

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION: CytoCell Fixative

Catalog number: CF001 series

General use: Fixative in frozen section, cytopins and cell culture

Product description: Bi-functional aldehyde in a buffered mixture of water and alcohol

Manufacturer:

BIOCARE Medical

2940 Camino Diablo, Suite 110

Walnut Creek, CA 94597

2. COMPOSITION AND INFORMATION ON INGREDIENTS

(Note: percentage composition is withheld as a trade secret).

Component	CAS#	Exposure Limits
Glyoxal	107-22-2	0.1 mg/m ³ based upon experimental exposure to aerosols-see Section 11
Ethanol	64-17-5	1000 ppm (OSHA 8 hr TWA) 1000 ppm (ACGIH 8 hr TWA)
Buffer (non-toxic)	proprietary	Not established
Water	-	-

3. HAZARDS IDENTIFICATION

Emergency Overview

Clear liquid; colorless to very slightly pale yellow; mild, acidic/alcohol odor. Irritant to eyes and skin. Prolonged or extensive unprotected skin contact may cause allergic skin responses in sensitive individuals. Not likely to pose an inhalation threat under normal conditions of use. Ingestion is likely to cause adverse effects on gastrointestinal tract. In case of a large spill (several gallons or more), or fire, respiratory protection should be worn. Beware of chronic exposure to aerosols.

Potential Health Effects

[Human health effects only; animal effects in Section 11: Toxicological Information]

Primary route(s) of exposure: Eyes and skin. Note: Cell Fix is an effective tissue fixative (preservative); it will kill and preserve living human cells if liquid is allowed to remain in contact with eyes, skin or gastrointestinal system.

Inhalation: Inhalation of vapors during normal conditions of use are not likely to present a health hazard because the solution exhibits almost no vapor pressure due to glyoxal. Breathing vapors from hot solutions is likely to cause irritation of the respiratory tract. No reports of respiratory irritation have been reported due to inhalation of concentrated glyoxal in an industrial setting.

Eye: Contact of liquid with eyes may cause irritation.

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Skin: Extended contact of liquid with skin will cause irritation and may initiate an allergic dermatitis. Brief contact is not likely to produce adverse effects.

Ingestion: Ingestion of liquid is likely to produce adverse effects on the gastrointestinal system. Chronic effects: No chronic effects reported. Glyoxal is not considered to be a carcinogen or potential carcinogen by the National Toxicology Program, the International Agency for Research on Cancer, or OSHA (USA).

Signs and symptoms: Affected skin will appear dry, tough and perhaps cracked. Affected corneas may appear cloudy; eyes may water and become reddened. Effects on the gastrointestinal tract are unknown, but presumably may include nausea and/or vomiting. Effects on the respiratory system are unknown, but presumably may include coughing and difficulty in breathing. There are no pre-existing medical conditions that are known to be aggravated by exposure to this solution.

4. FIRST AID MEASURES

Inhalation: First aid for inhalation exposure is not likely to be needed under foreseeable conditions of use and misuse, except in cases where the solution has been heated. Remove victim to fresh air if coughing or difficulty in breathing is experienced. Consult a physician if symptoms persist or worsen.

Eye: Flush eyes for 30 minutes in an eyewash station before seeking professional assistance. If symptoms persist after washing, consult a physician.

Skin: Remove contaminated clothing, including footwear; wash before reuse. For minor exposure, wash affected area with water and mild soap, rinsing thoroughly. In cases of prolonged, repeated or extensive exposure, rinse affected area or entire body for 20-30 minutes. For mild irritation, apply a good quality skin lotion. For more severe conditions, consult a physician.

Ingestion: Call a poison control center immediately. If victim is conscious, have him/her drink several glasses of water to dilute the solution. Induce vomiting only upon the advice of a physician or poison control authority.

Note to physician: CytoCell Fixative is a histology/cytology fixative. If ingested, it will fix lining cells of the gastrointestinal tract. The solution loses its efficacy as a fixative if the pH is raised to neutrality. In cases of accidental ingestion, neutralization could reduce the risk of damage to the lining; furthermore, neutralization might reduce the risk of damage to the respiratory tract if aspiration occurs during vomiting.

5. FIRE FIGHTING MEASURES

Flammable properties

Flash point: for Cell Fix ~ 103° F (~ 40° C), Closed Cup

Flammable limit: Not available

Autoignition temperature: Not available

Flammability classification: Combustible liquid (OSHA)

Flame propagation: Vapors can travel to source of ignition and flash back to liquid if vapor temperature exceeds flash point. This is likely only under conditions of intense heat.

Hazardous products of combustion: Carbon monoxide and carbon dioxide

Extinguishing media: Use water spray, dry chemical, carbon dioxide or alcohol foam.

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Fire fighting instructions: Firefighters should wear self-contained breathing apparatus and full protective clothing. Use water to cool nearby containers and structures exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Small spills: Wear protective gloves and splash-proof goggles. Use a damp sponge or mop to remove spilled liquid, or contain and solidify spilled liquid with absorbent booms, pillows or loose material. Wash contaminated area with water. Spills left to dry will become sticky. Discard absorbents and other contaminated solids in a receptacle suitable for hazardous chemical waste (they contain a combustible chemical). Liquid waste may be discarded down the drain with approval by wastewater authorities, or may be removed by a licensed waste hauler.

Large spills: A large spill is defined in part by the local situation, especially regarding ventilation. At room temperature in a well-ventilated room, 1-5 gallons might be handled safely without a respirator and could be considered a small spill (see above). At elevated temperature or in a poorly ventilated area, respiratory protection would be advisable; this would constitute a large spill. Evacuate the area and have an emergency response team perform the cleanup. All personnel should use protective gloves, rubber boots, impermeable aprons and full-face respirators. Eliminate all sources of ignition. Recover free liquid if possible and discard down the drain if given approval by wastewater authorities. Alternatively, contain and solidify spilled liquid with absorbent booms, pillows or loose material. Have a licensed waste hauler remove contaminated solids (they contain a combustible chemical). Comply with all applicable governmental regulations on spill reporting and on the handling and disposal of hazardous waste.

7. HANDLING AND STORAGE

Handling: Wear protective gloves and splash-proof goggles when handling this solution. An impermeable apron is also recommended as a prudent measure of protection. Avoid all contact with skin and eyes. Do not continue to wear contaminated clothing after a spill. If the solution is heated, use a fume hood.

Storage: Store in a well-ventilated area, at room temperature, away from heat, sparks and flames.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Engineering controls: General room ventilation is adequate when handling normally anticipated quantities in a laboratory setting. For larger scale exposure, local exhaust (a fume hood) is preferable. Personal protective equipment Respiratory protection: Not needed except under emergency conditions involving a large spill or significant aerosolization of the product, when a full facepiece respirator equipped for organic vapors is recommended. Alternatively, use a self-contained breathing apparatus or supplied-air respirator.

Skin protection: Wear nitrile gloves. Do not use latex surgical gloves for protection against any hazardous liquid. An eyewash station and safety shower should be nearby, preferably in the same room, no more than 100 feet or 10 seconds away.

Eye protection: Wear splash-proof goggles. Do not use safety glasses. If a face shield is worn as protection against biohazards, splash-proof goggles should still be used. Do not wear contact lenses when handling any hazardous chemical.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear; colorless to very slightly pale yellow

Odor: Mild, acidic/alcohol odor

Physical state: Liquid

pH: 4.5 – 5.0

Vapor pressure: Not determined. The vapor pressure due to glyoxal is negligible.

Vapor density: Not determined

Boiling range: 185-220° F (85-104°C)

Freezing point: 32°F (0°C)

Solubility in water: Complete

Specific gravity: 1.003 at 24°C (ready-to-use products); 1.134 at 19°C (concentrate)

10. STABILITY AND REACTIVITY

Chemical stability: Stable.

Conditions to avoid: Heating this solution may give off irritating fumes. Do not heat in a closed system to 200° C (392° F).

Incompatibility with other materials: Strong oxidants will convert glyoxal to formic acid.

Hazardous decomposition products: None

Hazardous polymerization: None

11. TOXICOLOGICAL INFORMATION

[Reports of occupational exposures and details of animal and microbial testing of relevance to humans]

Acute effects: 20 mg of concentrated glyoxal administered into rabbit eyes in the standard Draize test produced severe irritation.

Acute and chronic effects: Contact dermatitis and eczema have been reported in hospital workers who used strong antiseptics containing glyoxal. Symptoms abated when use of these products were discontinued. Workers handling a glyoxal-based resin reported eczema on their hands; fiberglass in the resin could not be ruled out as a contributing factor.

Acute oral effects: OSHA considers chemicals to be toxic if their LD50 is at or below 500 mg/kg. LD50 is the dose killing 50% of the test animals. Glyoxal is not considered to be toxic by OSHA. Using concentrated glyoxal, the LD50 was 760 mg/kg in guinea pigs, and ranged from 1.1 - 4.3 g/kg in rats. In another study the LD50 in rats was 3.08 ml/kg.

Acute and chronic inhalation effects: Inhalation of air saturated with glyoxal vapor for 8 hours was not lethal to rats. Inhalation of aerosols containing glyoxal is harmful but not likely to be encountered in laboratory use. ACGIH has established a TLV-TWA of 0.1 mg/m³ based upon unpublished findings of squamous cell metaplasia in the larynx of rats exposed to 2 mg/m³ to 10 mg/m³ for 6 hours/day, 5 days/week for 29 days.

Subchronic effects: A 90 day feeding study with rats and dogs found no effects on food consumption, mortality and gross or microscopic pathology. The no-observed-effect level for glyoxal in the diet of these animals was 0.12 g/kg/day.

Other chronic effects/carcinogenicity: There is no evidence of cancer or target organ effects deriving from workplace exposures or from reasonably relevant toxicological studies except for contact skin rashes.

Teratology: No data available

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Reproductive effects: No data available

Mutagenicity: Mutagen tests involving microorganisms and mammalian tissue cultures have dubious relevance to workplace exposures. Glyoxal was found to be mutagenic with and without metabolic activation in the Ames bacterial point mutation assay, was genotoxic in the CHO/SCE and primary hepatocyte DNA repair tests. Two whole-animal genotoxic studies have been conducted: the mouse micronucleus test showed no activity at 400 mg/kg; the *Drosophila* sex-linked recessive lethal assay was also negative.

12. ECOLOGICAL INFORMATION

Ecotoxicity: CytoCell Fixative exhibits a low order of environmental toxicity and a low potential to bioaccumulate. There is no inhibition of bacteria in wastewater effluent when glyoxal is properly introduced into an acclimated biological treatment facility. The following data are from studies using concentrated glyoxal:

Cyprinodont fish: LC50 2800 ppm (48 hr); zero mortality at 1000 ppm

Goldfish: >460<680 ppm (96 hr)

Daphnia (freshwater flea): 220 ppm (48 hr)

Daphnia magna : 48 hour static EC50 = 404 mg/liter (practically nontoxic)

Mysid shrimp (saltwater): 160 ppm (96 hr)

Algae: 96 hour EC50 > 500 ppm (practically nontoxic)

Bacteria: EC/LC50 = 133 ppm

Modified OEDD Confirmatory Test, Elimination > 70% (good potential for elimination)

Chemical Oxygen Demand = 350

Biological Oxygen Demand, 5 day = 14-175 mg/g

Environmental fate: All ingredients in Cell Fix consist solely of carbon, hydrogen and oxygen. CytoCell Fixative is readily biodegradable to carbon dioxide and water.

13. DISPOSAL CONSIDERATIONS

Glyoxal itself is not an EPA-listed hazardous waste. In the concentration present in these products, it does not possess any characteristics that qualify it as a hazardous waste by the EPA. It is the ethanol and the pH that qualifies Cell Fix as hazardous waste.

Drain disposal is the recommended method of disposal, based on ecotoxicity and biodegradation information given in Section 12, provided approval is granted by local wastewater treatment authorities. BIOCARE suggests that waste Cell Fix be introduced into the sanitary sewer system slowly, at the rate of 1-5 gallons per hour. To do this, trickle the waste into the sink from a 5-gallon carboy or drum equipped with a spigot that is barely turned on. The normal flow of wastewater through the generator's facility will dilute the waste and render it non-ignitable [flash point > 140° F (60° C)]. However, do not simply add water to the waste; rather, let the normal waste stream from the facility accomplish the dilution. Under this regimen, waste Cell Fix will have no effect on biological or chemical processes at wastewater treatment plants. Neutralization of the pH should not be necessary in most sewer districts, but in the event that it is,

use magnesium oxide or magnesium hydroxide (neither one will make the solution too alkaline). Alternatively, dibasic sodium phosphate may be used in areas where phosphates are not restricted in wastewater. Sodium carbonate and sodium bicarbonate are also effective but may cause foaming. Sodium hydroxide is more hazardous to work with and may make the waste too alkaline.

Canadian disposal regulations generally parallel those in the United States.

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Regardless of the method chosen for disposal, be sure to follow federal, state (provincial) and local regulations. Proper waste disposal is the generator's responsibility.

14. TRANSPORTATION INFORMATION

Ground transportation within the United States: CytoCell Fix is not considered hazardous material when shipped within the United States by ground transportation.

CytoCell Fixative is considered hazardous when shipped by air. Their proper shipping name is "Flammable Liquid, N.O.S. (ethanol)"; they are in Hazard Class 3, Packing Group III; and their identification number is UN 1993.

15. REGULATORY INFORMATION

OSHA (USA): Under the Hazard Communication Standard, CytoCell Fixative is a hazardous material: it is a combustible liquids, irritants and may cause contact dermatitis. That standard and the Laboratory Standard (Occupational Exposure to Hazardous Chemicals in Laboratories) mandate that exposed workers receive proper training in the properties of this product, work practices involved with its handling and disposal, and interpretation of its MSDS. Customers who in turn send this product on to their clients or satellite facilities must supply an MSDS at least with the initial shipment.

FDA (USA): CytoCell Fixative is for in vitro diagnostic use as a fixative in pathology and research laboratories.

EPA (USA): CytoCell Fixative is an ignitable liquid [flash point ~ 103° F (~40° C)] with a pH between 4.5 and 5.0.

WHMIS (Canada):

Class B, Division 3, Combustible liquid

Class D, Division 2, Subdivision B, Materials causing other toxic effects (irritant)

Note: Glyoxal itself is not a WHMIS-controlled substance.

16. OTHER INFORMATION

Label warnings: Irritant. Avoid prolonged, repeated contact with skin. Avoid all contact with eyes. Ingestion can cause damage to the gastrointestinal system.

NFPA (National Fire Protection Association) Rating:

General note: This rating is applicable only to safeguard the lives of individuals who may be concerned with fires occurring in an industrial plant or storage location. It is not descriptive of hazards under normal conditions of industrial use, and is even less applicable to anticipated laboratory-scale use.

Health 2: Materials that are hazardous to health, but areas may be entered freely with full-faced mask self-contained breathing apparatus that provides eye protection.

Flammability 2: Materials that must be moderately heated before ignition will occur. Water spray may be used to extinguish the fire because the material can be cooled below its flash point.

Reactivity 0: Materials that are normally stable even under fire exposure conditions and which are not reactive with water. Normal fire fighting procedures may be used.

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This Material Safety Data Sheet has been prepared in accordance with the requirements of the OSHA Hazard Communication Standard. It conforms to the provisions of the American National Standards Institute (ANSI) Standard Z400.1 (Standard for the Preparation of Material Safety Data Sheets).

Information contained herein was obtained from sources that BIOCARE Medical believes are reliable. It is the user's responsibility to determine suitability of the product for his/her own use, and to assure proper use and disposal of it to protect the safety and health of employees and the protection of the environment.