

Safety Data Sheet

Doc ID: SDS-0054	Effective Date: March 29, 2021	Revision: C
Trade name	Elite PAP Pen, Elite Mini PAP Pen	

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name	Elite PAP Pen, Elite Mini PAP Pen
Cat #	K039, K042

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

For in vitro diagnosis.
Marker pen for glass slide.

1.3 Details of the supplier of the safety data sheet

Diagnostic BioSystems, Inc.
6616 Owens Drive
Pleasanton, CA 94588
(925) 484-3350
Customersupport@dbiosys.com

1.4 Emergency telephone number


+1 925 484 3350; 8AM-5PM (PST)

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture

Hazard Class	Category	Hazard Statements (H-Statements)
Flam Liq.	2	H225 Highly flammable liquid and vapor.
Skin Irrit.	2	H315 Causes skin irritation.
STOT SE	3	H336 May cause drowsiness or dizziness
Muta.	1B	H340 May cause genetic defects.
Carc.	1B	H350 May cause cancer.
Repr.	2	H361d May damage the unborn child.
STOT RE	2	H373 May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements


Signal Word	Danger
Pictogram	GHS02, GHS07, GHS08 

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Hazardous substances for labelling	Toluene Solvent naphtha (petroleum), light aromatic
Hazard statements	H225 Highly flammable liquid and vapour. H315 Causes skin irritation. H340 May cause genetic effects. H350 May cause cancer. H361d Suspected of damaging the unborn child. H336 May cause drowsiness or dizziness. H373 May cause damage to organs through prolonged or repeated exposure.
Precautionary statements	P201 Obtain special instructions before use. P210 Keep away from heat, hot surfaces, open flames and other ignition sources. No smoking. P280 Wear protective gloves / protective clothing / eye protection. P308+P313 IF exposed or concerned: Get medical advice/attention P405 Store locked up.
Additional information	Restricted to professional users.

Labelling of packages where contents do not exceed 125 ml

Signal Word	Danger
Pictogram	GHS02, GHS07, GHS08 
Hazardous substances for labelling	Toluene Solvent naphtha (petroleum), light aromatic
Hazard statements	H340 May cause genetic effects. H350 May cause cancer. H361d Suspected of damaging the unborn child.
Precautionary statements	P201 Obtain special instructions before use. P405 Store locked up.
Additional information	Restricted to professional users.

2.3 Other hazards

Results of PBT and vPvB assessment: Substance(s) does/do not meet the criteria for PBT/vPvB according to Regulation (EC) No 1907/2006, Annex XIII.
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SECTION 3: Composition/information on ingredients

3.2 Chemical characterization: Mixtures

Name	Concentration	Classification (for pure substances)
Toluene EC: 203-625-9 CAS: 108-88-3	<35%	Flam Liq. 2, H225 Repr. 2, H360d STOT RE 2, H373 Asp. Tox. 1, H304 Skin Irrit. 2, H315 STOT SE 3, H336
Solvent naphtha (petroleum), light aroma EC: 265-199-0 CAS: 64742-95-6	<15%	Flam. Liq. 3, H26 Muta 1B, H340 Carc. 1B, H350 Asp. Tox. 1, H304
Xylene EC: 215-535-7 CAS: 1330-20-7	<15%	Flam. Liq. 2, H226 Acute Tox. 4, H312 Acute Tox. 4, H332 Skin Irrit. 2, H315

SVHC: Not applicable

Additional information: For the wording of the listed H-phrases please refer to Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled	Move to well-ventilated area and seek medical attention if needed. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.
If on skin	Wash thoroughly with soap and water. If pain or irritation occurs, obtain medical attention.
If in eyes	Irritating to eye, flush with plenty of water. If pain or irritation occurs, obtain medical attention.
If swallowed	Rinse mouth with water, Do NOT induce vomiting, immediately seek medical attention.
Self-protection of the first aider	No further relevant information available for this mixture.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available for this mixture.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available for this mixture.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	Form, dry chemical, or carbon dioxide
Unsuitable extinguishing media	No further relevant information available for this mixture.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products	No further relevant information available for this mixture.
Other information	No further relevant information available for this mixture.

5.3 Advice for firefighters

Wear protective clothing containing self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Protective equipment	Ensure adequate ventilation. Eye Protection: Wear goggles or safety glasses. Hand protection: Wear latex or vinyl gloves. Other protective equipment: Use lab coat or apron to prevent contact with eyes, skin and clothing.
Emergency procedures	No further relevant information available for this mixture.
For emergency responders	No further relevant information available for this mixture.

6.2 Environmental precautions

Do not allow to enter sewage system.

6.3 Methods and material for containment and cleaning up

For containment	Collect in a container that can be sealed.
For cleaning up	Do not flush product to drainage facilities. In case of spillage, contain spillage or absorbent material to prevent spilled product from entering sewers or rivers. For small leaks, absorb with dry chemical absorbent. When a large amount is leaked, use a pump or vacuum cleaner to suck it in, and then absorb it with a dry chemical absorbent to remove it. If necessary, dig up contaminated soil. Thoroughly clean contaminated objects and areas in accordance with environmental regulations.
Other information	No further relevant information available for this mixture.

6.4 Reference to other sections

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for information on disposal.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Measures to prevent fire	No further relevant information available for this mixture.
Measures to prevent aerosol and dust generation	No further relevant information available for this mixture.
Measures to protect the environment	No further relevant information available for this mixture.
Advice on general occupational hygiene	Universal precautions should be followed when using this product. Keep away from heat and open flame and small children. Do not open the back plug of the pen. In case of skin contact, flush with plenty of water.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions	Store container tightly closed in a cool location. Store at 25°C. Keep away from heat and open flame, strong oxidants and small children.
Storage class	See respective national guidelines.
Other information	No further relevant information available for this mixture.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2, no specific uses are stipulated.
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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Additional information about design of technical systems: Use in a well-ventilated place and keep away from heat and open flame.

Components with critical values that require monitoring at the workplace:	
108-88-3 toluene	
WEL	Short-term value: 384 mg/m ³ , 100 ppm Long-term value: 191 mg/m ³ , 50 ppm Sk
AGW	Long-term value: 190 mg/m ³ , 50 ml/m ³ 4(II); DFG, EU, H, Y
1330-20-7 xylene	
WEL	Short-term value: 441 mg/m ³ , 100 ppm Long-term value: 220 mg/m ³ , 50 ppm Sk; BMGV
AGW	Long-term value: 220 mg/m ³ , 50 ml/m ³ 2(II); DFG, EU, H

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DNELs No further information available.

PNECs No further information available.

Ingredients with biological limit values:	
108-88-3 toluene	
BGW	600 µg/l Medium: blood Sampling time: post shift Parameter: toluene
1330-20-7 xylene	
BMGV	650 mmol/mol creatinine Medium: urine Sampling time: post shift Parameter: methyl hippuric acid
BGW	1,5 ml/l Medium: blood Sampling time: post shift Parameter: xylene

Additional information: The official lists that were valid during the compilation were used as basis.

8.2 Exposure controls

Hygiene Measures	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes and skin. Remove contaminated clothing immediately. Do not eat or drink while working. Keep away from food and beverages. Wash hands during breaks and at the end of work.
Respiratory Protection	Use in well-ventilated laboratory. No special precautions are necessary if handled correctly.
Skin	Disposable medical gloves (AQL 1.5) The breakthrough times stated below base on laboratory test methods which cannot fully simulate working conditions. It is the responsibility of the end user to choose the appropriate gloves for his application. If working with substances or mixtures harmful in contact with skin, check the gloves beforehand for holes and fissures. Material of gloves: Natural rubber (NR), Nitrile rubber (NBR), Thickness: 0.11 mm, the product quality has to comply with DIN EN 455. Penetration time: > 120 min Product has not been designed for permanent contact.
Body protection	Wear protective work clothing.
Eye/face Protection	Wear safety glasses (standard EN 166).

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	Green, liquid
Odor	Fragrance
Order Threshold	No information available.
pH	5.8
Melting Point/ Freezing Point	No information available.
Initial Boiling Point/ Freezing Point	No information available.
Flash Point	No information available.
Evaporation Rate	No information available.
Flammability	No information available.
Upper/Lower Flammability or Explosive Limits	No information available.
Upper flame limit (volume % in air)	No information available.
Lower flame limit (volume % in air)	No information available.
Vapor Pressure	No information available.
Vapor Density	No information available.
Relative Density	No information available.
Solubility	No information available.
Partition Coefficient: n-octanol/water	No information available.
Auto-Ignition Temperature	No information available.
Decomposition temperature	No information available.
Viscosity	No information available.
Explosive Properties	No information available.
Oxidizing Properties	No information available.
Flash point method	No information available.
Autoignition temperature	No information available.
Flame propagation rate (solids)	No information available.
Osha flammability class	No information available.

9.2 Other Information

No further relevant information available for this mixture.

Section 10: Stability and Reactivity

10.1 Reactivity

No further relevant information available for this mixture.

10.2 Chemical Stability

Stable under recommended storage conditions

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10.3 Possibility of Hazardous Reactions

No further relevant information available for this mixture.

10.4 Conditions to Avoid

Use in well ventilated area and keep from heat and open flame.

10.5 Incompatible Materials

No further relevant information available for this mixture.

10.6 Hazardous Decomposition Products

No further relevant information available for this mixture.

SECTION 11: Toxicological Information

108-88-3 Toluene	Oral Dermal Inhalative	LD ₅₀ 5.000 mg/kg (rat) LD ₅₀ 12.124 mg/kg (rab) LD ₅₀ 5.320 mg/l (mouse)
Acute toxicity	Based on the available data, the classification criteria are not met.	
Skin corrosion/irritation	Causes skin irritation.	
Serious eye damage/irritation	Based on the available data, the classification criteria are not met.	
Respiratory or skin sensitization	No sensitizing effect known.	
Germ cell mutagenicity	May cause genetic defects.	
Carcinogenicity	May cause cancer.	
Reproductive toxicity	Suspected of damaging the unborn child.	
STOT-single exposure	May cause drowsiness or dizziness.	
STOT-repeated exposure	May cause damage to organs through prolonged or repeated exposure.	
Aspiration hazard	Based on the available data, the classification criteria are not meet.	

SECTION 12: Ecological Information

12.1 Toxicity

No further relevant information available for this mixture.

12.2 Persistence and Degradability

No further relevant information available for this mixture.

12.3 Bioaccumulative potential

No further relevant information available for this mixture.

12.4 Mobility in Soil

No further relevant information available for this mixture.

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12.5 Results of PBT and vPvB Assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other Adverse Effects

No further relevant information available for this mixture.

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

Recommendation for uncleaned packaging: Uncleaned packagings have to be disposed of in the same manner as the product residues.

SECTION 14: Transport Information

14.1 UN Number

ADR	UN1993
IMDG	UN1993
IATA	UN1993

14.2 UN Proper Shipping Name

ADR	1993 FLAMBALE LIQUID, N.O.S. (toluene, xylenes)
IMDG	1993 FLAMBALE LIQUID, N.O.S. (toluene, xylenes)
IATA	1993 FLAMBALE LIQUID, N.O.S. (toluene, xylenes)

14.3 Transport Hazard Class (es)

ADR	Class: 3 (F1) Flammable liquids. Label: 3 Limited Quantities (LQ): 1L Excepted Quantities (EQ): Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml Transport category: 2 Tunnel restriction code: D/E
IMDG	Class: 3 (F1) Flammable liquids. Label: 3 Limited quantities (LQ): 1L Excepted quantities (EQ): Code: E2 Maximum net quantity per inner packaging: 30 ml

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	Maximum net quantity per outer packaging: 500 ml
IATA	Class: 3 (F1) Flammable liquids. Label: 3

14.4 Packing Group

ADR	II
IMDG	II
IATA	II

14.5 Environmental Hazards

Marine pollutant: No

14.6 Special Precautions for User

Warning: Flammable liquids.	
Kremler Number	33
EMS Number	F-E, S-E
Storeware Category	B

14.7 Transport in Bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

<p>Labelling according to Regulation (EC) No 1272/2008 See Section 2.</p> <p>National regulations</p> <p>Information about limitation of use:</p> <p>Take note of the directive on the protection of young people at work in the latest version.</p> <p>Take note of the directive on the safety and health at work for pregnant and breast feeding mothers and workers of childbearing age in the latest version.</p> <p>Water hazard class: Water hazard class 3 (self-assessment): extremely hazardous for water.</p>
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15.2 Chemical Safety Assessment

A chemical safety assessment has not been carried out.
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SECTION 16: Other Information

<p>This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information of their particular purposes.</p>
Relevant phrases

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H225 Highly flammable liquid and vapor.
H226 Flammable liquid and vapor.
H304 May be fatal if swallowed and enters airways.
H312 Harmful in contact with skin.
H315 Causes skin irritation.
H332 Harmful if inhaled.
H336 May cause drowsiness or dizziness.
H340 May cause genetic defects.
H350 May cause cancer.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.