

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

1.1 Product identifiers

Product name

B ZERO AFLA B₁ – HU0040005/HU0040025

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.

1047 BUDAPEST

technologies.hu@eurofins.com

www.eurofins-technologies.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. 1907/2006: **Standard 0** (methanol, >10% wt/wt) classified as flammable liquid (category 2), acute toxicity, inhalation (category 3), acute toxicity, dermal (category 3), acute toxicity, oral (category 3), specific target organ toxicity - single exposure (category 1), **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



Standard 0

Stop solution

Developing solution

Hazard Class and Category

Flam. Liq. 2
Acute Tox. 3
STOT SE 1

Skin Corr. 1A

Repr. 1B

Signal word

Danger (Dng)

Danger (Dng)

Danger (Dng)

Hazard statements

H225
H331
H311
H301
H370

H314

H360D

Precautionary statements

P210
P260
P280
P301+P310+P311
P311

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 0	Methanol	> 10%	Flam. Liq. 2 Acute Tox. 3 STOT SE 1	67-56-1	200-659-6
Enzyme Conjugate	-	-	<u>non-hazardous</u>	-	-
Washing buffer 10x	-	-	<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, 6ml/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: due the small volumes involved, 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, DEVELOPING SOLUTION and STANDARD 0: 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

Standard 0 is flammable. Risks derived from fire are minimal due to small volume of material. The 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: Standard 0: carbon oxides. 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 methanol (data refer to pure substance): 200 ppm; 260 mg/m³(TWA).

Possible absorption through skin.

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

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)
Standard 0	liquid, colourless, odour characteristic
Enzyme Conjugate	liquid, colour pink, odourless
Washing buffer 10x	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.

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*: Standard 0: acid chlorides, acid anhydrides, oxidizing agents, alkali metals, reducing agents, acids. 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.^[1] 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

Standard 0 is classified as flammable liquid (category 2), acute toxicity, inhalation (category 3), acute toxicity, dermal (category 3), acute toxicity, oral (category 3), specific target organ toxicity - single exposure (category 1). Standard 0 is toxic if inhaled and may irritate respiratory mucous membranes. It is toxic if swallowed and if absorbed through skin. May irritate skin and eyes.

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.

Toxicological properties have not been further investigated.

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).

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 (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

Flam. Liq. 2 Flammable liquids (category 2)
 Acute Tox. 3 Acute toxicity (category 3)
 STOT SE 1 Specific target organ toxicity - single exposure (category 1)
 Skin Corr. 1A Corrosive to the skin (category 1A)
 Repr. 1B Toxic for reproduction (category 1B)
 H225: Highly flammable liquid and vapour
 H301: Toxic if swallowed
 H311: Toxic in contact with skin
 H314: Causes severe skin burns and eye damage
 H360D: May damage the unborn child
 H370: Causes damage to organs

Precautionary statements

P201: Obtain special instructions before use
 P210: Keep away from heat/sparks/open flames/hot surfaces – no smoking
 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
 P311: Call a poison center or a doctor
 P363: Wash contaminated clothing before reuse
 P405: Store locked up

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.