

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

1.1 Product identifiers

Product name

I'screen SEM Rapid – HU0050036

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

In vitro diagnostic kit.

1.3 Company/Undertaking identification

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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, $5 \leq x < 15\%$ wt/wt), classified as skin corrosive (category 1), **2-nitrobenzaldehyde** (ethanol $> 50\%$ wt/wt), classified as eye irritant (category 2) and flammable liquid (category 2) and **developing solution** (2-pyrrolidone $1 < x < 10\%$), may damage the unborn child (category 1B).

2.2 Label elements

Pictogram



	Stop solution	2-Nitrobenzaldehyde	Developing solution
Hazard Class and Category	Skin corr. 1A	Flam. Liq. 2 Eye Irrit. 2	Repr. 1B
Signal word	Warning (Wng)	Danger (Dng)	Danger (Dng)
Hazard statements	H314	H225 H319	H360D
Precautionary statements	P260 P264 P280 P302+P352 P305+P351+P338 P332+P313 P337+P313 P362	P280 P305+P351+P338 P337+P313 P403+P235	P202 P280 P308+P313 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.	C No.
Microtiter plate	-	-	<u>non- hazardous</u>	-	-
Standard SEM	2-NP-SEM	<0.01%	Acute Tox. 4 Eye Irrit. 2 Skin Irrit. 2 STOT SE 3	16004-43-6	-
SEM Spiking solution	SEM- HCl	<0,01%	Acute Tox. 3 Repr. 2 Skin Irrit. 2 Eye Irrit. 2 STOT RE 2	563-41-7	209-247-0
Enzyme Conjugate	Thimerosal	< 0,1%	Acute Tox. 2 Acute Tox. 1 STOT SE 2 Aquatic Chronic 2	54-64-8	200-210-4
2-Nitrobenzaldehyde	2- Nitrobenzaldehyde	< 1%	Acute Tox. 4 Eye Irr. 2 Skin Irr. 2 STOT SE 3	552-89-6	209-025-3
	Ethanol	>50%	Liq. Inf. 2 Eye Irr. 2	64-17-5	200-578-6
Washing Buffer 20x	-	-	<u>non- hazardous</u>	-	-
Developing Solution	2- Pyrrolidinone	1-10%	Eye Irrit. 2 Repr. 1B	616-46-6	210-483-1
	Urea Hydrogen peroxide	0-0.5%	Ox. Sol.3 Skin corr. 1B Eye dam. 1	124-43-6	204-701-4
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: 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

Developing solution: may cause irritation to respiratory system, may cause irritation to eyes. May cause irritation to skin. Ingestion may cause nausea and vomiting. May damage fertility or the unborn child.

Stop solution and 2- nitrobenzaldehyde: may cause irritation to eyes. May cause irritation to skin. Ingestion may cause nausea and vomiting.

4.3 *Indication of any immediate medical attention and special treatment needed*
No data available.

5. Firefighting Measures

2-Nitrobenzaldehyde is flammable. Risks derived from fire are minimal due to small volume of material. The other components of kit 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.

2-nitrobenzaldehyde: Carbon oxides.

Developing solution: contains oxidizing substance.

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).

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)
SEM Standard	liquid, colourless, odourless
SEM Spiking Solution	liquid, colourless, odourless
Enzyme Conjugate	liquid, light yellow, odourless
Washing buffer 20x	liquid, colourless, odourless
Developing solution	liquid, colourless, odourless
2-Nitrobenzaldehyde	liquid, colourless, odour characteristic
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*: 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.

2-Nitrobenzaldehyde: Alkali metals, Oxidizing agents, Peroxides

Developing solution: Oxidizing agents

10.6 *Hazardous decomposition products*: no data available.

11. Toxicological Information

11.1 *Information on toxicological effects*

Stop solution is classified as skin irritant (category 2) and eye irritant (category 2).

It may irritate skin, mucous and upper respiratory tract. Toxicological properties have not been further investigated.

Further information: RTECS: WS5600000 (sulfuric acid).

2-Nitrobenzaldehyde is classified as skin irritant (category 2). It may cause central nervous system depression, narcosis, damage to the heart. Toxicological properties have not been further investigated.

Further information: KQ6300000 (ethanol).

Developing solution may damage fertility or the unborn child - toxic for reproduction (category 1). May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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 (ethanol, UN1170 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

Skin Irrit. 2 Skin irritant (category 2)
Eye Irrit. 2 Eye irritant (category 2)
Flam. Liq. 2 Flammable liquids (category 2)
Repr. 1B Toxic for reproduction (category 1B)
H225: Highly flammable liquid and vapour
H315: Causes skin irritation
H319: Causes serious eye irritation
H360D: May damage the unborn child.

Precautionary statements

P202: Do not handle until all safety precautions have been read and understood.
P264: Wash thoroughly after handling
P280: Wear protective gloves/protective clothing/eye protection/face protection
P302+P352: If on skin, wash with plenty of soap and water
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 or rash occurs: get medical advice
P337+P313: If eye irritation persists: get medical attention
P362: Take off contaminated clothing and wash before reuse
P403+P235: Store in a well ventilated place. Keep cool
P308+313: If exposed call a doctor
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 Techna s.r.l. 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.