

Cat Nos: BLH 700-20, BLH 701-20; BLH 703-20, BLH 704-20, BLH 706-20;

Reference No.: SDS 04372

Revision Date: Aug 21<sup>th</sup>, 2020

## SECTION 1 - Kit / Preparation and Company Identification

- 1.1 **bioavid Lateral Flow for Allergen Detection** in vitro test only  
The bioavid rapid tests for allergen detection allow for the rapid, qualitative detection of allergen residues in food and environmental samples from swabs or from extracts made from finished products; The test is intended for use as an aid in the hygiene monitoring in food production.
- 1.2 **Manufacturer:** bioavid Diagnostics GmbH & Co. KG, Mikroforum Ring 1, 55234 Wendelsheim, Germany  
**Telephone No.:** +49 6734 9625876 **Fax No.:** +49 6734 96252882
- 1.4 **Emergency No.:** Poison Control Center Mainz: +49 6131 19240 (Germany only)

## SECTION 2 - Hazard Identification

**GHS classification in accordance with 29 CFR 1910.1200, (EC) No 1272/2008, 67/548/EEC or Directive 1999/45/EC**

No hazardous substances or mixtures.

**GHS label elements**

Not a hazardous substance or mixture.

**Other hazards**

None known

## SECTION 3 - Composition / Ingredients Information

**Description of Components:** Test Strips, Reagent Vials, Dropper Bottle with Running Buffer, Positive Control Vial

- 3.1 **Hazardous Ingredients:** Dangerous solid or liquid substances present in >1% (or as required by applicable U.S., Canadian and E.U. regulations):

CAS #	EINECS	Chemical Name	Kit Component	%Weight	Classification				
					US OSHA	WHMIS	EU	Risk Phrases	
No hazardous substances greater than 1% are contained within this kit									

## SECTION 4 - First Aid Measures

### Special Instructions:

**General** Do not leave victims unattended.

- 4.1 **Inhalation** Inhalation of any component in this kit is unlikely.
- 4.2 **Eye Contact** If components of this kit enter the eyes and cause discomfort, gently wash eyes under potable running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.
- 4.3 **Skin Contact** If components of this kit contact the skin and causes discomfort, remove any contaminated clothing. Wash affected area with plenty of soap and water. If pain or irritation occurs, obtain medical attention.
- 4.4 **Ingestion** If a component of this kit is ingested, wash mouth out with water. If irritation or discomfort occurs, obtain medical attention.

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## SECTION 5 - Fire Fighting Measures

- 5.1 Extinguishing Media:** For small fires, use dry chemical, carbon dioxide, or foam.
- 5.2 Special Fire Fighting Procedures:** This material will not significantly contribute to the intensity of a fire. Use extinguishing material suitable to the surrounding fire. Utilize proper personal protective equipment when responding to any fire. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.
- 5.3 Unusual Fire and Explosion Hazards:** When involved in a fire, this material can decompose and produce irritating fumes and toxic gases (e.g., Carbon monoxide, Carbon dioxide).
- Explosion Sensitivity to Mechanical Impact: Not sensitive under normal conditions.  
Explosion Sensitivity to Static Discharge: Not sensitive under normal conditions.
- 5.4 Additional Considerations:**
- |       |                               |                 |
|-------|-------------------------------|-----------------|
| 5.4.1 | Flash Point                   | Non-combustible |
| 5.4.2 | Auto-ignition Temperature     | Not available   |
| 5.4.3 | Upper / Lower Explosion Limit | Not available   |

**5.5 NFPA Ratings (see 'Definition of Terms' for explanation of numerical ratings):**

**bioavid Diagnostics Allergen Detection Kits**

Flammability	0
Health	0
Reactivity	0

*"Only trained and competent personnel shall attempt to extinguish a fire. Contact emergency response personnel as required. Be cautious of surrounding materials that may react with the extinguishing media."*

## SECTION 6 - Accidental Release Measures

- 6.1 Personal Precautions:** This kit contains materials of biological origin. Avoid personal contact. Use Universal Precautions during clean-up procedures.
- 6.2 Environmental Precautions:** No environmental hazard is anticipated provided that the material is handled and disposed of with due care. Contain spill to prevent migration.
- 6.3 Spill and Leak Procedures:** Large spills of this kit are unlikely. Utilize safety glasses, nitrile gloves, and lab coat/apron when responding to spills involving the components of this kit.

## SECTION 7 - Handling and Storage

- 7.1 Handling:** As with all chemicals, avoid getting components within this kit on you or in you. Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. This kit should be handled as though capable of transmitting infectious diseases. Universal Precautions should be followed when using this kit.  
***Not for use by the general public.***
- 7.2 Storage:** To maintain efficacy, store according to the package insert instructions.
- 7.3 Specific Use:** ***For in vitro diagnostic use only - Not for use by general public!***

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## SECTION 8 - Exposure Control and Personal Protection

**8.1 Exposure Limits:** Not available

**8.2 Occupational Exposure Controls:**

**8.2.1 Engineering Controls:**

No special engineering controls are required when working with this kit. Use with adequate ventilation to ensure exposure levels are maintained below the limits provided above.

**8.2.2 Personal Protective Equipment (PPE):**

Respiratory Protection: None needed under normal conditions of use.

Eve Contact: Safety glasses or face shield are recommended to prevent eye contact.

Hand Contact: Impervious gloves (nitrile or equivalent) should be worn to prevent hand contact.

Skin Contact: Lab Coat or similar garment should be worn.

**8.2.3 Environmental Controls:** No special environmental controls are required.

## SECTION 9 - Physical and Chemical Properties

Characteristic	Reaction Vial Positive Control Vial	Running Buffer	Test Stripes
Boiling Point (°C)	Not available	Not available	Not available
Melting Point (°C)	Not available	Not available	Not available
Specific Gravity	Not available	Not available	Not available
Vapor Pressure (mm Hg)	Not available	Not available	Not available
Vapor Density (AIR = 1)	Not available	Not available	Not available
Evaporation Rate (Ether = 1)	Not available	Not available	Not available
pH:	Neutral	Neutral	Neutral
Solubility in Water:	Soluble	Soluble	Not soluble
Appearance and Odor:	White or yellowish, turbid or clear pellet; dry, odorless	Yellowish liquid buffer with detergent; odorless	Test Stripes ca. 5 mm wide, plastic backing, white
Stability	Stable	Stable	Stable
Conditions to Avoid	Incompatible materials	Incompatible materials	Incompatible materials
Materials to avoid (Incompatibilities)	None known	None known	None known
Hazardous Decomposition or Byproducts	Thermal decomposition may release toxic fumes of CO and CO <sub>2</sub>	Thermal decomposition may release toxic fumes of CO and CO <sub>2</sub>	Thermal decomposition may release toxic fumes of CO and CO <sub>2</sub>
Hazardous Polymerization	None known	None known	None known

## SECTION 10 – Stability and Reactivity

**Stability:** Stable under recommended storage conditions.

**Polymerization:** None under normal processing.

**Hazardous decomposition products:** Thermal decomposition can lead to release of irritating gases and vapours.  
Carbon monoxide.

**Materials to avoid:** Incompatible with strong acids and bases. Oxidising agents (strong).

## SECTION 11 - Toxicological Information

### 11.1 Toxicity Data for Hazardous Ingredients:

There are currently no toxicity data available for the components contained within this kit.

### 11.2 Primary Routes of Exposure:

**Overexposures to components within this kit are not expected.** Common routes of exposure may include ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with eyes, contact with mucous membranes and inhalation of aerosolized material.

### 11.3 Potential Effects of Acute Overexposure, By Route Of Exposure:

This kit contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

**INHALATION:** Vapors, mists, sprays, or dusts of this kit may cause irritation to the respiratory tract.

**CONTACT WITH SKIN or EYES:** Contact may cause eye or skin irritation.

**SKIN ABSORPTION:** Skin absorption unlikely for intact skin.

**INGESTION:** If components of this kit are swallowed, irritation of the mouth, throat, and other tissues of the gastro-intestinal system may occur.

**INJECTION:** Accidental injection with components of this kit is highly unlikely. In the rare event an injection occurs, the puncture point may experience burning, reddening, and swelling in addition to the wound. Symptoms of such exposure can include those described under "Inhalation", "Contact with Skin or Eyes", and "Ingestion".

### 11.4 Potential Effects of Chronic Exposure:

Long-term skin or eye contact may result in dermatitis or eye irritation.

### 11.5 Symptoms of Overexposure:

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for these kits.

### 11.6 Medical Exposure Aggravated by Exposure:

Persons with pre-existing skin disorders, eye problems or impaired respiratory system function can be more susceptible to health effects associated with overexposures to components within these kits.

### 11.7 Carcinogenicity:

To the best of our knowledge, these kits do not contain any substances that are listed by ACGIH, IARC, NTP or California Prop 65.

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## SECTION 12 - Ecological Information

### 12.1 Ecotoxicity - Not Available

No adverse effects on the environment are expected from the components of these kits. There is no aquatic toxicity data for these kits at this time.

### 12.2 Mobility

Mobility data are not available for the components of these kits.

### Persistence and Degradability

There is no persistence or degradation data for any component of these kits at this time.

### 12.3 Bioaccumulative Potential

There is limited potential for the components within these kits to accumulate in plant or animal systems.

## SECTION 13 - Disposal Considerations

Dispose of waste materials, unused components and contaminated packaging in compliance with country (i.e., Canada, EU, etc.), federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

## SECTION 14-Transport Information

### 14.1 U.S. Transportation, Canadian Transportation, and International Air Transportation

These kits are not regulated for transport.

## SECTION 15 - Regulatory Information

### 15.1 U.S. Federal and State Regulations

	bioavid Lateral Flow Allergen Detection Test Kit
40 CFR 355.30/355.40 - SECTION 302	Not Listed
40 CFR 302.4 - SECTION 304	Not Listed
40 CFR 372.65 - SECTION 313	Not Listed

U.S. SARA SECTION 311/312 FOR KIT: \_\_\_\_\_ Not applicable

U.S. TSCA INVENTORY STATUS: \_\_\_\_\_ Not applicable

OTHER U.S. FEDERAL REGULATIONS: \_\_\_\_\_ Not applicable

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROP 65): None

CALIFORNIA - 8 CCR SECTION 339 - DIRECTOR'S LIST OF HAZARDOUS SUBSTANCES: None

### 15.2 Label Information-ANSI Z129.1: Not applicable

#### ENVIRONMENTAL HAZARDS:

Do not discharge effluent containing components of these kits into streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. For guidance, contact your State Water Board or Regional Office of the EPA.

### 15.3 EU Labeling Classification:

Not applicable

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**15.4 Japan - Existing and New Chemical Substances (ENCS):** None

**15.5 Canadian Regulations:**

CANADIAN DSL/NDSL INVENTORY STATUS:

The components of these kit are not listed on the DSL Inventory.

CANADIAN WHMIS SYMBOLS: Not applicable

**SECTION 16 - Other Information**

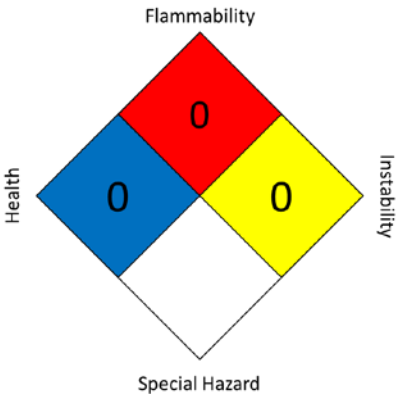
**16.1 HMIS Ratings (See 'Definition of Terms' for explanation of numerical ratings):**

**bioavid Diagnostics Lateral Flow Allergen Detection Test Kits**

Health	/	0
Flammability	0	0
Physical Hazard	0	0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**16.2 NFPA**



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This MSDS has been prepared in accordance with ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the US OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

The hazard ratings on this MSDS are for appropriately trained workers using the Hazardous Materials Identification System (HMIS®) or a National Fire Protection Association (NFPA) 704 Program. The ratings are estimates and should be treated as such. The hazard rating scales range from (0) minimal hazards to (4) significant hazards or risks (Refer to Definitions of Terms at the end of this MSDS). Chronic (long-term) health effects are indicated in the HMIS by an asterisk (\*). HMIS is a registered trade and service mark of the NPCA. For details on HMIS ratings visit [www.paint.org/hmis](http://www.paint.org/hmis). For details on NFPA 704 visit [www.nfpa.org](http://www.nfpa.org).

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# Safety Data Sheet

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### DEFINITIONS OF TERMS

A large number of abbreviations and acronyms appear on a MSDS. Some of these, which are commonly used, include the following:

CAS #: This is the Chemical Abstract Service Number that uniquely identifies each compound.

**ACGIH** - American Conference of Governmental Industrial Hygienists, a professional association that establishes exposure limits.

**TLV** - Threshold Limit Value - an airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers can be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour Time Weighted Average (**TWA**), the 15-minute Short Term Exposure Limit, and the instantaneous Ceiling Level (**C**). Skin absorption effects must also be considered.

**OSHA** - U.S. Occupational Safety and Health Administration PEL - Permissible Exposure Limit - This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL," is placed next to the PEL that was vacated by Court Order.

**IDLH** - Immediately Dangerous to Life and Health - This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury. **The DFG - MAK** is the Republic of Germany's Maximum Exposure Level, similar to the U.S. PEL. **NIOSH** is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (OSHA). NIOSH issues exposure guidelines called Recommended Exposure Levels (RELs). When no exposure guidelines are established, an entry of NE is made for reference **Protective Equipment - A**: Safety Glasses. **B**: Safety glasses and gloves. **C**: Safety glasses, gloves and body protection. **D**: Splash goggles with face shield, gloves and body protection. **E**: Eye protection, gloves and dust mask respiratory protection. **F**: Eye protection, gloves, body protection and dust mask respiratory protection. **G**: Eye protection, gloves and air purifying respiratory protection.

#### HAZARD RATINGS:

**HAZARDOUS MATERIALS IDENTIFICATION SYSTEM:** Health Hazard: 0 (minimal acute or chronic exposure hazard); 1 (slight acute or chronic exposure hazard); 2 (moderate acute or significant chronic exposure hazard); 3 (severe acute exposure hazard; onetime overexposure can cause permanent injury and can be fatal); 4 (extreme acute exposure hazard; single overexposure can be fatal). \* Indicates chronic hazard. Flammability Hazard: 0 (minimal hazard); 1 (materials that require substantial pre-heating before burning); 2 (combustible liquid or solids; liquids with a flash point of 38-93°C [100-200°F]); 3 (Class IB and 1C flammable liquids with flash points below 38°C [100°F]); 4 (Class IA flammable liquids with flash points below 23°C [73°F] and boiling points below 38°C [100°F]). Reactivity Hazard: 0 (normally stable); 1 (material that can become unstable at elevated temperatures or which can react slightly with water); 2 (materials that are unstable but do not detonate or which can react violently with water); 3 (materials that can detonate when initiated or which can react explosively with water); 4 (materials that can detonate at normal temperatures or pressures).

**NATIONAL FIRE PROTECTION ASSOCIATION:** Health Hazard: 0 (material that on exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials); 1 (materials that on exposure under fire conditions could cause irritation or minor residual injury); 2 (materials that on intense or continued exposure under fire conditions could cause temporary incapacitation or possible residual injury); 3 (materials that can on short exposure could cause serious temporary or residual injury); 4 (materials that under very short exposure could cause death or major residual injury). Flammability Hazard and Reactivity Hazard: Refer to definitions for "Hazardous Materials Identification System".

**FLAMMABILITY LIMITS IN AIR:** Much of the information related to fire and explosion is derived from the National Fire Protection Association (NFPA). Flash Point - Minimum temperature at which a liquid gives off sufficient vapors to form an ignitable mixture with air. Autoignition Temperature: The minimum temperature required to initiate combustion in air with no other source of ignition. LEL - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. UEL - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. **TOXICOLOGICAL INFORMATION:**

Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: **LD<sub>50</sub>** - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; **LC<sub>50</sub>** - Lethal Concentration (gases) which kills 50% of the exposed animals; **ppm** concentration expressed in parts of material per million parts of air or water; **mg/m<sup>3</sup>** concentration expressed in weight of substance per volume of air; **mg/kg** quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include **TDLo**, the lowest dose to cause a symptom and **TCLo** the lowest concentration to cause a symptom; **TDo**, **LDLo**, **LDo**, **TC**, **TCo**, **LCLo**, and **LCo**, the lowest dose (or concentration) to cause lethal or toxic effects. **BEI** - Biological Exposure Indices, represent the levels of determinants that are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV. **Ecological Information:** EC is the effect concentration in water.

Data from several sources are used to evaluate the cancer-causing potential of the material. The sources and ratings are: **IARC** - the International Agency for Research on Cancer; 1 = Carcinogenic to humans, 2A, 2B = Probably carcinogenic to humans, 3 = Unclassifiable as to carcinogenicity in humans, and 4 = Probably not carcinogenic to humans. **NTP** - the National Toxicology Program; K = Known to be a human carcinogen, and R = Reasonably anticipated to be a human carcinogen. **RTECS** - the Registry of Toxic Effects of Chemical Substances. **OSHA** - Occupational Safety and Health Administration and **CAUSHA** - California's subunit of the Occupational Safety and Health Administration; Ca = Carcinogen defined with no further categorization. **ACGIH** - American Conference of Governmental Industrial Hygienists; A1 = Confirmed human carcinogen, A2 = Suspected human carcinogen, A3 = Confirmed animal carcinogen with unknown relevance to humans, A4 = Not classifiable as a human carcinogen, and A5 = Not suspected as a human carcinogen. **NIOSH** - U.S. National Institute for Occupational Safety and Health; Ca = Potential occupational carcinogen, with no further categorization. **EPA** - U.S. Environmental Protection Agency; A = Human carcinogen, B = Probable human carcinogen, C = Possible human carcinogen, D = Not classifiable as to human carcinogenicity, E = Evidence of Non-carcinogenicity for humans, K = Known human carcinogen, L = Likely to produce cancer in humans, CBD = Cannot be determined, NL = Not likely to be carcinogenic in humans, and I = Data are inadequate for an assessment of human carcinogenic potential.

#### REGULATORY INFORMATION:

This section explains the impact of various laws and regulations on the material. **EPA** is the U.S. Environmental Protection Agency. **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **DOT** and **TC** are the U.S. Department of Transportation and the Transport Canada, respectively.

**Superfund Amendments and Reauthorization Act (SARA)**; the Canadian Domestic/Non-Domestic Substances List (**DSUNDSL**); the U.S. Toxic Substance Control Act (**TSCA**); Marine Pollutant status according to the DOT; the Comprehensive Environmental Response, Compensation, and Liability Act (**CERCLA** or **Superfund**); and various state regulations. This section also includes information on the precautionary warnings that appear on a material's industrial package label.