

1. Identification

Product identifier BioFire[®] COVID-19 Test (30 Pack)

Product Code: 423744

Hazardous Product FilmArray[®] Sample Buffer

Product Code: FAIV-GEN-0003

Recommended Use In vitro diagnostic medical device

Manufacturer/Importer/Supplier/Distributor information

Company name BioFire Defense, LLC

Address 79 West 4500 South, Suite 14, Salt Lake City, Utah 84107, USA

Telephone 801-262-3592

Emergency Telephone number 1-800-424-9300 (Chemtrec) or Call your local Poison Control Center

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 4

Skin corrosion/irritation Category 2

Serious eye damage/eye irritation Category 1

Environmental hazards Hazardous to the aquatic environment, long-term hazard Category 1

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement Very toxic to aquatic life with long lasting effects. Harmful if swallowed. Causes skin irritation. Causes serious eye damage.

Precautionary statement

Prevention Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection.

Response Collect spillage. If skin irritation occurs: Get medical advice/attention. IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. If eye irritation persists: Get medical advice/attention.

Storage Not available.

Disposal Dispose of waste and residues in accordance with local authority requirements.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information 15% of the mixture consists of component(s) of unknown acute oral toxicity. 70% of the mixture consists of component(s) of unknown acute dermal toxicity. 70% of the mixture consists of component(s) of unknown acute inhalation toxicity. 55% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
GUANIDINIUM CHLORIDE		50-01-1	50 - < 60
Triton X100		9002-93-1	10 - < 20
Other components below reportable levels			30 - < 40

4. First-aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. For breathing difficulties, oxygen may be necessary. Call a physician if symptoms develop or persist.
Skin contact	Wash with plenty of soap and water. For minor skin contact, avoid spreading material on unaffected skin. Get medical attention if irritation develops and persists.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most important symptoms/effects, acute and delayed	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Skin irritation. May cause redness and pain.
Indication of immediate medical attention and special treatment needed	Symptoms may be delayed.
General information	Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media	Foam. Powder.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	For personal protection, see section 8 of the SDS. Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation.
Methods and materials for containment and cleaning up	Prevent product from entering drains. Large Spills: Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.
Environmental precautions	Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Do not get this material in contact with eyes. Avoid contact with eyes, skin, and clothing. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits	This mixture has no ingredients that have PEL, TLV, or other recommended exposure limit.
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Provide eyewash station and safety shower.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Avoid contact with eyes. Face shield is recommended. Wear safety glasses with side shields (or goggles). Eye wash fountain is recommended.
Skin protection	
Hand protection	Use protective gloves made of: Nitrile.
Other	Avoid contact with the skin. Wear suitable protective clothing.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Not available.
General hygiene considerations	Wash hands after handling and before eating. Keep away from food and drink.

9. Physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Not available.
Color	Clear colorless or nearly colorless
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.

Oxidizing properties Not oxidizing.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation No adverse effects due to inhalation are expected.

Skin contact Causes skin irritation.

Eye contact Causes serious eye damage.

Ingestion Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Skin irritation. May cause redness and pain.

Information on toxicological effects

Acute toxicity Harmful if swallowed.

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye irritation Causes serious eye damage.

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity Not classifiable as to carcinogenicity to humans.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

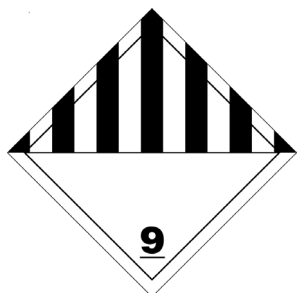
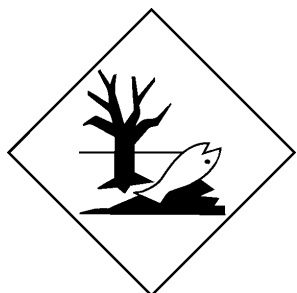
Aspiration hazard Not an aspiration hazard.

12. Ecological information

Ecotoxicity Very toxic to aquatic life with long lasting effects.

Product	Species		Test Results
BioFire® Global Fever Panel – FilmArray® Sample Buffer			
Aquatic			
Fish	LC50	Fish	401.3714 mg/l, 96 hours
Acute			
Fish	LC50	Fish	18.6667 mg/l, 96 hours estimated

Components	Species	Test Results
Triton X100 (CAS 9002-93-1)		
Aquatic		
Acute		
Fish	LC50	Bluegill (Lepomis macrochirus)
		2.8 - 3.2 mg/l, 96 hours
Persistence and degradability	No data is available on the degradability of this product.	
Bioaccumulative potential	No data available.	
Mobility in soil	No data available.	
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.	
13. Disposal considerations		
Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.	
Local disposal regulations	Dispose in accordance with all applicable regulations.	
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.	
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).	
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.	
14. Transport information		
DOT		
UN number	UN3082	
UN proper shipping name	Environmentally hazardous substances, liquid, n.o.s. (Triton X100), MARINE POLLUTANT	
Transport hazard class(es)		
Class	9	
Subsidiary risk	-	
Label(s)	9	
Packing group	III	
Environmental hazards		
Marine pollutant	Yes	
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.	
Special provisions	8, 146, 335, IB3, T4, TP1, TP29	
Packaging exceptions	155	
Packaging non bulk	203	
Packaging bulk	241	
IATA		
UN number	UN3082	
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (Triton X100)	
Transport hazard class(es)		
Class	9	
Subsidiary risk	-	
Packing group	III	
Environmental hazards	Yes	
ERG Code	9L	
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.	
Other information		
Passenger and cargo aircraft	Allowed with restrictions.	
Cargo aircraft only	Allowed with restrictions.	
IMDG		
UN number	UN3082	
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Triton X100), MARINE POLLUTANT	

Transport hazard class(es)**Class** 9**Subsidiary risk** -**Packing group** III**Environmental hazards****Marine pollutant** Yes**EmS** F-A, S-F**Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.**Transport in bulk according to** Not established.**Annex II of MARPOL 73/78 and
the IBC Code****DOT; IATA; IMDG****Marine pollutant****15. Regulatory information****US federal regulations**

All components are on the U.S. EPA TSCA Inventory List.

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous
chemical** Yes**Classified hazard
categories** Acute toxicity (any route of exposure)
Skin corrosion or irritation
Serious eye damage or eye irritation**SARA 313 (TRI reporting)**

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Triton X100 (CAS 9002-93-1)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date June 2023

Version # 01

Disclaimer BioFire Defense, LLC cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.