



FORMALDEHYDE EXPOSURE IN HEALTHCARE: HEALTH RISKS, REGULATIONS, AND SAFETY LIMITS

INTRODUCTION

Formaldehyde is a naturally occurring, colourless, strong-smelling organic compound in various forms – gas, solid, or liquid.¹ In medical settings, it is typically stabilised in a neutralised, aqueous methanol solution known as formalin. Here, it is used for tissue fixation and preservation for pathological examination. The tissue is normally preserved in a 4% formaldehyde solution (= 10% formalin) immediately after excision to maintain sample integrity for analysis.

Formaldehyde, in either liquid or vapour form, is not to be taken lightly. It is a highly reactive, acutely toxic substance that can lead to serious health issues such as skin and respiratory tract irritation and corrosion, skin sensitisation, genotoxicity, miscarriage, and even carcinogenicity in the respiratory tract. It is recognised as hazardous and carcinogenic and classified by the European Union (EU) as a Category 1B carcinogen.^{2,3,4,5} These risks are not to be underestimated, and it is crucial for health-care professionals to be fully informed and understand the potential dangers of formaldehyde exposure. This is particularly the case when open containers prefilled with formaldehyde are used in operating rooms and laboratories.

Consequently, strict regulatory measures, such as occupational exposure levels and indoor air quality guidelines, have been implemented to manage the health risks of formaldehyde exposure.

Adherence to the measures is not just a recommendation but a necessity for health-care professionals. These professionals face a higher risk of exposure due to regular handling of formaldehyde, often exceeding the recommended safety limits.

REGULATIONS AND LIMITS

Various authorities have established measuring scales and guidelines to protect workers' health. Exposure limits are mainly measured in Occupational Exposure Limits (OEL) or Short-Term Exposure Limits (STEL); see Table 1. Another scale for exposure is measured as Time-Weighted-Average (TWA).

Many EU countries follow the exposure limits recommended by the EU Scientific Committee, which is 0.3 ppm for 8-hour inhalation and 0.6 ppm for 15-minute inhalation periods.⁵

TWA, OEL, and STEL provide a structured framework for regulating exposure to potentially harmful substances like formaldehyde, balancing daily and short-term exposure controls to ensure a safe working environment.

GLOSSARY:

Occupational Exposure Limit (OEL)

OEL is the maximum amount of a hazardous substance that workers can be exposed to in workplace air during a typical 8-hour day. It is designed to protect workers' health by limiting their exposure to potentially harmful substances such as formaldehyde.^{12,13}

Time-Weighted Average (TWA)

TWA measures the average exposure to a hazardous substance over a specified period, typically an 8-hour or 40-hour workweek. For instance, maintaining the TWA below recommended levels in settings where formaldehyde is used helps minimise long-term health risks from repeated exposure. The 8-hour TWA is the highest level of exposure an employee may be exposed to daily.^{12,13}

Short-Term Exposure Limit (STEL)

STEL represents the maximum concentration of a hazardous substance that workers can safely be exposed to over a short, specific period, typically 15 minutes. STEL values are set to prevent acute health effects like irritation, headache, and other acute responses from brief but intense exposures to not compromise workers' health.¹⁴

TABLE 1

COUNTRY	OEL ppm (8-hour average)	STEL ppm (15-min average)	REFERENCE
Denmark	0.30 ppm	0.60 ppm	(6) At (2023)
Sweden	0.30 ppm	0.60 ppm	(7) ECHA (2019)
Finland	0.30 ppm	1.00 ppm	(7) ECHA (2019)
Germany	0.30 ppm	0.60 ppm	(7) ECHA (2019)
The Netherlands	0.12 ppm	0.42 ppm	(7) ECHA (2019)
France	0.50 ppm	1.00 ppm	(7) ECHA (2019)
UK	2.00 ppm	2.00 ppm	(7) ECHA (2019)
US OSHA	0.75 ppm	2.00 ppm	(8) OSHA (2021)
US NIOSH*	0.016 ppm	0.10 ppm	(9) NIOSH (2018)
US ACGIH	0.10 ppm	0.30 ppm	(8) ACGIH

***NOTE:** The OEL and STEL values given by NIOSH are considerably lower than those provided by others. This can be explained by the praxis used by NIOSH when considering protection against carcinogens, for which residual risk cannot be ruled out.

Formaldehyde occurs naturally in the atmosphere but typically in low concentrations that are not harmful. However, healthcare workers working with formaldehyde face a greater risk of exceeding the exposure limits because they are subjected to higher amounts of formaldehyde daily.¹⁰

According to Annex III of Directive 2004/37/EC (CMRD), employers must minimise workers’ exposure to formaldehyde where possible. Hence, formaldehyde needs to be in closed systems wherever possible. The directive further says, ‘Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible.’ The employer must also arrange for medical surveillance of workers exposed to the substances. Hospital staff handling biopsies must follow the national authority’s OEL.¹¹

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We are deeply committed to help ensure a safe working environment for medical staff involved in biopsy procedures and to spread awareness of the many health risks associated with exposure to formalin. That is why we invented BiopSafe in 2014, an innovative solution that not only eliminates any exposure to formalin during the procedure but is also fast and easy to use. BiopSafe is part of Axlab, specialized in solutions for pathology. Today, BiopSafe is used by thousands of healthcare professionals around the world and distributed globally through a dedicated partner network.

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