



ADDAX
B I O S C I E N C E S

Non Toxic Non Carcinogenic alternative to Formalin



For Safe and Reliable Tissue Fixation

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The unmet need

The fixation of histological specimens is crucial in pathological anatomy, as it prepares the samples for subsequent analyses required for diagnosis. Formalin, an aqueous solution of formaldehyde, is the most widely used histological fixative for tissue preservation in histopathology. However, formaldehyde is a **carcinogenic, toxic, and allergenic** substance. Nearly one million medical operators in the EU are exposed to formaldehyde daily, facing a fivefold increased cancer risk. Reports indicate higher mortality from nasopharyngeal cancer and deaths from leukemia. Despite these risks, formaldehyde continues to be used in hospitals due to the lack of a safe and effective alternative, so far...

Safer Alternatives Required

Formaldehyde is a highly reactive gas at room temperature and pressure. It is classified as a category 1B carcinogen, category 2 mutagen, category 3 acute toxicant, category 1B skin corrosive, and category 1 skin sensitizer. The International Agency for Research on Cancer (IARC) classified it as a certain human carcinogen (Group 1) in 2006, alongside **asbestos and benzene**.

European Regulation

EU regulations are increasingly restricting formaldehyde use, demanding safer alternatives to protect consumers and workers. In fact, European regulation essentially already mandates the abandonment of formaldehyde **where valid and safe alternatives exist**.

For **consumers**, regulations EU 2018/675 and EU 2023/1464 prohibit the sale of items containing formaldehyde above neglectable concentrations. EU 2018/675 sets a limit of 0.1% w/w, while EU 2023/1464 sets a limit of 0.080 mg/m³ for formaldehyde release. Regarding **workers' safety**, EU 2019/983 allows formaldehyde-based products only when no valid alternative exists. Furthermore, it mandates progressively reducing occupational exposure limits, transitioning from 0.62 mg/m³ (0.5 ppm) **until July 2024** to 0.37 mg/m³ (0.3 ppm) thereafter.

Both the public sector and formaldehyde users **are legally obliged to seek and implement safer alternatives**. Article 235 of Legislative Decree 81/08 ("Italy's consolidated text on health and safety at work") explicitly states that Employers **must avoid or reduce the use of carcinogens** in the workplace, replacing them with less harmful substances **whenever technically possible**.

US regulation

Globally, legislation recognizes formaldehyde's toxicity, with measures to protect individuals from exposure risks. Legislation in the United States acknowledges the toxicity of formaldehyde, with regulatory measures such as the Toxic Substances Control Act (TSCA) and the Clean Air Act. The TSCA regulates the introduction of chemicals, while the Clean Air Act sets limits on air pollutants. The Resource Conservation and Recovery Act (RCRA) addresses hazardous waste disposal. Moreover, specific standards for formaldehyde emissions have been established by the EPA and recently updated.

[The latest study](#) (15/03/2024) conducted by the US Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA) has identified **formaldehyde as posing an unreasonable risk to human health**. This conclusion, reached after analyzing 62 different use conditions and exposure scenarios, underscores the intricate nature of formaldehyde's toxicology and exposure profiles.

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Even better than formalin

Turin Hospital Validation Study

A study at Molinette Hospital in Turin validated GAF® as an alternative to formalin. Processing 500 endoscopic tissues with GAF® using standard histological protocols, the medical team found no issues and praised GAF® 's operational and diagnostic performance. Published in *Plos-one*, the study concluded that GAF®, with its improved toxicological profile and lack of carcinogenicity, **can successfully replace formalin**. [*"Acid-free glyoxal as a substitute of formalin for structural and molecular preservation in tissue samples"*. [Available at this link](#)]

Multicentric European Clinical Trial

An independent European study coordinated by Swiss CRO 1MED further validated GAF®. Evaluating 100 tissue samples fixed in both GAF® and standard buffered formalin (PBF), the trial produced 1000 slides and was conducted at IRCCS of Candiolo, Vall d'Hebron Barcelona Hospital, and The Christie NHS Foundation Trust of Manchester. Published in *Virchows Archiv*, the results showed GAF® is **as valid for diagnosis as formalin**, providing optimal tissue fixation **without carcinogenic activity**. [*"GAF® histological fixative is a suitable alternative to formalin: results from an open-label comparative non-inferiority study"* [Available at this link](#)]

Molecular Biology Validation

Extending the evaluation to molecular biology, a study found **GAF® outperforms formalin in DNA quality**, providing longer fragments and reducing false positives. In clinical practice, poor-quality genetic material from formalin-fixation can compromise next-generation sequencing (NGS) accuracy. GAF® significantly improves DNA quality, enhancing genomic analysis and enabling comprehensive profiling, **crucial for reliable molecular diagnostics in precision oncology**. Published in *Laboratory Investigation*, these findings confirm GAF® 's efficacy. [*"Alternative protocols of tissue fixation dramatically reduces the impact of DNA artifacts, unravelling the interpretation of clinical Comprehensive Genomic Profiling"* [Available at this link](#)]

Validation in Veterinary Pathology

A multicentre study with Italian veterinary pathology institutes compared GAF® with formalin for surgical resections, large pieces, and whole organs. GAF® showed superior performance, **better preserving DNA, RNA, and cell structure**. Evaluating over 50 biopsies and 14 necropsies across various species, the study confirmed GAF® 's efficacy for routine diagnostics and detection of infectious agents. Results were published in the *Journal of Comparative Pathology*. [*"Non-toxic acid-free glyoxal fixative for veterinary histopathology, immunohistochemistry and molecular analysis"* [Available at this link](#)]

GAF® Interest Among US Institutions

GAF® has sparked the interest and curiosity of several prestigious universities and research centers in the United States. Institutions such as The University of Texas Southwestern Medical Center in Dallas, Drexel University in Philadelphia, the Howard Hughes Medical Institute in Washington, the Salk Institute for Biological Studies in La Jolla, CA, and Mount Sinai Hospital in New York have acquired GAF® for their initial tests. Additionally, DNA Genotek in Ontario, Canada, and Illumina in Foster City, CA, have also purchased GAF® for genomic profiling purposes. These early adoptions, though small, represent a potential starting point for significant collaborations and broader integration of GAF® in advanced research, highlighting its promising future in the scientific community.

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Social and Environmental Benefits

Benefits for Worker Safety

Exposure to formaldehyde is linked to several **serious health issues**, including acute and chronic respiratory problems, asthma, and an increased risk of nasopharyngeal **cancer and leukaemia**. Given its significantly less severe toxicological characteristics, the use of GAF® represents a major improvement in safety conditions for healthcare workers.

	H301 TOXIC IF INGESTED	H311 TOXIC IF IN CONTACT WITH SKIN	H314 CAUSES SEVERE SKIN BURNS AND EYE INJURIES	H317 MAY CAUSE AN ALLERGIC SKIN REACTION	H331 TOXIC IF INHALED	H341 SUSPECTED OF CAUSING GENETIC ALTERATIONS	H350 SUSPECTED OF CAUSING GENETIC ALTERATIONS
GAF®				●			
FORMALIN	●	●	●	●	●	●	●

Environmental Benefits

Formaldehyde is a highly volatile and toxic substance known for its significant contribution to air pollution. Its use releases hazardous emissions that require strict control measures. Replacing formaldehyde with GAF® leads to savings in:

- **Emission treatment systems:** Expensive systems such as air filtration units, thermal oxidizers, and enhanced ventilation are required to manage pollutants released by formaldehyde. Switching to GAF® simplifies these requirements, significantly reducing installation and maintenance costs.
- **Continuous air quality monitoring:** Constant workplace monitoring and equipment inspections are mandatory when using formaldehyde. By using GAF®, organizations can significantly reduce the frequency and cost of these inspections.
- **Employee health surveillance:** Managing formaldehyde exposure requires specific and ongoing health monitoring for employees exposed to this carcinogen. Adopting a non-carcinogenic product like GAF® eliminates this burden at its source.
- **Hazardous waste disposal:** The disposal of non-carcinogenic waste is significantly less expensive than that of toxic and carcinogenic waste, reducing both financial burden and the complexity of waste management.

Additional Social Impacts

Adopting GAF® also helps to:

1. **Lower insurance premiums:** Health risks associated with formaldehyde require higher premiums for worker health and safety. The adoption of GAF® allows organizations to minimize these costs.
2. **Avoid legal issues:** Companies face significant legal liabilities due to the health impacts of formaldehyde exposure. GAF® mitigates the risk of costly lawsuits, compensation claims, and penalties for exceeding environmental concentration limits.
3. **Ensure operational continuity:** Accidental spills and formaldehyde-related violations can lead to laboratory shutdowns and operational disruptions. GAF® reduces these risks, ensuring smoother and uninterrupted operations.

In a context where workplace safety and environmental sustainability are strategic priorities, embracing a model that integrates safety, sustainability, and innovation not only meets regulatory compliance and health protection needs but also promotes a modern and resilient system capable of addressing global complexities with vision and responsibility.

Use GAF® for your NGS analysis

GAF®

*Innovating Histological Fixation for
Environmental and Occupational Health*

Why replace NBF fixative?

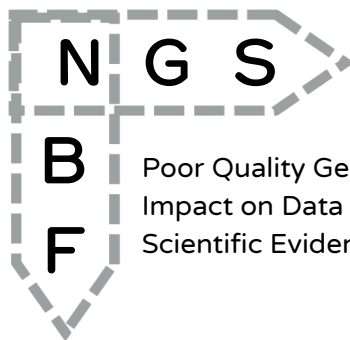
- Formalin fixation induces DNA fragmentation and chemical alterations, significantly skewing NGS results.
- A high frequency of sequence alterations is due to Formalin fixation of archival specimens.
- Scientific and regulatory perspectives recognize Formalin's carcinogenicity.



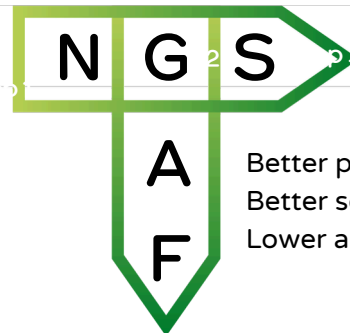
Can GAF® solve this issue?

- Glyoxal Acid-free (GAF®) overcomes the artifacts and low DNA preservation observed in Formalin fixation.
- GAF® allows for improved genomic analysis of tissues and enables broader and more complete profiling.
- GAF® does not present carcinogenic activity, so it is safe for workers.

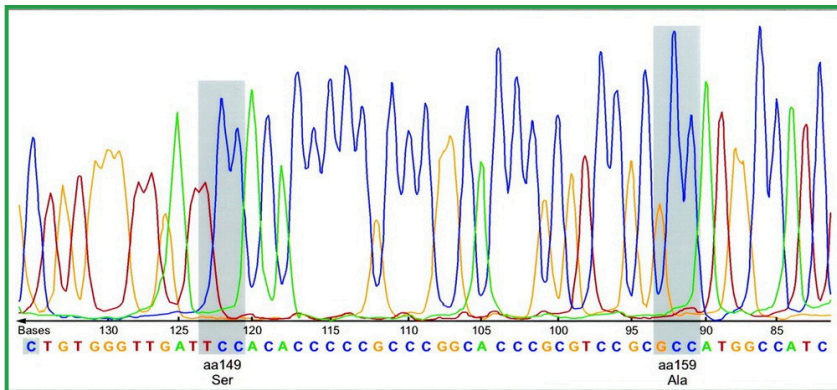
TO BETTER PRESERVE THE NUCLEIC ACIDS USE GAF®



Poor Quality Genetic Material
Impact on Data Reliability
Scientific Evidence



Better preservation of DNA integrity
Better sequencing results
Lower amount of artifactual mutations

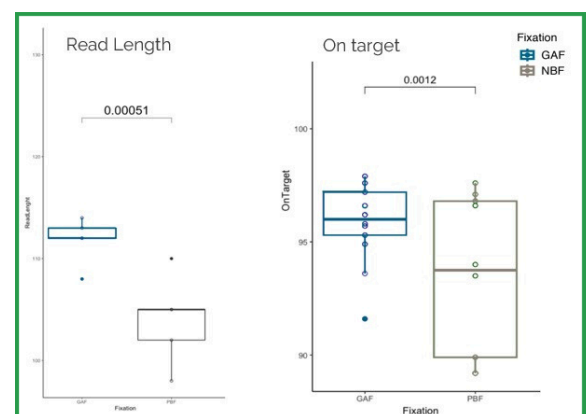


Proven Benefits

DNA integrity is better preserved in GAF® than in NBF



Fixation is a crucial initial step in histological processing, essential for creating paraffin-embedded tissue blocks used in pathology. Various fixation methods affect DNA integrity, influencing genomic profiling results. GAF® offer optimal DNA preservation, allowing for advanced molecular profiling of tissue samples.



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Catalogue: PRE-FILLED



PRODUCT Code	NAME
GAF000010P40	GAF® fixative 10 ml
PRE-FILLED PP container with screw cap pre-filled with 10ml of GAF® in a total volume of 20ml PACKAGING: 40 containers per box	



PRODUCT Code	NAME
GAF000025P40	GAF® fixative 25 ml
PRE-FILLED PP container with screw cap pre-filled with 25ml of GAF® in a total volume of 60ml PACKAGING: 40 containers per box	



PRODUCT Code	NAME
GAF000090P12	GAF® fixative 90 ml
PRE-FILLED PP container with screw cap pre-filled with 90ml of GAF® in a total volume of 160ml PACKAGING: 12 containers per box	



PRODUCT Code	NAME
GAF000090P24	GAF® fixative 90 ml
PRE-FILLED PP container with screw cap pre-filled with 90ml of GAF® in a total volume of 160ml PACKAGING: 24 containers per box	



PRODUCT Code	NAME
GAF000125P24	GAF® fixative 125 ml
PRE-FILLED PP container with screw cap pre-filled with 125ml of GAF® in a total volume of 250ml PACKAGING: 24 containers per box	



PRODUCT Code	NAME
GAF000250P12	GAF® fixative 250 ml
PRE-FILLED PP container with screw cap pre-filled with 250ml of GAF® in a total volume of 500ml PACKAGING: 12 containers per box	

Catalogue: BULK



PRODUCT Code	NAME
GAF000250B8	GAF® fixative 250 ml
BULK 250ml Bottle - PET PACKAGING: 8 bottles per box	



PRODUCT Code	NAME
GAF001000B1	GAF® fixative 1000 ml
BULK 1-Liter Bottle - PET PACKAGING: single	



PRODUCT Code	NAME
GAF003000B1	GAF® fixative 3 lt
BULK 3-liter Jerrycan - HDPE PACKAGING: single	



PRODUCT Code	NAME
GAF005000B1	GAF® fixative 5 lt
BULK 5-liter Jerrycan - HDPE PACKAGING: single	



PRODUCT Code	NAME
GAF010000B1	GAF® fixative 10 lt
BULK 10-liter Jerrycan - HDPE PACKAGING: single	

PP: Polypropylene **PET:** Polyethylene Terephthalate **HDPE:** High-Density Polyethylene

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