



FDA: TATTOOS AND PERMANENT MAKEUP

Marketplace and Chemistry

Presented by: Bhakti Petigara Harp, Ph.D.

Thursday, December 17, 2009

TATTOOS AND PERMANENT MAKEUP

Marketplace and Chemistry



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December 17, 2009**



Modules

- **Regulatory status of tattoo inks and pigments**
- **Marketplace**
 - General body tattoos
 - Permanent makeup tattoos
 - Problems with tattoos and permanent makeup
- **Adverse reactions and FDA responses**
- **Chemistry of tattoo pigments**
 - Inorganic tattoo pigments
 - Organic tattoo pigments



Module 1

- Regulatory status



Regulatory Definitions

- **Color additive** – any material capable of imparting color to a food, drug, **cosmetic**, medical device, or **the human body**
- **Types of color additives** – organic dyes and pigments, inorganic pigments
- **Mixture** – two or more color additives with or without diluents
- **Diluent** – component of a color additive mixture added to facilitate the use of the mixture in coloring the human body



Are tattoo pigments regulated by the FDA?

Yes	No

Regulatory Status of Tattoo Pigments

- **Color additives** must be **pre-approved** by FDA for use in food, drugs, cosmetics, and medical devices
- **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)**

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

- **Tattoo inks** are cosmetics
- **Tattoo pigments** are color additives requiring pre-market approval
- FDA traditionally has not exercised its regulatory authority over tattoo inks or tattoo pigments
- The practice of tattooing is regulated by local jurisdictions for sanitation
- Recent adverse events have raised FDA's concern

Regulation of Tattooing in Other Countries

- **E.U.** – Tattoos are “non-food products,” not cosmetics
 - See Opinion of Scientific Committee on Cosmetic Products and Non-Food Products, 17 February 2000
 - Pigments and implements are being assessed
- **Canada** – Infection control guidelines
 - In partnership with provincial and territorial governments
 - Developed for tattoo practitioners
- **Australia and New Zealand** – Regulation is aimed at infection control
 - Oversight by individual States and Territories
 - Legislation does not address irritation, allergy, trauma⁹



Let's Pause Two Minutes for Questions from the Audience





Module 2

- Marketplace

Marketplace – Definitions

- **Tattoo ink** – a mixture of pigments and diluents intended for introduction into the skin
- **Pigments** – wide variety of inorganic and organic compounds
- **Diluents** – glycerin, propylene glycol, ethanol, witch hazel
- **Dyes** – must be converted to pigments for use in tattoo inks to limit migration

Inorganic vs. Organic Tattoo Pigments

- **Inorganic compounds** are easily obtainable from natural sources (e.g., iron oxides)
- **However,**
 - **Iron oxides** fade or change color
 - Historically used **mercury** and **cadmium** salts are toxic
- **Organic pigments** first synthesized in mid-1800s
 - Satisfied need for new pigments

Advantages of Organic Tattoo Pigments

- **More intense colors** than inorganic pigments
- Give **wider range** of colors
- Are **removable** with laser techniques



Marketplace – Inks and implements





Spaulding Supreme Tattoo Machine



What percentage of people have tattoos?

Multiple Choice

- A. 10%
- B. 40%
- C. 90%



General Body Tattooing

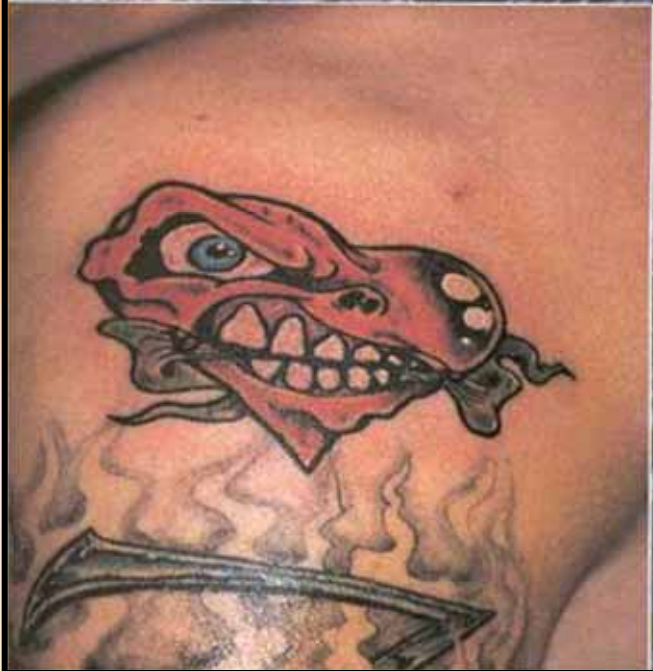




GREG JAMES, SUNSET STRIP TATTOO
HOLLYWOOD, CA



GREG JAMES, SUNSET STRIP TATTOO
HOLLYWOOD, CA





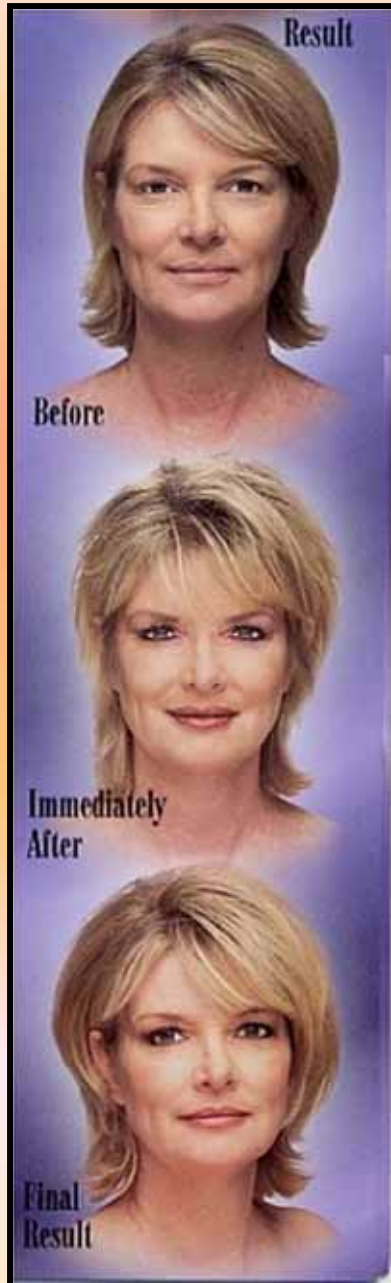
Fluorescent Tattoo Inks



- General body tattoo inks
 - Tattoo parlors historically avoided the face
-
- Permanent cosmetics inks (face/eyes)



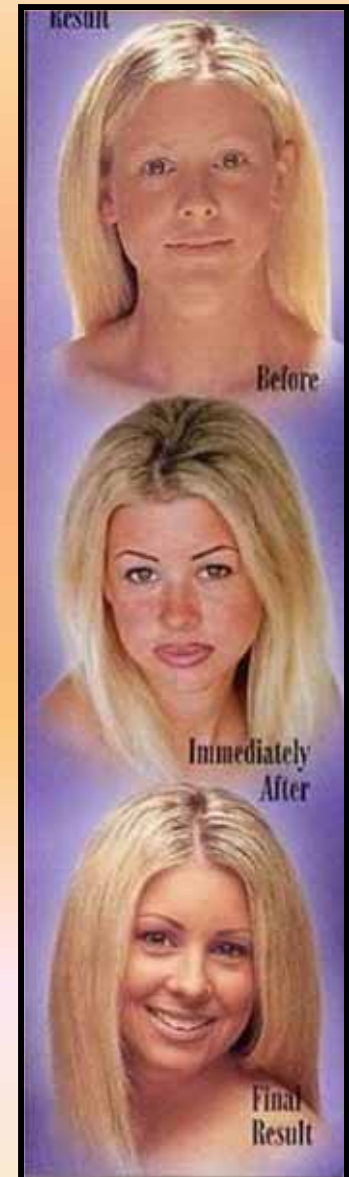
Permanent Makeup



- Before and after photos (Premier Pigments web site)

- Eyeliner
- Eyebrows
- Lipliner
- Full lips
- Blusher

- Also called micropigmentation



Examples of Permanent Makeup

EYELINER
MOLE

EYEBROWS



Permanent Makeup Tattoo Machine



COLOR: IT STAYS
 ACCESSORIES: INEXPENSIVE, STERILE AND
 THE KEY TO PERMANENT BEAUTY.....

Permanent Make-up device
 kit. (A) to (K)

- A. Custom-made leather carrying case
- B. Permanent make-up device (applicator)
- C. Non-toxic pigments (assorted colors), 10 bottles, 1/2 oz. each
- D. Color remover lotion, 1/2 oz.
- E. Pigment dilutant, 1/2 oz.
- F. AC Adaptor, 4-speed, UL Listed

TINNY PERMANENT MAKE-UP
 COLOR CHART:

	
Black	Maroon
	
Dark Brown	Blue
	
Medium Brown	Yellow
	
Light Brown	Beige
	
Red	White



Before



Problems with Tattoos and Permanent Makeup

- **Safety** for skin injection has not been demonstrated
- **Adverse reactions** have occurred
- **Photosensitivity** is a problem
- **Removal** is a problem

Problems with Tattoo/Permanent Makeup Industry

- **Technicians diverse:** amateurs to MDs/RNs
- **Non-medical technicians** have little training in sterile techniques
- **Medical personnel** may have limited expertise in makeup application
- **Beauty salons/tattoo parlors** regulated by State and local Health Departments

Permanent Makeup in Medical Setting

- Injected anesthesia
- **Clamp** secures eyelid
- **Calipers** ensure placement
- **Varying** artistic ability



Figure 15c-1:
An example of Zwerling-Christensen no-bruise injection technique in blepharopigmentation patient. Note the lack of advancement of the needle with the ballooning effect of the subepidermal tissue.



Figure 15c-2:
A lid clamp secures the lid from any movement and allows the practitioner a safer angle of approach to the lid margin.



Figure 15c-3:
The use of calipers to demarcate the nasal extreme of the eyeliner ensures bilateral symmetry. Note the temporal mark from the use of the lid clamp; however, there is no evidence of lid bleeding.

Tattoos/Permanent Makeup in Salon, Home, Workshop Settings

- **No** injected anesthesia
- **Varying** sterile techniques





Let's Pause Two Minutes for Questions from the Audience





Module 3

- Adverse Reactions

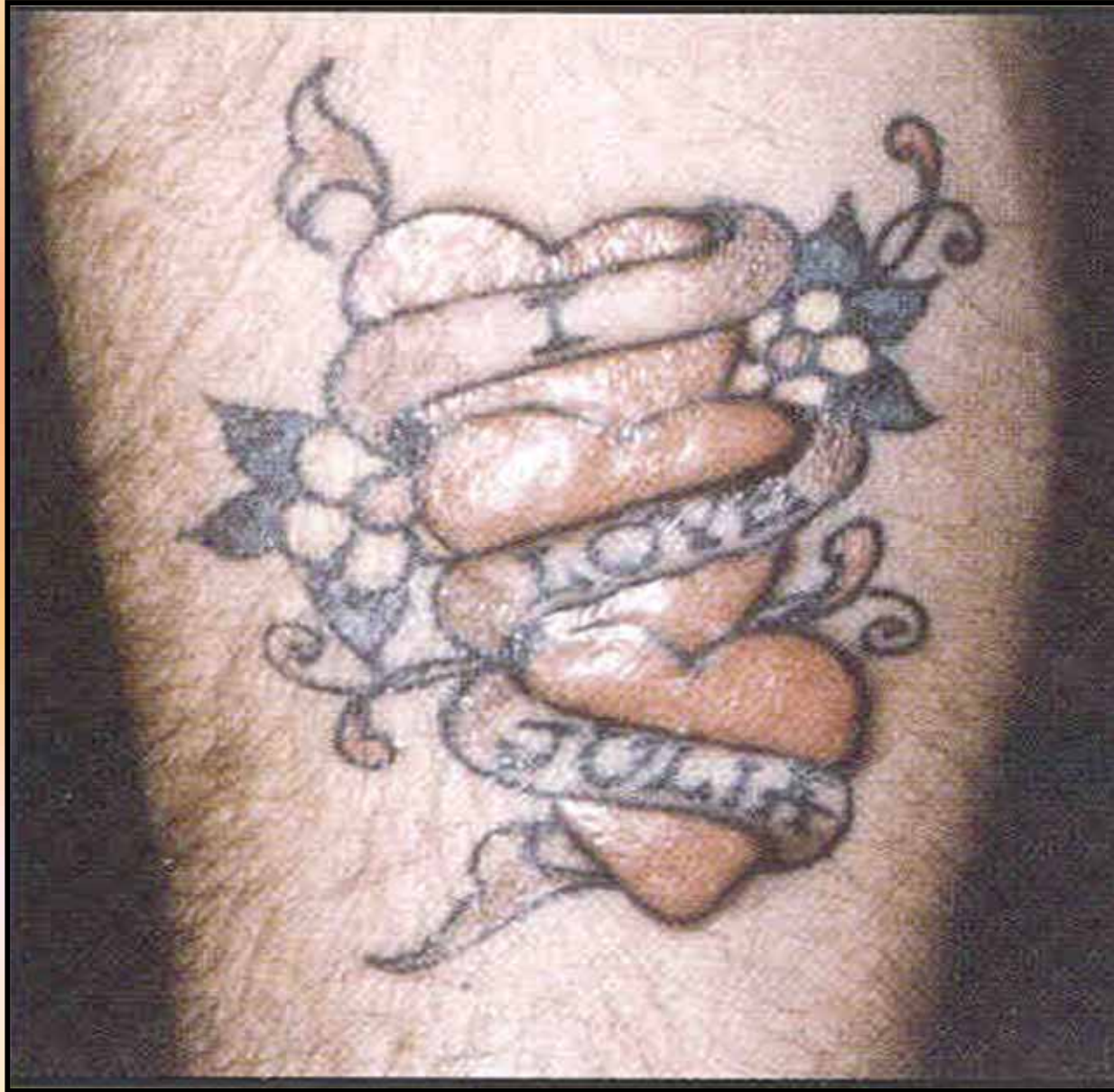
Adverse Reactions to Tattoos and Permanent Makeup

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

Adverse Reactions – Granulomas



Adverse Reactions in Sunlight



Adverse Reactions to Surgical Removal

- **Laser removal**
 - Painful
 - Expensive
 - Usually leaves scarring
 - Iron oxide and titanium dioxide pigments turn black



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 or granulomatous reactions

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)
 - **Web site** (archived)
- **Sept 27 2004** – Product line recalled by manufacturer
- **July 2005** – Case study in *Archives of Dermatology*
- **June 28 2007** – Letter to *New England Journal of Medicine*
- **Current web site** “Tattoos and Permanent Makeup”
<http://vm.cfsan.fda.gov/~dms/cos-204.html>

Adverse Reactions to Tattoo Inks Without Preservatives

- “The ingredients of “... “ UV Tattoo Inks: (PMMA) *Polymethylmethacrylate 97.5% and microspheres of fluorescent dye 2.5% suspended in UV sterilized, distilled water with **no preservatives** or other additives.*”
- “*TATTOOISTS REMEMBER - these black light tattoo inks are made with sterilized distilled waters, do not add foreign objects into your ink bottles!. This is **not an alcohol based tattoo ink.***”



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 (Class II, reversible injury)
- Starbrite ink became contaminated because the manufacturer **removed alcohol preservative** from their ink formula



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02184
(781) 596-7700
FAX: (781) 596-7896

March 15, 2005

Meredith Nicholson
President
Papillon Supply and Manufacturing
118 Pearl Street
Enfield, Connecticut 06082

Recall Number: F-213-5

Dear Ms. Nicholson:

The U.S. Food and Drug Administration agrees with your decision to recall the Starbrite brand Black Magic Color , packaged in individual ½ oz., 1 oz., 2 oz., 4 oz. and 8 oz. size translucent plastic, codes 7996988, 7996989. We consider the product to be adulterated as it is contaminated with Acremonium mold and Pseudomonas aeruginosa.

We have reviewed your action and conclude that it meets the formal definition of a firm initiated recall. This is significant, as your action is an alternative to a Food and Drug Administration (FDA) legal action to remove your product from the market. The recall will be reported in an issue of the FDA Weekly Enforcement Report.

The recall has been classified as a Class II recall. A Class II recall is defined as a situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Our evaluation indicates the "Depth of Recall" should be conducted to the direct account level. Level A effectiveness checks have been assigned to your recall. Effectiveness checks are actions taken by your firm to verify that consignees at user level have received notification and have taken appropriate action. Level C effectiveness requires that your firm conduct effectiveness checks on 10% of all direct accounts contacted.

We request that you submit monthly status reports until your recall is completed. The status reports should contain the information outlined in Section 7.53(b)(1-6) of the Recall Enforcement Policy.

Problems with Tattoo Ink: Claiming FDA Approval on Web Sites

- **Polymethylmethacrylate in tattoo inks:**
“We researched scientific articles on bone repair, plastic surgery, orthodontics, body modification, and other medical uses of polymethylmethacrylate (PMMA). The PMMA is what makes this ink absolutely safe, and gives this ink its **FDA Approval**.”
- **On “Chameleon Body Art Supply” web site:**
<http://www.crazychameleonbodyartsupply.com/bmx-1000-chameleon-tattoo-inks.htm>

Problems with Tattoo Ink: Citing FDA Approval for Tattooing Fish

- **FDA letter dated April 3, 1995:**
*“Having reviewed the information supplied by you [our manufacturer of the ink] and your supplier ... **FDA** would have **no objection** to the use of your **photonic dye marking [tattooing]** system ...”*
- **On “Captain Jack’s Tattoo Studio” web site:**
<http://www.captainjackstattoo.com/content/blacklight-inks>

Temporary Tattoos – Decals

- **Temporary tattoos** are regulated as **cosmetics**
- **Declaration of ingredients** is required
- **Approved color additives** are required
- **Import alert** – for temporary tattoos containing non-permitted (illegal) color additives
- <http://www.fda.gov/Cosmetics/ProductandIngredientSafety/ProductInformation/ucm108569.htm>

Body Decoration with Henna





Is henna approved for use on the skin?

Yes	No

Henna Tattoos and Body Decoration (Mehndi)

- **Henna** is derived from the leaves of the shrub *Lawsonia inermis*
 - Brown, orange-brown, or reddish-brown tints
- **Approved color additive** for coloring hair
 - See 21 CFR 73.2190
- **Coloring the skin** is an unapproved use of the color additive
- **Import alert** – for “Henna based skin color” products

Body Decoration with Black Henna



Adverse Reactions to Black Henna

- “**Black henna**” contains additional coloring ingredients
 - Allows darker, more intense color
 - Speeds up tattooing process, makes tattoo last longer
- ***p*-Phenylenediamine (PPD)** may be added
 - A hair dye
 - Not approved for direct application to the skin
- **Allergic reactions** to PPD
 - Potent skin sensitizer, possibly for lifetime
 - Allergic contact dermatitis
 - **Cross-reactions** to PABA, benzocaine, indigo
- **Feb 13 2007** Article in Canadian Medical Assn Journal



Let's Pause Two Minutes for Questions from the Audience





Module 4

- Chemistry of Tattoo Pigments

Chemistry of Tattoo Pigments

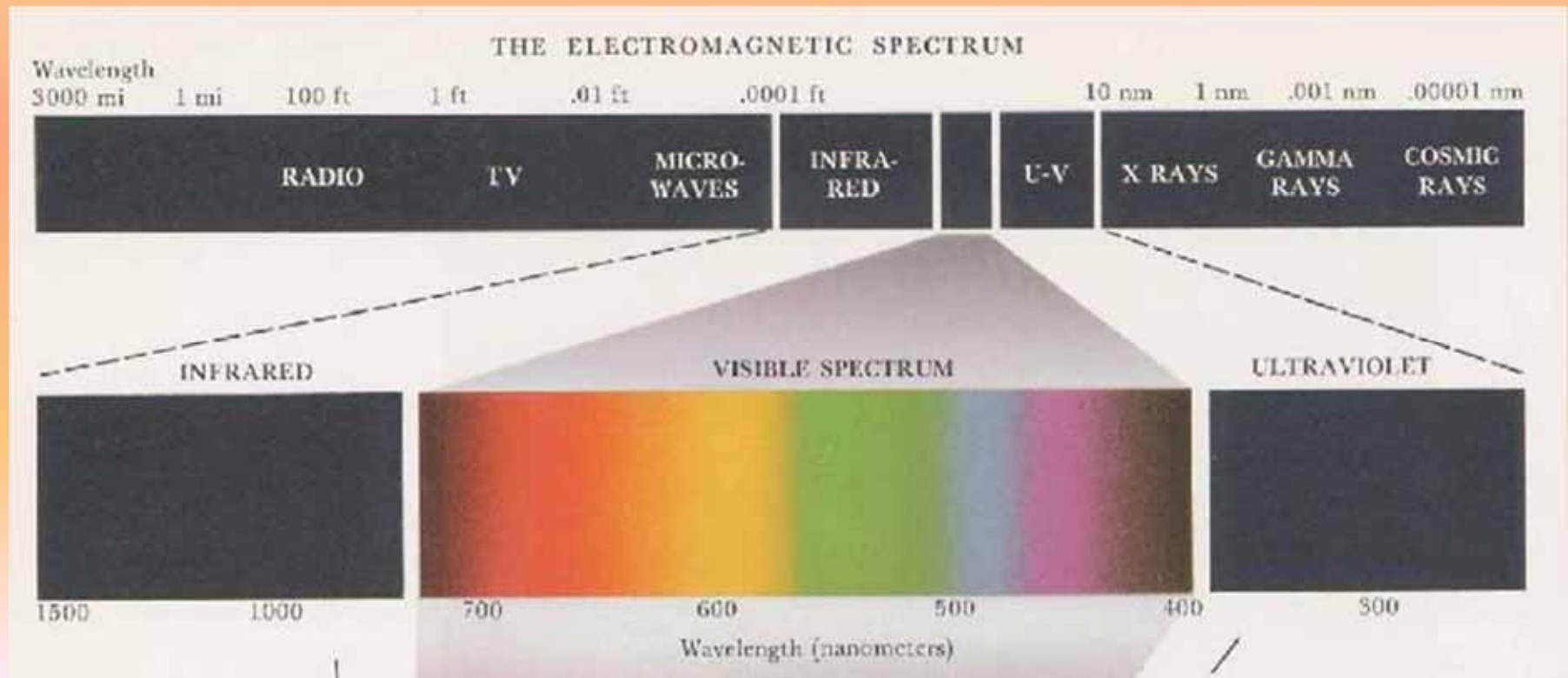
- Basic concept of color
- Inorganic pigments
- Organic pigments
 - Insoluble organic compounds
 - Dyes converted to insoluble pigments
- None are FDA approved for use in injections (tattoos)



Why not use FD&C colors in tattoos?

Type in the chat

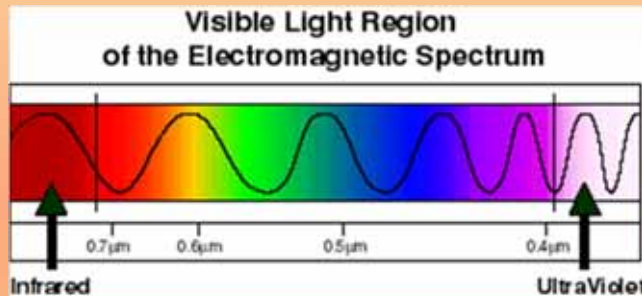
Electromagnetic spectrum



Basic Concepts of Color

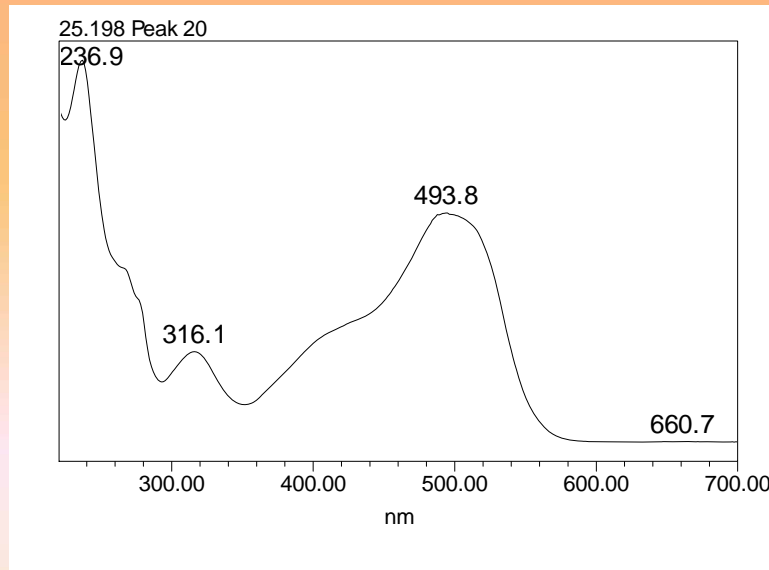
- **Interaction of visible light with a compound**
 - Wavelengths of light
 - Types of atoms in the compound
- **Dye molecules contain electrons at many energy levels**
 - Some of the electrons can absorb visible light
 - These electrons undergo transitions from lower to higher energy levels
- **Absorption removes some visible light**
 - We see the complementary color

Production of complementary colors

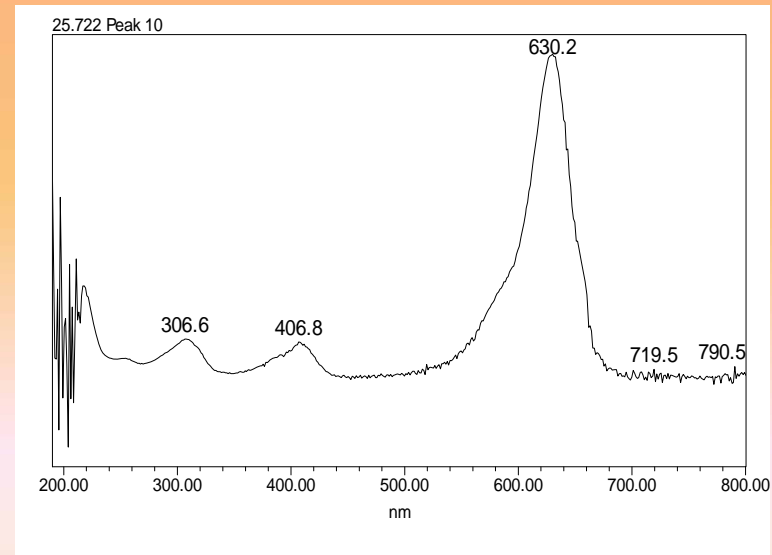


Absorption bands

- 400-430 nm (violet) see yellow
- 430-480 nm (blue) see orange
- 480-550 nm (green) see red
- 550-600 nm (yellow) see violet
- 600-700 nm (red) see blue



**D&C Red
No. 6**



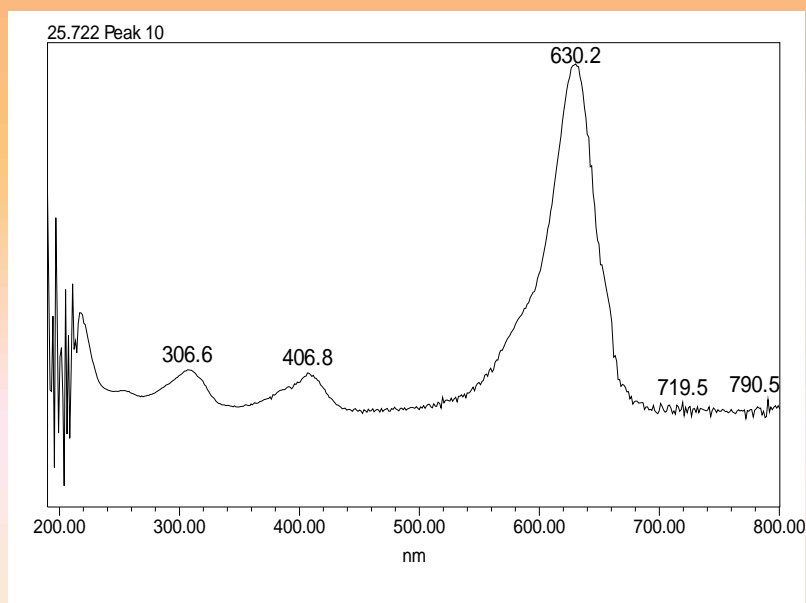
FD&C Blue No. 1



What color would you see?

Absorptions bands:

- | | |
|-----------------------|------------|
| • 400-430 nm (violet) | see yellow |
| • 430-480 nm (blue) | see orange |
| • 480-550 nm (green) | see red |
| • 550-600 nm (yellow) | see violet |
| • 600-700 nm (red) | see blue |



Multiple Choice

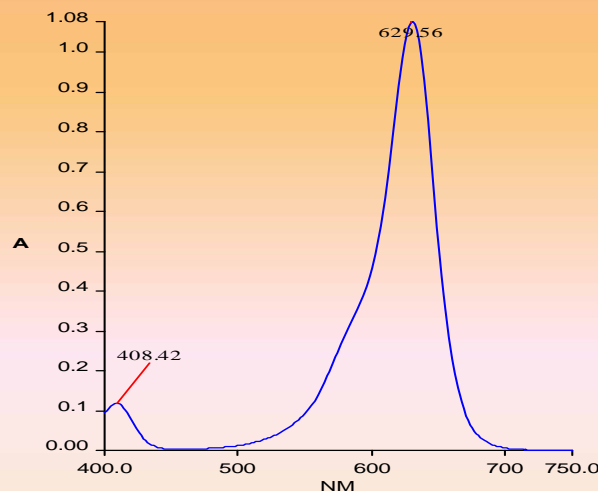
A. Red

B. Yellow

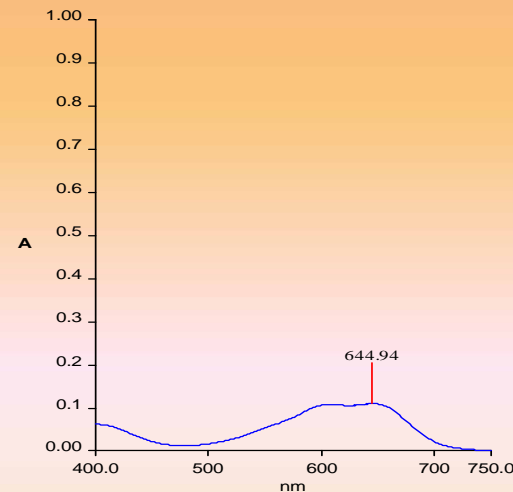
C. Blue

Absorptivity value

- **Measure of dye's ability to absorb light**
- **High absorptivity value: more efficient, more economical**
 - Dye absorbs a large amount of energy so you only need a small amount in the product
- **Low absorptivity value: not as efficient, less economical**
 - Dye absorbs less energy so more is needed in the product



FD&C Blue No. 1, $\alpha = 0.16$



D&C Green No. 5, $\alpha = 0.02$

Early food and cosmetic uses of dyes and pigments

- **Foods colored with spices and minerals**
 - Paprika, turmeric, saffron, iron oxides
 - Wine artificially colored in 300 B.C.
- **Cosmetics from vegetable and mineral sources**
 - White lead
 - Kohl (contains lead or antimony)
 - Copper ore for eye shadow
 - Vegetable extracts for the skin
- **Tattooing**
 - Charcoal, inorganic pigments

Historically Used Tattoo Pigments

- **Black** – iron oxide, carbon
- **Red** – mercury sulfide, iron oxide
- **Yellow** – cadmium sulfide, iron oxide
- **Blue** – cobaltous aluminate, ferric ferrocyanide
- **Green** – chromium oxide, chromium hydroxide
- **White** – titanium dioxide

Historically Used Minerals in Tattoo Pigments

- **Black**
 - Magnetite ($\text{FeO} \cdot \text{Fe}_2\text{O}_3$)
 - Charcoal (C)
- **Red**
 - Hematite (Fe_2O_3)
 - Cinnabar (HgS)
- **Yellow**
 - Limonite ($\text{FeO} \cdot \text{OH} \cdot n\text{H}_2\text{O}$)
- **White**
 - Corundum (Al_2O_3)
 - Rutile (TiO_2)
 - Zincite (ZnO)

FDA Analyses of Inorganic Pigments in Tattoo/Permanent Makeup Inks

- **Samples** of sixty-three tattoo/permanent makeup inks from three different manufacturers
- **Analyzed** by x-ray fluorescence spectrometry
- Results found **Ti, Al, and Fe** to be most common
- Historically reported **Hg, Cd, Co, and Ni** were not found

Inorganic Elements Found in Tattoo Pigments

- **Black** – Fe
- **Gray** – Fe, Ti, Al
- **Brown** – Fe, Ti, Al, Ca
- **Blue** – Ti, Al, Cu
- **Green** – Fe, Ti, Al, Ba, Br, Cr, Cu
- **Red and Magenta** – Ti, Al, Fe
- **Orange** – Ti, Fe, Al
- **Yellow** – Ti, Fe, Al
- **White** – Ti, Al

FDA Analyses of Organic Pigments in Tattoo/Permanent Makeup Inks

- **Samples** of thirty-five tattoo/permanent makeup inks analyzed from four different manufacturers
- Compounds in inks **extracted** and **separated** by HPLC
- **Organic pigments** identified by comparison of UV-visible spectra and HPLC retention times with reference standards
- **Results** showed mixtures of organic pigments from different chemical classes

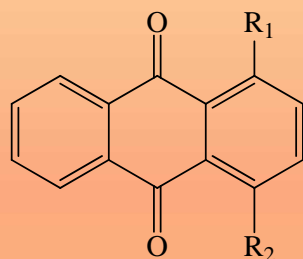
Organic Pigments in Tattoo/Permanent Makeup Inks

Chemical Class	Benzimidazolones			Monoazo Naphthol		Quinacridone	Monoazo Arylide
Sample	Pigment Brown 25	Pigment Orange 36	Pigment Orange 62	Pigment Red 170	Pigment Red 22	Pigment Red 122	Pigment Yellow 74
1	x	x					
2		x					
3	x	x	x				
4		x	x				
5		x	x				
6	x		x				
7	x	x	x				
8	x	x	x				
9	x						
10					x	x	
11						x	
12					x		x
13							
14				x			
15					x		
16					x		
17					x		
18							x
19							x
20	x						x
21	x						x
22	x						x
23	x						x
24	x						x
25	x						x
26							x
27						x	
28						x	x
29							
30					x		
31					x		
32					x		
33					x		
34							
35							66

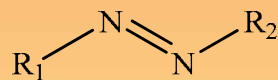
**Other unidentified peaks were found

Organic Tattoo Pigments – Dye Structures

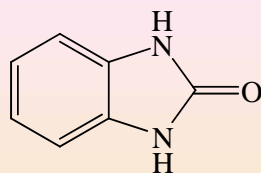
- Anthraquinone



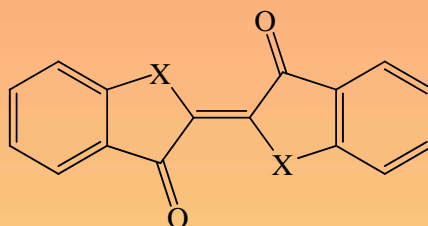
- Azo, Disazo



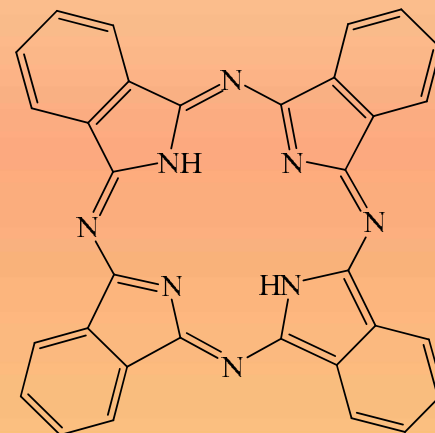
- Benzimidazolone



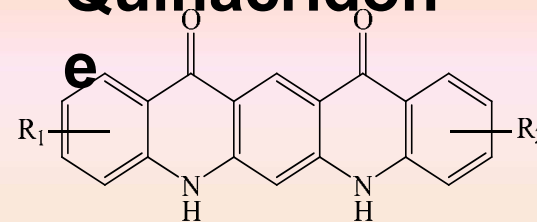
- Indigoid



- Phthalocyanine

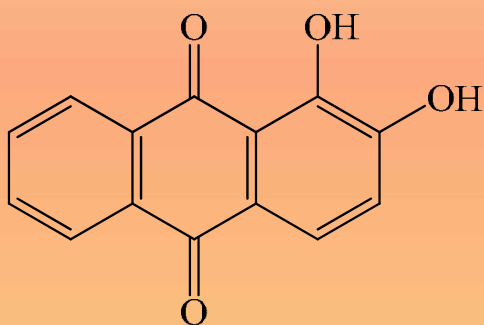


- Quinacridon





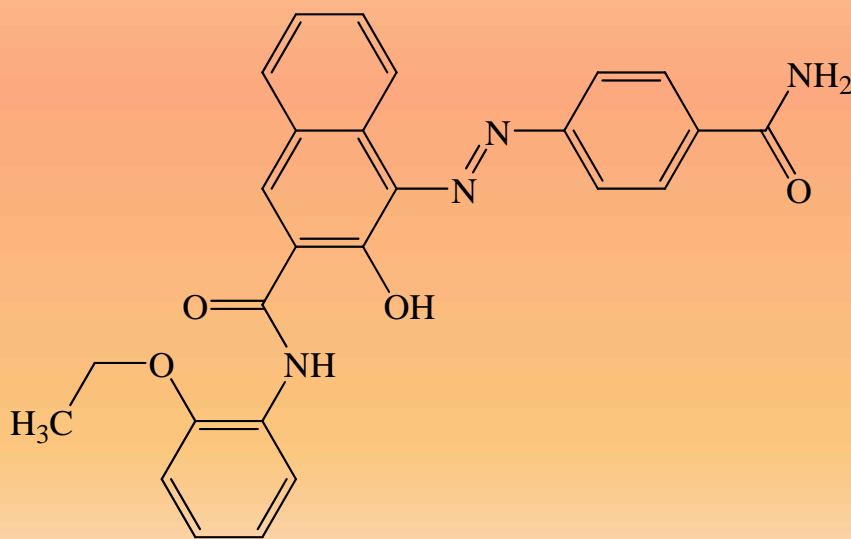
C.I. Pigment Red 83



- C.I. 58000
- CAS No. 72-48-0
- Alizarin Red
- Anthraquinone dye
- 1,2-Dihydroxy-9,10-anthracenedione



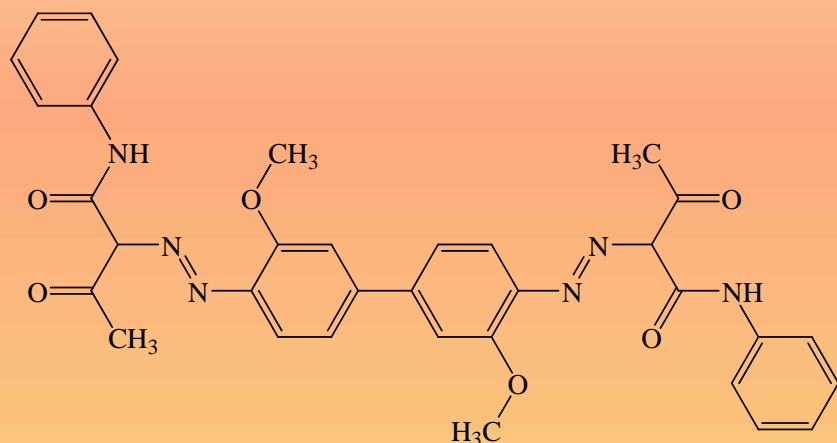
C.I. Pigment Red 170



- C.I. 12475
- CAS No. 2786-76-7
- Fast Red F5RK
- Monoazo dye
- 4-((4-(Aminocarbonyl)phenyl)azo)-N-(2-ethoxyphenyl)-3-hydroxy-2-naphthalenecarboxamide



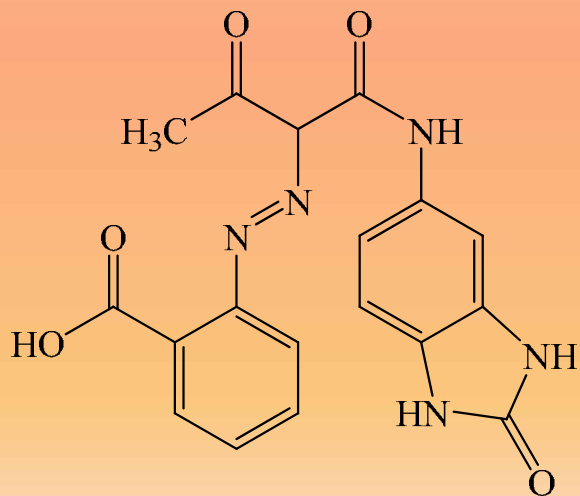
C.I. Pigment Orange 16



- C.I. 21160
- CAS No. 6505-28-8
- Dianisidine Orange or Benzidine Orange R
- Disazo dye
- 2,2'-((3,3'-dimethoxy (1,1'-biphenyl)-4,4'-diyl)bis(azo))bis(3-oxo-N-phenyl-butanamide)



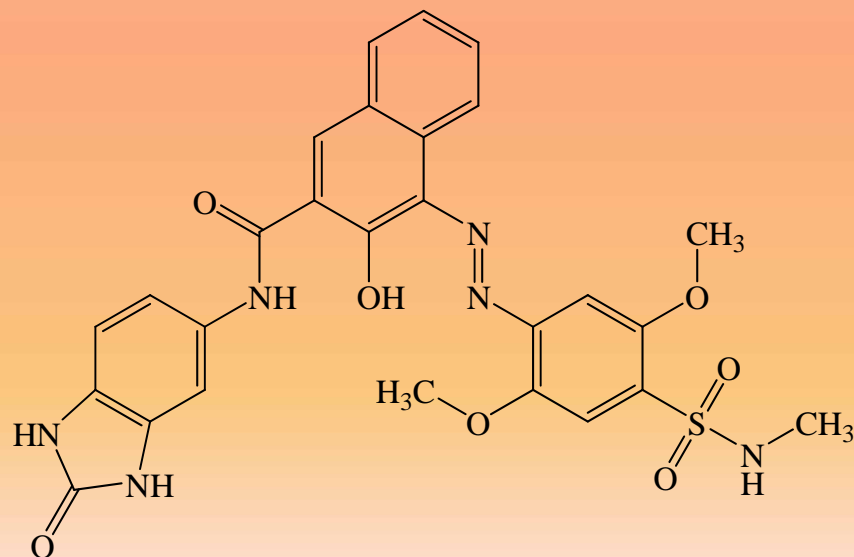
C.I. Pigment Yellow 151



- C.I. 13980
- CAS No. 31837-42-0
- Fast Yellow H4G
- Benzimidazolone and monoazo dye
- 2-[[1-[[[(2,3-Dihydro-2-oxo-1H-benzimidazol-5-yl) amino]carbonyl]-2-oxopropyl]azo]benzoic acid



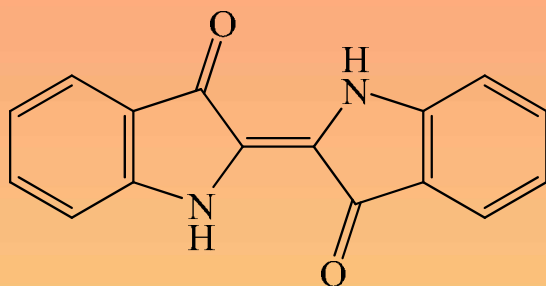
C.I. Pigment Violet 32



- C.I. 12517
- CAS No. 12225-08-0
- Brillfast Vivid Magenta
- Benzimidazolone and monoazo dye
- N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-4-[[2,5-dimethoxy-4-[(methylamino)-sulfonyl]-phenyl]-azo]-3-hydroxy-2-naphthalene-carboxamide



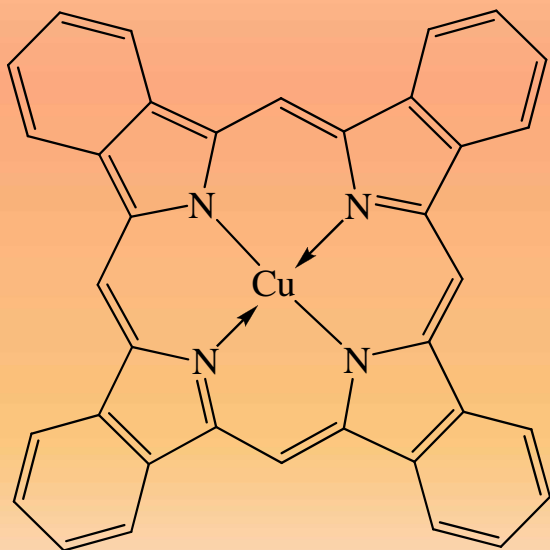
C.I. Pigment Blue 66



- C.I. 73000
- C.I. Vat Blue 1
- CAS No. 482-89-3
- Indigo
- Indigoid dye
- 2-(1,3-Dihydro-3-oxo-2H-indol-2-ylidene)-1,2-dihydro-3H-indol-3-one



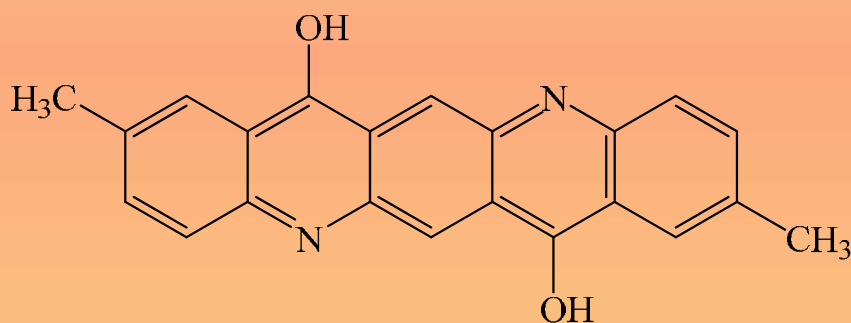
C.I. Pigment Blue 15



- C.I. 74160
- CAS No. 147-14-8
- Copper phthalocyanine
- Cyan Blue GTNF or Heliogen Blue 7044T
- Phthalocyanine dye
- Copper, (29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32)-



C.I. Pigment Red 122



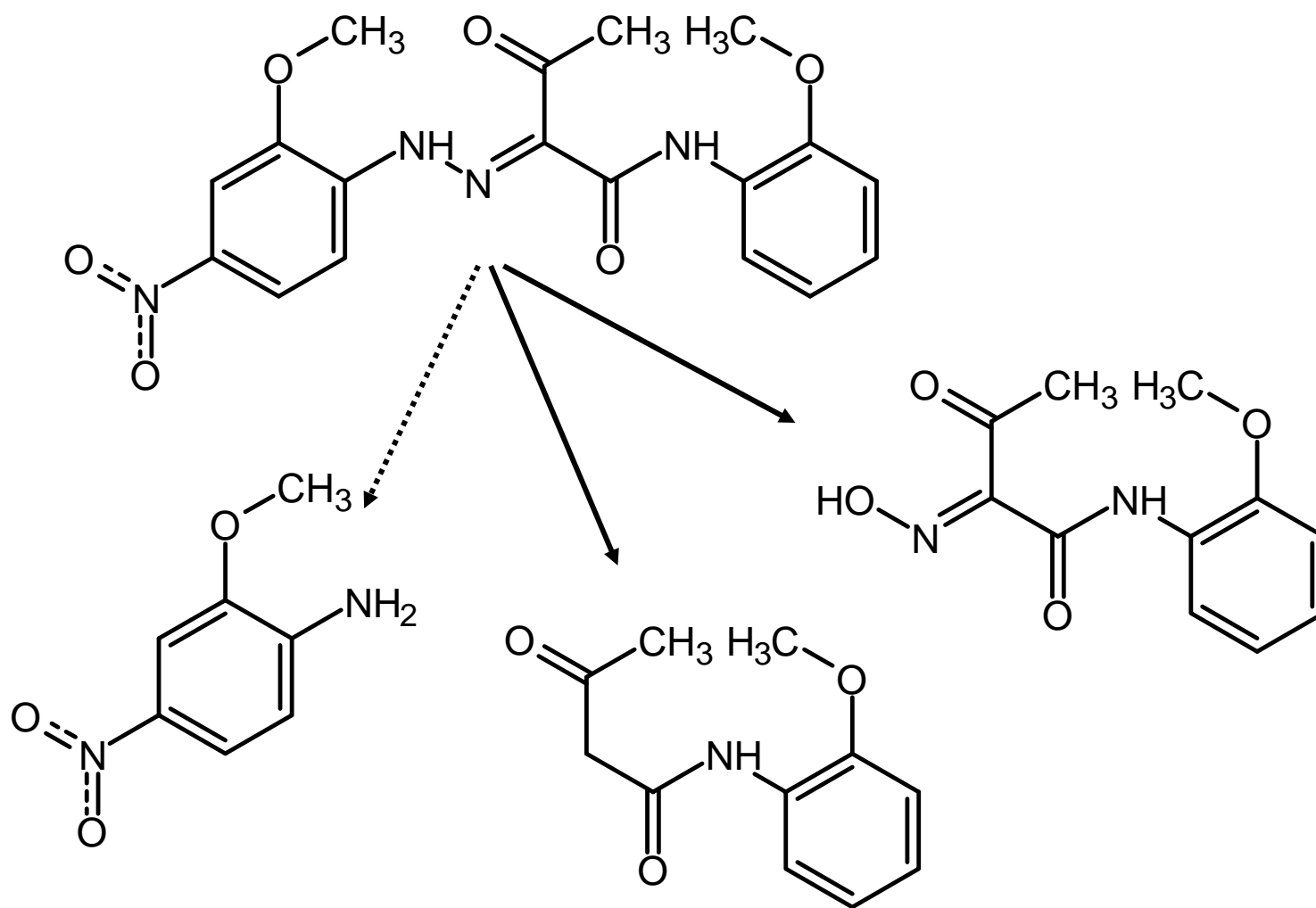
- C.I. 73915
- CAS No. 980-26-7
- Acramin Scarlet LDCN or Fastogen Super Magenta R
- Quinacridone dye
- 5,12-Dihydro-2,9-dimethylquino(2,3-b)acridine-7,14-dione

Tattoo Pigment Photodecomposition Studies

- **FDA's National Center for Toxicological Research (NCTR)**
- Cui, Y., Spann, A. P., Couch, L. H., Gopee, N. V., Evans, F. E., Churchwell, M. I., Williams, L. D., Doerge, D. R., and Howard, P.C., "Photodecomposition of Pigment Yellow 74, a Pigment Used in Tattoo Inks, Photochemistry and Photobiology, vol. 80, pp. 175 -184, 2004

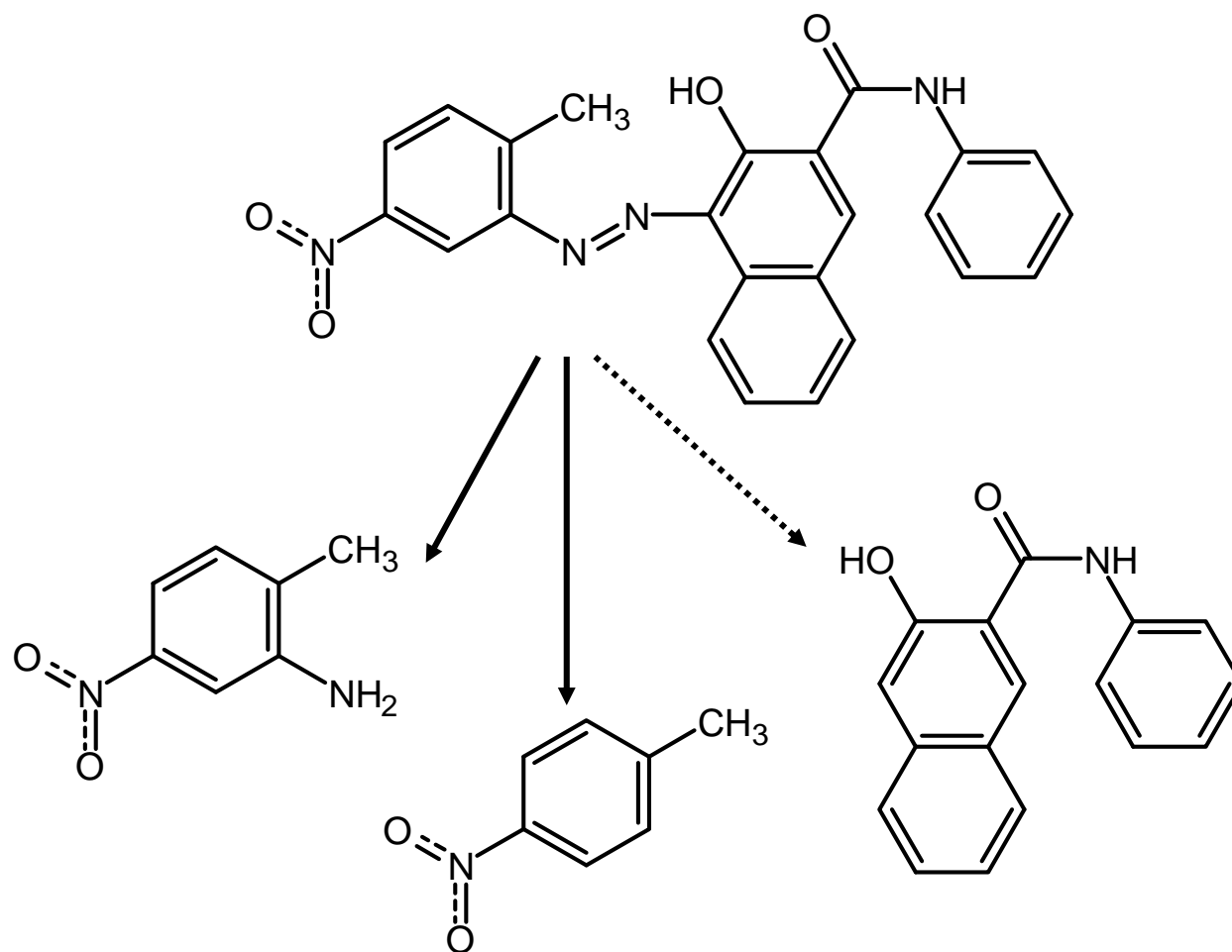


Photodecomposition of Pigment Yellow 74 in simulated solar light

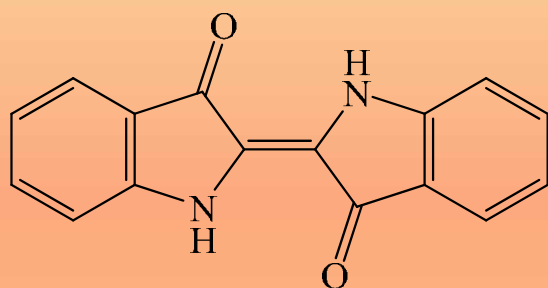




Photodecomposition of Pigment Red 22 in 532 nm Nd:YAG laser light



Tattoo Pigments and Color Additives



Indigo (tattoo pigment)

and

21 CFR 74.3106

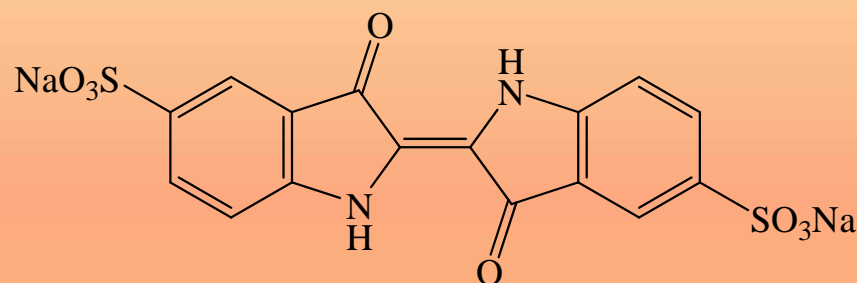
drugs,

D&C Blue No. 6

sutures,

(for use in sutures only)

cement)



21 CFR 74.101

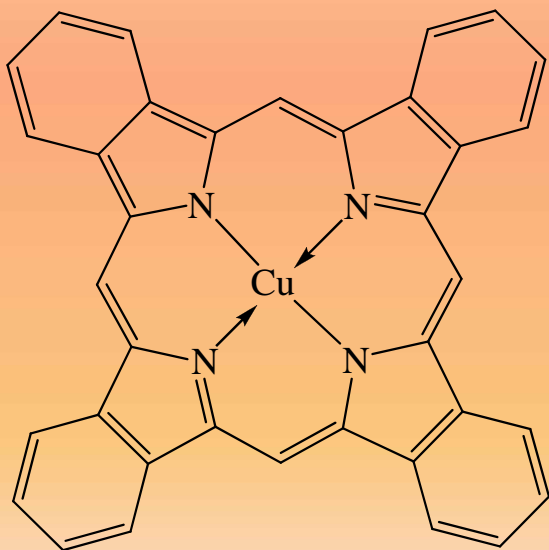
FD&C Blue No. 2

(for use in food,

cosmetics,

and bone

Tattoo Pigments and Color Additives



- C.I. Pigment Blue 15
- Copper phthalocyanine
- 21 CFR 74. 3045
[Phthalocyaninato(2-)]
copper (for use in
sutures only)

Tattoo Pigments and Color Additives

- Aluminum oxide
 - 21 CFR 73.1010
- Carmine
 - 21 CFR 73.100
 - 21 CFR 73.1100
- Iron oxides
 - 21 CFR 73.2250
 - 21 CFR 73.3125
- Manganese violet
 - 21 CFR 73.2775
- Mica
 - 21 CFR 73.1496
 - 21 CFR 73.2496
- Titanium dioxide
 - 21 CFR 73.575
 - 21 CFR 73.1575
 - 21 CFR 73.2575
 - 21 CFR 73.3126
- Ultramarines
 - 21 CFR 73.50
 - 21 CFR 73.2725
- Zinc oxide
 - 21 CFR 73.1991
 - 21 CFR 73.2991
- Luminescent zinc oxide
 - 21 CFR 73.2995

Conclusions

- **Marketplace** – Wide variety of inorganic and organic pigments and diluents in tattoos and permanent makeup
- **Adverse reactions** – and FDA responses
- **Chemistry** – Some tattoo pigments have been shown to **photodecompose**
 - C.I. Pigment Yellow 74
 - C.I. Pigment Red 22
- **Misleading** web sites!!! **No** pigments have been approved by FDA for tattooing humans

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