals in articles - Case Study Textiles - published by The Finnish Environment Institute, Helsinki, 2011, page 41.

⁵ There is evidence that pre- and post-natal exposure to PBB in girls leads to menarche at an earlier age. PBBs are listed as one of six controlled substances under the Restriction of Hazardous Substances (RoHS) Directive. It is understood that recently, with the introduction of a new analytical instrument IA-Mass, screening of plastic material for these substances is possible.

4. The physical and mechanical hazards likely to be present in CFDs

4.1 Cords and drawstrings on children's clothing

CEN has developed a safety standard concerning cords and drawstrings on clothing intended for children up to age 14, viz.: EN 14862: 2007 - Safety of children's clothing. Cords and drawstrings on children's clothing. Specifications.

The aim of EN 14862:2007 is to minimise the risk of accidental entrapment by cords or drawstrings on children's clothing taking into account:

- (a) The child's age
- (b) Normal behaviour and activities of children for their age and stage of development, for example playing in playgrounds, climbing trees, travelling by bus or train, ability to look after themselves, and where relevant, level of supervision
- (c) National accident statistics indicate that serious accidents involving cords and drawstrings on children's clothing fall into two main groups by age of child

The standard draws attention to the fact that national accident statistics involving cords and drawstrings on children's clothing fall into two main groups by age of child, viz.:

- (1) Younger children - the entrapment of hood cords in playground equipment such as slides, resulting in fatalities;
- (2) Older children and young persons - entrapment of cords and strings from the waist and lower hems of garments in moving vehicles such as bus doors, lifts and bicycles resulting in severe injuries or death from being dragged along or run over by a vehicle.

In addition, elasticated hood or neck cords have resulted in a number of fatalities.

Cords and drawstrings are occasionally found on CFDs. EN 14862 details the safety requirements relating to the hazards presented by these items.

4.2 Solar UV Protection

Clothing is the single most effective form of sun protection. It is our first line of defence against the sun's harmful ultraviolet rays.

Nearly 3.7 million skin cancers are diagnosed in the US annually. The vast majority of them are caused by solar UV radiation (UVR). UVR also causes up to 90 percent of the visible changes commonly attributed to aging, such as wrinkles, brown spots, and sagging skin. Fortunately, clothing can absorb or block much of this radiation. A UPF (ultraviolet protection factor) label, conveys how much of the sun's UV radiation can penetrate the fabric; a garment with a UPF of 30 will let just 1/30th of the UV reach the skin.). UPF ratings range from 15 (good) to 50+ (excellent). Increasingly manufacturers of children's clothing are UPF rating their clothing, a trend that may start to catch on for CFDs. The relevant safety standards are:

EN 13758-1: 2002 Textiles. Solar UV properties. Method of test for apparel fabrics
EN 13758-2: 2003 Textiles. Solar UV properties. Classification & marking of apparel

4.3 The design & manufacture of children's clothing to promote mechanical safety

The British Standards Institution (BSI) has published BS 7907: 2007 - Code of practice for the design & manufacture of children's clothing to promote mechanical safety.

This standard, uniquely, covers a wide range of physical and mechanical hazards likely to be present in children's clothing. It is intended to be used at all stages of the clothing supply chain, including use by designers, specifiers and manufacturers of children's clothing. It is also intended to be used by importers, distributors and retailers to assist them in the selection of clothing that does not present a mechanical hazard.