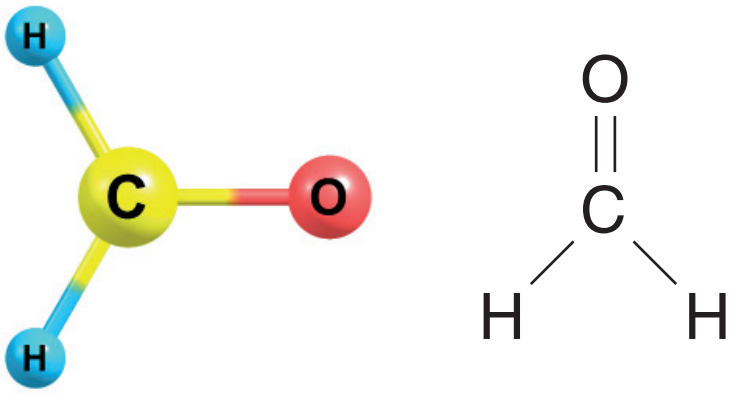
GOBIERNO DE ESPAÑA
MINISTERIO DE TRABAJO Y ECONOMÍA SOCIAL
insst Instituto Nacional de Seguridad y Salud en el Trabajo

Formaldehyde

CARCINOGENS AT WORK:
Know to prevent

Information about the substance and where it can be found

Formaldehyde is a colourless gas with a strong and pungent odour, very volatile and extremely flammable. It is an organic chemical agent belonging to aldehydes; specifically, it is the simplest molecule in this group. It is highly reactive and has a tendency to spontaneously polymerise, that is, to bond with itself to form assemblies of two, three or more molecules, making it a common component of various resins. These properties, along with its potential as a disinfectant, make it widely used in many different activities.



Molecular structure of formaldehyde

Formaldehyde is generated naturally in various processes such as our cellular metabolism and incomplete combustion of organic material, such as petroleum fuels, so there is always a background concentration in the environment. This background level will vary by location; in large cities it will be higher than in rural areas due to, among other things, the fact that emissions from fuel-powered vehicles are a major source of this agent.

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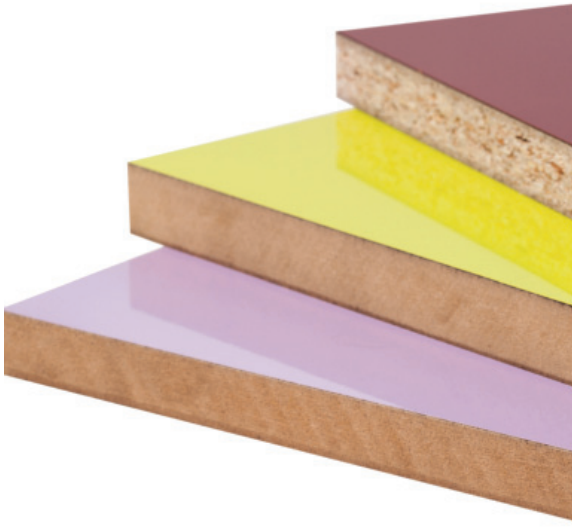


In households there is also a background concentration of formaldehyde, which can come from a variety of sources, such as furniture or textiles. However, it is tobacco smoke that is most likely to increase the concentration of formaldehyde in the home. Exposure can also occur in an everyday environment through skin contact with cosmetics, cleaning products and other items containing this agent, for example, fabrics treated with this agent that have not been washed prior to use (IARC, 2012).

Formaldehyde is commonly used to manufacture various types of resins, which are then used to produce plastics, wood panels and other consumer goods. It is used in the textile industry to give fabrics certain characteristics and in the food industry as a disinfectant. It is widely used as a preservative in the sanitary and funeral sector, in the form of a solution with water and methanol (known as formalin). It is also used in these sectors as a disinfectant.

European Union legislation sets out several restrictions on the use of formaldehyde in different areas such as cosmetic products, where it is banned; food contact materials, where it is limited by its migration capacity; and toys, where its maximum content and migration capacity is regulated. It is also classified as hazardous waste.

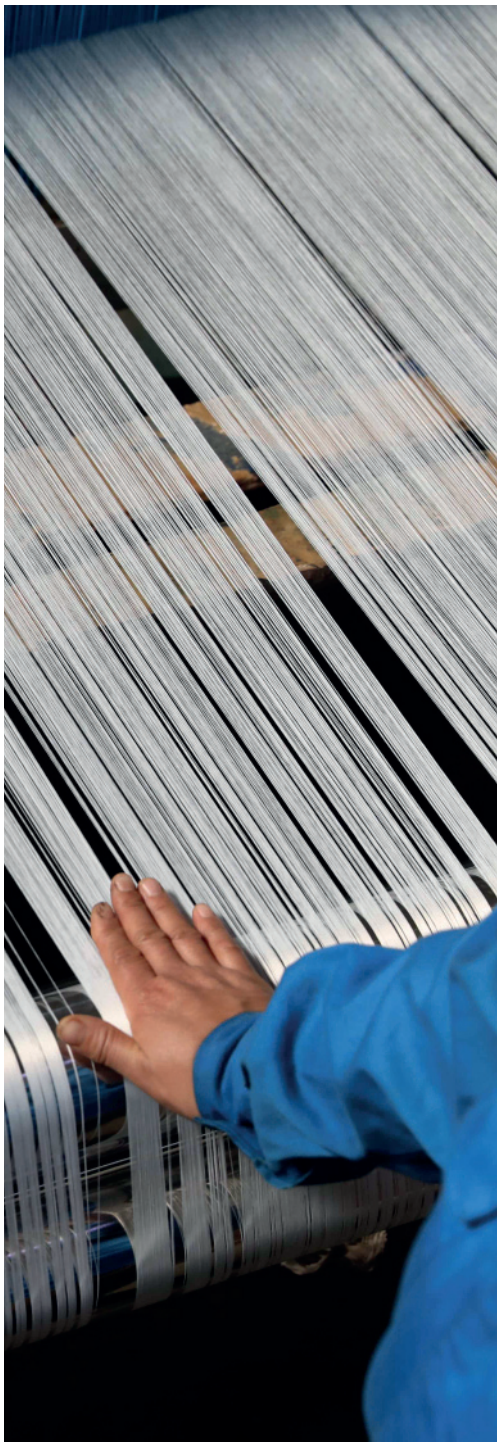


Table 1
Other areas where formaldehyde is regulated in the European Union

Scope	Legislation
Ambient air quality and cleaner air	Directive 2008/50/EC
Cosmetic products	Regulation (EC) No 1223/2009
EU Ecolabel	Regulation (EC) No 66/2010
Inland transport of dangerous goods	Directive 2008/68/EC
Plastic materials and articles intended to come into contact with food	Regulation (EU) No 10/2011
Safety of toys	Directive 2009/48/EC
Waste	Directive 2008/98/EC

Health effects

In the workplace, the main route of exposure is inhalation, because it is a very volatile agent in solution. More than 90% of formaldehyde is absorbed through the upper respiratory tract. Once absorbed, it is metabolised very rapidly, and other chemical species are synthesised. Its high solubility in water and its high reactivity explain why the adverse effects caused by formaldehyde occur locally, at the contact site.

Acute exposure to formaldehyde can cause headaches and irritation of the respiratory tract, skin and eyes. Chronic exposure, at low levels of airborne concentration, may cause asthma-like respiratory problems and skin contact may cause irritation manifesting as dermatitis or itching.

Formaldehyde is a skin sensitising agent. Sensitising chemical agents can produce allergic reactions after initial exposure. Thus, it is capable of producing eczema, dermatitis and itching, when a person has previously been exposed to this agent and a new contact occurs, even in very small quantities.

It is also an acute oral, dermal and inhalation toxicant. Ingestion or accidental exposure to significant quantities may cause death in humans within short periods of time (hours).

On the other hand, this agent is known to cause nasopharyngeal cancer and is believed to be capable of causing myeloid leukaemia and has been classified by the International Agency for Research on Cancer (IARC) as carcinogenic to humans (Group 1). There is also a positive association between formaldehyde exposure and sinus cancer (IARC, 2012).

Table 2
Hazard classification of formaldehyde according to Regulation (EC) No 1272/2008 and related pictograms

Formaldehyde CAS No: 50-00-0	
CLP classification	**Hazard statement code**
Acute toxic cat. 3	H301 (oral)
Acute toxic cat. 3	H311 (dermal)
Skin corrosive cat. 1 B	H314
Skin sensitiser cat. 1	H317
Acute toxic cat. 3	H331 (inhalation)
Mutagen cat. 2	H341
Carcinogen cat. 1 B	H350

Hazard pictograms

The IARC (iarc.who.int) is an autonomous agency of the World Health Organization of the United Nations. It seeks to promote international collaboration in cancer research. It runs studies that are widely recognised for their quality and independence.

In the European Union it is classified as a category 1B carcinogen according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation). Moreover, it is considered a mutagen (category 2); an acute toxicant (category 3) by oral, dermal and inhalation routes; a skin corrosive (category 1B); and a skin sensitiser (category 1).

Where the exposure can take place

Formaldehyde is used in many industries since it is part of various types of widely-used resins. The industry that uses the largest volume of this agent in Europe is the wood-based panel manufacturing industry, since it is one of the components of the binders and adhesives that bind wood particles, fibres or sheets together in different types of panels (Brasseur, 2020; SUBSPORT, 2013).

According to data available from the European Chemicals Agency (ECHA), at least one million tonnes of formaldehyde are produced or distributed annually in Europe.

Table 3
Main formaldehyde products and their consumption in the EU and Norway

Main formaldehyde by-products	Formaldehyde consumption in the European Union + Norway in 2004
Urea-formaldehyde resins UF	55%
Melamine-formaldehyde resins MF	14%
Phenol-formaldehyde resins PF	7%
Polyacetal POM resins	4%
Pentaerythritol	3%

Source: (GlobalInsight, 2007)

Regulatory references

Formaldehyde was classified as a car cinogen (Carc. 1B) in the European Union through the sixth adaptation to technical and scientific progress (ATP 6) Regulation (EU) No 605/2014 of Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (CLP Regulation).

Given the widespread use of this agent by a large number of companies and sectors, time was allowed for them to adapt to the regulations on carcinogens and mutagens, and this new ATP 6 came into force on 1 January 2016.

The plastics production industry is another major consumer of formaldehyde, where it is used as one of the components of the polymers used to manufacture them. In the chemical industry, workers may be exposed in the formaldehyde manufacturing process itself, as well as in other processes where it is used as an intermediate agent to manufacture other chemical agents.

Formaldehyde-containing resins are also used in the paper industry, to form paper pulp, in the synthetic fibreglass manufacturing industries, in foundries and in construction.

Another widespread use is in the health sector, since it is used as a preservative and tissue fixative in pathological anatomy services and also as a disinfectant in sterilisation. In the funeral industry it is used for the temporary preservation and embalming of corpses by morticians, due to its biocidal and preservative properties. Formaldehyde solution in water, stabilised with methanol, is called formalin.

The third largest industry, based on estimates of the number of workers exposed in the European Union, is the textile industry, where formaldehyde is used as a component of impregnating agents used to give a certain finish and properties to fabrics, for example, permanent printing fabrics, water repellents and flame retardants (IARC, 2012).

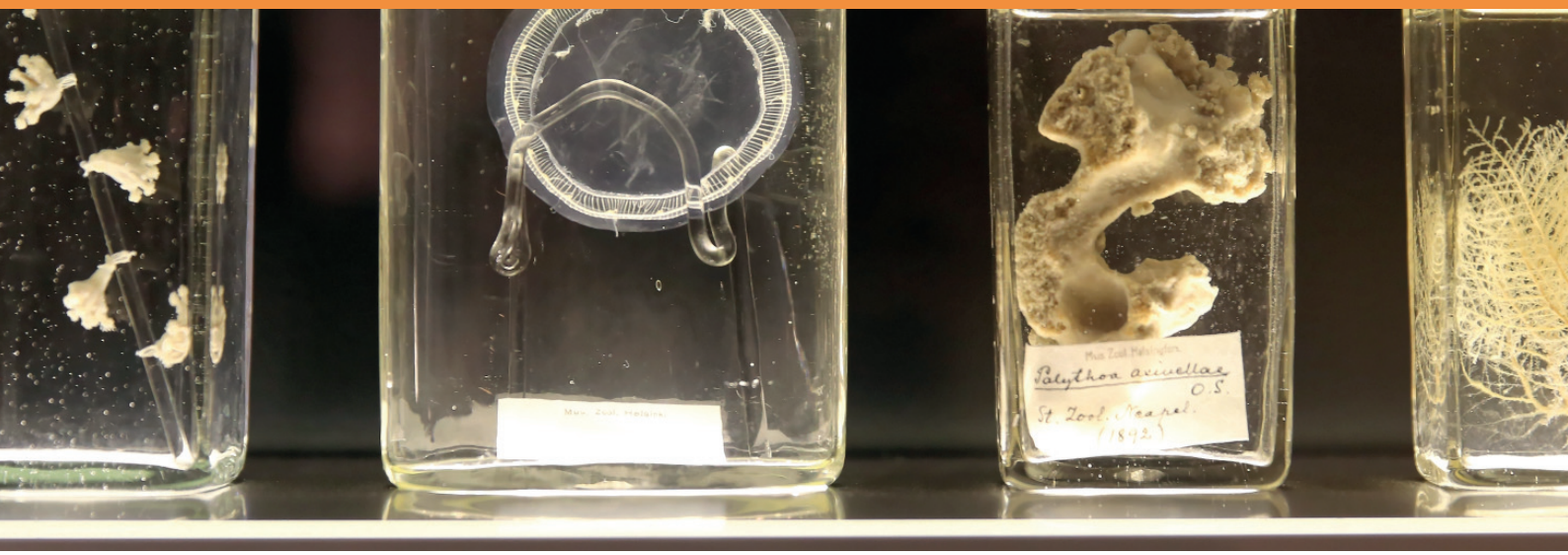
As mentioned above, this agent is also used in certain activities in the agri-food sector, such as livestock and agriculture, and in the food production industry, both to disinfect premises and machinery and for other uses such as, for example, seed treatment.

Table 4 identifies the industries and activities with the highest estimated number of workers exposed to formaldehyde in the European Union, from highest to lowest (IARC, 2012).

Formaldehyde is used as a fixing agent in anatomical pathology, which is necessary, among other things, to diagnose tumours. The quantities of formaldehyde used can be significant, especially in the early stages of fixation.

Table 4
Industries and occupational activities with the highest estimated number of workers exposed to formaldehyde in the European Union and the main uses of formaldehyde in these industries. Source: IARC Monograph 100F year 2012 (IARC, 2012) and SUBSPORT

Industry	Estimated workers	Typical uses
Manufacture of furniture and fixtures, except primarily of metal	179.000	Binder: resins and adhesives.
Medical, dental and other health and veterinary services	174.000	Disinfectant / preservative. Tissue fixative.
Manufacture of wearing apparel, except footwear	94.000	Impregnating agent: resins for anti-wrinkle finish, waterproofing, flame retardant.
Manufacture of wood and wood and cork products, except furniture	70.000	Binder: resins and adhesives.
Personal and household services	62.000	Biocides in cleaning agents, disinfectants
Construction	60.000	Component of paints, varnishes and resins used as binders and adhesives.
Manufacture of textiles	37.000	Impregnating agent: resins for anti-wrinkle finish, waterproofing, flame retardant.
Iron and steel basic industries	29.000	Corrosion inhibitor. Mould making with resins.
Manufacture of fabricated metal products, except machinery	29.000	Biocidal agent in cutting fluids.
Manufacture of other non-metallic mineral products	23.000	Binder for glass wool and mineral wool.
Manufacture of machinery, except electrical	20.000	Binder and adhesive. Biocidal agent in cutting fluids. Polymer preparations and compounds.
Manufacture of industrial chemicals	17.000	Intermediate for multiple products, for example, 4,4'-methylene diphenyl diisocyanate.
Manufacture of other chemical products	17.000	Resins, paints, detergents, disinfectants, etc.
Manufacture of plastic products not classified elsewhere	16.000	Polymer
Agriculture and hunting	16.000	Disinfectant.
Manufacture of paper and paper products	13.000	Binder for pulp, surface treatment, inks, finishing products.
Printing, publishing and allied industries	13.000	Surface treatment, inks, finishing products.
Wholesale and retail trade and restaurants and hotels	13.000	Disinfectant in cleaning products, adhesives, etc.
Manufacture of transport equipment	11.000	Bonding agent. Intermediate agent component of thermoplastic polymers.
Manufacture of electrical machinery, apparatus and appliances	10.000	Bonding agent. Intermediate agent component of thermoplastic polymers.



Exposure assessment

Work involving exposure to formaldehyde falls within the scope of Royal Decree 665/1997 *on the protection of workers from the risks related to exposure to carcinogens at work* and, therefore, the risk assessment and preventive measures to be applied must take into account the requirements of this regulation.

Once the risk from exposure to this agent has been identified, it shall be eliminated or avoided, as a priority, in the activity's conception and design phases. For those risks which cannot be eliminated, an assessment of the risks shall be performed to determine the nature, degree and duration of exposure of workers. The risk assessment will provide information about the preventive measures to be implemented to reduce exposure to as low a level as technically feasible.

Formaldehyde has an occupational exposure limit (8 hour-OEL) of 0.3 ppm (0.37 mg/m^3) and a short-term exposure limit (STEL) of 0.6 ppm (0.74 mg/m^3). These exposure values may not be exceeded during any working day, weighted at 8 hours, in the case of OEL, and at any time of the working day, weighted at 15-minute periods, in the case of the STEL (INSST, 2021).

For carcinogens or mutagens for which a limit value for occupational exposure has been established, the assessment of exposure by inhalation is based on measuring the concentration of the chemical agent in the breathing area of the worker, the weighting of the result according to the reference period, 8 hours or 15 minutes, and its comparison with the established reference criterion, in this case 8 hour-OEL and STEL.

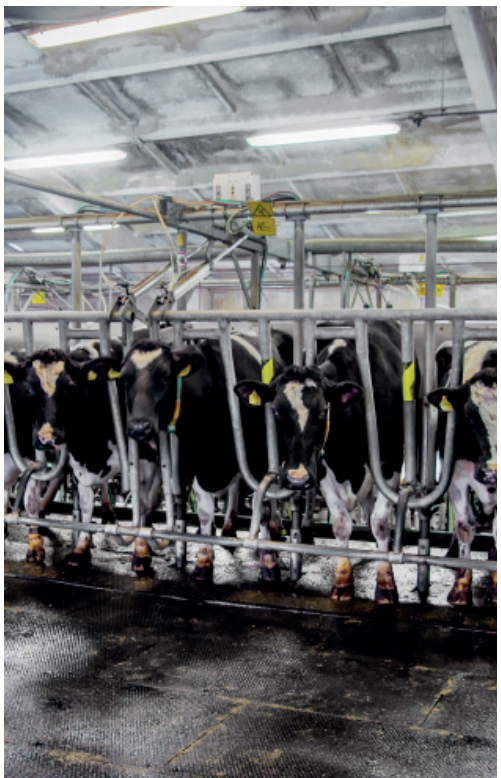
Table 5
Occupational Exposure Limit Values for formaldehyde

	ppm	mg/m^3
8 hours	0,3	0,37
Short-term	0,6	0,74
Notes	C1B, Sen, s	

C1B: Category 1B, presumed to have carcinogenic potential for humans, based on animal evidence. RD 665/1997 applies.

Sen: Sensitiser.

s: The substance is totally or partially prohibited from being placed on the market and use as a phytosanitary or biocide.



Along with the design of the sampling strategy, the first step in sampling formaldehyde for further analysis in the laboratory is the choice of the most appropriate method for the object of measurement, bearing in mind the specific conditions of the working environment and the materials or other substances that may be present and that may cause interference or error in the measurement result. Interferences with other aldehydes and ketones may occur in these circumstances.

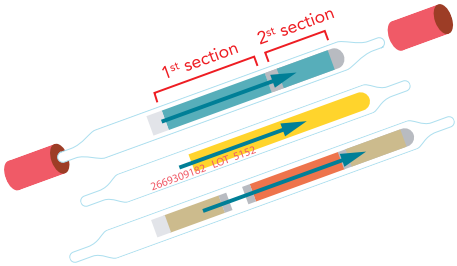
The INSST has validated the method MTA/MA - 062/A08 for sampling and analysing formaldehyde in air, and later comparison with STEL, given that until 2018 formaldehyde only had this occupational exposure limit. However, the method could also be used for sampling of longer duration to compare with 8 hour-OEL by modifying the sampling time and the total volume sampled (INSST, 2020).

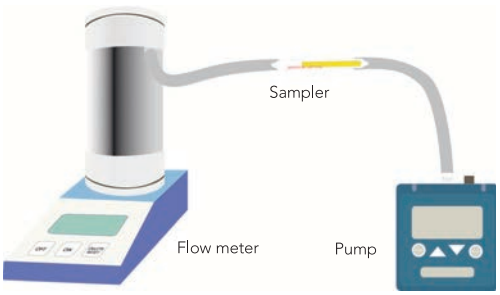
Another possible reference method, validated by the National Institute for Occupational Safety and Health (NIOSH) is the NMAM - Method 2016 – Formaldehyde (NIOSH, 2016), which, like the INSST method, proposes using of sampling in silica gel tubes impregnated with 2,4-dinitrophenyl hydrazine. The same internationally recognised body has other methods for formaldehyde sampling and analysis, including one for particulate matter and one for exhaust fumes.

In recent years, great progress has been made in measuring and monitoring formaldehyde in hospital laboratories. These include the use of ergonomic chairs in which the personal sampling device is attached to the chair itself and sensors are used to take continuous environmental measurements and transmit the data remotely in real time, which allows greater knowledge of emission patterns depending on the task and, therefore, greater control of exposure (Dugheri et al., 2020).

Representativeness of the samples

Whenever a quantitative assessment of inhalation exposure to a hazardous chemical agent is performed, a sampling strategy must be adopted to ensure the representativeness of the data obtained. The standard UNE-EN 689:2019+AC:2019, *Workplace exposure. Measurement of exposure by inhalation of chemical agents. Strategy for testing compliance with the occupational exposure limit values*, provides a possible strategy for comparing daily exposure with the occupational exposure limit values.





Controlling exposure

Preventive measures should be prioritised according to their effectiveness. The first option should always be substitution; where this is not possible, the possibility of working in a closed system should be explored; where this is also not possible, it should be ensured that the level of exposure of workers is reduced to as low a level as is technically possible, and finally, where the above measures are not sufficient, personal protective equipment (PPE) must be used.

Prioritisation of preventive measures for carcinogens:

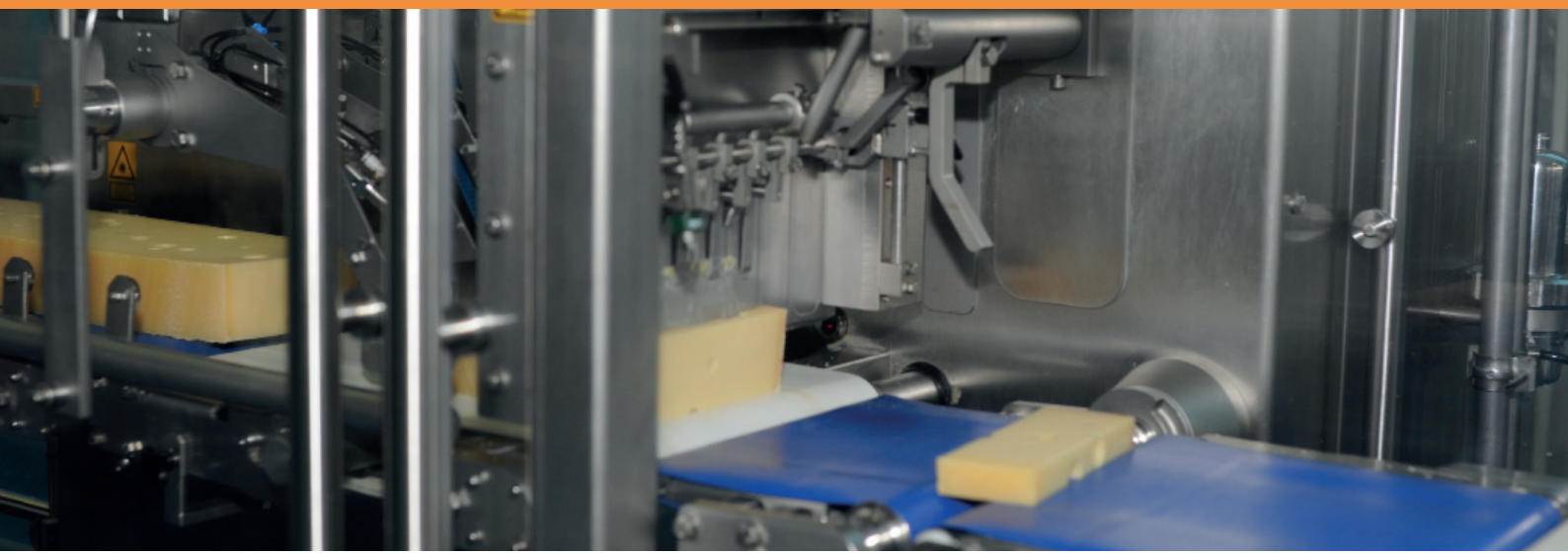
1. Substitution
2. Closed system
3. Reduction of exposure to as low a level as is technically possible
4. Personal protective equipment

1. Substitution

The priority measure, and mandatory whenever it is possible, when working with carcinogens or mutagens, is always substitution with another agent or process not dangerous or is less dangerous. This measure is the most difficult to implement, especially when a production process is already in place, and many variables must be taken into account, but it must be planned and implemented whenever feasible, even if it is more costly, and it is necessary to keep up to date with technological advances in each sector.

Substitution may be based on a change of an agent to a less dangerous agent or a change in procedures. In any case, the new risks that may be introduced by substitution must always be assessed.

In the wood-based panel production sector, some synthetic resins that do not contain formaldehyde, usually based on different types of isocyanates, and some natural options based on soy proteins or tannins, are already testing. Another substitution option is to use other materials such as gypsum, cement or clay construction panels (SUBSPORT, 2013). In the wood-based panel industry, difficulties in finding a substitute include the large volumes of product required, which would compromise availability, and technical problems in using them in presses.



The substitution of formaldehyde as a fixative in the healthcare sector is complex, as it is involved in the diagnostic chain and therefore in the international comparability of results. Moreover, the fixing and disinfecting properties of this agent are difficult to find in other agents. However, experiments have been performed on formaline substitution using various mixtures with ethanol such as glyoxal and ethanol, glyoxal, ethanol and acetic acid or a mixture of polyvinyl alcohol, propylene glycol and ethanol (Laborales, 2011), among other proposed alternatives (SUBSPORT, 2013).

Bronopol-based products are already being used in the funeral sector as an alternative agent, with good results (Brasseur, 2020). In short, formaldehyde is a well-studied agent for which multiple substitutes have been proposed depending on the different industries, products and services in which it is used. Among the various sources of information available, on the Substitution Support Portal (SUBSPORT), you can find a good number of cases and specific applications in which its possible substitution has been explored.

2. Closed system

It consists of preventing the dispersion of the agent into the air breathed by the worker by placing the process in which it is generated within a closed system with evacuation of the pre-treated air to a safe environment to prevent the agents from harming the environment or public health.

A good example of closed system using formaldehyde is low-temperature sterilisation in hospitals, which is performed in airtight, automatic equipment that delivers a low concentration of formaldehyde along with water vapour and only allows its programmed opening, when the level of formaldehyde concentration inside has decreased to appropriate levels.

3. Reduction of exposure to as low a level as is technically possible

The aim is to implement technical and organizational measures so that exposure is reduced as much as technically possible. This obligation implies that it is not sufficient to achieve exposure levels below the established occupational exposure limit, but rather that it is necessary to go beyond it by applying all available measures.

Resources for substitution:

More practical experiences of risk substitution or elimination can be found in the following links:

- Solutions, examples of substitution and good practice for carcinogens, from the Roadmap on carcinogens initiative.

- https://roadmaponcarcinogens.eu/solutions/good-practices/

- SUBSPORT Substitution Support Portal.

https://www.subsportplus.eu/

- OECD Substitution Toolkit Portal.

http://www.oecdsaatoolbox.org/

- INRS Substitution Fact Sheets.

http://www.inrs.fr/actualites/nouvelles-far-fas.html

Royal Decree 665/1997 establishes the obligation to adopt all necessary measures as set out in article 5.5. In general, these requirements are in line with the requirements of Royal Decree 374/2001 on the protection of the health and safety of workers from the risks related to chemical agents at work, adding the express mention of installing detection and warning devices in the event of situations that could generate abnormally high exposures, such as a failure in a local exhaust ventilation system.

Board manufacturing industry

In the manufacture of particleboard and fibreboard, there are closed gluing systems based on high-pressure resin spraying. They increase the efficiency of gluing processes by reducing the quantity of resin required. This means that the quantity of formaldehyde released in the subsequent pressing process is much lower.

In the same direction, in order to reduce formaldehyde exposure to a level as low as technically possible, it is important to select resins with the lowest possible formaldehyde emission. Low Emission Formaldehyde and Ultra-Low Emission Formaldehyde resins (LEF and ULEF) are already available on the market.

These two measures must be complemented by local exhaust systems in hot work areas, in presses, which must be located as close as possible to the emission areas, and by other technical and organizational measures, which can be consulted in the document Formaldehído en la industria de fabricación de tableros by INSST (INSHT, 2016).

Hospitals and laboratories

In anatomical pathology laboratories, a total closing of the process is not possible, since samples need to be handled, and at the moment no generally-accepted substitute has been implemented, so measures need to be taken to reduce exposure as far as possible.

As an example of good practice to reduce in this sector, the Regional Cancer Institute of Montpellier (ICM) modified the carving tables with local exhaust ventilation systems, which are often used in these laboratories, to better protect workers by modifying the existing tables. For this purpose, after several tests and taking ergonomics into

BASEQUIM. Ficha 27: Fabricación de tableros contrachapados para envases con prensa discontinua: exposición a formaldehído. (2019)

BASEQUIM. Ficha 010A: Tallado de muestras en anatomía patológica: exposición a formaldehído.*

account, they installed a transparent cover on the table, which increased the suction flow rate to above the 0.4 m/s considered effective in this case. They also facilitated the delivery of fixative solution by using a foot-operated pump that dispenses it directly from the container on the floor (Brasseur, 2020).

The local exhaust ventilation solutions must be designed on a case-by-case basis and take into account the general ventilation systems, to prevent cross currents that would reduce the efficiency of these systems. In the portal of hazardous work situations (BASEQUIM-STP), which is produced by the INSST in collaboration with the autonomous communities, more information can be found on specific preventive measures for this activity (INSST, 2018) (INSST, 2018).

Funeral services

The rooms in which thanatopraxy treatments involving formaldehyde are performed must allow to control exposure to formaldehyde through the use of appropriate tables, with fluid collection and local exhaust ventilation combined with well-designed general ventilation and ensuring the minimum flow rates for proper collection of formaldehyde vapours.

Other sectors

In general, regardless of the sector and the use to which the formaldehyde is put, measures must be taken to:

- Use as little of the agent as possible. For example, in the food industry, use of formaldehyde can be prevented by modifying parameters such as process temperature to avoid clogging and buildup of organic matter, by using raw material selection systems to prevent microorganisms such as fungi from entering the system, or by increasing the frequency of steam cleaning to minimize the number of times facilities need to be disinfected with formaldehyde.

  The formaldehyde content of diverse products on the market should also be taken into account and the lowest concentration suitable for the intended use should be chosen, and consideration given to using other, less aggressive disinfectants.

- Install correctly-sized and -designed local exhaust ventilation systems at points where a higher emission of the agent is expected.
- Combine local exhaust ventilation with proper general ventilation.

Colour code	Type of filter	Application
	B	Vapours and gases Inorganic
	P	Particles

4. Personal protective equipment

Personal protective equipment should not be used as the only preventive measure. All previous technical measures that can be applied must have been implemented beforehand.

The results of the risk assessment shall be the basis for determining the need for personal protective equipment as well as for selecting the most appropriate equipment. Moreover, when selecting equipment, the anatomy of the workers who will be using it should be taken into account and, in the case of respiratory protective equipment, it is highly recommended that a fit test be performed on each individual.

Since formaldehyde is toxic in contact with skin (H311), causes severe skin burns and eye damage (H314) and may cause an allergic skin reaction (H317), PPE must protect against skin and eye contact by splashes

(gloves, aprons, goggles or face mask) and against inhalation of environmental vapours by means of respiratory protection with full face mask or half mask or quarter mask face shields fitted with filters, type BP (B2P2 or BP3).

Formaldehyde is an organic compound with a boiling point below 65°C, so if only the European standard EN 14387 were considered, type AX filters would be selected; however, the formaldehyde molecule is polar, so it behaves more like inorganic compounds from the point of view of its retention in filters, so type B filters should be used. If aerosols are generated during handling, a particulate filter must be added (INSHT, 2016). Always consult the manufacturer about the usefulness of the PPE you intend to purchase and read the instruction manuals carefully.

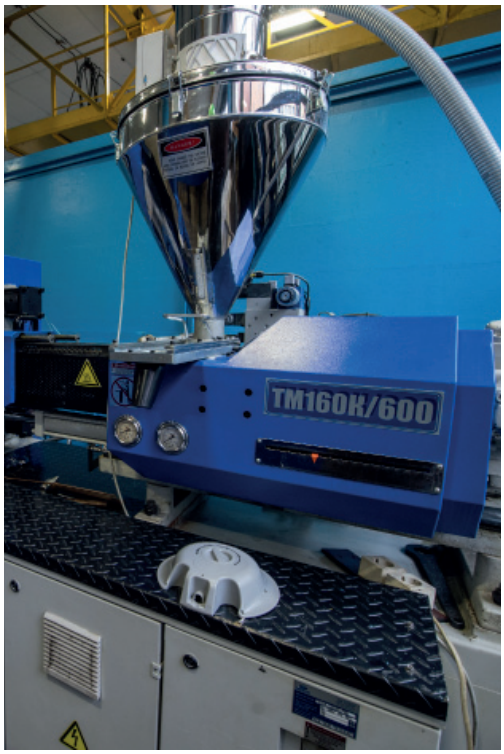
Cleaning and maintenance procedures for these PPE are as important as their proper selection and use. Manufacturers' recommendations must be strictly followed and workers must be trained to know and apply them correctly. A suitable storage place for PPE must be provided.

Other preventive measures

At work involving the risk of exposure to formaldehyde, another series of preventive measures established in the Royal Decree 665/1997 must be complied with, such as the following:

- Personal hygiene measures (article 6).
- Measures to be taken in case of accidental and non-regular exposures (article 7).
- Obligations with regard to documentation (article 9).

- Information for the competent authorities (article 10).
- Consultation, information and training of workers (articles 11 and 12).



Health surveillance

Carcinogens or mutagens are generally characterised by long-term effects or diseases with long latency periods. Thus, Royal Decree 665/1997 establishes a right for workers who have been exposed to these agents to the extension of health surveillance beyond the end of the exposure or of the employment relationship.

In order for the health surveillance programme to be adjusted to the risks arising from the presence of chemical agents in the workplace, the employer must provide information about these risks and safety data sheets to the basic health unit (BHU). In the absence of specific guidelines and action protocols, this BHU, based on the risk assessment and the effects of formaldehyde, will draw up a protocol and document the method and criteria used for the aforementioned health surveillance (INSST, 2018).

Although there is currently no specific worker health surveillance protocol for formaldehyde, medical services in charge of health surveillance can use the generic occupational dermatosis protocol published by the Ministry of Health as a basis, at least for this formaldehyde-related pathology. There is also an occupational asthma protocol, which could be used as a basis for health surveillance of workers with chronic exposures to low concentrations.

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