

*KOZMETİKLERİN REGÜLASYONU VE
RISK DEĞERLENDİRMESİ*



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Yönetmelikler

Kozmetikler ve Avrupa Birliği Pazarı

Yeni EU Cosmetic Products Regulation “(EC) No 1223/2009” 30 Ekim 2009 tarihinde kabul edilmiştir. Bu yeni regülasyonun hükümleri 11 Temmuz 2013 tarihinden itibaren geçerli olarak Cosmetics Directive (76/768/EEC) in yerini almıştır.

22.12.2009

EN

Official Journal of the European Union

L 342/59

REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 30 November 2009
on cosmetic products
(recast)
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee (1),

(5) The environmental concerns that substances used in cosmetic products may raise are considered through the application of 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) and establishing a European Chemicals Agency (4), which enables the assessment of environmental safety in a cross-sectoral manner.

(6) This Regulation relates only to cosmetic products and not to medicinal products, medical devices or biocidal prod-

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COUNCIL DIRECTIVE

of 27 July 1976

on the approximation of the laws of the Member States relating to cosmetic products

(76/768/EEC)

(OJ L 262, 27.9.1976, p. 169)

Amended by:

Official Journal

	No	page	date
►M1	Council Directive 79/661/EEC of 24 July 1979	L 192	35 31.7.1979
►M2	Commission Directive 82/147/EEC of 11 February 1982	L 63	26 6.3.1982
►M3	Council Directive 82/368/EEC of 17 May 1982	L 167	1 15.6.1982
►M4	Commission Directive 83/191/EEC of 30 March 1983	L 109	25 26.4.1983
►M5	Commission Directive 83/341/EEC of 29 June 1983	L 188	15 13.7.1983
►M6	Commission Directive 83/406/EEC of 27 September 1983	L 275	20 9.10.1983

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Temel değişiklikler yanda sıralanmıştır.

22.12.2009	EN	Official Journal of the European Union	L 342/59
REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance)			
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Merkezi bir dijital platformda bildirim (notification) hükümlerinin uyumlaştırılması.

- **Product Information File (PIF)**
 - **Cosmetic Product Safety Information (CPSI)**
 - **Cosmetic Product Safety Assessment (CPSA)**
- Dosyalarının hazırlanmasında daha açık hükümler**

Kozmetik nedir?

Article 2.1 a defines cosmetic products as any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors.

İnsan vücudunun dış yüzeyleri (epidermis, saç, tırnak, dudak, eksternal genital organlar) ile ya da diş ve oral mukoza ile temas eden ve temizleme, hoş bir koku verme, görünümünü değiştirme, koruma, iyi durumda tutma ve vücut kokusunu düzenleme amacıyla kullanılan madde veya karışımlara KOZMETİK denir.



Yönetmelikler

Kozmetikler ve Avrupa Birliği Pazarı

1 - Ürünün EU yönetmeliklerine göre kozmetik olup olmadığı tespit edilmelidir

Peruk kozmetik bir ürünmüdür?

Yönetmelikler

Kozmetikler ve Avrupa Birliği Pazarı

1 - Ürünün EU yönetmeliklerine göre kozmetik olup olmadığı tespit edilmelidir

Peruk kozmetik bir ürünmüdür?

Cevap: hayır

Kozmetikler bir madde yada müstahzar olmalıdır. Peruk mevzuata göre bir müstahzar olmadığından kozmetik sayılamaz ve Kozmetik yönetmeliğine tabi değildir.

Kürdan veya diş ipleri kozmetik bir üründür mü?

Cevap: hayır

Hayır bu ürünler madde yada müstahzar olmadığından kozmetik bir ürün değildir ve kozmetik yönetmeliğine tabi değildirler. Ancak bu ürünler koku verici veya ferahlatıcı maddeler içerir ise bu maddeler kozmetik regülasyonu kapsamında girmektedir.

Daha fazla bilgi için:

http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/manual_borderlines_version50_en.pdf

Tükürükte çözünüp yutularak ağızdaki kötü kokulara karşı geliştirilmiş tablet formundaki bir ürün kozmetik üründür mü?

Cevap: hayır

Kozmetik direktifi kozmetikleri şu şekilde tanımlamaktadır: İnsan vücudunun çeşitli dış (external) bölgeleri ile (epidermis, saç, tırnak, dudaklar ve eksternal genital organlar) yada dişler, ağız mukozası ile temel olarak temizleme, koku verme, görünüşlerini değiştirme, vücut kokusunu düzenleme yada iyi durumda tutmak amacıyla temas eden madde yada müstahsarlara kozmetik denir. Bu tanımlama 2 temel kavram üzerine oturmaktadır.

1. Uygulama yeri (vücut, diş yada mukoz membranlar uygulanır)
2. Amaçlanan ana fonksiyon (temizleme, koku verme, görünüşün düzeltilmesi, vücut kokularının düzenlenmesi, koruma ve iyi durumda tutma)

Kozmetik direktifine göre; yutulan, inhale edilen, insan vücuduna injekte yada implante edilen ürünler kozmetik olarak tanımlanmamaktadır.

2 - Ürün içeriğinin Avrupa Birliğinde yasak olup olmadığı bilinmelidir

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ANNEX II

LIST OF SUBSTANCES PROHIBITED IN COSMETIC PRODUCTS

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1	N-(5-Chlorobenzoxazol-2-yl)acetamide	35783-57-4	
2	(2-Acetoxyethyl)trimethylammonium hydroxide (Acetylcholine) and its salts	51-84-3	200-128-9
	2-Propanediol and its salts, when used as a substance in hair dye products	102/6/-2/-1	
1327	3-[[4-[Ethyl(2-Hydroxyethyl)Amino]-2-Nitrophenyl]Amino]-1, 2-Propanediol and its salts, when used as a substance in hair dye products	114087-41-1/ 114087-42-2	
1328	Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, and its salts, when used as a substance in hair dye products	2390-60-5	219-232-0

Yönetmelikler

Kozmetikler ve Avrupa Birliği Pazarı

ANNEX III

LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
1a	Boric acid, borates and tetraborates with the exception of substance No 1184 in Annex II	Boric acid	10043-35-3/ 11113-50-1	233-139-2/ 234-343-4	(a) Talc (b) Oral products	(a) 5 % (as boric acid) (b) 0,1 % (as boric acid)	(a) Not to be used in products for children under 3 years of age Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1,5 % (as boric acid) (b) Not to be used in products for chil-	(a) Not to be used for children under 3 years of age Not to be used on peeling or irritated skin (b) Not to be swallowed Not to be used for
256	(4-(4-Aminophenyl)-2,5-dienylidene)methyl-2-methylaniline hydrochloride (CI 42510) and other salts	Basic Violet 14 (CI 42510)	632-99-5	211-189-6	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0,3 % (b) 0,3 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,15 % Not to be used after 31.12.2009	

ANNEX IV

LIST OF COLORANTS ALLOWED IN COSMETIC PRODUCTS

Preamble

Without prejudice to other provisions in this Regulation, a colorant shall include its salts and lakes and when a colorant is expressed as a specific salt, its other salts and lakes shall also be included.

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	E:C number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
1	Sodium tris(1,2-naphthoquinone 1-oximato-O,O')ferrate(1-)	10006			Green	Rinse-off products			
2	Trisodium tris[5,6-dihydro-5-(hydroxyimino)-6-oxonaphthalene-2-	10020			Green	Not to be used in products applied on mucous mem-			
152	Phenol, 4,4'-(3H-2,1-benzoxathiol-3-ylidene)bis[2,6-dibromo-3-methyl-,S,S-dioxide	Bromocresol green	76-60-8	200-972-8	Green	Rinse-off products			
153	Sodium 4-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]-3-hydroxynaphthalene-1-sulphonate	Acid red 195	12220-24-5	—	Red	Not to be used in products applied on mucous membranes			

ANNEX V

LIST OF PRESERVATIVES ALLOWED IN COSMETIC PRODUCTS

Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
1	Benzoic acid and its sodium salt	Benzoic acid Sodium Benzoate	65-85-0 532-32-1	200-618-2 208-534-8	Rinse-off products, except oral products Oral products Leave-on products	2,5 % (acid) 1,7 % (acid) 0,5 % (acid)		
1a	Salts of benzoic acid other than that listed under reference number 1 and esters of benzoic acid	Ammonium benzoate, calcium benzoate, potassium benzoate, magnesium benzoate, MEA-benzoate, methyl benzoate, ethyl benzoate, propyl benzoate,	1863-63-4, 2090-05-3, 582-25-2, 553-70-8, 4337-66-0, 93-58-3, 93-89-0, 2315-68-6, 136-60-7, 120-50-3, 939-48-0, 93-99-2	217-468-9, 218-235-4, 209-481-3, 209-045-2, 224-387-2,		0,5 % (acid)		
57	2-Methyl-2H-isothiazol-3-one	Methylisothiazolinone	2682-20-4	220-239-6		0,01 %	3 years of age	

ANNEX VI

LIST OF UV FILTERS ALLOWED IN COSMETIC PRODUCTS

Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN/XAN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
1	4-Aminobenzoic acid	PABA	150-13-0	205-753-0		5 %		
2	N,N,N-Trimethyl-4-(2-oxoborn-3-ylidenemethyl)anilinium methyl sulfate	Camphor Benzalkonium Methosulfate	52793-97-2	258-19 -8		6 %		
3	Benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester/Homosalate	Homosalate	118-56-9	204-260-8		10 %		
4	2-Hydroxy-4-methoxybenzophenone/Oxybenzone	Benzophenone-3	131-57-7	205-031-5		10 %		Contains
26	Dimethyldiethylbenzylmalonate	Polysilicone-15	20754/4-1	426-000-4		10 %		
27	Titanium dioxide (2)	Titanium Dioxide	13463-67-7/ 1317-70-0/ 1317-80-2	236-675-5/ 205-280-1/ 215-282-2		25 %		
28	Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexylester	Diethylamino Hydroxybenzoyl Hexyl Benzoate	302776-68-7	443-860-6		10 % in sun-screen products		

3 - Ürün bilgi dosyası Product Information File
“PIF”

PIF; her bir kozmetik ürün için hazırlanmalıdır ve yetkili makamların denetimine açık durumda olmalıdır.

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ANNEX I

COSMETIC PRODUCT SAFETY REPORT

Yönetmelikler

Kozmetikler ve Avrupa Birliği Pazarı

Product Information File

Kozmetik ürünün tanımlanması

Kozmetik ürünün güvenlik raporu
Cosmetic Product Safety Report
(CPSR)

Üretim metodu ile ilgili
açıklamalar ve GMP'ye
uygunluğunun belirtilmesi

Kozmetik ürünün etkileri ile ilgili
kanıtlar

Kozmetik ürünün ve içerikleri ile
ilgili güvenlik değerlendirmesinde
kullanılabilecek hayvan testleri
verileri.

Kısım A – Kozmetik ürün güvenlik bilgileri Cosmetic Product Safety Information

- Kozmetik ürünün kantitatif ve kalitatif kompozisyonu
- Kozmetik ürünün stabilitesi ve fiziksel / kimyasal özellikleri
- Mikrobiyal kalitesi
- Safsızlıklar ve paketlenme materyali ile ilgili bilgiler
- Makul sınırlar içinde öngörülebilir ve normal kullanım
- Kozmetik ürüne maruziyet (cosmetic product)
- Maddelere maruziyet (substance)
- Maddenin toksikolojik profili
- İstenmeyen etkiler ve ciddi istenmeyen etkiler
- Kozmetik ürün ile ilgili bilgi

Kısım B – Kozmetik ürün güvenlik değerlendirmesi Cosmetic Product Safety Assessment

- Değerlendirme sonucu
- Kullanım bilgileri ve etiketli uyarılar
- Karar
- Değerlendirenin kimlik bilgileri ve onayı

ANNEX I

COSMETIC PRODUCT SAFETY REPORT

PART A – Cosmetic product safety information

1. **Quantitative and qualitative composition of the cosmetic product**
2. **Physical/chemical characteristics and stability of the cosmetic product**
3. **Microbiological quality**
4. **Impurities, traces, information about the packaging material**
5. **Normal and reasonably foreseeable use**
6. **Exposure to the cosmetic product**
7. **Exposure to the substances**
8. **Toxicological profile of the substances**
9. **Undesirable effects and serious undesirable effects**
10. **Information on the cosmetic product**

PART B – Cosmetic product safety assessment

1. **Assessment conclusion**
2. **Labelled warnings and instructions of use**
3. **Reasoning**
4. **Assessor's credentials and approval of part B**

Yönetmelikler

Kozmetikler ve Avrupa Birliği Pazarı

ANNEX I

COSMETIC PRODUCT SAFETY REPORT

PART A – Cosmetic product safety information

1. Quantitative and qualitative composition of the cosmetic product
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1. Assessment conclusion
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4. Assessor's credentials and approval of part B

Kozmetik ürünün toksisite profili, içerdiği tüm bileşenler göz önünde bulundurularak değerlendirilmelidir.

- Cilt ve göz iritasyonu,
- Cilt hassasiyeti,
- Fototoksiste

gibi lokal toksik etkiler de özellikle göz önünde bulundurulmalıdır.

Olası tüm absorpsiyon yolları göz önünde bulundurularak sistemik etkiler için

- No Observed Adverse Effect Level “NOAEL”

değerleri belirlenmeli ve bu değerler üzerinden

- Margin of Safety “MoS” (NOAEL / Exposure)

hesaplanmalıdır.

Kozmetik ürünlerde maruziyetin tahmini

Örnek;

Koruyucu (preservative) amaçla kullanılan bir "X" kimyasal maddesi için maruziyet değerlendirmesi.

Bu "preservative"e maruz kalınabilecek tüm kozmetik ürünler bir arada düşünülmesi ve toplam maruziyet hesaplanmalıdır.

Mümkün olabilecek en yüksek maruziyet üzerinden toplam maruziyet hesaplanmalıdır.

- Bayanların kullanım sıklığı ve miktarı baz alınır.
- Tüm kozmetik ürünlerin en aşırı miktarda kullanıldığı varsayılır.
- Değerlendireceğimiz "preservative"nin tüm kozmetik ürünlerde maksimum düzeyde bulunduğu kabul edilir.

Kozmetik ürünlerde maruziyet değerlendirilirken genelde kozmetikler 4 ana grupta incelenmektedir;

- Oral hijyen ürünleri
- Göz ürünleri
- Temizlenerek uzaklaştırılmayan ürünler
- Temizlenerek uzaklaştırılan ürünler

Yönetmelikler

Kozmetikler ve Avrupa Birliği Pazarı

Oral hygiene products	Product type	Total amount ingested per application (g)	Frequency of application per day	Exposure grams/day
	Toothpaste	1,40 (Rf:0.17)	2	0,48
	Mouthwash	10,0 (Rf: 0.1)	3	3,00
	Lipstick	0,01	4	0,04
	Total			3,52
Eye products	Product type	Total amount per application (g)	Frequency of application per day	Exposure grams/day
	Eye make-up	0,010	2	0,020
	Mascara	0,025	1	0,025
	Liner	0,005	1	0,005
	Total			0,050
Non rinse-off products	Product type	Total amount per application (g)	Frequency of application per day	Exposure grams/day
	Face cream	0,8	2	1,6
	General purp. cream	1,2	2	2,4
	Body lotion	8	1	8,0
	Anti-perspirant	0,5	1	0,5
	Hair styling prod.	5	2	1,0
Total			13,5	
Rinse-off products	Product type	Total amount per application (g)	Frequency of application per day	Exposure grams/day
	Make-up remover	2,5 (Rf: 0.1)	2	0,50
	Shower gel	5,0 (Rf: 0.01)	1	0,05
	Shampoo	8,0 (Rf: 0.01)	1	0,08
	Hair conditioner	14,0 (Rf: 0.01)	0,28	0,04
	Total			0,67

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Kozmetikler ve Avrupa Birliği Pazarı

Table 2 : Calculation of the daily exposure to cosmetics using Colipa data [SCCNFP/0321/02].

Product type	Amount of substance applied	Frequency of application	Retention factor ¹⁸	Daily exposure calculated
Hair care				
Shampoo	8.0 g	1 / day	0.01	0.08 g/day
Hair conditioner	14.0 g	0.28 / day	0.01	0.04 g/day
Hair styling products	5.0 g	2 / day	0.1	1.00 g/day
Oxidation or permanent hair dyes	100 ml	1 / month (30 min.)	0.1	Not calculated ¹⁹
Semi-permanent hair dyes (and lotions)	35 ml	1 / week (20 min.)	0.1	Not calculated ²
Bathing, showering				
Shower gel	5.0 g	2 / day	0.01	0.10 g/day
Skin care				
Face cream	0.8 g	2 / day	1.0	1.6 g/day
General purpose cream	1.2 g	2 / day	1.0	2.4 g/day
Body lotion	8.0 g	1 / day	1.0	8.0 g/day
Make-up and nail care				
Make-up remover	2.5 g	2 / day	0.1	0.5 g/day
Eye make-up	0.01 g	2 / day	1.0	0.02 g/day
Mascara	0.025 g	1 / day	1.0	0.025 g/day
Eyeliners	0.005 g	1 / day	1.0	0.005 g/day
Lipstick, lip salve	0.01 g	4 / day	1.0	0.04 g/day
Deodorant				
Deodorant stick / roller	0.5 g	1.0 / day	1.0	0.50 g/day
Oral hygiene				
Toothpaste (adult)	1.4 g	2.0 / day	0.17	0.48 g/day
Mouthwash	10.0 g	3.0 / day	0.10	3.0 g/day



Scientific Committee on Consumer Products

SCCP

THE SCCP'S NOTES OF GUIDANCE
FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR
SAFETY EVALUATION

6TH REVISION

Finally, for a **sunscreen lotion**, an application of 18.0 g/day is assumed to be a realistic value [SCCNFP/0321/02].

Adopted by the SCCP during the 10th plenary meeting of 19 December 2006

Yönetmelikler

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Total			0,67

Kozmetiklere maruziyet

Total oral hijyen:	3,52 g
Total göz ürünleri:	0,05 g
Total “non rinse-off” ürünler:	13,50 g
Total “rinse-off” ürünler:	0,67 g
Total maruziyet:	17.74 g

Preservative maruziyeti (X)

$$SED = \frac{A \text{ (g/day)} \times 1000\text{mg/g} \times C \text{ (\%)/100} \times DA_p \text{ (\%)/100}}{60 \text{ kg}}$$

Absorblanan miktar

Oral ürünler için absorpsiyon %100 kabul edilir.
Veri yok ise cilt den absorpsiyon da %100 kabul edilir.

Yönetmelikler

Kozmetikler ve Avrupa Birliği Pazarı

Margin of Safety

“Margin of Safety” nin hesaplanması

Uygulanan koruyucunun maksimum miktarı (mg)	A
Koruyucunun üründeki % miktarı	C
İnsan vücut ağırlığı (kg)	60
Cilt den maksimum absorpsiyon (%)	DA _p
Sistemik maruziyet dozu (mg/kg/bw) “SED”	$\frac{AxCxDA_p}{60}$
Margin of Safety (MoS)	$\frac{NOAEL}{SED}$

Kozmetiklere maruziyet

Total oral hijyen:	3,52 g
Total göz ürünleri:	0,05 g
Total “non rinse-off” ürünler:	13,50 g
Total “rinse-off” ürünler:	0,67 g
Total maruziyet:	17.74 g

Preservative maruziyeti (X)

$$SED = \frac{A \text{ (g/day)} \times 1000\text{mg/g} \times C \text{ (\%)/100} \times DA_p \text{ (\%)/100}}{60 \text{ kg}}$$

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Kozmetikler ve Avrupa Birliği Pazarı

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Sistemik maruziyet dozu (mg/kg/bw) “SED”	$\frac{AxCxDA_p}{60}$
Margin of Safety (MoS)	$\frac{NOAEL}{SED}$

Margin of Safety’
nin 100 den büyük
olması gerekiyor.

Kozmetiklere maruziyet

Total oral hijyen:	3,52 g
Total göz ürünleri:	0,05 g
Total “non rinse-off” ürünler:	13,50 g
Total “rinse-off” ürünler:	0,67 g
Total maruziyet:	17.74 g

Preservative maruziyeti (X)

$$SED = \frac{A \text{ (g/day)} \times 1000\text{mg/g} \times C \text{ (\%)/100} \times DA_p \text{ (\%)/100}}{60 \text{ kg}}$$

Absorblanan miktar

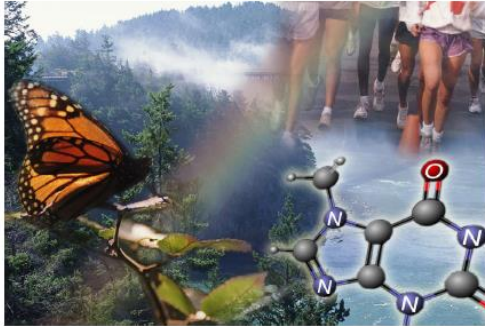
Oral ürünler için absorpsiyon %100 kabul edilir.
Veri yok ise cilt den absorpsiyon da %100 kabul edilir.

Yönetmelikler

Kozmetikler ve Avrupa Birliği Pazarı

ECHA

**Guidance on
information requirements and
chemical safety assessment**
Chapter R.15: Consumer exposure
estimation



May 2008
(version 1.1)

Guidance for the implementation of REACH

The rules governing cosmetic products
in the European Union

Volume 3
Guidelines
Cosmetic products

Notes of guidance for testing of
cosmetic ingredients for their safety
evaluation

1999 Edition



EUROPEAN COMMISSION
Enterprise Directorate-General
Directorate-General Health and Consumer Protection

ECHA
<http://echa.europa.eu>

**Guidance on
information requirements and
chemical safety assessment**
Chapter R.15: Consumer exposure estimation

Version: 2
April 2010

Yönetmelikler

Kozmetikler ve Avrupa Birliği Pazarı

22.12.2009

EN

Official Journal of the European Union

L 342/59

REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 30 November 2009

on cosmetic products

(recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee⁽¹⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁽²⁾,

Whereas:

- (1) Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products⁽³⁾ has been significantly amended on several occasions. Since further amendments are to be made, in this particular case it should be recast as one single text in the interests of clarity.
- (2) A Regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for diverging transposition by Member States. Moreover, a Regulation ensures that legal requirements are implemented at the same time throughout the Community.
- (3) This Regulation aims at simplifying procedures and streamlining terminology, thereby reducing administrative burden and ambiguities. Moreover, it strengthens certain elements of the regulatory framework for cosmetics, such as in-market control, with a view to ensuring a high level of protection of human health.
- (4) This Regulation comprehensively harmonises the rules in the Community in order to achieve an internal market for cosmetic products while ensuring a high level of protection of human health.

(5) The environmental concerns that substances used in cosmetic products may raise are considered through the application of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency⁽⁴⁾, which enables the assessment of environmental safety in a cross-sectoral manner.

(6) This Regulation relates only to cosmetic products and not to medicinal products, medical devices or biocidal products. The delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use.

(7) The assessment of whether a product is a cosmetic product has to be made on the basis of a case-by-case assessment, taking into account all characteristics of the product. Cosmetic products may include creams, emulsions, lotions, gels and oils for the skin, face masks, tinted base (liquids, pastes, powders), make-up powders, after-bath powders, hygienic powders, toilet soaps, deodorant soaps, perfumes, toilet waters and eau de Cologne, bath and shower preparations (salts, foams, oils, gels), depilatories, deodorants and anti-perspirants, hair colorants, products for waving, straightening and fixing hair, hair-setting products, hair-cleansing products (lotions, powders, shampoo), hair-conditioning products (lotions, creams, oils), hairdressing products (lotions, lacquers, brillantines), shaving products (creams, foams, lotions), make-up and products removing make-up, products intended for application to the lips, products for care of the teeth and the mouth, products for nail care and make-up, products for external intimate hygiene, sunbathing products, products for tanning without sun, skin-whitening products and anti-wrinkle products.

(8) The Commission should define the categories of cosmetic products which are relevant for the application of this Regulation.

(9) Cosmetic products should be safe under normal or reasonably foreseeable conditions of use. In particular, a risk-benefit reasoning should not justify a risk to human health.

⁽¹⁾ OJ C 27, 3.2.2009, p. 34.

⁽²⁾ Opinion of the European Parliament of 24 March 2009 (not yet published in the Official Journal) and Council Decision of 20 November 2009.

⁽³⁾ OJ L 262, 27.9.1976, p. 169.

⁽⁴⁾ OJ L 396, 30.12.2006, p. 1.



Yönetmelikler

Kozmetikler ve Avrupa Birliği Pazarı



Scientific Committee on Consumer Products

SCCP

THE SCCP'S NOTES OF GUIDANCE

FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR

SAFETY EVALUATION

6TH REVISION

The rules governing cosmetic products
in the European Union

Volume 3 **Guidelines** Cosmetic products

Notes of guidance for testing of
cosmetic ingredients for their safety
evaluation

Adopted by the SCCP during the 10th plenary meeting of 19 December 2006



EUROPEAN COMMISSION
Enterprise Directorate-General
Directorate-General Health and Consumer Protection

1999 Edition

Yönetmelikler

Kozmetikler ve Avrupa Birliği Pazarı

4 - Ürünün etiketlemesi

AB deki adresi:
Nominal içeriği: ağırlık, hacim
Raf ömrü:

Raf ömrü 30 aydan fazla olanlar için. Ürün açıldıktan sonra kaç ay kullanılabileceği de belirtilir.



6 months

Kum saati sembolü; 30 aydan az kullanım ömrüne sahip ürünleri için.



08/2012

Kullanım için özel uyarılar;
Batch numarası:
Ürünün fonksiyonu:
İçindekiler listesi:

Nanopartikül içeriği belirtilmelidir.
Örnek: Titanium dioxide (nano)

Geldiği ülke (menşe) belirtilmelidir.