

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

1.1. Product identifier

1. Identification

Product identifier	BioFire[®] Global Fever Panel
	Product Code: DFA2-ASY-0004
Hazardous Product	FilmArray[®] Sample Buffer
	Product Code: FAIV-GEN-0003
Recommended Use	In vitro diagnostic medical device

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

Identified uses	In vitro diagnostic medical device
Uses advised against	None known.

1.3. Details of the supplier of the safety data sheet

Supplier	
Company name	BioFire Defense, LLC
Address	79 W 4500 S Suite 14 Salt Lake City, Utah, 84107 USA
Telephone	For information call: 1-801-262-3592

1.4. Emergency telephone number	Call your local poison control center
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended

Health hazards

Acute toxicity, oral	Category 4	H302 - Harmful if swallowed.
Skin corrosion/irritation	Category 2	H315 - Causes skin irritation.
Serious eye damage/eye irritation	Category 1	H318 - Causes serious eye damage.

Environmental hazards

Hazardous to the aquatic environment, acute aquatic hazard	Category 1	H400 - Very toxic to aquatic life.
Hazardous to the aquatic environment, long-term aquatic hazard	Category 1	H410 - Very toxic to aquatic life with long lasting effects.

Hazard summary	Causes serious eye damage. Harmful if swallowed. Risk of serious damage to eyes. Irritating to skin. Causes skin irritation. Dangerous for the environment if discharged into watercourses. Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
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2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Contains: guanidinium chloride; guanadine hydrochloride, Triton X100

Hazard pictograms



Signal word Danger

Hazard statements

H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.

Precautionary statements

Prevention

P273 Avoid release to the environment.
P280 Wear eye protection/face protection.

Response

P391 Collect spillage.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313 If skin irritation occurs: Get medical advice/attention.
P301 + P312 IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell.
P337 + P313 If eye irritation persists: Get medical advice/attention.

Storage Not available.

Disposal Not available.

Supplemental label information None.

2.3. Other hazards This mixture does not meet vPvB / PBT criteria of Regulation (EC) No 1907/2006, Annex XIII.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	Index No.	Notes
guanidinium chloride; guanadine hydrochloride	50 - < 60	50-01-1 200-002-3	01-2119977063-35-XXXX	607-148-00-0	
Classification: Acute Tox. 4;H302;(ATE: 500 mg/kg), Skin Irrit. 2;H315, Eye Irrit. 2;H319					
Triton X100	10 - < 20	9002-93-1	-	-	
Classification: Eye Dam. 1;H318, Aquatic Chronic 2;H411					
Other components below reportable levels	30 - < 40				

List of abbreviations and symbols that may be used above

DSD: Directive 67/548/EEC.
CLP: Regulation No. 1272/2008.
#: This substance has been assigned Union workplace exposure limit(s).
#: This substance has been assigned Community workplace exposure limit(s).
M: M-factor
PBT: persistent, bioaccumulative and toxic substance.
vPvB: very persistent and very bioaccumulative substance.
All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments The full text for all H-statements is displayed in section 16. The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information If you feel unwell, seek medical advice (show the label where possible). Show this safety data sheet to the doctor in attendance.

4.1. Description of 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 CENTRE 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.

4.2. Most important symptoms and effects, both acute and delayed Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Irritating to mouth, throat, and stomach. Skin irritation. May cause redness and pain.

4.3. Indication of any immediate medical attention and special treatment needed

Symptoms may be delayed.

SECTION 5: Firefighting measures

General fire hazards

No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media

Foam. Powder.

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures

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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear appropriate personal protective equipment.

For emergency responders

Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions

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. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. 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.

Never return spills to original containers for re-use.

6.4. Reference to other sections

For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Do not breathe vapour. 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.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s)

Not available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures

Follow standard monitoring procedures.

Derived no effect levels (DNELs)

Not available.

Predicted no effect concentrations (PNECs)

Not available.

8.2. Exposure controls

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	
General information	Use personal protective equipment as required. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Eye wash fountain is recommended.
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.
Hygiene measures	When using, do not eat, drink or smoke. Wash hands after handling and before eating.
Environmental exposure controls	Inform appropriate managerial or supervisory personnel of all environmental releases. Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. Fume scrubbers, filters or engineering modifications to the process equipment may be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid.
Colour	Clear colorless or nearly colorless
Odour	Not available.
Melting point/freezing point	Not available.
Boiling point or initial boiling point and boiling range	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Flash point	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
pH	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Particle characteristics	Not available.
Other safety characteristics	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.

10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	No hazardous decomposition products are known.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
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	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Irritating to mouth, throat, and stomach. Skin irritation. May cause redness and pain.

11.1. 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 sensitisation	Due to partial or complete lack of data the classification is not possible.
Skin sensitisation	Due to partial or complete lack of data the classification is not possible.
Germ cell mutagenicity	Due to partial or complete lack of data the classification is not possible.
Carcinogenicity	Due to partial or complete lack of data the classification is not possible.
Reproductive toxicity	Due to partial or complete lack of data the classification is not possible.
Specific target organ toxicity - single exposure	Due to partial or complete lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Due to partial or complete lack of data the classification is not possible.
Aspiration hazard	Due to partial or complete lack of data the classification is not possible.
Mixture versus substance information	No information available.

11.2. Information on other hazards

Endocrine disrupting properties	Not available.
Other information	Not available.

SECTION 12: Ecological information

12.1. Toxicity Very toxic to aquatic life with long lasting effects.

Product	Species		Test Results
BioFire® Respiratory Panel 2.1 <i>plus</i> (RP2.1 <i>plus</i>) - Sample Buffer			
Aquatic			
Fish	LC50	Fish	401.3714 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

12.2. Persistence and degradability No data is available on the degradability of this product.

12.3. Bioaccumulative potential No data available.

Partition coefficient n-octanol/water (log Kow) Not available.

Bioconcentration factor (BCF) Not available.

12.4. Mobility in soil No data available.

12.5. Results of PBT and vPvB assessment This mixture does not meet vPvB / PBT criteria of Regulation (EC) No 1907/2006, Annex XIII.

12.6. Endocrine disrupting properties	Not available.
12.7. 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.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	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). Avoid discharge into water courses or onto the ground.
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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company. Waste codes should be assigned by the user based on the application for which the product was used.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations. This statement only applies to countries within the EU with regard to the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC 1907/2006): It is recommended that all material associated with the test, including material used to clean up spills, contaminated packaging, and/or unused and expired IVD tests, is incinerated. Please ensure that you follow local regulations regarding disposal.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

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
Transport hazard class(es)	
Tunnel restriction code	E
Label(s)	9
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Transport hazard class(es)	
Hazard No. (ADR)	90

RID

14.1. UN number	UN3082
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Triton X100)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
14.4. Packing group	III
14.5. Environmental hazards	Yes
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

ADN

14.1. UN number	UN3082
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Triton X100)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
14.4. Packing group	III
14.5. Environmental hazards	Yes

14.6. Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IATA

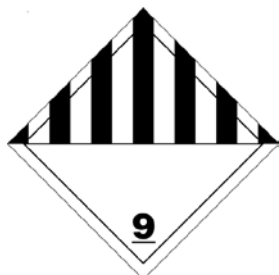
UN number UN3082
UN proper shipping name Environmentally hazardous substance, liquid, n.o.s. (Triton X100)
Transport hazard class(es)
class 9
Subsidiary risk -
Packing group III
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.
Environmental hazards Yes
ERG Code 9L

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.
Not established.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

ADN; ADR; IATA; IMDG; RID



Marine pollutant



SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EU) 2019/1021 On persistent organic pollutants (recast), as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Triton X100 (CAS 9002-93-1)

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Triton X100 (CAS 9002-93-1)

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Triton X100 (CAS 9002-93-1)

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended.

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Not listed.

Other regulations

This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. The product is classified and labelled in accordance with EC directives or respective national laws. The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended.

National regulations

Follow national regulation for work with chemical agents in accordance with Directive 98/24/EC, as amended.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

Not available.

References

Not available.

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any H-statements not written out in full under Sections 2 to 15

H302 Harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H411 Toxic to aquatic life with long lasting effects.

Revision information

None.

Training information

Follow training instructions when handling this material.

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.