

Facts About Salon Nail Polish Products For Consumers

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Nail Manufacturers Council (NMC) of the Professional Beauty Association

1. What is in salon nail polish products?

Brands compete with each other to make the best polish, with the right balance of ingredients to be safe, good-looking and long-lasting. The specific formulas are guarded as trade secrets, but they all are combinations of:

- Pigment, for color and covering power. There are many different colors and color combinations.
- Film-former, to make the polish hard and shiny when it dries. The most common film-former is nitrocellulose. Old-fashioned black-and-white movie film is made of nitrocellulose.
- Resin, to make the polish tough and resilient. Tosylamide/formaldehyde is the resin of choice for salon nail polish.
- Solvent, to make the polish easy to apply. Most salon brands use a combination of butyl acetate, ethyl acetate, and toluene. Solvents are also used in nail polish removers.
- Clay, to suspend and keep the ingredients mixed and make the polish easier to apply.
- Plasticizer, to prevent chips and cracks. Dibutyl phthalate (DBP) has been used for many decades as a nail polish plasticizer. It is also used in soft toys, and baby bottles, and tubes for dispensing food and medicine.
- UV stabilizer, to prevent sun and light from fading or changing the color.

2. Do most leading salon brands contain the same ingredients?

Yes. While the formula of each manufacturer varies, salon brands have used these ingredients as a base for nail polish products for decades. In most instances, with the exception of clays and pigments, salon base coats and top coats also use the same primary ingredients.

3. Is nail polish safe?

Yes. Nail polish products have been used safely for many decades by millions of consumers. Fingernails and toenails are made of keratin, which is hard and largely impenetrable. Once nail polish dries, the ingredients in the polish become embedded in the hardened film coating, and are not absorbed by the body or released into the environment. Nail polish products come in small

bottles with tiny openings that release very little of the product into the environment. Unless they are being used, the bottles are typically closed. A single bottle contains enough polish for 30-60 sets of nails.

4. Are nail polish products tested?

Yes. Nail polish companies compete to make the safest, best-looking, longest-wearing product. Manufacturers and their suppliers rigorously test nail polish products and ingredients for quality, performance, and safety, as well as monitoring data and reports from nail technicians and consumers.

5. Is nail polish regulated by governmental agencies?

Yes. All cosmetics, including nail polish products, are regulated by the U.S. Food and Drug Administration (FDA). The FDA has broad authority to regulate and seize cosmetic products which are poisonous, deleterious, adulterated, misbranded, or otherwise pose health risks. Further, the FDA regulates the colorants that may be used in cosmetics. The FDA and other federal agencies, such as the Consumer Product Safety Commission and the Federal Trade Commission, also have authority to deal with cosmetics, packaging, labeling and advertising issues. A quick visit to the FDA website and to its FDA Handbook on Cosmetics makes plain the FDA's interest in cosmetics and its authority. **SALON NAIL POLISH PRODUCTS MEET ALL LEGAL REQUIREMENTS.**

See <http://www.cfsan.fda.gov/~dms/cos-toc.html>.

6. Why doesn't the government require pre-market approval for nail polish?

The Congress decided nearly seventy years ago that the risks associated with cosmetics were very low. The intervening decades have proven the Congress right. We know the tremendous expense required and how many years it takes the FDA to approve a drug before it is marketed. Can you imagine the resources and tax dollars that would be consumed if the government had to approve every new cosmetic? Can you imagine how few choices we would have, if every company had to get government review before selling a new product? Instead, FDA uses its resources and our tax dollars to go after the few companies who break the law and try to sell harmful products. Additionally, it is important to note that most countries in the world do not require pre-market approval for cosmetics.

7. Why hasn't the FDA taken more enforcement action against cosmetics?

Because most cosmetics are safe. For the few exceptions, the FDA has ample authority to enforce cosmetic laws. FDA can and does inspect production and packaging sites, embargo products to prevent them from being sold, and force manufacturers to recall them.

8. What is the CIR?

The Expert Panel of the Cosmetic Ingredient Review (CIR) is an independent body of leading scientists and dermatologists from colleges and universities. The CIR reviews the safety of cosmetic ingredients and conducts risk assessments. Since its founding in 1976, the CIR has conducted several thousand reviews. The CIR prioritizes the ingredients it reviews based on how frequently such ingredients are used and their safety profile. **THE CIR HAS REVIEWED ALL THE SIGNIFICANT INGREDIENTS IN NAIL POLISH AND FOUND THEM SAFE.** The CIR also re-reviews ingredients when new data develop. Representatives of the FDA and the Consumer Federation of America participate in the panel's deliberations. Concerned members of the public are invited to present information to the panel, and often do. The CIR, which is totally independent, publishes its own peer review scientific journal. Like other businesses, the cosmetics industry supports scientific research and inquiry, including the CIR, to make its products better, safer, and more environmentally sensitive.

See <http://www.cir-safety.org/>.

9. What is a risk assessment?

A risk assessment is a tool that has been used for decades by virtually all governmental and academic scientists to assess the health risk associated with a chemical. Since many chemicals can have an adverse effect at a high level, but no effect, or even in many instances, a beneficial effect at lower levels (e.g., aspirin, Vitamin A), scientists and policy makers created this tool to set exposure limits for consumers or workers. Generally, such an analysis studies all available laboratory and other data to find the lowest level at which an adverse effect is observed. The scientists next consider how people are exposed, how often, and how much. They also consider cumulative exposures from other products or settings and sensitive populations. Based on this information, scientists then establish an exposure limit, for regulatory or other purposes, where they are confident exposures will not harm people. In doing so, many conservative assumptions and margins of safety are utilized. That is, toxicologists assume that ingredients are more dangerous, and exposures are higher, than they actually are. This gives each risk assessment a large margin of safety.

10. How are nail polish products regulated in Europe?

The regulation of cosmetic ingredients, labeling, and packaging varies by country and region. Like the U.S., the EU does not require pre-market approval for cosmetics. Also like the US, the EU requires cosmetics to be safe and bans certain specific ingredients. The EU used to base those restrictions on risk assessments, as the US does. But recently a new law came into effect in the EU--the "Seventh Amendment to the Cosmetics Directive." This new law allows ingredients to be banned from cosmetics based on fears that they might be hazardous, without any consideration of their actual risks and benefits as used. The new law automatically banned many common ingredients, including DBP, from cosmetics even though a risk assessment by European governmental scientists concluded DBP in nail polish is safe. Ignoring real data in deciding what products are legal, as the new EU law does, is bad policy. It also contradicts many other European laws. Such an approach means Europeans are unable to buy products that they want,

even though those products are available elsewhere, and even though those products are perfectly safe.

11. Aren't several of the ingredients in nail polish regulated by California's Proposition 65?

Yes, along with over 750 other substances, including aspirin, Vitamin A, alcoholic beverages, and gasoline. In California, it is almost impossible to go to a restaurant, grocery store, drug store, parking lot, hotel or shopping mall without seeing a Proposition 65 warning. Proposition 65 is not a safety law and does not ban anything; it is a warning law, with the most stringent warning levels in the world. Proposition 65 requires warnings if the potential exposures for listed ingredients exceed a certain, low threshold for theoretical risk. This threshold is set as low as 1,000 times below the level at which the state believes there was no observable adverse effect in laboratory studies. For many products, levels that low cannot even be detected.

12. How are formaldehyde, toluene, and DBP currently treated under Proposition 65?

The California governmental authorities ruled, after formaldehyde and toluene were first listed under Proposition 65 more than a decade ago, based on extensive salon exposure data, that the levels of exposure for these ingredients in salon nail polish products are **SO LOW THAT NO CONSUMER WARNINGS ARE REQUIRED** under Proposition 65. The NMC expects the California government to reach a similar conclusion on DBP in nail polish (which was only recently listed under Proposition 65). Until such time as a formal decision is made by California authorities, some NMC manufacturers may choose to remove DBP from their products. That is not because there is anything dangerous about their products—it is only to prevent frivolous lawsuits.

Each of these ingredients continues to be widely used in many industries, including cosmetics, in California. Formaldehyde is used to make furniture, wallpaper, carpets, and ceiling tile, and is used by science students and scientists. Toluene is used to make ink, paint, glue, and detergent. DBP and other phthalates are used in many plastic products, including food packaging, medical devices, blood bags, breast pumps, and toys.

13. Aren't even a few molecules of exposure to nail polish and other cosmetics bad?

No. Many things are safe as we use them that would be bad for us if we had too much. Vitamin A is an essential nutrient, but too much of it causes birth defects. A spoonful of ice cream is a treat, a gallon every day is a heart attack. Even the California authorities, who set the threshold below which no warning is required, recognize that there are low levels of exposure that cause no harm. Using DBP as an example, even if one were able to absorb five bottles of nail polish every day for a lifetime, that amount would still be below the no effect level for DBP in laboratory experiments. There is an old adage that continues to ring true—"the dose makes the poison." Example: water is a necessity for life. If you breathe a little, as humidity, you enjoy a sea breeze. If you breathe a spoonful, you choke. If you breathe a cupful, you drown.

14. Doesn't nail polish contain formaldehyde?

No, nail polish products contain a resin with a long name that sounds like formaldehyde—tosylamide/formaldehyde resin. Formaldehyde is a gas. Resins are gummy, and do not evaporate. While the resin is manufactured from formaldehyde, once the product becomes a resin, the formaldehyde is chemically changed and essentially no longer present. Most nail hardeners contain formaldehyde. The levels of formaldehyde, however, are well below those set by the FDA for hardeners. Further, exposure levels to the formaldehyde for hardeners are so low that even the California authorities rule that no warnings are required for hardeners under Prop 65.

15. Are nail technicians who use nail polish safe?

Yes. The amount of exposure from nail polish products for salon workers is very low and well below the levels recognized and legally established as safe by the U.S. Department of Labor, Occupational Safety & Health Administration (OSHA). The OSHA limit for toluene is 200 parts per million (ppm) average exposure during an eight-hour period, with levels up to 500 ppm allowed on a short term basis. The California authorities found that the levels of formaldehyde in nail polish products were not even present. Nail technicians, of course, should always follow appropriate workplace safety practices and follow manufacturer recommendations and material safety data sheets.

16. Why don't manufacturers use safer natural, organic products?

NMC member companies continue to look for green alternatives. This is more difficult to do with nail polish products than with a cream or lotion. There are a number of nail polish products available that are water-based. Unfortunately, these products don't wear well or look good, so hardly anyone wants to wear them. If water worked well in nail polish products, manufacturers would be rushing to make a product that costs substantially less to buy, less to handle and manufacture, and less to ship. Moreover, the notion that natural or organic products are necessarily safer is misguided. Most "natural" or "organic" substitutes are too new to have been subjected to long-term testing--unlike the well-known "chemical" ingredients, which have been thoroughly tested and safely used for decades. The chemical vs. natural distinction is a false dichotomy. All life is a carbon-based, chemical process. Even water is a combination of the chemicals hydrogen and oxygen. Meanwhile arsenic, lead, mercury, and nicotine occur naturally. So do snake venom and poison ivy.

See <http://www.senseaboutscience.org.uk/PDG/MakingSenseofChemicalStories.pdf>.

17. Why is there so much in the news lately about the safety of cosmetics?

The safety of cosmetics, including nail care products, has been an issue promoted by several organizations making extreme claims based on little or no evidence in order to draw attention to themselves. Because cosmetics are used by so many people, and are so widely recognized as safe, these accusations make great headlines. Meanwhile, the story that cosmetics are still safe is simply considered "old news." While the NMC welcomes dialogue, we believe in responsible,

sound science. Responsible scientists raised and answered the question of cosmetic safety many decades ago. Responsible scientists are still continuing to update and review the issues. The results: cosmetics are safer than ever. See <http://www.cosmeticsaresafe.org>.

Most NMC companies are not large, public corporations, but privately-held, family businesses run by people who use their own products for themselves, their families and friends. They have personal reasons, as well as business reasons, to make safe nail polish products.

18. Aren't cosmetics and nail polish frivolous? Since we don't really need them, why have them at all?

Our experience tells us that cosmetics play an important role in making people look good and feel better, something all of us need, especially in these stressful times. One of our industry's significant contributions is in assisting cancer survivors to deal with the ravages of the disease and the treatment.

See <http://www.lookgoodfeelbetter.org>.

We are also very active, as an industry, in education and fundraising in support of causes related to cancer and other diseases. Cosmeticians do rewarding, fulfilling work for people who truly appreciate it. A teenager getting ready for a party, a bride preparing for her wedding, a commuter taking a break for herself--they are all making their own choices about what is important to them.

19. What is the salon industry?

The U.S. salon industry is a \$60 billion a year industry (five times larger than movie box office sales) that employs several million people. In terms of frequency of listing in the Yellow Pages, the beauty industry (barbers, salons, etc.) ranks seventh out of 3,000 industry listings. The industry is one of the largest employers of single mothers and, because of flexible scheduling, is very family-friendly. Many businesses are minority-owned. One need not have a formal education or strong language skills to succeed and to move up the socio-economic ladder. Since only limited capital is required, the industry is predominately made up of small business owners and entrepreneurs. There is literally a barber, beauty or nail salon on every corner.

20. Where can I get more information?

If you have questions about specific products, contact the manufacturer. If you have questions about this document, contact:

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