Color Confusion Resolved

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United States
How Are Colors Defined?

- “Coal Tar Colors”
- Others

- All colors must be pre-approved by the FDA before they can be used.
  - Not meeting these requirements is adulteration
  - 21 CFR 73 for exempt
  - 21 CFR 74 for certified
All Colors Must be Certified By The FDA

- Coal tar colors are FDA batch certified.
  - They are sometimes called “organic” colors.

- The other colors (mostly inorganic) are batch certified by the manufacturer as compliant with FDA requirements.
  - They are sometimes referred to as exempt colors.
Coal Tar Colors

- Originally made from the by-products of converting coal to coke. Now they are mostly petro-chemical derived. They used to be named by their permitted use:
  - Food, Drug & Cosmetics (FD & C)
  - Drug and Cosmetics (D & C)
  - External Drug and Cosmetics (ext. D & C)
Natural Colors

- Annatto
- Caramel
- β-Carotene (if natural sources)
- Guanine
- Henna
- Mica
Current US Labeling Terms

- The name of the color and the old number
  - Black 2 or Blue 1, etc.

- Two exceptions:
  - Violet 2 and Yellow 7 could both be D & C and a totally different color approved for external use only.
  - To differentiate which is being used, the external dyes are denoted by the abbreviation Ext.
    - Ext. Violet 2; Ext. Yellow 7
Permitted Colors

- Certified: 36 approved (2 are not used)
- Exempt Colors: 29 approved (2 are not used)
- Restrictions: Eye area, General (including lipsticks), External (subject to limitations) and other limitations and comments
European Union
All Colors Must be Pre-Approved

- The list of permitted colors is found on Annex IV.
- There are 144 permitted colors listed by their Reference number, IUPAC name, followed by their Colour Index number (CI).
- These are followed by 9 colours that do not have CI numbers but are permitted as colors.
- Colors are restricted by: Rinse off, no mucous membrane contact, purity, %, eye products.
Other Issues

- Colours must be listed by their CI numbers in the Ingredient Listing (IL) of the label
  - If they are not used as a color, they must be listed by their INCI designation
- Colours on the Annex that have an E number must meet the specifications as listed for that E number (food specifications)
- Permitted Colors are listed in Annex IV
- Prohibited Colors are listed in Annex II
- **JUST BECAUSE A COLOR HAS A CI NUMBER DOES NOT MEAN IT IS A PERMITTED COLOR!**
Japan
Regulations

- Japan pre-approves coal tar colors and uses their unique identification for these.

- All other colors are considered cosmetic ingredients and do not require pre-approval!
The Confusion lies in....

- Definitions
- Labeling of colors and their uses
- May Contains
Definition of a Dye

- Dyes-These are colors where each molecule contributes to the color. They must be soluble in the solvent.

- Picture a glass of water where you place 1 drop of a yellow dye. The entire glass of water turns yellow.
Definition of a Pigment

- Pigments - These are colors where each particle contributes to the color. They are insoluble in the solvent.

- Picture the same glass of water and drop some iron oxides in. The particles just float around and do not color the water.
Definitions

- Lakes-These are pigments that are produced by absorbing a water soluble dye onto an insoluble inorganic substrate. There is a metal ion, usually aluminum, that partially precipitates the dye as the metal salt. The unprecipitated dye is absorbed by the substrate but is not chemically bound.

- This is what Japan defines for their regulations
Definitions

- Lakes defined by the FDA-The FDA uses that definition but then goes further to call any color that is extended onto an approved substrate a lake. There is no chemical reaction.
- Japan considers these to be mixtures, not lakes!
- If you check some databases you will see some US “lakes” not allowed in Japan; when they really are permitted as mixtures.
Definitions

- Toners- this is a pigment produced by precipitating an acid dye as the metal salt.
- This differs from a lake as no substrate is used.
Definitions

- True Pigment - This is a “dye” that as produced, is insoluble because of its chemical structure.

- Examples of True pigments are Red 30 and Red 36
Revealing What You Can and Cannot Use
Red 6

- Approved as a dye in Japan as Aka 201 and the US, but the FDA prohibits its use in eye area cosmetics.
- The FDA will certify batches that are extended with listed substances (rosin or Barium Sulfate) and calls them lakes.
- These lakes do not meet Japan’s definition but are permitted as a mixture!
- However, Japan does not allow this to be precipitated using Barium salts.
Structure Red 6
Red 7

- Permitted in Japan as Aka 202.
- This is a toner and so is allowed.
- Red 6 is the sodium salt (soluble-dye) while Red 7 is the calcium salt (not soluble-toner)
- The EU uses the same CI number for both CI 15850.
Red 7 Structure
Other Colors

- Red 21 Aluminum Lakes are **not** allowed in Japan
- Red 22 Aluminum Lakes are allowed in Japan (Aka 230)
- Red 27 Aluminum Lakes are **not** allowed in Japan
- Red 28 Aluminum Lakes are allowed in Japan (Aka 104)
More

- Red 30 Aluminum Lakes (FDA definition) are allowed in Japan (Aka226) as this not a Japanese lake but a True pigment
- Red 33 Aluminum Lakes are allowed in Japan (Aka 227)
- Red 34 is allowed in Japan (Aka 220) as it is a toner. The Calcium salt precipitates this in water when manufactured. The FDA allows this to be extended as a lake, which is allowed in Japan as a mixture
Red 34
More

- Red 36 is a true pigment and allowed in Japan (Aka 228) and the US.

- Red 40 is prohibited as a dye and a lake in Japan.
Red 36
Confusion in US & EU

- Yellow 10 (and its lakes) are allowed in Japan (Ki 203) and the US (mono & disodium salt)
- EU allows only the disodium salt (CI 47005)
- The FDA will not certify the disodium salt
Yellow 10
Ferric Ammonium Ferrocyanide

- The FDA has approved this as Ferric Ferrocyanide
- The EU Cosmetic Regulation lists this as CI 77510, Ferric Ammonium Ferrocyanide
- CosIng lists this as Ferric Ferrocyanide!
- In reality we all use Ferric Ammonium Ferrocyanide
Mica

- Mica is an approved color in the US
- Mica is a cosmetic ingredient in the EU
- Labeling Mica with its CI number is not permitted in the EU as it is not an approved color.
May Contain (+/-)

- When IL became required in the US, the FDA recognized that due to variations from batch to batch of the color, cosmetic producers would need to add some other colors to obtain the same shade. This was the origin of the May Contain section.

- At industry’s request, the FDA allows colors in this section if the base formulation is the same.

- OTC Drugs cannot have a May Contain section.
US Exceptions

- If a color is present in all shades, it is not permitted in the May Contain section.

- Carmine is not permitted in the May Contain section.
Carmine

- As a result of an NGO’s Citizen’s petition, effective 1/5/11 Carmine must be listed in all foods, Professional Use only cosmetics and cosmetics.

- For products without IL’s this is the suggested label:
  - Contains carmine as a color additive
Why?

- Officially because of allergic responses to this in foods
  - Foods only said: contains artificial and natural colors
  - Professional use cosmetics did not require any IL

- Unofficially because they are of animal origin
  - Carmine comes from insects, which are animals!
The EU Regulations

- Colorants (other than colorants intended to color the hair) may be listed in any order after the other cosmetic ingredients.

- For decorative cosmetic products marketed in several color shades, use in the range may be listed, provided that the words ‘may contain’ or the symbol ‘+/-’ are added. The CI (Color Index) nomenclature shall be used, where applicable.
More Issues

- Titanium Dioxide
- Zinc Oxide
- Black 2
Titanium Dioxide

- EU approved as a color CI 77891
- Also approved as a UV filter as Titanium Dioxide
- If you have nano size for any use, you need pre-approval for its use.
  - Colorant: Labeled CI 77891 (nano)
  - UV filter: Labeled Titanium Dioxide (nano)
Zinc Oxide

- EU Approved as a color CI 77947
- EU has not approved as a UV filter
  - SCCS has recommended its approval but no ATP has been issued
- If you have nano size for any use, you need pre-approval for its use.
  - Colorant: Labeled CI 77947 (nano)
Black 2

- Eu approved as a color CI 77266
- All Black 2 as produced contains nano
- Is now exempt from nano labeling
  - It is used as a pigment so no nano particles exist as used!
Regulatory Enforcement

- Most enforcement occurs at customs
  - US issues
    - Illegal colors
      - Red 2
    - Non-certified colors
      - Just because it meets US specs, they still need FDA approval
  - Mislabeled colors
    - Not using US names
  - Non-permitted ingredients in “May Contain”
Common Consequences

- **Exporter** is put on customs alert
  - All shipments may be inspected and detained
- Detained products
  - You miss your ship date
  - Products may be inspected for anything
- Destroyed products
  - Total loss and the importer may have to pay for the destruction
Outstanding and Unresolved Issues

- Special effects pigments
  - Are they new colors?
  - How do you deal with their additives?
  - Confusion on having non-colors in May Contain
  - What about coatings of colors?

- PET
  - Fused sheets of plastic film with color between sheets. Often called Glitter
Glitter

- This is the stuff we played with in grade school
- Found that this adhered to the skin and gave unique effects in the theater by actors
- Many use unapproved colors or will not say what colors are used
- Safety issues
  - Film is chopped to give ragged edges which allows adherence to skin
  - If glitter gets into your eye, you should seek medical care to remove.
Conclusion

 ICCR can and should deal with all these issues
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Questions?

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Thank You!