

**KNOW YOUR PIGMENT SUPPLIER/MANUFACTURER
UNDERSTAND YOUR PRODUCT
&
KNOW WHAT TO ASK**

Darlene P. Story
Lasting Impression I, Inc.
www.LiPigments.com

Introduction

With the continued growth and popularity of Permanent Cosmetics, those in the industry should have an understanding of the characteristics of the pigments used to implant color into clients' skin. As a professional, one should be familiar with pigment suppliers/manufacturers, have a basic knowledge of pigments & dyes, the physical and chemical properties they possess and most importantly, the quality, safety and assurance of the pigment product used.

Pigment Classification

The quality of pigments today far surpasses that of yesteryear. Many of today's pigments are created to offer the quality results that both the client and technician can be satisfied with. The key to this "satisfaction" is "knowing your pigment," which begins with a basic understanding of how pigments and dyes are classified according to their physical and chemical properties. These classifications are a method of identifying coloring agents and the characteristics they possess.

Pigments are not to be confused with dyes. Pigments are finely ground particles that are insoluble in water. These particles vary in size and are usually more stable in the light. Dyes are molecules that are soluble in water, uniform in size and the colors are usually more vibrant. Dyes are organic compounds that are exclusively derived from carbon-based compounds while pigments are inorganic compounds that contain metal oxides. One needs to understand the differences in these substances because of the effect they may have on clients' skin. For more information on this topic, refer to *The World Of Micropigmentation* that can be obtained from Mei-Cha International, Inc.

“All pigments and dyes can be classified by their chemical composition, source of origin, shade, or usage.”

Chemical Composition - Permanent Cosmetic colors can be classified as organic or inorganic compounds.

- Inorganic pigments are derived from inorganic substances that do not contain carbon or their derivatives – nonliving matter. Inorganic pigments are made of metals, such as iron ore.

- ❑ Dyes are derived from organic, carbon-based compounds, such as plants, insects and animals. Organic dyes are derived from living matter. All living matter contains the element carbon.

Source or Origin – Pigments and dyes can be classified by their source or origin.

- ❑ Natural sources, such as rocks, minerals, plants and insects
- ❑ Synthetic processing (manmade)

Shades – Pigments and dyes are classified according to how different shades of colors are mixed.

- ❑ A pigment/dye color is made from the mixture of two or more pigment/dye colors. For example, when mixing red oxides and yellow oxides an orange-colored iron oxide is created.
- ❑ Prime colors of pigments or dyes may be mixed together to create other colors. Pigments can be lightened with titanium dioxide (a white oxide compound.) For example, adding white to black to create grays.

Usage – Pigments/Dyes are manufactured to serve a variety of purposes and are classified according to usage.

- ❑ Paints, Dyes, Inks
- ❑ Cosmetics
- ❑ Crayons, Colored Pencils
- ❑ Hair Coloring
- ❑ Soaps
- ❑ Perfumes
- ❑ Foods
- ❑ Tattoo/Permanent Cosmetic Pigments/Dyes

FROM: THE WORLD OF MICROPIGMENTATION

Chapter 5 – ‘Understanding Pigments and Organic Dyes’

Author: Yolanda L. Moore/LeMor Micropigmentation Institute

MEI-CHA International

Copyright, 2002

Know Your Pigment Supplier/Manufacturer

While temporary and permanent tattoos are subject to regulation as cosmetics and are under the jurisdiction of the Food and Drug Administration, state and local agencies have direct jurisdiction over the practice of tattooing by salon technicians. The FDA is currently evaluating the safety of tattoos and micropigmentation because of their growing popularity. Among the

issues being considered are tattoo removals, adverse reactions to tattoo colors and infections and infectious disease that result from the use of these products.

The inks or dyes used for tattoos are color additives. Currently no color additives have been approved for tattoos, including those used in micropigmentation.

FROM THE U.S. FOOD AND DRUG ADMINISTRATION (FDA)
Center for Food Safety and Applied Nutrition
Office of Cosmetics Fact Sheet
February 3, 1995

The FDA does not directly regulate the practice of tattooing (micropigmentation) or approve the **color additives** used in the industry. A color additive is any dye, pigment or substance that can impart color when added or applied to food, drug, cosmetic, or to the human body. Until the FDA sets specific guidelines for the MP industry, it is recommended to use only pigments and dyes that are formulated from ingredients currently listed on the FDA register for topical cosmetic applications. These well-known ingredients have been used in cosmetic products and have been approved by the FDA for cosmetic use as listed in 21 CFR parts 73 & 74.

FROM: *THE WORLD OF MICROPIGMENTATION*
Chapter 5 – ‘Understanding Pigments and Organic Dyes’
Author: Yolanda L. Moore/LeMor Micropigmentation Institute
MEI-CHA International
Copyright © 2002

Protect yourself and your client using products that are safe, high quality, and made by a reputable supplier/manufacturer. The company you choose to deal with should understand the safety concerns of the public, the government agencies and the technicians regarding pigment usage in the skin. Using a high quality pigment is imperative! Not only will you save time and money by achieving the end result faster with less effort but also, more importantly, you will be provided peace of mind in knowing the product is safe to use on your clients.

Existing legislation, Occupational Safety and Health Administration (OSHA) regulations require all manufacturers to provide a Material Safety Data Sheet (MSDS) listing all product ingredients, possible adverse risks and recommended handling and storage practices. Upon request, every manufacturer or distributor must provide this information. As a professional within this industry, it is very important to understand the chemical composition and quality of the different pigments available in today’s market and know that the supplier/manufacturer is extremely cautious to select and formulate pigments from well known ingredients for cosmetic use as listed in the FDA Section 21 CFR parts 73 & 74.

Pigments are usually formulated with iron oxide, glycerin, alcohol, titanium dioxide, and certain ultramarines, chromium oxides, FD&C & D&C dyes. Substances that can lead to allergic reactions or possibly contribute to pigmentation migration (i.e. vegetable dyes or India ink) should not be used. Look for ingredients that are rather inert (non-reactive.) For example, iron

oxide has been used successfully for years without any known adverse effects. (Note: Magnetic Resonance Imaging (MRI) case studies have shown a small percentage of clients reported slight tingling and swelling in areas where iron oxide pigment had been used in a tattoo, or altered an MR reading.) The D&C and FD&C dye formulations should be FDA approved dyes used in food and cosmetic products. It is important to also use a pigment product that has ingredients listed on the bottle. If it does not contain this information, request a detailed ingredient list along with an MSDS before using the product.

Lastly, for your security, confirm that the pigment supplier/manufacturer follows all the guidelines outlined by the FDA for cosmetics and maintains product liability insurance. Ask for proof!

Your pigment supplier/manufacturer should supply upon request the following information:

1. **Material Safety Data Sheets (MSDS)**
2. **Documents for International Customers** such as:
 - Certificate of Good Standing
 - Certificate of Free Sale
 - Certificate of Origin
 - Testing Reports: (if applicable)
 - Bio-Burden Batch Testing
 - Gamma Sterilization Reports
 - Spore Strip Test Reports
 - County Health Department & Government Documents
3. **Good Manufacturing Practices (GMP)** – Deal with a company that follows GMPs, state & local laws and OSHA guidelines for manufacturing.
4. **Company Recall Policy** – Be sure the pigment supplier/manufacturer can recall a particular pigment should the need arise.
5. **Testing Structure** – Don't be afraid to ask if testing guidelines are followed prior to the release of a new pigment product.
6. **Adverse Reaction File** – Confirm that the pigment company maintains an Adverse Reaction File and ask about the procedures implemented in the event of an occurrence.
7. **Proof of Insurance** – The pigment supplier/manufacturer should maintain product liability insurance. Ask for a copy of the 'Certificate of Insurance' to keep on file. This protects the technician and the client. If you private label or distribute, ask to be added as an additional insured and obtain proof of such with the document referred to as "Additional Insured Vendors Endorsement." This is "no additional" expense to you and ensures your company's protection.
Some benefits of product liability insurance include:
 - Protection to you and your customer. How? If the supplier/manufacturer does not maintain product liability insurance, you as the distributor may be

considered the manufacturer and could be held liable in the event of an occurrence.

- Knowledge that your supplier/manufacturer has met Underwriting Guidelines to ensure all products are safe (the manufacturer is assessed by the insurance company to ascertain compliance with certain guidelines for product safety, quality control, etc.)
- Assurance that the company is completely protected in the event of a loss.

Look for the following characteristics in your pigment product:

1. ***Ingredient Listing*** – Pigment ingredients should be clearly stated on the bottle.
2. ***Lot & Batch Numbers*** – If there is a negative reaction to the pigment, both a lot and batch number can be used to help determine the cause of the reaction. Make sure the pigment bottle has this listed clearly.
3. ***Expiration Date*** – No pigment lasts forever! Pigments should have both a manufacture and expiration date.
4. ***Manufactured by or Distributed by*** – In the event of an occurrence, know immediate contact information from the label. ***Know your pigment and make a concerted effort to know your supplier/manufacturer.***

Summary

Remember, all pigments are not created equal! Know your pigment supplier/manufacturer. Don't be afraid to ask about your pigments and obtain a clear understanding of some of the characteristics one should be looking for within the pigments. Through this knowledge of your permanent cosmetics materials, you can better protect yourself and your clients.