



BiopSafe

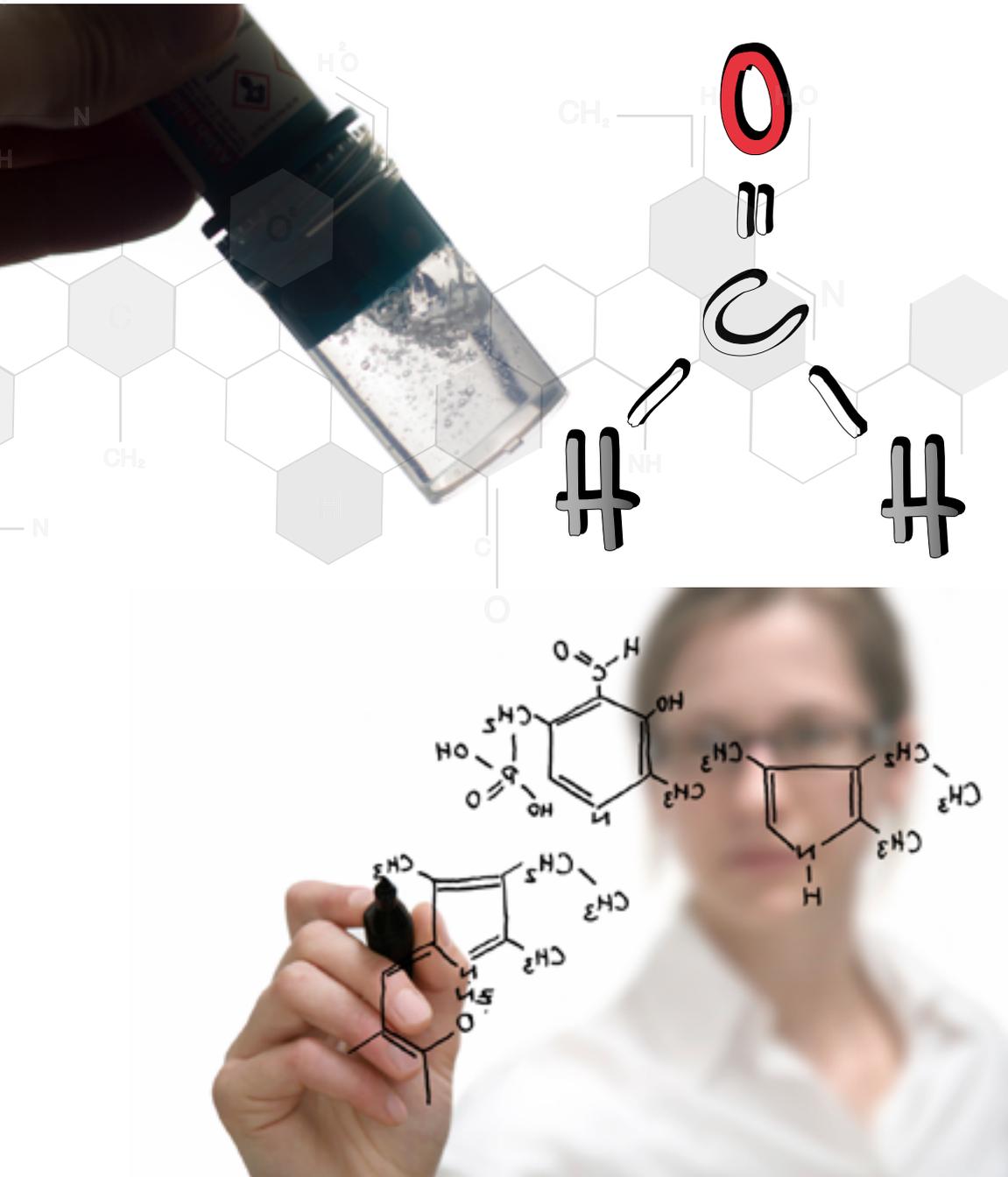
PRESS FOR BETTER SAFETY

Hundreds of millions of biopsies are made every year.



In the process of placing the tissue in the vial, physicians or nurses are in contact with the **FORMALDEHYDE**





What is the **FORMALDEHYDE** or **FORMALIN**?

General description

Formaldehyde (molecular formula $H_2-C=O$; CAS number 50-00-0) is a colourless **gas**, **flammable** and highly **reactive** at room temperature. **Formaldehyde** can also be obtained commercially as a 30–50% (by weight) aqueous solution known as **Formalin**



IS THE FORMALDEHYDE HARMFUL FOR HUMAN HEALTH?

LET'S HAVE A LOOK AT WHAT THE ADMINISTRATIONS AND MOST PRESTIGIOUS AGENCIES IN THE WORLD CONSIDER

Formaldehyde, a carcinogen officially declared by the European Commission

On 5th June 2014, in the EU regulation 605/2014 concerning amendments of EU regulation 1272/2008 (CLP-V) the long discussed reclassification of **formaldehyde** was published: **The appendix VI to this regulation was changed in so far that formaldehyde must be marked as carcinogenic 1B and mutagenic 2.**



DANGER

**FORMALDEHYDE
IRRITANT & POTENTIAL
CANCER HAZARD**



SPANISH NEWS

The Spanish Ministry of Health penalized the management of a Madrid region hospital, €40.986 due to excess **formaldehyde** concentration in the air.

Reference: Newspapers El Mundo and El Pais.
July 15th 2014



DANGER
FORMALDEHYDE
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ITALIAN NEWS

The nurses union complained about the exposure to **formaldehyde** in their work environment. The Italian Senate asked the second largest hospital in Italy, to reconsider the safety of their employees. They have been using **BiopSafe** ever since.

Reference: Atto 4-28070
October 21st 2014



IN AMERICAN CANCER SOCIETY WEBSITE WE CAN FIND:

What expert agencies say.

Several agencies (national and international) study different substances in the environment to determine if they can cause cancer. (A substance that causes cancer or helps cancer grow is called a carcinogen.) The American Cancer Society looks to these organizations to evaluate the risks based on evidence from laboratory, animal, and human research studies.

Based on the available evidence, some of these expert agencies have evaluated the **cancer-causing** potential of **formaldehyde**.



**American
Cancer
Society®**

THEIR CONCLUSION...



The National Toxicology Program (NTP) is formed from parts of several different US government agencies, including the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA).

The NTP lists **formaldehyde** as “**known to be a human carcinogen.**”

International Agency for Research on Cancer



The International Agency for Research on Cancer (IARC) is part of the World Health Organization (WHO). Its major goal is to identify causes of cancer. IARC has concluded that **formaldehyde** is “**carcinogenic to humans**” based on higher risks of **nasopharyngeal cancer and leukemia.**



The Environmental Protection Agency (EPA) maintains the Integrated Risk Information System (IRIS), an electronic database that contains information on human health effects from exposure to various substances in the environment. The EPA has classified **formaldehyde** as a “**probable human carcinogen.**”



National Cancer Institute researchers have concluded that, based on data from studies in people and from lab research, exposure to **formaldehyde may cause leukemia, particularly myeloid leukemia, in humans.**

DANGER

**FORMALDEHYDE
IRRITANT & POTENTIAL
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The United States Department of Labor (DOL)

There is a cabinet-level department of the U.S. federal government responsible for occupational safety, wage and hour standards, unemployment insurance benefits, reemployment services, and some economic statistics. The department is headed by the U.S. Secretary of Labor.



THIS DEPARTMENT IS KNOWN WORLDWIDE AS OSHA, THE MOST RECOGNIZED VOICE IN HEALTH & SAFETY DEPARTMENTS WORLDWIDE: THE OCCUPATIONAL SAFETY HEALTH ADMINISTRATION OF USA. WHAT DOES OSHA SAY ABOUT

FORMALDEHYDE?





Regulations (Standards - 29 CFR) - Table of Contents

- Part Number: 1910
- Part Title: Occupational Safety and Health Standards
- Subpart: Z
- Subpart Title: Toxic and Hazardous Substances
- Standard Number: 1910.1048
- Title: Formaldehyde.
- Appendix: A, B, C, D, E
- GPO Source: e-CFR

REGULATIONS

1910.1048(c)

Permissible Exposure Limit (PEL)

1910.1048(c)(1)

TWA: The employer shall assure that no employee is exposed to an airborne concentration of **formaldehyde** which exceeds 0.75 parts **formaldehyde** per million parts of air (0.75 ppm) as an 8-hour TWA.

1910.1048(c)(2)

Short Term Exposure Limit (STEL): The employer shall assure that no employee is exposed to an airborne concentration of **formaldehyde** which exceeds two parts **formaldehyde** per million parts of air (2 ppm) as a 15-minute STEL.

1910.1048(e)(1)

Signs.

1910.1048(e)(1)(i)

The employer shall establish regulated areas where the concentration of airborne **formaldehyde** exceeds either the TWA or the STEL and post all entrances and access ways with signs bearing the following legend:

DANGER
FORMALDEHYDE
MAY CAUSE CANCER
CAUSES SKIN, EYE, AND RESPIRATORY IRRITATION
AUTHORIZED PERSONNEL ONLY

1910.1048(e)(2)

The employer shall limit access to regulated areas to authorized persons who have been trained to recognize the hazards of **formaldehyde**.



FORMALDEHYDE



MAY CAUSE CANCER
CAUSES SKIN, EYE AND
RESPIRATORY IRRITATION



AUTHORIZED PERSONNEL ONLY



The occupational health hazards of **formaldehyde** are primarily due to its toxic effects after inhalation, after direct contact with the skin or eyes by **formaldehyde** in liquid or vapor form, and after ingestion.

II. TOXICOLOGY

A. Acute Effects of Exposure

1. Inhalation (breathing): **Formaldehyde** is highly irritating to the upper airways. The concentration of **formaldehyde** that is immediately dangerous to life and health is 100 ppm. Concentrations above 50 ppm can cause severe pulmonary reactions within minutes. These include **pulmonary edema**, **pneumonia**, and **bronchial irritation** which can result in death. Concentrations above 5 ppm readily cause lower airway irritation characterized by cough, chest tightness and wheezing. There is some controversy regarding whether formaldehyde gas is a pulmonary sensitizer which can cause occupational asthma in a previously normal individual. **Formaldehyde** can produce symptoms of bronchial asthma in humans. The mechanism may be either sensitization of the individual by exposure to **formaldehyde** or direct irritation by **formaldehyde** in persons with pre-existing asthma. Upper airway irritation is the most common respiratory effect reported by workers and can occur over a wide range of concentrations, most frequently above 1 ppm. However, airway irritation has occurred in some workers with exposures to **formaldehyde** as low as 0.1 ppm. Symptoms of upper airway irritation include dry or sore throat, itching and burning sensations of the nose, and nasal congestion. Tolerance to this level of exposure may develop within 1-2 hours. This tolerance can permit workers remaining in an environment of gradually increasing formaldehyde concentrations to be unaware of their increasingly hazardous exposure.



2. Eye contact: Concentrations of **formaldehyde** between 0.05 ppm and 0.5 ppm produce a sensation of irritation in the eyes with burning, itching, redness, and tearing. Increased rate of blinking and eye closure generally protects the eye from damage at these low levels, but these protective mechanisms may interfere with some workers' work abilities. Tolerance can occur in workers continuously exposed to concentrations of **formaldehyde** in this range. Accidental splash injuries of human eyes to aqueous solutions of **formaldehyde (formalin)** have resulted in a wide range of ocular injuries including corneal opacities and blindness. The severity of the reactions have been directly dependent on the concentration of **formaldehyde** in solution and the amount of time lapsed before emergency and medical intervention.



3. Skin contact: Exposure to formaldehyde solutions can cause irritation of the skin and allergic contact dermatitis. These skin diseases and disorders can occur at levels well below those encountered by many **formaldehyde** workers. Symptoms include erythema, edema, and vesiculation or hives. Exposure to liquid **formalin** or **formaldehyde** vapor can provoke skin reactions in sensitized individuals even when airborne concentrations of **formaldehyde** are well below 1 ppm.



4. Ingestion: Ingestion of as little as 30 ml of a 37 percent solution of **formaldehyde (formalin)** can result in death. Gastrointestinal toxicity after ingestion is most severe in the stomach and results in symptoms which can include **nausea, vomiting, and severe abdominal pain**. Diverse damage to other organ systems including the liver, kidney, spleen, pancreas, brain, and central nervous systems can occur from the acute response to ingestion of **formaldehyde**.



B. Chronic Effects of Exposure

Long term exposure to **formaldehyde** has been shown to be associated with an increased risk of **cancer** of the nose and accessory sinuses, nasopharyngeal and oropharyngeal cancer, and lung cancer in humans. Animal experiments provide conclusive evidence of a causal relationship between nasal cancer in rats and **formaldehyde** exposure. Concordant evidence of carcinogenicity includes DNA binding, genotoxicity in short-term tests, and cytotoxic changes in the cells of the target organ suggesting both preneoplastic changes and a dose-rate effect. **Formaldehyde** is a complete carcinogen and appears to exert an effect on at least two stages of the carcinogenic process.



USA NEWS

Government Says 2 Common Materials Pose Risk of Cancer Formaldehyde is added to list of carcinogens

Reference New York Times

By GARDINER HARRIS - JUNE 10, 2011

WASHINGTON — The government issued warnings on Friday about two materials used daily by millions of Americans, saying that one causes **cancer and the other might**.

Government scientists listed **formaldehyde** as a **carcinogen**, and said it is found in worrisome quantities in plywood, particle board, mortuaries and hair salons. They also said that styrene, which is used in boats, bathtubs and in disposable foam plastic cups and plates, may cause cancer but is generally found in such low levels in consumer products that risks are low.

Frequent and intense exposures in manufacturing plants are far more worrisome than the intermittent contact that most consumers have, but government scientists said that consumers should still avoid contact with **formaldehyde** and styrene along with six other chemicals that were added to the government's official Report on Carcinogens. **Its release was delayed for years because of intense lobbying from the chemical industry, which disputed its findings.**

John Bucher, associate director of the National Toxicology Program, which produced the report, said evidence of **formaldehyde's** carcinogenicity was far stronger than for styrene and that consumers were more likely to be exposed to potentially dangerous quantities of formaldehyde.

The federal Occupational Safety and Health Administration warned in April that a hair-care product, Brazilian Blowout Acai Professional Smoothing Solution, contained unacceptable levels of **formaldehyde**, and salon workers have reported headaches, nosebleeds, **burning eyes, vomiting and asthma attacks after using the product and other hair-straighteners.**



Is there a solution for nurses
and physicians in order to avoid
contact with **FORMALDEHYDE**?



FORMALDEHYDE



MAY CAUSE CANCER

**CAUSES SKIN, EYE AND
RESPIRATORY IRRITATION**



AUTHORIZED PERSONNEL ONLY



Safe biopsy handling



Yes!
We have it



HOW DOES BiopSafe WORK?



1

Turn the lid off

2

The biopsy is placed in the vial.



3



Tighten the lid

4



Press the thumb and the formalin is released.

5



The formalin and the biopsy are mixed.

6



The biopsy is ready for safety transportation.





....and during this
short process you have
avoided contact with
formaldehyde



BiopSafe

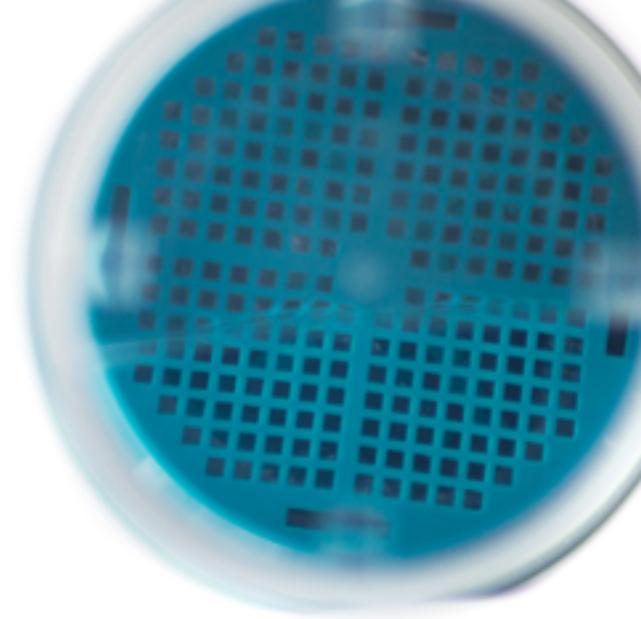
PRESS FOR BETTER SAFETY



The secret is in the lid

With **BiopSafe** there are no difficult formalin bags and wall holders that often leads to formalin waste. The system consists of a small, easy to use container (vial) with formalin capsuled in the lid. When the biopsy is placed at the bottom of the container, you screw the lid on and gently apply pressure with your thumb, allowing the formalin to flow out and cover the biopsy. Everything is done inside the container and no formalin is released in either liquid or vapor form.

BiopSafe
has been specially created
for your safety

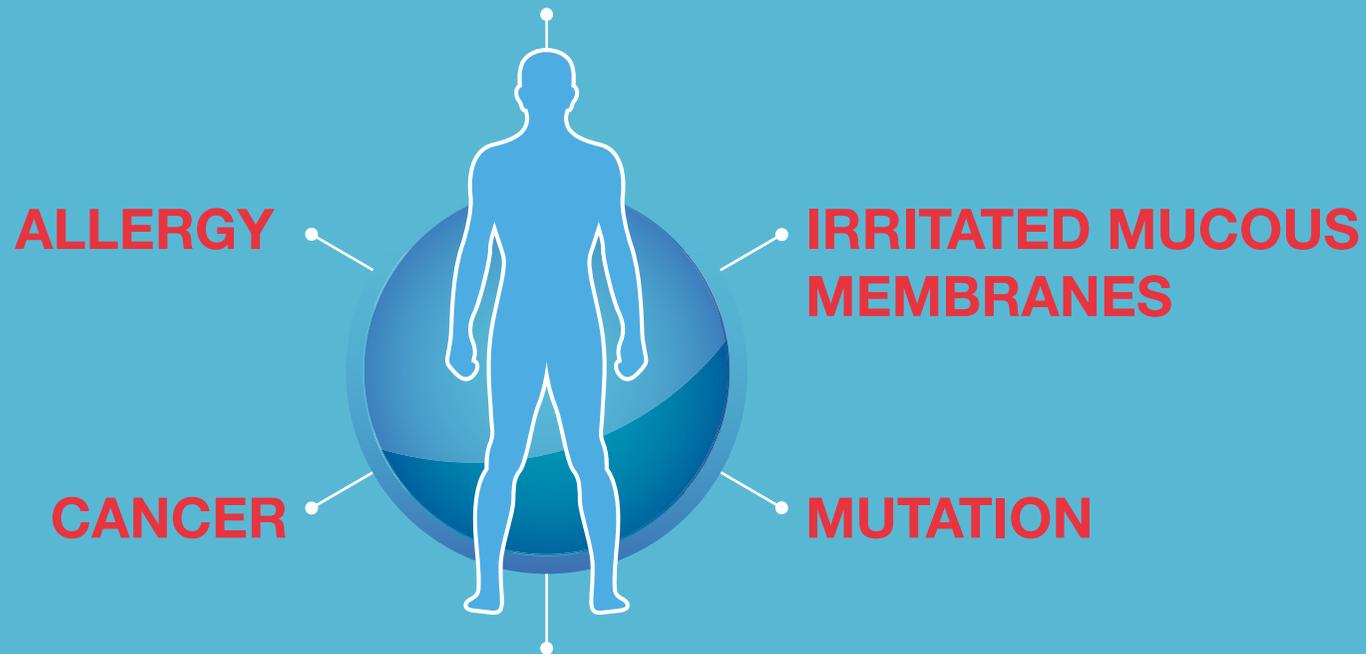


Ready in seconds

Besides from being safe, the method is also fast. **BiopSafe** is always at hand and the process of placing the biopsy, adding the formalin and making it ready for transportation to the laboratory is done in a matter of seconds. **BiopSafe** saves valuable time and at the same time ensures that concentration is not broke unnecessarily during operations. And you are sure it's always in the perfect proportion.



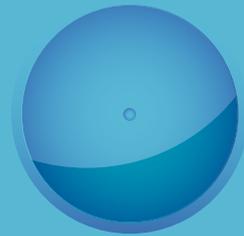
WITH BIOPSAFE you can avoid contact with formaldehyde, which may damage your health.



TAKE CARE OF YOUR HEALTH TOO!



PRESS FOR
BETTER SAFETY



BiopSafe

PRESS FOR BETTER SAFETY