

Product Safety Compliance Update



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Introduction

New Chinese standard published

On 23 December 2015, China Food and Drug Administration released Notification No. 268 of Year 2015 that *Safety and Technical Standards for Cosmetics* (Version 2015) was published

Korea announces special Act

The Korean Agency for Technology and Standards (KATS) has established a common safety standard for all products designed for children.

OEKO-TEX® Standard update

OEKO-Tex website released the Version 2016 of Oeko-Tex® Standard 100 in several languages on 4 January 2016.

EU publishes NPE restrictions

On 14 January 2015, European Commission published Regulation [\(EU\) 2016/26](#) to amend Entry 46 in Annex XVII to REACH by including NPE restrictions on textile articles.



European Commission publishes NPE restrictions on textile articles under REACH

On 14 January 2015, European Commission published Regulation (EU) 2016/26 to amend Entry 46 in Annex XVII to REACH by including NPE restrictions on textile articles. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*. It shall be binding in its entirety and directly applicable in all Member States.

In Annex XVII to Regulation (EC) No 1907/2006, the following new entry 46a is added:

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
'46a. Nonylphenol ethoxylates (NPE) (C2H4O) _n C15H24O	<p>1. Shall not be placed on the market after 3 February 2021 in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than 0,01 % by weight of that textile article or of each part of the textile article.</p> <p>2. Paragraph 1 shall not apply to the placing on the market of second-hand textile articles or of new textile articles produced, without the use of NPE, exclusively from recycled textiles.</p> <p>3. For the purposes of paragraphs 1 and 2, "textile article" means any unfinished, semi-finished or finished product which is composed of at least 80 % textile fibres by weight, or any other product that contains a part which is composed of at least 80 % textile fibres by weight, including products such as clothing, accessories, interior textiles, fibres, yarn, fabrics and knitted panels.'</p>

The previous Entry 46 only targeted at "the placing on the market or use of NPE as substances or in mixtures" and the limit value was 0,1%. However, the amendment extends the scope and adds a limit value of 0,01% by weight of that textile article or of each part of the textile article.

With the Regulation effective since 24 January 2016, textile articles with NPE in concentrations of equal to or greater than 0,01% shall not be placed on EU market since 3 February 2021.

Korea Announces a Special Act on Safety Management of Children's Products

The Korean Agency for Technology and Standards (KATS) has established a common safety standard for all products designed for children. According to the legislation, infant and children's textile and leather products are regulated under the Special Act on Safety Management of Children's Products by Enactment of the Common Safety Standards of Children's Products, Safety Confirmation Act and Suppliers' Declaration of Conformity Act. The new regulation will become effective after 4th June 2016.

(A) Safety Confirmation Act

All textile products for infants are regulated under the Special Act on Safety Management of Children's Products – Enactment of Common Safety Standards of Children's Products and Safety Confirmation Act Annex 1 (Textile Products for Infants). Products must be tested and certified by local authorized Korean testing and inspection institutions, an approval Korea Certification Mark (KC Mark) must be attached on the products before distribution to the Korean market.

Product scope for infant textile products includes outerwear, innerwear, sleeping gear, shoes, socks, gloves, headgear, bags and baby goods.

(B) Supplier's Declaration of Conformity Act

Infant and children's leather products and children's textile products are regulated under the Special Act on Safety Management of Children's Products – Enactment of Common Safety Standards of Children's Products and Supplier's Declaration of Conformity Act Annex 1 (Leather Products) and Annex 15 (Textile Products).

Manufacturer or importer shall confirm the satisfaction by self-test or test conducted by a third party service provider (ISO 17025 accredited labs) for existence of any hazardous substances. Inspection agency shall verify the standard compliance according to the Supplier's Declaration of Conformity Act.

Product scope for infant leather products is the same as those listed for infant textile products. Product scope for children's textile and leather products includes innerwear and midwear with direct skin contact, outerwear without direct skin contact, bedding and others (e.g. bags) (Note: Natural or synthetic leather or fur material with more than 60% surface area on shell are considered as leather items.)

(C) Safety Quality Mark Act

Apart from infant and children's products, textile and leather products designated for ages over 13 years old are regulated under the Quality Management and Safety Control of Industrial Products Act – Safety Quality Mark Act Annex 1 (Household Textile Products) and Annex 3

Leather Products). Manufacturer or importer shall confirm the satisfaction by self-test or test conducted by a third party service provider (ISO 17025 accredited labs) for existence of any hazardous substances. Inspection agency shall verify the standard compliance according to Safety Quality Mark Act.

Product scope for textile and leather products includes innerwear and midwear with direct skin contact, outerwear without direct skin contact and bedding.

New Chinese standard for cosmetics published

On 23 December 2015, China Food and Drug Administration released Notification No. 268 of Year 2015 that *Safety and Technical Standards for Cosmetics* (Version 2015) was published upon review of experts from Cosmetics Standard Committee and would take into force on 1 December 2016.

Safety and Technical Standards for Cosmetics (hereinafter referred to as "Standard") provides for safety technical requirements for cosmetics, including general requirements, requirements on prohibited/restricted components, requirements on allowable components and methods for test and assessment, applicable to cosmetics that are produced or intended for sale in domestic China. (Except to products intended for sale in foreign countries).

The Standard is an update for *Hygienic Standard for Cosmetics* (Version 2007). The major amendments to the Standard include the following:

- I) **Clarify the definitions of terms.** It provides definitions for terms involved thereof, clarifying the concepts and connotation.
- II) **Specify general safety and technical requirements for cosmetics.** According to the risk assessment concerning heavy metals and other substances of high concern in cosmetics, the lead limit is adjusted from 40mg/kg to 10mg/kg and arsenic limit from 10mg/kg to 2mg/kg. Besides, it also adds a limit of 5 mg/kg for cadmium. In the meanwhile, it also requires that dioxane should not exceed 30mg/kg and asbestos should be ND in

accordance with requirements in normative technical documents in China Food and Drug Administration.

Hazardous Substances in Cosmetics

Hazardous Substance	Limit (mg/kg)	Remarks
Mercury	1	Excluding cosmetics containing organic mercury preservatives
Lead	10	
Arsenic	2	
Cadmium	5	
Methanol	2,000	
Dioxane	30	
Asbestos	ND	

Microbiological Limits for Cosmetics

Microbiological	Limit	Remarks
Total bacteria colonies(CFU/g or CFU/ml)	≤500	Cosmetics for eyes, mouth/lips and children
	≤1,000	Other cosmetics
Sum of mycete and saccharomycetes (CFU/g or CFU/ml)	≤100	
Thermotolerant coliform bacteria /g (or ml)	ND	ND
Staphylococcus aureus /g (or ml)	ND	
P.Aeruginosa /g (or ml)	ND	

- III) **Amend the lists for prohibited/restricted and allowable components in cosmetics.** The new standard includes: 1,388 prohibited components in total (with 133 additions and 137 amendments), 47 restricted components in total (with 1 addition, 31 amendments and 27 deletions). Besides, it also includes 51 allowable preservatives in total (with 14 amendments and 5 deletions); 27 allowable sun-screening agents in total (with 6 amendments and 1 deletion); 157 allowable colourants in total (with 1 addition and 69 amendments); 75 allowable hair dyes in total (with 63 amendments and 21 deletions).



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IV) **Amend physical and chemical inspection methods for cosmetics testing and assessment.** Based on original test in *Hygienic Standard for Cosmetics*, it adds 60 test methods on prohibited/restricted components for cosmetics and deletes other contents beyond the scope of the Standard, for instance, test methods for strontium and fluorine. Minor errors in the previous version are also corrected. Furthermore, it standardises microbiological and toxicological test methods and adjusts the format. For body safety and performance assessment, the test methods are categorised as body safety inspection and body performance assessment inspection. SPF also adds preparation method for P2 and P3.

OEKO-TEX® Standard 100 (Version 2016) Updated

OEKO-Tex website released the Version 2016 of OEKO-Tex® Standard 100 in several languages on 4 January 2016. For new or more severe requirements an interim arrangement is valid until 1 April 2016.

In addition to the general requirements for certification according to OEKO-Tex® Standard 100, the product specific requirements given in Appendix 4, have to be fulfilled by each component. The approach is also valid for untypical textile products such as furniture, cradles, pushchairs, beds and so on. The major changes are made to Appendix 4 and Appendix 5 to OEKO-Tex® Standard 100.

Compared with the previous version, the major changes in the new version of OEKO-Tex® Standard 100 are as the following:

I) Limit values and fastness, part 1

1. The sum of limit remains unchanged though eight new pesticides are added.

Product Class	I	II	III	IV
Pesticides [mg/kg]				
Sum	0.5	1.0	1.0	1.0

The pesticides of this addition are shown in the following table:

Substance	CAS
Acetamiprid	135410-20-7
Aldicarb	116-06-3
Clothianidin	210880-92-5
Dinotefuran	165252-70-0
Imidacloprid	105827-78-9
Nitenpyram	150824-47-8
Thiacloprid	111988-49-9
Thiamethoxam	153719-23-4

2. DCP and MCP are included in the restriction list, totaling nine new chlorinated phenols.

Product Class	I	II	III	IV
Chlorinated phenols[mg/kg]				
Dichlorophenols(DCP), Sum	0.5	3.0	3.0	3.0
Monochlorophenols(MCP), Sum	0.5	3.0	3.0	3.0

The chlorinated phenols of this addition are as the following:

Substance	CAS
2,3-Dichlorophenol	576-24-9
2,4-Dichlorophenol	120-83-2
2,5-Dichlorophenol	583-78-8
2,6-Dichlorophenol	87-65-0
3,4-Dichlorophenol	95-77-2
3,5-Dichlorophenol	591-35-5
2-Chlorophenol	95-57-8
3-Chlorophenol	108-43-0
4-Chlorophenol	106-48-9

3. DCHP is added on the list of phthalate restriction. After the inclusion, Oeko-Tex regulates 15 phthalates in total. Besides, it also adjusts calculation methods of the limits. The restrictions after adjustment are as the following:

Product Class	I	II	III	IV
Phthalates[w-%]				
Sum	0.1	0.1	0.1	
Sum without DINP				0.1

II) Limit values and fastness, part 2

4. It adds ten organic tin compounds:

Product Class	I	II	III	IV
Organic tin compounds[mg/kg]				
TBT, TPhT	0.5	1.0	1.0	1.0
DBT, DMT, DOT, DPT, MBT, MOT, MT, TeBT, TCyHT, TMT, TOT, TPT	1.0	2.0	2.0	2.0

The organic tin compounds of this addition are as the following:

Substance	Abbreviation
Dimethyltin	DMT
Diphenyltin	DPT
Methyltin	MT
Monobutyltin	MBT
Monooctyltin	MOT
Tetrabutyltin	TeBT
Tricyclohexyltin	TCyHT
Trimethyltin	TMT
Trioctyltin	TOT
Tripropyltin	TPT

5. Three new carcinogenic colorants and coatings are added.

Oeko-Tex prohibits the use of carcinogens.

Substance	CAS
C.I.BasicBlue26(with≥0.1%Michler'sketoneorbase)	2580-56-5
C.I.BasicGreen4(oxalate,chlorideorfree)	2437-29-8
C.I.BasicViolet3(with≥0.1%Michler'sketoneorbase)	548-62-9

6. Chlorobenzene is added. However, the sum of chlorinated benzenes and toluenes limit remains 1.0 ppm.

Product Class	I	II	III	IV
Chlorinated benzenes and toluenes [mg/kg]				
Sum	1.0	1.0	1.0	1.0

7. Three new flame retardants are banned:

Substance	CAS	Abbr
2,2-bis(bromomethyl)-1,3-propanediol	3296-90-0	BBMP
Bis-(2,3-dibromopropyl)phosphate	5412-25-9	BIS
TetrabromobisphenolA	79-94-7	TBBPA

III) Limit values and fastness, part 3

8. Requirement for formamide is added.

Product Class	I	II	III	IV
Solvent residues[w-%]				
Formamide	0.02	0.02	0.02	0.02

9. Three new PFC's are added:

Product Class	I	II	III	IV
PFC's, Perfluorinated Compounds[mg/kg]				
PFHpA	0.05	0.1	0.1	0.5
PFNA	0.05	0.1	0.1	0.5
PFDA	0.05	0.1	0.1	0.5

10. New restrictions for UV stabilizers in decoration materials:

Product Class	I	II	III	IV
UV stabilizers[w-%]				
UV320				0.1
UV327				0.1
UV328				0.1
UV350				0.1

Remarks: Class I: baby, Class II: in direct contact with skin, Class III: with no direct contact with skin, Class IV: decoration material.

