



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
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MALAYA AT MALUSOG
NA PAMAYANAN

09 December 2008

BUREAU CIRCULAR
No. 2008- 005

SUBJECT: Grace Period for the 3rd Updates and Amendments of the ASEAN Cosmetic Directive (ACD)

In the interest of service, and for the information of all, the Bureau of Food and Drugs (BFAD) hereby provides the Final report of the 10th ASEAN Cosmetic Scientific Body (ACSB) and 11th ASEAN Cosmetic Committee (ACC) Meetings as attachments.

Company/s or person/s responsible for placing the cosmetic product/s in the market are responsible for continually checking any **updates and amendments** to the ACD for proper guidance and compliance through the following websites:

www.bfad.gov.ph (under ASEAN Cosmetic Harmonization)

www.aseancosmetic.org

www.asean.org

You are hereby directed to take note of the cited grace period as agreed during the 11th ACC Meeting.

This order shall take effect immediately after its posting at the BFAD website.


Prof. LETICIA BARBARA B. GUTIERREZ, M.S.
Director

Progress of the ASEAN Cosmetic Scientific Body (ACSB)

The Meeting agreed to the following proposal from ACSB:

EU Annex Update

- a) Addition of 40 ingredients as hair dyes in Annex II (see attached European Commission Directive 2008/88/EC)
- b) Transfer from Annex III to Annex II of Hydroquinone as oxidizing colouring agent for hair dyeing.

AHA Labeling

Guidelines will be developed to clarify where mandatory sunscreen labeling is unnecessary.

Botanical Ingredients

- a. To invite a speaker from the SFDA China to attend the 11th ACSB meeting to provide inputs on review and control of botanicals in cosmetics in China.
- b. Regulators to review lists of cosmetic ingredients notified in their own markets against the lists of Chinese Cosmetic Banned Botanical List and UK banned lists, and to send the results of this review to Indonesia 1 month before the next ACSB meeting.

Alpha-arbutin

Not to regulate the use of alpha-arbutin in cosmetic products at this point of time.

IFRA Guidelines

The incorporation of the IFRA guidelines into the ASEAN Cosmetic Directive was impracticable for the following reasons:

1. It involves inefficient duplication of large amounts of data which are already publicly available.
2. Generally, cosmetic manufacturers do not have access to detailed fragrance formulations.
3. It is the responsibility of the fragrances houses to issue certificates of compliance with IFRA guidelines for specified fragrances products, this forms parts of the product safety assessment.

Note: IFRA guidelines also covers flavours used in oral care and lip products.

Methanol

Thailand to review the safety data package from the US Cosmetic Ingredient Review (CIR) and to share the view of TISI on the CIR and report at the next ACSB meeting.

Zinc Pyrithione

To add to Annex III Part 1 the use of zinc pyrithione at 2% in rinse-off products.

Tranexamic Acid

The inclusion of tranexamic acid to Annex III Part 2 up to a maximum concentration of 3% in leave-on skin products and not to be used in products intended to be placed in contact with mucous membranes.

Implementation date: 30 November 2009

INCI/CI name labeling

- a) That where an ingredient has both a CI number and an INCI name, the nomenclature used should indicate the purpose of the ingredient in that formulation i.e. if it is being used as a colourant the CI number should be used, whereas if it is being used for another purpose the INCI name should be used. This will make it easier for regulators to check ingredients specified on labels for compliance with the ACD.
- b) That failure to comply with this guideline is a minor labeling issue and should not be cause for rejection of a notification or product withdrawal. The company should be advised and asked to correct the form/label in a timely manner.
- c) That Mica (CI77019) should be added to the approved colourants lists (Annex IV) with a footnote explaining that although it is not strictly a colourant it is added to change the appearance of the product by giving luster.

Sunscreen Guidelines

Adopted the proposed Sunscreen Labeling Guideline with the following clarifications:

- a) That the guideline applies only to sunscreen products i.e. those product whose primary function is UV protection as indicated by relative order, size and extent of claim material. It does not apply to products which make secondary UV protection claims, such as moisturising and skin lightening products.

b) That warning claims additional to those already mandated by ACD can be chosen by industry from the list of examples according to suitability for the product involved.

c) That the guideline is not mandatory but strongly recommended to industry.

Grace period: 2 years

Silver Nitrate

- a) Not to extend the current ASEAN Regulation on the use of silver nitrate as hair dye for eyebrows and eyelashes to the whole head.
- b) The 36 month grace period for products registered prior to the implementation of the ACD and that the ACD does not prohibit the manufacture of products in ASEAN Member States for export outside ASEAN.

Period After Opening (PAO)

Not to adopt the proposed EU regulations on PAO in the ASEAN labeling Requirements but products carrying PAO labeling in addition to ASEAN labeling requirements will be accepted.

ISO Update

- Indonesia and Thailand, as P-members of ISO/TC 217 and ISO/TC 106 will provide the relevant ISO documents that will have an impact on the ACSB/ACC activities.
- ACSB to provide inputs on relevant issues to the ISO committees endorsed by the ACC through Indonesia and Thailand.

Mercury Limits

Limit of Mercury as unavoidable traces is 1 ppm

DIRECTIVES

COMMISSION DIRECTIVE 2008/88/EC

of 23 September 2008

amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and III thereto to technical progress

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products ⁽¹⁾, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Consumer Products,

Whereas:

- (1) Following the publication of a scientific study in 2001, entitled 'Use of permanent hair dyes and bladder cancer risk', the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, replaced by the Scientific Committee on Consumer Products (SCCP), by Commission Decision 2004/210/EC ⁽²⁾, concluded that the potential risks were of concern. It recommended that the Commission take further steps to control the use of hair dye substances.
- (2) The Scientific Committee on Consumer Products further recommended an overall safety assessment strategy for hair dye substances including the requirements for testing substances used in hair dye products for their potential genotoxicity/mutagenicity.
- (3) Following the opinions of the SCCP, the Commission, together with Member States and stakeholders, agreed on an overall strategy to regulate substances used in hair dye products, according to which the industry was required to submit files containing the scientific data on hair dye substances to be evaluated by the SCCP.
- (4) Substances for which no updated safety files are submitted allowing an adequate risk assessment should be included in Annex II to Directive 76/768/EEC.
- (5) Some hair dye substances have already been banned, either as a result of opinions by the SCCP or due to

lack of safety data. The substances currently under consideration were carefully selected to be regulated together since they are listed in Annex IV. As no safety files on these substances for their use in hair dye products were submitted to the SCCP for a risk assessment by the agreed deadlines, there is no evidence that these substances, when used in hair dye products, can be considered safe for human health.

- (6) Substances without safety files 1-Hydroxy-2,4-diaminobenzene (2,4-Diaminophenol) and its dihydrochloride salt; 1,4-Dihydroxybenzene (Hydroquinone); 4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene]dimethylammoniumchloride (Basic Blue 26); Disodium 3-[[2,4-dimethyl-5-sulphonatophenyl]azo]-4-hydroxynaphthalene-1-sulpho-nate (Ponceau SX) and 4-[[4-Aminophenyl](4-aminocyclohexa-2,5-dien-1-ylidene)methyl]-o-toluidine and its hydrochloride salt (Basic Violet 14), currently listed as colorants in Annex IV and as hair dye substances in Annex III, Part 1 and Part 2, shall be deleted from Annex III and banned for use in hair dye products in Annex II.
- (7) Directive 76/768/EEC should therefore be amended accordingly.
- (8) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II and III to Directive 76/768/EEC are amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 14 February 2009 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

⁽¹⁾ OJ L 262, 27.9.1976, p. 169.

⁽²⁾ OJ L 66, 4.3.2004, p. 45.

They shall apply those provisions from 14 August 2009.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 23 September 2008.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX

Directive 76/768/EEC is amended as follows:

1. in Annex II, the following reference numbers 1329 to 1369 are added:

Reference No	Chemical name/INCI-name
1329	4-[(4-Aminophenyl)(4-iminocyclohexa-2,5-dien-1-ylidene)methyl]-o-toluidine (CAS 3248-93-9; EINECS 221-832-2) and its hydrochloride salt (Basic Violet 14; CI 42510) (CAS 632-99-5; EINECS 211-189-6) when used as a substance in hair dye products
1330	4-(2,4-Dihydroxyphenylazo)benzenesulphonic acid (CAS 2050-34-2; EINECS 218-087-0) and its sodium salt (Acid Orange 6; CI 14270) (CAS 547-57-9; EINECS 208-924-8) when used as a substance in hair dye products
1331	3-Hydroxy-4-(phenylazo)-2-naphthoic acid (CAS 27757-79-5; EINECS 248-638-0) and its calcium salt (Pigment Red 64:1; CI 15800) (CAS 6371-76-2; EINECS 228-899-7), when used as a substance in hair dye products
1332	2-(6-Hydroxy-3-oxo-(3H)-xanthen-9-yl)benzoic acid; Fluorescein (CAS 2321-07-5; EINECS 219-031-8) and its disodium salt (Acid yellow 73 sodium salt; CI 45350) (CAS 518-47-8; EINECS 208-253-0), when used as a substance in hair dye products
1333	4',5'-Dibromo-3',6'-dihydroxyspiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one; 4',5'-Dibromofluorescein; (Solvent Red 72) (CAS 596-03-2; EINECS 209-876-0) and its disodium salt (CI 45370) (CAS 4372-02-5; EINECS 224-468-2) when used as a substance in hair dye products
1334	2-(3,6-Dihydroxy-2,4,5,7-tetrabromoxanthen-9-yl)-benzoic acid; Fluorescein, 2',4',5',7'-tetrabromo-; (Solvent Red 43) (CAS 15086-94-9; EINECS 239-138-3), its disodium salt (Acid Red 87; CI 45380) (CAS 17372-87-1; EINECS 241-409-6) and its aluminium salt (Pigment Red 90:1 Aluminium lake) (CAS 15876-39-8; EINECS 240-005-7) when used as a substance in hair dye products
1335	Xanthylium, 9-(2-carboxyphenyl)-3-(2-methylphenyl)amino)-6-((2-methyl-4-sulphophenyl)amino)-, inner salt (CAS 10213-95-3); and its sodium salt (Acid Violet 9; CI 45190) (CAS 6252-76-2; EINECS 228-377-9) when used as a substance in hair dye products
1336	3',6'-Dihydroxy-4',5'-diiodospiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one; (Solvent Red 73) (CAS 38577-97-8; EINECS 254-010-7) and its sodium salt (Acid Red 95; CI 45425) (CAS 33239-19-9; EINECS 251-419-2) when used as a substance in hair dye products
1337	2',4',5',7'-Tetraiodofluorescein (CAS 15905-32-5; EINECS 240-046-0), its disodium salt (Acid Red 51; CI 45430) (CAS 16423-68-0; EINECS 240-474-8) and its aluminium salt (Pigment Red 172 Aluminium lake)(CAS 12227-78-0; EINECS 235-440-4) when used as a substance in hair dye products
1338	1-Hydroxy-2,4-diaminobenzene (2,4-Diaminophenol) (CAS 95-86-3; EINECS 202-459-4) and its dihydrochloride salt (2,4-Diaminophenol HCl) (CAS 137-09-7; EINECS 205-279-4) when used as a substance in hair dye products
1339	1,4-Dihydroxybenzene (Hydroquinone) (CAS 123-31-9; EINECS 204-617-8) when used as a substance in hair dye products
1340	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (Basic Blue 26; CI 44045) (CAS 2580-56-5; EINECS 219-943-6) when used as a substance in hair dye products
1341	Disodium 3-[(2,4-dimethyl-5-sulphonatophenyl)azo]-4-hydroxynaphthalene-1-sulphonate (Ponceau SX; CI 14700) (CAS 4548-53-2; EINECS 224-909-9) when used as a substance in hair dye products

Reference No	Chemical name/INCI-name
1342	Trisodium tris[5,6-dihydro-5-(hydroxyimino)-6-oxonaphthalene-2-sulphonato(2-)-N5,O6]ferrate(3-) (Acid Green 1; CI 10020) (CAS 19381-50-1; EINECS 243-010-2) when used as a substance in hair dye products
1343	4-(Phenylazo)resorcinol (Solvent Orange 1; CI 11920) (CAS 2051-85-6; EINECS 218-131-9) and its salts, when used as a substance in hair dye products
1344	4-[(4-Ethoxyphenyl)azo]naphthol (Solvent Red 3; CI 12010) (CAS 6535-42-8; EINECS 229-439-8) and its salts, when used as a substance in hair dye products
1345	1-[(2-Chloro-4-nitrophenyl)azo]-2-naphthol (Pigment Red 4; CI 12085) (CAS 2814-77-9; EINECS 220-562-2) and its salts when used as a substance in hair dye products
1346	3-Hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide (Pigment Red 112; CI 12370) (CAS 6535-46-2; EINECS 229-440-3) and its salts when used as a substance in hair dye products
1347	N-(5-Chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulphonyl]-2-methoxyphenyl]azo]-3-hydroxy-naphthalene-2-carboxamide (Pigment Red 5; CI 12490) (CAS 6410-41-9; EINECS 229-107-2) and its salts when used as a substance in hair dye products
1348	Disodium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate (Pigment Red 48; CI 15865) (CAS 3564-21-4; EINECS 222-642-2) when used as a substance in hair dye products
1349	Calcium 3-hydroxy-4-[(1-sulphonato-2-naphthyl)azo]-2-naphthoate (Pigment Red 63; CI 15880) (CAS 6417-83-0; EINECS 229-142-3) when used as a substance in hair dye products
1350	Trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate (Acid Red 27; CI 16185) (CAS 915-67-3; EINECS 213-022-2) when used as a substance in hair dye products
1351	2,2'-[(3,3'-Dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide] (Pigment Yellow 13; CI 21100) (CAS 5102-83-0; EINECS 225-822-9) when used as a substance in hair dye products
1352	2,2'-[Cyclohexylidenebis(2-methyl-4,1-phenylene)azo]bis[4-cyclohexylphenol] (Solvent Yellow 29; CI 21230) (CAS 6706-82-7; EINECS 229-754-0) when used as a substance in hair dye products
1353	1-[(4-Phenylazo)phenylazo]-2-naphthol (Solvent Red 23; CI 26100) (CAS 85-86-9; EINECS 201-638-4) when used as a substance in hair dye products
1354	Tetrasodium 6-amino-4-hydroxy-3-[[7-sulphonato-4-[(4-sulphonatophenyl)azo]-1-naphthyl]azo]naphthalene-2,7-disulphonate (Food Black 2; CI 27755) (CAS 2118-39-0; EINECS 218-326-9) when used as a substance in hair dye products
1355	Ethanaminium, N-(4-[(4-(diethylamino)phenyl)(2,4-disulfofenyl)methylene]-2,5-cyclohexadien-1-ylidene)-N-ethyl-, hydroxide, inner salt, sodium salt (Acid Blue 1; CI 42045) (CAS 129-17-9; EINECS 204-934-1) when used as a substance in hair dye products
1356	Ethanaminium, N-(4-[(4-(diethylamino)phenyl)(5-hydroxy-2,4-disulfofenyl)methylene]-2,5-cyclohexadien-1-ylidene)-N-ethyl-, hydroxide, inner salt, calcium salt (2:1) (Acid Blue 3; CI 42051) (CAS 3536-49-0; EINECS 222-573-8) when used as a substance in hair dye products
1357	Benzenemethanaminium, N-ethyl-N-(4-[(4-(ethyl(3-sulfofenyl)methyl)amino)phenyl)(4-hydroxy-2-sulfofenyl)methylene]-2,5-cyclohexadien-1-ylidene)-3-sulfo-, hydroxide, inner salt, disodium salt (Fast Green FCF; CI 42053) (CAS 2353-45-9; EINECS 219-091-5) when used as a substance in hair dye products

Reference No	Chemical name/INCI-name
1358	1,3-Isobenzofurandione, reaction products with methylquinoline and quinoline (Solvent Yellow 33; CI 47000) (CAS 8003-22-3; EINECS 232-318-2) when used as a substance in hair dye products
1359	Nigrosine (CI 50420) (CAS 8005-03-6) when used as a substance in hair dye products
1360	8,18-Dichloro-5,15-diethyl-5,15-dihydrodiindolo[3,2-b:3',2'-m]triphenodioxazine (Pigment Violet 23; CI 51319) (CAS 6358-30-1; EINECS 228-767-9) when used as a substance in hair dye products
1361	1,2-Dihydroxyanthraquinone (Pigment Red 83; CI 58000) (CAS 72-48-0; EINECS 200-782-5) when used as a substance in hair dye products
1362	Trisodium 8-hydroxypyrene-1,3,6-trisulphonate (Solvent Green 7; CI 59040) (CAS 6358-69-6; EINECS 228-783-6) when used as a substance in hair dye products
1363	1-Hydroxy-4-(p-toluidino)anthraquinone (Solvent Violet 13; CI 60725) (CAS 31-48-1; EINECS 201-353-5), when used as a substance in hair dye products
1364	1,4-bis(p-Tolylamino)anthraquinone (Solvent Green 3; CI 61565) (CAS 128-80-3; EINECS 204-909-5) when used as a substance in hair dye products
1365	6-Chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)-ylidene)-4-methylbenzo[b]thiophene-3(2H)-one (VAT Red 1; CI 73360) (CAS 2379-74-0; EINECS 219-163-6) when used as a substance in hair dye products
1366	5,12-Dihydroquino[2,3-b]acridine-7,14-dione (Pigment Violet 19; CI 73900) (CAS 1047-16-1; EINECS 213-879-2) when used as a substance in hair dye products
1367	(29H,31H-Phthalocyaninato(2-)-N29,N30,N31,N32)copper (Pigment Blue 15; CI 74160) (CAS 147-14-8; EINECS 205-685-1) when used as a substance in hair dye products
1368	Disodium [29H,31H-phthalocyaninedisulphonato(4-)-N29,N30,N31,N32]cuprate(2-) (Direct Blue 86; CI 74180) (CAS 1330-38-7; EINECS 215-537-8) when used as a substance in hair dye products
1369	Polychloro copper phthalocyanine (Pigment Green 7; CI 74260) (CAS 1328-53-6; EINECS 215-524-7) when used as a substance in hair dye products

2. Annex III is amended as follows:

- (a) in Part 1, reference number 10 is deleted;
- (b) in Part 1, column c of reference number 14, item (a) is deleted;
- (c) in Part 2, reference numbers 57, 59 and 60 are deleted.