TATTOOS AND PERMANENT MAKEUP

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Topics for Discussion

- **Regulatory status of color additives, tattoo inks, and pigments**
- **Chemistry of tattoo pigments**
  - Inorganic tattoo pigments
  - Synthetic organic tattoo pigments
- **Marketplace**
  - General body tattoos
  - Permanent makeup tattoos
  - Problems with tattoos and permanent makeup
  - FDA responses

What is a color additive?

- Any material that can impart color to a food, drug, cosmetic, or medical device, or to the human body
- Important components of many products
- Allow us to identify
  - candy flavors
  - drug tablets
- One of FDA's roles is to assure that color additives are used safely and appropriately

Regulatory Status of Tattoo Pigments

- **Color additives** must be **approved** by FDA for use in food, drugs, and cosmetics
- **Approved color additives** are listed in the U.S. Code of Federal Regulations
  - *See* **21 CFR Parts 73, 74, and 82**
- **No** color additives have been listed for injected use
  - *See* **21 CFR 70.5(b)**
- **Tattoo pigments** are unapproved color additives

Regulation of Tattoo Inks and Tattoo Pigments in the U.S.

- **Tattoo inks** are a mixture of pigments and diluents intended for introduction into the skin
  - **Tattoo inks** are cosmetics
- FDA traditionally has not exercised its regulatory authority over tattoo inks or tattoo pigments
  - **Safety information** posted on FDA's website
- The **practice** of tattooing is regulated by state and local jurisdictions

Chemistry of Tattoo Pigments

- Inorganic pigments
- Synthetic organic pigments

Inorganic Tattoo Pigments: Mineral Sources

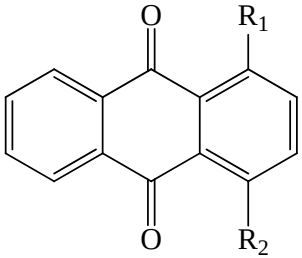
- **Black**
  - Magnetite ($FeO \bullet Fe_2O_3$)
  - Charcoal (C)
- **Red**
  - Hematite (Fe_2O_3)
  - Cinnabar (HgS)
- **Yellow**
  - Limonite ($FeO \bullet OH \bullet nH_2O$)
- **White**
  - Corundum (Al_2O_3)
  - Rutile (TiO_2)
  - Zincite (ZnO)
- **Blue**
  - ferric ferrocyanide ($Fe_4[Fe(CN)_6]_3$)
  - cobaltous aluminate ($CoAl_2O_4$)

Inorganic Tattoo Pigments, cont.

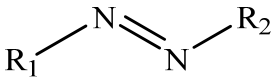
- **Inorganic compounds** are easily obtainable from naturally occurring minerals, such as iron oxides
- **However,**
  - **Iron oxides** fade or change color
  - Historically used **mercury** and **cadmium** salts are toxic

Synthetic Organic Tattoo Pigments: Dye Structures

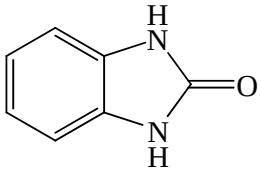
- **Anthraquinone**



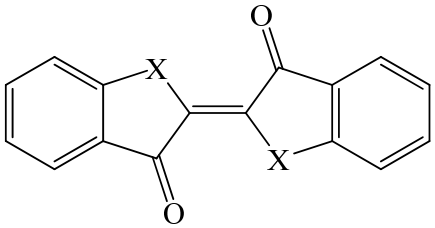
- **Azo, Disazo**



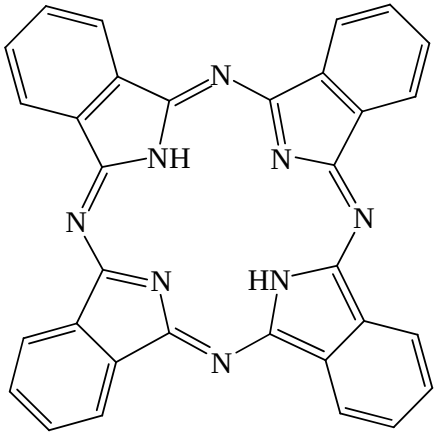
- **Benzimidazolone**



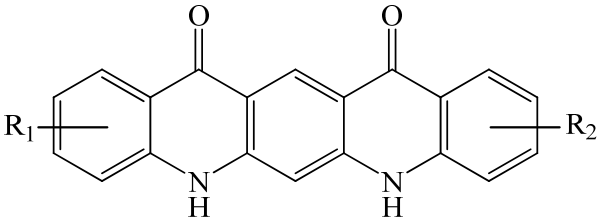
- **Indigoid**



- **Phthalocyanine**



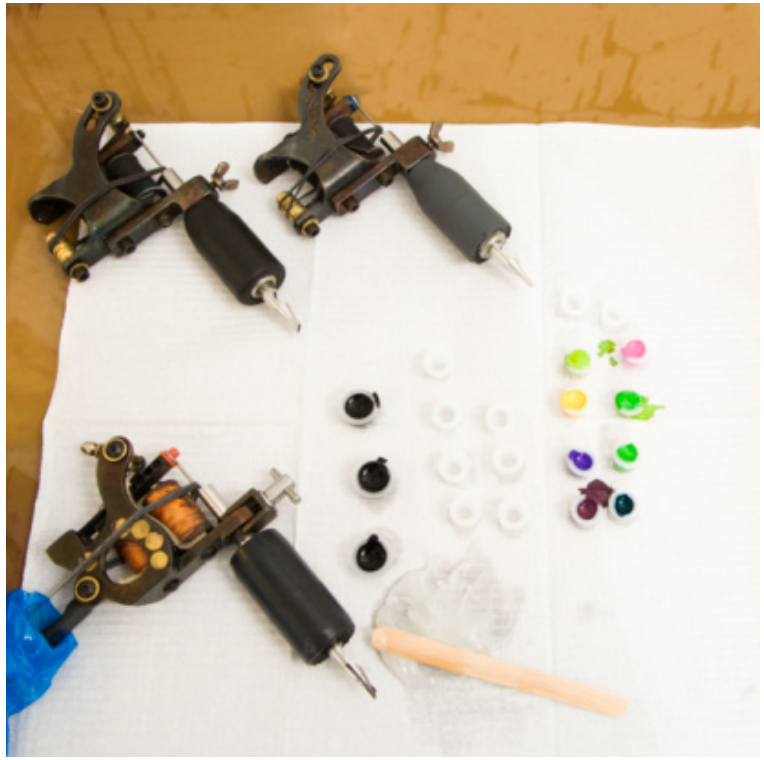
- **Quinacridone**



Synthetic Organic Tattoo Pigments

- **More intense colors** than inorganic pigments
- Give **wider range** of colors
- Some are **removable** by laser

Marketplace – Inks and implements



Home-made tattoo machine

Commercially produced tattoo machine

General Body Tattooing

General Body Tattooing

Permanent Makeup

- **Tattoo parlors historically <u>avoided the face</u>**
- **Permanent makeup inks: face, eye area**

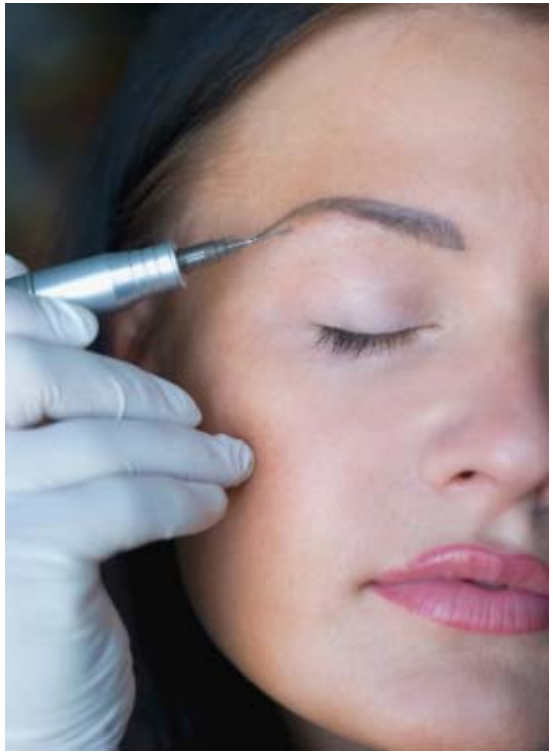
Permanent Makeup

- **Replaces traditional makeup**
  - **Eyeliner**
  - **Eyebrows**
  - **Lipliner**
  - **Full lips**
  - **Blusher**

- **Also called "micropigmentation"**

Examples of Permanent Makeup

Eyebrows



Lips

Tattoo/Permanent Makeup Industry

- **Technicians diverse:** amateurs to RNs and MDs
- **Salons/tattoo parlors** regulated by state and local health departments
- **Tattoos/permanent makeup in salon, home, workshop settings**
  - No injected anesthesia
  - Varying sterile techniques
- **Permanent makeup in medical setting**
  - Injected anesthesia
  - Varying artistic ability

Problems with Tattoos and Permanent Makeup

- **Tattoo pigments** have not been approved by FDA
  - **Safety** for skin injection has not been demonstrated
- **Adverse reactions** have occurred
- **Removal** can be difficult

Adverse Reactions to Tattoos and Permanent Makeup

- **Swelling, cracking, peeling, blistering, scarring**
- **Granulomas** (small nodules of inflamed skin)
- **Keloids** (scars that grow beyond normal boundaries)
- **Allergic Reactions**
- **Photosensitivity**
- Serious **disfigurement**
- **MRI** complications

Allergic Reaction

Adverse Reactions to Permanent Makeup

- **1988 to 2003** – FDA received only five reports of adverse reactions
- **2003 to 2004** – FDA received more than 150 reports of adverse reactions
- **FDA and CDC** – identified 101 patients with adverse reactions
- **Adverse reactions –** tenderness, swelling, itching, and bumps
- **Clinical diagnoses** – allergic reactions or granulomas

Adverse Reactions to Permanent Makeup

FDA and CDC Actions

- **July 2, 2004** – FDA alerted public to concerns with Premier Pigment brand of ink shades
  - **"FDA Talk Paper"** (press release)
  - **Website**
- **Sept. 27, 2004** – Product line recalled by manufacturer
- **July 2005** – Case study in *Archives of Dermatology*
- **June 28, 2007** – Publication in *New England Journal of Medicine*
- **Current web site** "Tattoos and Permanent Makeup" **http://www.fda.gov/Cosmetics/ProductandIngredientSafety/ProductInformation/ucm107327.html**

Adverse Reactions to Tattoo Inks Without Preservatives

- Website brags that no preservatives or other additives have been used in their tattoo inks. Claims include—
  - *The inks are made with sterilized distilled water*
  - *The ink is* ***not an alcohol-based tattoo ink***

- **Problem: Removing the alcohol and not using any other preservatives allows bacteria to grow**

FDA Action – Starbrite Ink Contamination

- **2004:** Belgium withdrew "Starbrite Colors" tattoo ink from market because of microbial contamination
- FDA analyses found **bacteria** (*Pseudomonas aeruginosa)* and **mold** *(Acremonium)*
- Resulted in **manufacturer recall** of Starbrite ink
- Starbrite ink became contaminated because the manufacturer **removed alcohol preservative** from their ink formula

Removing Tattoos

Laser Treatments

- Painful
- Expensive
- Time consuming
- May result in discoloration of skin
- May not be complete
- Iron oxide and titanium dioxide pigments turn black

Surgery

- Painful
- Expensive
- Scarring

More Problems: Misleading Websites

- **Website claims:**
  - The company uses an ingredient, polymethylmethacrylate (PMMA)
  - The company claims this makes the ink safe and the ingredient gives the ink FDA approval
- **Problem: False claims!**
  - **No data showing the ingredient is safe for this use**
  - **FDA did NOT approve these inks**

Conclusions

- **Marketplace** – wide variety of inorganic and synthetic organic pigments and diluents in tattoos and permanent makeup
- **Adverse reactions** – FDA responded
- **Misleading** websites!!!
- **No** pigments have been approved by FDA for tattooing humans

Thank you!

- For more information: www.fda.gov
- Email questions: consumer@fda.gov
- Report a reaction: www.fda.gov/MedWatch

Questions?