

# Nail Hardeners: Formaldehyde or Formalin?

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### Introduction

Nail hardeners are specialized products used to harden or strengthen natural nails. They are distinct, niche products, separate and apart from nail polishes and other nail treatments. Less than one percent of the entire category of nail polishes and nail treatments are nail hardeners. Most nail hardeners use **formalin** (methylene glycol dissolved in water) as the nail hardening ingredient.<sup>1</sup> Frequently, the name "formaldehyde" is loosely and imprecisely applied, although "formalin" is the current proper chemical name for this ingredient. At present, the labeling rules in most jurisdictions make no distinction, requiring both to be declared as "formaldehyde" in product ingredient listings, despite important differences between the two substances.

Nail hardeners have been used safely for many decades. The **primary** concern with these formalin-containing hardeners is their potential for skin irritation or sensitization (allergies). It is incorrect to associate any risks related to dry formaldehyde gas with these types of products.<sup>2</sup> The FDA (US) and governmental authorities in Canada, the European Union (EU), and elsewhere authorize the use of formalin in hardeners and focus their regulatory attention, as is appropriate, on the potential for skin irritation or sensitization. It is important to note that nail manufacturers use less than one-half the levels of formalin allowed by these governmental authorities.

### Terminology

There is considerable confusion about the type or form of formaldehyde used in hardeners and associated terminology.<sup>3</sup> Here are the facts--the word "formaldehyde" is used to describe the dry gas, even though most people incorrectly think formaldehyde is a liquid. Formalin is not the same as formaldehyde from both a chemical and safety

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<sup>1</sup> While many manufacturers also offer alternatives, formalin (methylene glycol)-based hardeners remain the most popular and appear to be most effective with certain types of nail problems. Methylene glycol is made by reacting dry formaldehyde gas with water to create a completely new, unique and entirely different substance.

<sup>2</sup> Inhalation of dry formaldehyde gas has been determined to be a probable cause of a rare form of human cancer. This conclusion is based on findings for formaldehyde gas at high concentrations, more likely to be found in **industrial** or **manufacturing** settings. These findings do not apply to liquid formalin. Formalin is **not** classified as a carcinogen. Only extremely low traces of formaldehyde residuals can be found in cosmetic, personal care, or nail hardener products and formaldehyde gas is not added as an ingredient.

<sup>3</sup> Government agencies and others often confuse and imprecisely use, interchangeably, the terms "formaldehyde," and "formalin," when they are entirely different chemicals with different chemical properties and from separate and different chemical families.

standpoint. They are entirely different ingredients. Formalin is a liquid comprised mostly of methylene glycol and water and used in nail hardeners to strengthen and harden natural nail plates.

### Significantly Below Regulatory Limits

The FDA (US) and other governmental authorities established 5% as the maximum safe level for formalin in nail hardening products. Most manufacturers use from 0.5 to 2% formalin in their nail hardeners. Further, significantly, nail hardeners are sold in small bottles with tiny openings; the bottles are generally kept closed and the nail hardener is applied to the largely impenetrable nail on which a hard film coating is quickly formed, locking-up the ingredients therein.

### California Proposition 65 (iProp 65î)

Whenever formalin is used, there will be a trace level of formaldehyde contaminant at an extremely low level (in the parts per billion range). This is considered so low that the State of California concluded based on a multi-year statewide study of nail salons conducted under its auspices, that the measured levels of formaldehyde gas in nail salon air was **no higher** than levels found in many common workplaces, including offices, **where no nail products whatsoever were present**. This conclusion resulted in an extraordinary ruling from the State of California that **no warnings** for formaldehyde exposure need be provided to **consumers or nail salon workers** using nail hardeners containing formalin. This is one of only a few such rulings in which no warnings were required by the California authorities for a substance (formaldehyde gas) on the Prop 65 list.<sup>4</sup>

### Tosylamide/Formaldehyde Resin

There is also much confusion about the film forming resin (tosylamide/formaldehyde resin) used to increase the adhesion of the nail hardener formulations and many other nail products. As the name suggests, formaldehyde is one of the raw materials that is used to make the resin, but when the resin is manufactured the formaldehyde is consumed in the reaction. As a result, this high molecular weight resin (which is its own ingredient, distinct from both formaldehyde and formalin) contains only trace amounts of residual formaldehyde. It is not a significant source of free formaldehyde.

### Avoid Skin Contact

As noted earlier, it is, nonetheless, important to **avoid skin contact** due to the potential for irritation and sensitization (allergies). Manufacturers label their products accordingly with appropriate warnings and instructions. MSDS sheets also make this plain, as well as suggest other ways to work and use nail hardeners safely. Skin contact should be avoided

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<sup>4</sup> In other words, even the most stringent warning law in the world, Prop 65 does not require a warning for formaldehyde in nail care products.

or the skin protected with grease, oil or other nail shields. Bottles should be kept closed when not in use. Use should be immediately discontinued if an adverse reaction occurs.

### Conclusion

Nail hardeners are important specialty products that can be used safely to harden or strengthen nails and there is no significant risk to health, beyond the potential to develop skin irritation or sensitization (allergy), which can usually be avoided if the products are used properly and skin contact is avoided.

### Legal Notice

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