



09 JUL 2018

FDA CIRCULAR
No. 2018-009

TO: ALL COSMETIC MANUFACTURERS, TRADERS, DISTRIBUTORS AND OTHER CONCERNED PARTIES

SUBJECT: Updates and Amendments of the ASEAN Cosmetic Directive (ACD) as Adopted During the 28th ASEAN Cosmetic Committee (ACC) Meeting and Its Related Meetings

1. BACKGROUND AND RATIONALE

In 2005, the Department of Health (DOH) – Food and Drug Administration (FDA), then called Bureau of Food and Drugs (BFAD), has adopted and implemented the ASEAN Harmonized Cosmetic Regulatory Scheme and the ASEAN Common Technical Documents through Administrative Orders No. 2005-0015 and 2005-0025, respectively. The harmonization scheme involves the conduct of alignment meetings for the purpose of eliminating trade barriers and enhancing cooperation within the ASEAN Member States (AMS) in ensuring the safety, quality and claimed benefits of cosmetic products.

On 1-4 May 2018, the ASEAN Cosmetic Committee (ACC) convened in Vientiane, Lao PDR for the 28th ACC, 28th ASEAN Cosmetic Scientific Body (ACSB) and 11th ASEAN Cosmetic Testing Laboratories Committee (ACTLC) Meetings. As part of our continuous commitment to provide timely and relevant information on standards, rules, and regulations, the Center for Cosmetics Regulation and Research (CCRR) of the FDA hereby reports the highlights of the aforementioned meetings and presents the updates to the ASEAN Cosmetic Directive (ACD).

2. OBJECTIVE AND SCOPE

This Circular aims to provide the updates and amendments to the ACD as adopted in the 28th ACC meeting and its related meetings which covers cosmetic products made available in the local market. This Circular shall guide establishments that are engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, and where applicable, the use, testing, promotion, advertising, or sponsorship of cosmetic products.



3. UPDATES AND AMENDMENTS TO THE ACD

3.1. Updates and Amendments to the ACD Ingredient Annexes

The following items are the updates and amendments on cosmetic ingredients and their restrictions as indicated in the ACD Ingredient Annexes. The latest revision of the ACD Ingredient Annexes are accessible at the FDA website.

For easy reference, a table of the new and modified entries as well as the given grace period is provided in Annex A.

3.1.1. Thioglycolic Acid and Thiolactic Acid (ACD Annex III Ref. Nos. 2a and A9 respectively)

3.1.1.1. The Meeting agreed to revise an existing restriction in both Thioglycolic acid and Thiolactic acid entries in ACD Annex III to provide further clarification on the combination use of these ingredients.

3.1.1.2. The restriction is changed from “Percentages calculated as total thioacids, i.e. either singly (thiolactic acid or thioglycolic acid alone) or combination of thiolactic acid and thioglycolic acid in a given formula” to “**For general use of hair waving or straightening products the maximum concentration for combination of Thioglycolic acid and Thiolactic acid must not exceed 8% calculated as Thioglycolic acid.**”

3.1.2. EU 2013/344 (ACD Annex III Ref. Nos. 103 to 184 and 186)

3.1.2.1. ACD Annex III Ref. Nos. 103 to 184 and 186 will continue to be “**intentionally left blank**” after the Meeting agreed that there was no need to make changes in the annex.

3.1.2.2. This resulted after the discussion on EU 2013/344 which determined that chemicals in EU 2013/344 (Ref. Nos. 103-184, 196) are commonly used fragrance ingredients and are already controlled by IFRA standards while the other chemicals in the EU regulation including Diethylene Glycol (Ref. No. 186, CAS No. 111-46-6) are already included in ACD Annex II or Annex III.

3.1.3. EU 2017/237

3.1.3.1. The meeting agreed to include the following new entries into Annex III:

3.1.3.1.1. N,N'-Bis(2-Hydroxyethyl)-2-Nitro-p-Phenylenediamine (Ref. No. 8c)

3.1.3.1.2. 2,6-Dihydroxyethylaminotoluene (Ref. No. 9b)

3.1.3.1.3. HC Red No. 17 (Ref. No. 314)

3.1.3.1.4. HC Yellow No. 17 (Ref. No. 315)

3.1.3.1.5. 1-Hexyl-4,5-Diamino Pyrazole Sulfate (Ref. No. 316)

3.1.3.1.6. 2,5,6-Triamino-4-Pyrimidinol (Ref. No. 317)

3.1.3.1.7. Hydroxyethoxy Aminopyrazolopyridine HCl (Ref. No. 318)

3.1.3.1.8. 3-Amino-2,6-Dimethylphenol (Ref. No. 319)

- 3.1.3.1.9. Basic Brown 17 (Ref. No. 320)
3.1.3.1.10. Basic Blue 124 (Ref. No. 321)
- 3.1.3.2. Effective **01 December 2019**, only compliant products can be placed in the market, and non-compliant products must be completely withdrawn from the market.
- 3.1.4. EU 2017/1410
- 3.1.4.1. During the 27th ACC Meeting and its Related Meetings, all ASEAN Member States (AMS) with the exception of Indonesia has agreed to adopt EU 2017/1410 and include entries for (a) Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde or Lyril, (b) 2,6-Dihydroxy-4-methylbenzaldehyde or Atranol, and (c) 3-Chloro-2,6-Dihydroxy-4-methylbenzaldehyde or Chloroatranol into ACD Annex II.
- 3.1.4.2. During the 28th ACC Meeting and its Related Meetings, Indonesia informed the Meeting that following its review of adverse events associated with Lyril, Indonesia has decided to adopt the same implementation date as agreed to by the other nine (9) AMS. Effective **23 August 2021**, no cosmetic product with the banned materials can be placed in the market in Indonesia and non-compliant products must be completely withdrawn from the market.
- 3.1.5. EU 2017/1413, Zinc Oxide (Annex IV Color Index 77947)
- 3.1.5.1. Following the adoption of a new restriction for Zinc Oxide in Annex IV (Color Index 77947) - ***not be used in applications that may lead to exposure of the end-user's lungs by inhalation***, the Meeting discussed that expert risk assessment based on multiple factors is needed to determine whether product use may lead to exposure of the end-user's lungs by inhalation.
- 3.1.6. ACD Annex II Ref. No. 307
- 3.1.6.1. The Meeting agreed to revise ACD Annex II Ref. No. 307 to clarify the scope of the entry.
- 3.1.6.2. The entry is changed from Sulphonamides (sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the -NH₂ groups) and their salts to "***Sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the -NH₂ groups, and their salts.***"
- 3.1.7. EU 2017/2228
- 3.1.7.1. The Meeting with the exception of Indonesia agreed to include Peanut Oil and Hydrolyzed Wheat Protein in ACD Annex III.

3.1.7.2. Effective **01 December 2019**, only compliant products can be placed in the market, and non-compliant products must be completely withdrawn from the market.

3.2. 1,4-Dioxane

Following the discussion on 1,4-Dioxane as trace impurity, the Meeting agreed to adopt a maximum trace limit of **25 parts per million (ppm)** in finished cosmetic products. The ASEAN Guideline for Limits of Contaminants for Cosmetics shall be updated accordingly and shall be posted in the FDA website in due course.

3.3. ASEAN Cosmetic Methods (ACM)

Aside from the FDA website, the revised versions of the first eight (8) ACM's are uploaded and are available for download from the following links:

ASEAN Trade Repository - <http://atr.asean.org/standards/result/body/13/1>

ASEAN Secretariat's website - http://asean.org/?static_post=asean-sectoral-mras

ACM 009 Revision N°0 "Determination of Salicylic Acid (Beta Hydroxy Acid) in Cosmetic Products by High Performance Liquid Chromatography (HPLC)" will be published and uploaded in the aforementioned sites in due course.

3.4. Updated List of Cosmetic Accredited Laboratories

The list of accredited testing laboratories in the Philippines may be found in the Department of Trade and Industry – Philippine Accreditation Bureau (DTI-PAB) website (www.pabaccreditation.dti.gov.ph/public/public_test.php) and includes the scope of their accreditation.

AMS's web-linkages to National Accreditation Bodies may also be found in the ASEAN Secretariat's website - <http://asean.org/asean-economic-community/sectoral-bodies-under-the-purview-of-aem/standards-and-conformance/links>.

3.5. Question and Answer (Q&A) on Specific Provisions of the ACD


The Q&A on the Specific Provisions of the ACD has been uploaded in the ASEAN website and accessible at <http://asean.org/storage/2012/05/QA-on-Specific-Provisions-of-the-ASEAN-Cosmetic-Directive-ACD.pdf>. The document is also posted and available for download in the FDA website.

4. PENALTY CLAUSE

Establishments engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, and where applicable, the use, testing, promotion, advertising, or sponsorship of cosmetic products who are found to be operating outside the rules and regulations of FDA shall be subjected to sanctions and penalties as prescribed by Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009."

5. EFFECTIVITY

This Circular shall take effect immediately. Updates and amendments to the ACD Ingredient Annexes (Section 3.1) shall allow a grace period as specified above except for the entries with no specified grace periods.


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FDA Director General



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Annex A
Updates and Amendments to the ASEAN Cosmetic Directive (ACD) Ingredient Annexes

The updated ASEAN Cosmetic Directive (ACD) Ingredient Annexes incorporating the new and amended entries adopted during the 28th ASEAN Cosmetic Committee (ACC) Meeting and its related meetings are posted in the Food and Drug Administration (FDA) website. The tabulation below representing the new and modified entries (highlighted in yellow) of the ACD Ingredient Annexes are shown only for easy reference of the cosmetic industry.

A. ACD Annex II - List of Substances Which Must Not Form Part of the Composition of Cosmetic Products

1. ACD Annex II Ref. No. 307

From:

Substances	CAS Number	Ref. No
Sulphonamides (sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the -NH ₂ groups)	63-74-1	307

To:

Substances	CAS Number	Ref. No
Sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the -NH₂ groups, and their salts	63-74-1	307

B. ACD Annex III - List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down

1. Thioglycolic acid and Thiolactic Acid (ACD Annex III Ref. Nos. 2a and A9 respectively)

From:

“Percentages calculated as total thioacids, i.e. either singly (thiolactic acid or thioglycolic acid alone) or combination of thiolactic acid and thioglycolic acid in a given formula.”

To:


Ref No ACD # (EU #)	Substance/CAS No ⁽⁴⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
2a	Thioglycolic acid and its salts CAS No 68-11-1	(a) Hair waving or straightening products: 1. General use 2. Professional use (b) Depilatories (c) Other hair care products which are removed after application	(a) 1. 8% ready for use at pH 7-9.5 2. 11% ready for use at pH 7-9.5 (b) 5% ready for use at pH 7-12.7 (c) 2% ready for use at pH 7-9.5 For general use of hair waving or straightening products the maximum concentration for combination of Thioglycolic acid and thiolactic acid must not exceed 8% calculated as Thioglycolic Acid.	(a) (b) (c) The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: • Avoid contact with eyes • In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice. • Wear suitable gloves (a) and (c) only.	(a) 1. • Contains thioglycolate • Follow the instructions • Keep out of reach of children 2. • For professional use only • Contains thioglycolate • Follow the instructions • Keep out of reach of children (b) and (c) • Contains thioglycolate • Follow the instructions • Keep out of reach of children


Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
A9	Thiolactic acid and its salts	(a) Hair waving or straightening products (b) Depilatories (c) Other hair care products which are removed after application	(a) 8.5% ready for use at pH<9.5 (b) 5% ready for use pH 7- 12.7 (c) 2% ready for use pH 7-9.5 For general use of hair waving or straightening products the maximum concentration for combination of Thioglycolic acid and thiolactic acid must not exceed 8% calculated as Thioglycolic Acid.	For (a), (b) and (c): The direction for use drawn up in the national or official language(s) must incorporate the following sentences: - Avoid contact with eyes - In the event of contact with eyes, rinse immediately with plenty of water and seek medical assistance. - Wear suitable gloves (a) and (c) only	(a), (b) and (c) • Contains thiolactic acid • Follow the instructions • Keep out of reach of children.


2. EU 2013/344 (ACD Annex III Ref. Nos. 103 to 184)


Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
103 to 184	Entries left intentionally blank				
186	Entry left intentionally blank				


3. EU 2017/237


Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
8c	Ethanol, 2,2'-[(2-nitro-1,4-phenylene)diimino]bis- (9CI) N,N'-Bis(2-Hydroxyethyl)-2-Nitro-p-Phenylenediamine CAS No. 84041-77-0	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.	(b) 1.5%	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1% For (a) and (b) The direction for use "wear suitable gloves" must be included in label or leaflet text. <ul style="list-style-type: none"> Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/kg⁽²¹⁾ Keep in nitrite-free containers 	(a) To be printed on the label: The mixing ratio.  "Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: <ul style="list-style-type: none"> - you have a rash on your face or sensitive, irritated and damaged scalp, - you have ever experienced any reaction after colouring your hair, - you have experienced a reaction to a temporary 'black henna' tattoo in the past. (a) and (b) Do not use to dye eyelashes or eyebrows."


Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
9b	1-Methyl-2,6-bis-(2-hydroxyethylamino)-benzene 2,6-Dihydroxyethylaminotoluene CAS No 149330-25-6	Hair dye substance in oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1% The direction for use "wear suitable gloves" must be included in label or leaflet text. <ul style="list-style-type: none"> Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/kg⁽²¹⁾ Keep in nitrite-free containers 	To be printed on the label: The mixing ratio.  "Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: - you have a rash on your face or sensitive, irritated and damaged scalp, - you have ever experienced any reaction after colouring your hair, - you have experienced a reaction to a temporary 'black henna' tattoo in the past. Do not use to dye eyelashes or eyebrows."
314 (298)	Di[2-[4-[(E)-2-[4-[bis(2-hydroxyethyl)aminophenyl]vinyl]pyridin-1-ium] butanoyl]aminoethyl] di-sulfanyl dichloride HC Red No 17 CAS No 1449471-67-3	Hair dye substance in non-oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.	0.5%	— Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg ⁽²¹⁾ — Keep in nitrite-free containers The direction for use "wear suitable gloves" must be included in label or leaflet text.	Do not use to dye eyelashes or eyebrows


Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
315 (299)	Di[2-[4-[(E)-2-[2,4,5-trimethoxyphenyl]vinyl]pyridin-1-ium]butanoyl]aminoethyl]disulfanyl dichloride HC Yellow No 17 CAS No 1450801-55-4	Hair dye substance in non-oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.	0.5%	The direction for use "wear suitable gloves" must be included in label or leaflet text.	To be printed on the label:  "Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: - you have a rash on your face or sensitive, irritated and damaged scalp, - you have ever experienced any reaction after colouring your hair, - you have experienced a reaction to a temporary 'black henna' tattoo in the past. Do not use to dye eyelashes or eyebrows."

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
316 (300)	1H-Pyrazole-4,5- diamine, 1- hexyl-, sulfate (2:1) 1-Hexyl 4,5- Diamino Pyrazole Sulfate CAS No 1361000-03-4	Hair dye substance in oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1% The direction for use "wear suitable gloves" must be included in label or leaflet text.	To be printed on the label:  "Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: - you have a rash on your face or sensitive, irritated and damaged scalp, - you have ever experienced any reaction after colouring your hair, - you have experienced a reaction to a temporary 'black henna' tattoo in the past. Do not use to dye eyelashes or eyebrows."

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
317 (301)	4-Hydroxy-2,5,6- triaminopyrimidine sulfate 2,5,6-Triamino- 4-Pyrimidinol CAS No 1603-02-7	Hair dye substance in oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.5% The direction for use "wear suitable gloves" must be included in label or leaflet text.	To be printed on the label:  "Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: - you have a rash on your face or sensitive, irritated and damaged scalp, - you have ever experienced any reaction after colouring your hair, - you have experienced a reaction to a temporary 'black henna' tattoo in the past. Do not use to dye eyelashes or eyebrows."

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions		Conditions of use and warning which must be printed on the labels	
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation		Other limitations and requirements
A	B	C	D	E	F
318 (302)	302 2-[(3-Aminopyrazolo[1,5-a]pyridin-2-yl)oxy]ethanol hydrochloride Hydroxyethoxy Aminopyrazolopyridine HCl CAS No 1079221-49-0	Hair dye substance in oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.0% The direction for use "wear suitable gloves" must be included in label or leaflet text.	To be printed on the label:  "Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: - you have a rash on your face or sensitive, irritated and damaged scalp, - you have ever experienced any reaction after colouring your hair, - you have experienced a reaction to a temporary 'black henna' tattoo in the past. Do not use to dye eyelashes or eyebrows."

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
319 (303)	Phenol, 3-amino- 2,6-dimethyl 3-Amino-2,6- Dimethylphenol CAS No 6994-64-5	Hair dye substance in oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.0% The direction for use "wear suitable gloves" must be included in label or leaflet text.	To be printed on the label:  "Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: - you have a rash on your face or sensitive, irritated and damaged scalp, - you have ever experienced any reaction after colouring your hair, - you have experienced a reaction to a temporary 'black henna' tattoo in the past. Do not use to dye eyelashes or eyebrows."
320 (304)	2-Naphthalenaminium, 8-[(4- amino-3- nitrophenyl)azo]-7-hydroxy-N,N,N- trimethyl-, chloride Basic Brown 17 CAS No 68391-32-2	Hair dye substance in non- oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.	2.0%	The direction for use "wear suitable gloves" must be included in label or leaflet text.	Do not use to dye eyelashes or eyebrows

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
321 (305)	3-Amino-7-(dimethylamino)-2- methoxyphenoxazin-5-ium chloride Basic Blue 124 CAS No 67846-56-4	Hair dye substance in non- oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.	0.5%	— Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg ⁽²¹⁾ — Keep in nitrite-free containers The direction for use “wear suitable gloves” must be included in label or leaflet text.	To be printed on the label:  “Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary ‘black henna’ tattoos may increase your risk of allergy. Do not colour your hair if: - you have a rash on your face or sensitive, irritated and damaged scalp, - you have ever experienced any reaction after colouring your hair, - you have experienced a reaction to a temporary ‘black henna’ tattoo in the past. Do not use to dye eyelashes or eyebrows.”

4. EU 2017/2228

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
322 (306)	Peanut oil extracts and derivatives Arachis Hypogaea Oil Arachis Hypogaea Seedcoat Extract Arachis Hypogaea Flour Arachis Hypogaea Fruit Extract Arachis Hypogaea Sprout Extract Hydrogenated Peanut Oil Peanut Acid Peanut Glycerides Peanut Oil PEG-6 Esters Peanutamide MEA Peanutamide MIPA Potassium Peanutate Sodium Peanutamphoacetate Sodium Peanutate Sulfated Peanut Oil CAS Nos 8002-03-7/8002-03-7/8002-03-7 8002-03-7/68425-36-5 91051-35-3/91744-77-3 68440-49-3/93572-05-5 61789-56-8/61789-57-9/73138-79-1			Maximum concentration of peanut proteins: 0.5 ppm	

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
322 (307)	Hydrolyzed wheat protein CAS Nos 94350-06-8 / 222400-28-4 / 70084-87-6 / 100209-50-5			Maximum molecular weight average of the peptides in hydrolysates: 3.5 kDa	