

1. Identification of the substance/preparation and of the Company/Undertaking

1.1 Product identifiers

Product name

I'screen AFLA M₁ – HU0040002

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

In vitro diagnostic kit.

1.3 Company/Undertaking identification

Eurofins Technologies Hungary Kft.

Fóti út 56. A épület

1047 Budapest

Hungary

e-mail: technologies.hu@eurofins.com

1.4 Emergency telephone

Please, contact your local Poison Centre

2. Hazards Identification

2.1 Classification: Known hazardous components according to Regulation (EC) No. 1272/2008: **stop solution** (sulfuric acid, 5≤x<15% wt/wt), classified as corrosive to the skin (category 1A) and **extraction buffer** (methanol, 10<x<20% wt/wt), classified as flammable liquid (category 3), acute toxicity, inhalation (category 4), acute toxicity, dermal (category 4), acute toxicity, oral (category 4), specific target organ toxicity - single exposure (category 1).

2.2 Label elements

Pictogram



Extraction Buffer



Stop solution

Hazard Class and
Category

Flam Liq. 3
Acute Tox. 4
STOT SE 1

Skin Corr. 1A

Signal word

Danger (Dng)

Danger (Dng)

Hazard statements

H226
H302 + H312 + H332
H370

H314

Precautionary
statements

P260
P280
P307+P311

P260
P264
P280
P301+P330+P331
P303+P361+P353
P363
P304+P340
P310
P305+P351+P338
P405
P501

Hazard statements and precautionary statements full text in section 16.

2.3 Supplemental Hazard – none.

3. Composition/information on ingredients

Component	Hazardous substance	% (wt/wt)	Component classification	CAS No.	EC No.
Microtiter plate	-	-	<u>non-hazardous</u>	-	-
Standard Aflatoxin M ₁	Sodium azide	< 0,1%	Acute Tox. 2 Aquatic Acute 1 Aquatic Chronic 1	26628-22-8	247-852-1
	Aflatoxin M ₁	<0,01%	Acute Tox. 2 Carc. 1B	6795-23-9	229-865-4
Enzyme Conjugate	-	-	<u>non-hazardous</u>	-	-
Washing buffer 20x	-	-	<u>non-hazardous</u>	-	-
Extraction Buffer	Methanol	10%<x>20%	Flam. Liq. 2 Acute Tox. 3 STOT SE 1	67-56-1	200-659-6
Developing solution	Citric acid	< 5%	Eye Irrit. 2	77-92-9	201-069-1
Stop solution, 15ml	Sulfuric acid	5≤x<15% (1M)	Skin Corr. 1A	7664-93-9	231-639-5

4. First Aid Measures

4.1 Description of first aid measures

If inhaled: there is a minimal risk of inhalation. In case there appear to be symptoms of exposure, supply fresh air. Monitor respiration. If breathing becomes difficult, consult a doctor and give oxygen. Get medical aid.

In case of skin contact: immediately flush with large amounts of water and soap. Remove all contaminated clothing and wash them before reusing. In presence of irritation, get medical aid.

In case of eye contact: flush eyes with large amounts of water for at least 15 minutes. Insure adequate washing by keeping eyelids open with fingers. Get medical aid.

If swallowed: STOP SOLUTION and EXTRACTION BUFFER: DO NOT induce vomit. Do not administer anything if victim is unconscious. Rinse mouth with water. Get medical aid.

4.2 Most important symptoms and effects, both acute and delayed

See section 2.2 and section 11.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5. Firefighting Measures

Extraction buffer is flammable. Risks derived from fire are reduced thanks to small volume of material. Other kit components are not flammable.

5.1 Extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. Keep surrounding materials cool with water spray.

5.2 Special hazards arising from the mixture: Stop solution: sulphur oxides. Extraction buffer: carbon oxides.

5.3 Advice for firefighters: in case of fire, if necessary, wear approved self-contained breathing apparatus and appropriate protective clothing.

5.4 Further information: Keep surrounding materials cool with water spray.

6. Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures:

The small supplied volumes and packaging insure minimal risk of accidental release. In case of spill, wear protective clothing as indicated in section 8. Ensure adequate ventilation.

6.2 *Environmental precautions:* avoid seepage into water course or sewage system.

6.3 *Methods and materials for containment and cleaning up:* Absorb spill with inert absorbent material or absorbent paper. Discard all material into biohazard waste collection container for proper disposal. Wash the contaminated area taking care to avoid seepage into water course or sewage system.

6.4 *Further information:* see section 13 for disposal.

7. Handling and Storage

7.1 *Precautions for safe handling*

There are not special warnings if used according to instruction. Avoid skin and eyes contact. Avoid inhalation of vapour or mist. Wear appropriate personal protective equipment as specified in section 8. For extraction buffer: Take measures to prevent the build-up of electrostatic charge.

7.2 *Conditions for safe storage, including any incompatibilities*

Keep products tightly sealed in their original containers. Store the bottles between +2°C and +8°C. Avoid physical damage to containers. Do not expose to heat or direct light.

The packaging guarantees the component isolation from incompatible material.

7.3 *Specific end uses*

In vitro diagnostic reagents, as described in section 1.2.

8. Exposure Controls/Personal Protection

8.1 *Control parameters*

Components with workplace control parameters.

Exposure workplace limit values for sulfuric acid (data refer to pure substance): 0,05 mg/m³ (TWA).

Exposure workplace limit values for sodium azide (data refer to pure substance): 0,1 mg/m³ (TWA), 0,3 mg/m³ (STEL).

Exposure workplace limit values for methanol (data refer to pure substance): 200 ppm; 260 mg/m³(TWA).

Possible absorption through skin.

8.2 *Exposure controls:* Adhere to instructions and good laboratory practice. Use disposable latex or nitrile rubber gloves and protective lab coat. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Have emergency shower and eye wash stations available. Always avoid direct contact of the solution with eyes, skin and clothing. Avoid inhalation. Avoid prolonged or repeated exposure.

9. Physical and Chemical Properties

Microtiter plate	polystyrene plastic material, 96-wells breakable (or 48-wells) microtiter plate (12 strips each of 8 wells)
Aflatoxin M ₁ Standard	liquid, white, odour characteristic
Enzyme Conjugate	liquid, colour pink, odourless
Extraction Buffer	liquid, colourless, odour characteristic
Washing buffer 20x	liquid, colourless, odourless
Developing solution	liquid, colourless, odourless
Stop solution	liquid, colourless, viscous, odour characteristic

10. Stability and reactivity

10.1 *Reactivity:* no data available.

10.2 *Chemical stability:* stable under the conditions for storage and handling described in the instructions. Keep in their original containers.

10.3 Possibility of hazardous reactions: no data available.

10.4 Conditions to avoid: heat, flame, sparks, direct light, incompatible materials.

10.5 Incompatible materials: Aflatoxin M₁ standards: metals. Stop solution: bases, halides, organic materials, carbides, nitrates, picrates, cyanides, chlorates, alkali halides, zinc salts, permanganates, hydrogen peroxide, azides, perchlorates, nitromethane, phosphorous, cyclopentadiene, cyclopentanone oxime, nitroaryl amines, hexalithium disilicide, phosphorous(iii) oxide, powdered metals. Extraction buffer: acids, oxidizing agents, alkali metals, acid chlorides, acid anhydrides, reducing agents.

10.6 Hazardous decomposition products: no data available.

11. Toxicological Information

11.1 Information on toxicological effects

Extraction buffer is harmful if inhaled, if swallowed and if absorbed through skin. It may cause skin, eye and respiratory tract irritation. It has specific target organ toxicity - single exposure (category 1).

Methyl alcohol may be fatal or cause blindness if swallowed. Effects due to ingestion may include: headache, dizziness, drowsiness, metabolic acidosis, coma, seizures. Symptoms may be delayed. Target organ: liver, kidney.

Further information: RTECS: PC1400000 (methanol).

Stop solution is classified as corrosive to the skin (category 1A).

Causes severe skin burns and eye damage.

Toxicological properties have not been further investigated.

Further information: RTECS: WS5600000 (sulfuric acid).

12. Ecological Information

The components are furnished in volumes that do not represent hazard for the environment if used and disposed of correctly.

This product contains no components considered to be either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

13. Disposal Considerations

Use the components according to good laboratory practice. Avoid release to the environment. Do not allow product to reach sewage system. Observe all international and local environmental regulations. Send surplus and non-recyclable solutions to a licensed disposal company.

14. Transport Information

Though some components are mentioned in legislation on transport of hazardous goods (methanol, UN1230 and sulphuric acid, with not more than 51% pure acid, UN2796), the volumes and the types of containers used with this product are such that this product is exempt from these norms.

15. Regulatory Information

This safety data sheet is in accordance with Regulation (EC) No. 1907/2006 and Regulation No. 453/2010.

16. Other information

Hazard statements and precautionary statements full text

Full text of H-Statements referred to sections 2 and 3

H314: Causes severe skin burns and eye damage
H226: Flammable liquid and vapour
H302+H312+H332: Harmful if swallowed, in contact with skin or if inhaled
H370: Causes damage to organs
Flam Liq. 3 Flammable liquids (category 3)
Acute Tox. 4 Acute toxicity (category 4)
STOT SE 1 Specific target organ toxicity - single exposure (category 1)
Skin Corr. 1A Corrosive to the skin (category 1A)

Precautionary statements

P260: Do not breathe dust/fume/gas/mist/vapours/spray
P264: Wash thoroughly after handling
P280: Wear protective gloves/protective clothing/eye protection/face protection
P301+330+331: if swallowed: Rinse mouth. Do NOT induce vomiting
P303+361+353: if on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower
P304+340: if inhaled: Remove person to fresh air and keep comfortable for breathing
P305+P351+P338: If in eyes: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P307+P311: IF exposed: Call a POISON CENTER or doctor/ physician
P310: Immediately call a POISON CENTER/doctor
P363: Wash contaminated clothing before reuse
P405: Store locked up
P501: Dispose of contents in accordance with local regulation

IMPORTANT! Read the safety data sheets before the use and disposal of this product. Insure that this information is understood by the operators exposed to this product. Use this product for the intended purpose as indicated in the instruction manual.

The above information is believed to be accurate and up to date. It is, however, liable to change due to the continuous modification of legislation and of standards and security data. Since the correct or incorrect use of this product is beyond our jurisdiction, this information cannot be expressed or implied to be comprehensive. Eurofins Technologies Hungary cannot be held responsible for any improper use of the product, including those uses that could violate current patents or other copyrights. Only the user is responsible for the evaluation of this product's conformity and of the risks involved before use, and must adopt appropriate precautions towards self and other persons involved.