

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

1.1 Product identifiers

Product name

Celer AFLA M₁ 500 – HU0040081

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 **Developing solution** (N-Methyl-2-pyrrolidone 1<x<5%), may damage the unborn child (category 1B).

2.2 Label elements

Pictogram



Stop solution

Skin Corr. 1A



Developing solution

Repr. 1B

Hazard Class and
Category

Signal word

Hazard statements

Precautionary
statements

Danger (Dng)

H314

Danger (Dng)

H360D

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

P201
P280
P308+P313
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 Acute tox. 1 STOT RE 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>	-	-
Developing solution	N-Methyl-2-pyrrolidone (NMP)	1<x< 5%	Repr. 1B Skin Irrit. 2 Eye Irrit. 2 STOT SE 3	872-50-4	212-828-1
Stop solution, 8ml	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 DEVELOPING SOLUTION: 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.

DEVELOPING SOLUTION: Larger amounts of vapours may cause fatigue, dizziness, headache, nausea and vomiting. May cause irritation of eyes and skin. Prolonged exposure to vapours may result in damage on liver, kidneys, blood or central nervous system (including brain damage).

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5. Firefighting Measures

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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Keep products tightly sealed in their original containers. Store 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 N-methyl-2-pyrrolidone (data refer to pure substance): 10 ppm; 40 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 Standard	M ₁ liquid, white, odour characteristic
Enzyme Conjugate	liquid, colour pink, odourless
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.^[SEP] Developing solution: Strong oxidizing agents.

10.6 *Hazardous decomposition products*: developing solution- thermal decomposition may produce oxides of carbon and nitrogen.

11. Toxicological Information

11.1 *Information on toxicological effects*

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).

Developing solution may damage the unborn child (Repr. 1B).

It may irritate skin, mucous and eyes. If it inhaled may cause dizziness, headache and nausea.

May cause irritation to mucous membranes in mouth, throat and stomach.

Prolonged or frequent exposure to vapours of volatile organic compounds may result in damage on liver, kidneys, blood or central nervous system (including brain damage).

According to animal tests, N-methyl-2pyrrolidone may cause harm to the unborn child

Further information: RTECS: UY5790000 (N-methyl-2pyrrolidone).

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 (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

Repr. 1B Toxic for reproduction (category 1B)
Skin Corr. 1A Corrosive to the skin (category 1A)
H314: Causes severe skin burns and eye damage
H360D: May damage the unborn child

Precautionary statements

P201: Obtain special instructions before use
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
P308+313: If exposed call a doctor
P310: Immediately call a POISON CENTER/doctor
P363: Wash contaminated clothing before reuse
P405: Store locked up
P501: Dispose of contents to 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.

