

Safety Data Sheet
GAF® HISTOLOGICAL FIXATIVE



Safety Data Sheet dated 25/11/2024 Revision 08 - replaces Revision 07 dated 17/08/2024
First issue dated 16/02/2018

SECTION 1: Identification of the substance/mixture and of the company/corporation

1.1. Product identifier

Identification of the mixture:

Trade name: GAF® FIXATIVE - GLYOXAL ACID FREE- Trade code: GAF000010P40 - GAF00025P40 -
GAF000090P12 - GAF000090P24 - GAF000125P24 - GAF000250P12 - GAF000250B8 - GAF001000B1 -
GAF005000B1 - GAF010000B1
UFI: FK80-K094-C009-TE6E

1.2. Relevant identified uses of the substance or mixture and uses advised against

Professional
Recommended use: Histological fixative
Uses not recommended: N.A.

1.3. Details of the supplier of the safety data sheet

Supplier: ADDAX Biosciences S.r.l Str Mongreno 247
0132 Torino (TO) Italy

Competent person responsible for the safety data sheet: info@addaxbio.com

1.4. Emergency telephone number

ITALIAN POISON CONTROL CENTRES:

CAV "Bambino Gesù Paediatric Hospital" DEA. Rome, P.za Sant'Onofrio, 4 - 00165. Tel 0668593726
Az. Osp. Univ. Foggia, V.le Luigi Pinto, 1 - 71122. Tel 800183459
Az. Osp. 'A. Cardarelli'. Naples, Via A. Cardarelli, 9 - 80131. Tel 081-5453333
CAV Policlinico "Umberto I". Rome, V.le del Policlinico, 155-161. Tel 06-49978000
CAV Policlinico 'A. Gemelli'. Rome, Largo Agostino Gemelli, 8 - 168. Tel 06-3054343
Az. Osp. 'Careggi' U.O. Medical Toxicology. Florence, Largo Brambilla, 3 - 50134. Tel 055-7947819
CAV National Centre for Toxicological Information. Pavia, Via Salvatore Maugeri, 10 - 27100. Tel 0382-24444
Niguarda Ca' Granda Hospital. Milan, Piazza Ospedale Maggiore, 3 - 20162. Tel 02-66101029
Azienda Ospedaliera Papa Giovanni XXII. Bergamo, Piazza OMS, 1 - 24127. Tel 800883300
Azienda Ospedaliera Integrata Verona. Verona, Piazzale Aristide Stefani, 1 - 37126. Tel 800011858

SECTION 2: Hazard identification



2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008 (CLP)

Skin Sens.1 May causes allergic skin reaction.
Physico-chemical effects harmful to human health and the environment: No other hazards

2.2. Label Elements

Regulation (EC) No 1272/2008 (CLP) Hazard

Pictograms and warnings



Attention

Indications of danger

H317 May cause an allergic skin reaction.

Cautionary Advice

P261 Breathe in dust/fume/gas/mist/vapours/spray.
P272 Contaminated work clothes should not be worn outside the workplace. P280 Wear protective gloves.
P302+P352 IF ON SKIN: Wash with plenty of water.
P333+P313 In case of skin irritation or rash: Get medical advice.
P501 Dispose of product/container in accordance with regulations.

Contains:

glyoxal...%

UFI: FK80-K094-C009-TE6E

Special provisions according to Annex XVII of REACH and subsequent adaptations:

None

2.3. Other dangers

No PBT, vPvB or endocrine disrupting

substances present at a concentration $\geq 0.1\%$.

Other hazards: No other hazards

SECTION 3: composition/information on ingredients**3.1. Substances**

N.A.

3.2. Mixtures

Identification of the mixture: GAF® HISTOLOGICAL FIXATIVE

Hazardous components within the meaning of the CLP Regulation and their classification:

Quantity	Name	Identification Number	Classification	Registration Number
≥ 1 -<2.5 %	glyoxal...%.	CAS:107-22-2 EC:203-474-9 Index:605-016-00-7	Muta. 2, H341; Acute Tox. 4, H332; Eye Irrit. 2, H319; Skin Irrit. 2, H315; Skin Sens. 1, H317	01-2119461733-37-XXXX

SECTION 4: First aid measures**4.1. Description of first aid measures**

In case of skin contact:

Remove contaminated clothing immediately.

Remove contaminated clothing immediately and dispose of it safely.

In case of contact with the eyes:

Wash immediately with water.

In case of ingestion:

Do not induce vomiting, seek medical attention by showing this SDS and hazard labelling.

In case of inhalation:

Take the injured person outdoors and keep him warm and at rest.

4.2. Main symptoms and effects, both acute and delayed

N.A.

4.3. Indication of any need for immediate medical attention and special treatment

In the event of an accident or if you feel unwell, consult a doctor immediately (show directions for use or safety data sheet if possible).

SECTION 5: Fire-fighting measures**5.1. Extinguishing media**

Suitable extinguishing media:

Water.

Carbon dioxide (CO₂).

Extinguishing media that must not be used for safety reasons: None in particular.

5.2. Special hazards arising from the substance or mixture

Do not inhale gases produced by explosion and combustion.

Combustion produces heavy smoke.

5.3. Recommendations for firefighters

Use appropriate respiratory equipment.

Collect contaminated water used to extinguish the fire separately. Do not discharge it into the sewage system.

If safe to do so, move undamaged containers from the immediate danger area.

SECTION 6: measures in the event of accidental release**6.1. Personal precautions, protective equipment and procedures in case of an emergency****For those who do not intervene directly:**

Wear personal protective equipment.

Move people to a safe place.

Please refer to the protective measures set out in sections 7 and 8.

For those who intervene directly:

Wear personal protective equipment.

6.2. Environmental precautions

Prevent penetration into the soil/subsoil. Prevent runoff into surface water or sewage system.

Retain contaminated water and dispose of it.

In the event of a gas leak or leakage into watercourses, soil or sewage system, inform the responsible authorities.

Suitable material for collection: absorbent material, organic material, sand

6.3. Methods and materials for containment and remediation

Material suitable for collection: absorbent material, organic material, sand

Wash with plenty of water.

6.4. Reference to other sections

See also paragraphs 8 and 13

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.

Do not use empty containers before they have been cleaned.

Before transfer operations, ensure that there are no incompatible materials remaining in the containers.

Please also refer to section 8 for recommended protective equipment.

General recommendations on occupational hygiene:

Contaminated clothing must be changed before entering the dining areas.

Do not eat or drink while working.

7.2. Conditions for safe storage, including any incompatibilities

Store at 2-8°C (up to 24 months). Between 5°C and 25°C the product can be stored for 90 days.

Discard if yellow.

Incompatible materials:

None in particular.

Indication for premises:

Suitably ventilated rooms.

7.3. Particular end uses

No particular use

Industry-specific solutions:

No special use

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational Exposure Limits (OELs)

glyoxal...%

CAS: 107-22-2ACGIH Long-term 0.1 mg/m³

Notes: (IFV), DSEN, A4 - URT irr, larynx metaplasia

Long-term 0.1 mg/m³

Notes: (IFV), DSEN, A4 - URT irr, larynx metaplasia

8.2. Exposure controls

Eye protection:

Protective goggles

Skin protection:

Wear clothing that provides total protection for the skin, e.g. cotton, rubber, PVC or viton.

Hand protection:

Use protective gloves that provide full protection, e.g. PVC, neoprene or rubber.

Respiratory protection:

N.A.

Thermal risks:

N.A.

Environmental exposure controls:

N.A.

Technical and Hygiene Measures

N.A.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	pink
Odour:	odourless
pH:	7.10 - 8
Kinematic viscosity:	N.A.
Melting point/freezing point	N.A.
Boiling point or initial boiling point and boiling range:	100 °C (212 °F)
Flash point:	92°C (198 °F)
Lower and upper explosion limit:	N.A.
Relative vapour density:	N.A.
Vapour pressure:	N.A.
Density and/or relative density:	0.95 - 1.05 g/cm ³
Water solubility :	soluble
Solubility in oil:	N.A.
Partition coefficient n-octanol/water (logarithmic value):	N.A.
Self-ignition temperature:	N.A.
Decomposition temperature:	N.A.
Flammability:	N.A.
Volatile Organic Compounds - VOC =	N.A.

Particle characteristics:

Particle size:N.A.

9.2. Other information

No other relevant information

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions

10.2. Chemical stability

Data not available.

10.3. Possibility of dangerous reactions

None.

10.4. Conditions to avoid

Stable under normal conditions.

10.5. Incompatible materials

None in particular.

10.6. Hazardous decomposition products

None.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicological information concerning the product:

- | | |
|--------------------------------|--|
| a) acute toxicity | Not classified
Based on the available data, the classification criteria are not met.
STAmix - Inhalation (Vapours): 550 mg/l |
| b) corrosion/dermal irritation | Not classified
Based on the available data, the classification criteria are not met. |

c) serious eye injuries/irritations	Not classified Based on the available data, the classification criteria are not met.
d) respiratory or skin sensitisation	The product is classified: Skin Sens. 1(H317)
e) germ cell mutagenicity	Not classified Based on the available data, the classification criteria are not met.
f) carcinogenicity	Not classified Based on the available data, the classification criteria are not met.
g) reproductive toxicity	Not classified Based on the available data, the classification criteria are not met.
h) specific target organ toxicity (STOT) - single exposure	Not classified Based on the available data, the classification criteria are not met.
i) specific target organ toxicity (STOT) - repeated exposure	Not classified Based on the available data, the classification criteria are not met.
j) danger in case of aspiration	Not classified Based on the available data, the classification criteria are not met.

Toxicological information on the main substances in the product:

glyoxal...%

CAS: 107-22-2 a) acute toxicity LC50 Inhalation Rat = 2.41 mg/l 4h
LD50 Oral Rat = 2960 mg/kg bw
LD50 Skin Rat <= 800 mg/kg bw

11.2. Information on other dangers

Endocrine-disrupting properties:

No endocrine disruptors present at a concentration \geq 0.1%.

SECTION 12: ecological information

12.1. Toxicity

Use according to good working practices, avoiding dispersal in the environment. Eco-Toxicological Information

List of Eco-Toxicological Properties of the Product

Not classified for environmental hazards

No data available for the product.

12.2. Persistence and degradability

N.A.

12.3. Bioaccumulative potential

N.A.

12.4. Mobility in the soil

N.A.

12.5. Results of PBT and vPvB assessment

No PBT, vPvB substances present at a concentration \geq 0.1%.

12.6. Endocrine-disrupting properties

No endocrine disruptors present at a concentration \geq 0.1%.

12.7. Other adverse effects

N.A.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Operate in accordance with current local and national regulations.

SECTION 14: Transport Information

Not dangerous goods within the meaning of transport regulations.

14.1. UN or ID number

N.A.

4.2. Official UN transport designation

N.A.

4.3. Transport hazard classes

N.A.

4.4. Packaging group

N.A.

4.5. Environmental hazards

N.A.

4.6. Special precautions for users

N.A.

Road and Rail (ADR-RID):

N.A.

Air (IATA):

N.A.

Sea (IMDG):

N.A.

14.7. Maritime transport in bulk according to IMO Acts

N.A.

SECTION 15: Regulatory Information

15.1. Safety, health and environmental regulations specific to the substance or mixture

Legislative Decree 9/4/2008 no. 81

D.M. Lavoro 26/02/2004 (Occupational Exposure Limits)

Regulation (EC) No 1907/2006 (REACH)

Regulation (EC) No 1272/2008 (CLP)

Regulation (EC) No 790/2009 (ATP 1 CLP) and (EU) No 758/2013

Regulation (EU) No 286/2011 (ATP 2 CLP)

Regulation (EU) No. 618/2012 (ATP 3 CLP)

Regulation (EU) No. 487/2013 (ATP 4 CLP)

Regulation (EU) No. 944/2013 (ATP 5 CLP)

Regulation (EU) No. 605/2014 (ATP 6 CLP)

Regulation (EU) No. 2015/1221 (ATP 7 CLP)

Regulation (EU) No. 2016/918 (ATP 8 CLP)

Regulation (EU) No. 2016/1179 (ATP 9 CLP)

Regulation (EU) No. 2017/776 (ATP 10 CLP)

Regulation (EU) No. 2018/669 (ATP 11 CLP)

Regulation (EU) No. 2018/1480 (ATP 13 CLP)

Regulation (EU) No. 2019/521 (ATP 12 CLP)

Regulation (EU) No. 2020/217 (ATP 14 CLP)

Regulation (EU) No. 2020/1182 (ATP 15 CLP)

Regulation (EU) No 2021/643 (ATP 16 CLP)

Regulation (EU) No 2021/849 (ATP 17 CLP)

Regulation (EU) No 2022/692 (ATP 18 CLP)

Regulation (EU) No 2020/878

Restrictions on the product or contained substances according to Annex XVII of Regulation (EC) 1907/2006 (REACH) and subsequent adaptations:

Product restrictions: 3

Restrictions relating to contained substances: 40, 75

Provisions relating to EU Directive 2012/18 (Seveso III):

None

Regulation (EU) No 649/2012 (PIC Regulation)

No listed substance

Water hazard class (Germany).

Class 3: very dangerous.

German 'Lagerklasse' standard according to TRGS 510

LGK 10

SVHC substances:

No SVHC substances present at a concentration $\geq 0.1\%$.

15.2. Chemical Safety Assessment

A chemical safety assessment was not carried out for the mixture.

SECTION 16: other information

Code	Description
H315	Causes skin irritation.
H317	May cause allergic skin reaction.
H319	Causes severe eye irritation.
H332	Harmful if inhaled.
H341	Suspected of causing genetic alterations.

Code	Danger class and category	Description
3.1/4/Inhal	Acute Tox. 4	Acute toxicity (inhalation), Category 4
3.2/2	Skin Irrit. 2	Skin Irritation, Category 2
3.3/2	Eye Irrit. 2	Eye Irritation, Category 2
3.4.2/1	Skin Sens. 1	Sensitisation of the skin, Category 1
3.5/2	Muta. 2	Mutagenicity on germ cells, Category 23

Classification and procedure used to derive it under Regulation (EC) 1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) No 1272/2008

Skin Sens. 1, H317

Classification procedure

Method of calculation

This document has been prepared by a technician who is competent in SDS and has received appropriate training.

Main bibliographical sources

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities

SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van Nostrand Reinold

The information contained herein is based on our knowledge at the date stated above. They refer only to the product indicated and do not constitute a guarantee of any particular quality.

The user is responsible for ensuring the suitability and completeness of this information in relation to the specific use to be made of it.

This sheet cancels and replaces all previous editions.

Key to abbreviations and acronyms used in the safety data sheet:

ACGIH: American Conference of Governmental Industrial Hygienists

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland

Waterways ATE: Acute Toxicity Estimation

ATEmix: Acute Toxicity Estimate (Mixtures)

BCF: Biological Concentration Factor BEI:

Biological Exposure Index

BOD: biochemical oxygen demand

CAS: Chemical Abstracts Service (division of the American Chemical Society).

CAV: Poison Control Centre

EC: European Community

CLP: Classification, Labelling, Packaging

CMR: Carcinogenic, mutagenic, reproductive toxic

COD: Chemical Oxygen Demand

VOC: Volatile Organic Compound

CSA: Chemical Safety Assessment

CSR: Chemical Safety Report

DMEL: Derived level with minimal effect

DNEL: Derived level without effect

DPD: Dangerous Products Directive

DSD: Dangerous Substances Directive

EC50: Median Effective Concentration

ECHA: European Chemicals Agency

EINECS: European Inventory of Existing European Chemical Substances.

ES: Exposure Scenario

GefStoffVO: Hazardous Substances Ordinance in Germany.
GHS: Globally Harmonised System of Classification and Labelling of Chemicals.
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association.
IATA-DGR: Dangerous Goods Regulation of the International Air Transport Association (IATA).
IC50: Medianinhibition concentration
ICAO: International Civil Aviation Organisation.
ICAO-TI: Technical Instructions of the International Civil Aviation Organisation (ICAO).
IMDG: International Maritime Dangerous Goods Code.
INCI: International Nomenclature of Cosmetic Ingredients
IRCCS: Scientific Hospitalization and Care Institutes
KAFH: KAFH
KSt: Explosion coefficient.
LC50: Lethal concentration for 50 per cent of the test population.
LD50: Lethal dose for 50 per cent of the test population.
LDLo: Minimum Lethal Dose
N/A: Not Applicable
N/A: Not determined / not available
NA: Not available
NIOSH: National Institute for Occupational Safety and Hygiene
NOAEL: No Observed Adverse Effect Dose
OSHA: Agency for Safety and Health at Work
PBT: Persistent, Bioaccumulative and Toxic
PGK: INSTR Packing instructions
PNEC: Predicted no-effect concentration.
PSG: Passengers
RID: Regulation concerning the international carriage of dangerous goods by rail.
STEL: Short-term exposure limit.
STOT: Organ-specific toxicity.
TLV: Threshold Limit Value.
TWATLV: Threshold limit value for 8-hour weighted average. (ACGIH Standard).
vPvB: Very persistent and very bioaccumulative
WGK: Water hazard class (Germany).