

PUBLIC NOTICE

October 8, 2010

As a result of recent changes in CIR Procedures, CIR is now further categorizing ingredients for which the CIR Expert Panel has made an Insufficient Data determination. Three such categories will be used:

1. **No Reported Uses:** Ingredients for which there is no reported use under FDA's Voluntary Cosmetics Reporting Program. Because these ingredients are not in use, no further action is needed. Were these ingredients to be used in the future, CIR expects data will be provided to support the safety of these ingredients.
2. **Insufficient Data or Information:** Ingredients for which there is a reported use in FDA's VCRP. Because these ingredients remain in use, further action is needed if they remain in use. CIR will move these ingredients to category 3 below after two years have passed and data adequate to resolve the insufficiencies are not received.
3. **Use Not Supported by the Data and Information Submitted to the CIR:** The use of these ingredients, for which there is a reported use in FDA's VCRP and data adequate to resolve the insufficiencies have not been received, is not supported.

Attachment 1 lists Ingredients for which no uses have been reported as of September 14, 2010.

Attachment 2 lists ingredients for which there is a reported use as of the same date. Because these ingredients may have been Insufficient Data ingredients for some time, the CIR Procedures established this one-time public notice that effective October 8, 2012, ingredients in Attachment 2 will be reclassified under the category 3, Use Not Supported by the Data and Information Submitted to the CIR.

If any individual or entity has data or information they believe supports the safety of any of these ingredients, such data or information may be submitted to Director, CIR, 1101-17th St. NW. Suite 412, Washington, DC, 20036-4702 or to infocir@cir-safety.org. Upon review, the CIR Expert Panel may determine that the information warrants initiation of proceedings for a change in classification.

Attachment 1

Zero use ingredients with Insufficient Data (September, 2010).

#	Ingredient
1	4-Amino-2-Nitrophenol
1	Acacia Catechu Gum
1	Acacia Dealbata Leaf Extract
1	Acacia Dealbata Leaf Waxa
1	Acacia Farnesiana Gum
1	Adipic Acid Dihydrazide
1	Aldioxa
1	Aloe Andongensis Extract
1	Aloe Andongensis Leaf Juice
1	Arachis Hypogaea (Peanut) Flour
1	Basic Violet 1
1	Basic Violet 3
1	Basic Violet 4
1	Benzoxiquine
2	Chlorophene and Dichlorophene
1	Corylus Americana (Hazel) Leaf Extract
1	Corylus Avellana (Hazel) Seed Extract
1	Corylus Rostrata (Hazel) Leaf Extract
1	Corylus Rostrata (Hazel) Seed Extract
1	Di- t-Butylhydroquinone
1	Disperse Yellow 3
1	Hydrolyzed Human Placental Protein
1	Human Placental Enzymes
1	Human Placental Lipids
2	Human Umbilical Extract and Umbilical Extract
1	Isopropyl Linoleate
1	Juniperus Oxycedrus Fruit Extract
1	Juniperus Phoenicea Gum Extract
1	Lauramine
2	Mixed Cresol and p-Cresol
1	4-Nitro-m-Phenylenediamine
4	PEG-2 Cocamine, PEG-3 Cocamine, PEG-10 Cocamine, PEG-20 Cocamine
1	Phloroglucinol
1	Piper Methysticum Root Extract
1	Polyoxymethylene Melamine (formerly Melamine/Formaldehyde Resin)
1	Potassium Chlorate
1	PPG-40 Diethylmonium Chloride
3	Quassin, Brucine (alcohol denaturants) and SD Alcohol 39
1	Sodium Iodate
1	Sodium Lauraminopropionate
1	Stearic Hydrazide
1	Toluene-3,4-diamine
1	Urocanic Acid
51	TOTAL

Attachment 2

Cosmetic ingredients with insufficient data to support safety (51 total, through September, 2010)

Ingredient	#
Acacia Concinna Fruit Extract, Acacia Decurrens Extract, Acacia Farnesiana Flower/Stem Extract, Acacia Farnesiana Flower Wax, Acacia Senegal Extract	5
Achillea Millefolium Extract	1
Aloe Arborescens Leaf Extract, Aloe Arborescens Leaf Juice, Aloe Arborescens Leaf Protoplasts, Aloe Ferox Leaf Extract, Aloe Ferox Leaf Extract, Aloe Ferox Leaf Juice Extract	6
Arachidonic Acid	1
Arnica Montana and Arnica Montana Flower Extract	2
Azulene ¹	1
Brucine Sulfate	1
Captan	1
Cetethyl Morpholinium Ethosulfate	1
Coal Tar	1
Corylus Avellana (Hazel) Leaf Extract Corylus Americana (Hazel) Seed Extract	2
Corylus Avellana (Hazel) Seed Oil Corylus Americana (Hazel) Seed Oil	2
Disperse Blue 7	1
Glucose Glutamate ²	1
Glyceryl Arachidonate	1
Human Placental Protein, Hydrolyzed Placental Protein, Placental Lipids, Placental Enzymes, and Placental Proteins	5
Hypericum Perforatum Extract and Oil	2
Juniperus Communis Fruit Extract, Juniperus Oxycedrus Tar, Juniperus Virginiana Wood Extract	3
Morpholine	1
2, 3 Naphthelenediol	1
PEG-5 Cocamine and PEG-15 Cocamine	2
Pentaerythrityl rosinat	1
Piper Methysticum Leaf/Root/Stem Extract	1
PPG-9 Diethylmonium Chloride, PPG-25 Diethylmonium Chloride	2
Pyrocatechol ³	1
SD Alcohol 40	1
Sodium lauriminodipropionate	1

Ingredient	#
Sodium-M-Nitrobenzenesulfonate	1
Stearamide DIBA Stearate	1
Stearamine	1
	51

¹ this ingredient may not be in use; confusion with guiazulene

² this ingredient is currently called Deoxyglutaryl Fructose

³ unsafe for leave-on products; insufficient data for hair dyes