

Safety Data Sheet
Elite PAP Pen, Elite Mini PAP Pen (EU)



DIAGNOSTIC BIOSYSTEMS

Safety Data Sheet
Elite PAP Pen, Elite Mini PAP Pen (EU)

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

1.1 Product identifier

Product name	Elite PAP Pen, Elite Mini PAP Pen (EU)
Product number	K039, K042
Brand	Elite PAP Pen, Elite Mini PAP Pen

1.2 Relevant identified uses of the substance or mixture and uses advised against
In Vitro Diagnostic Use

1.3 Details of the supplier of the safety data sheet

Name	Diagnostic Biosystems
Address	6616 Owens Drive Pleasanton CA 94588 USA
Telephone	(888) 896-3350
email	customersupport@dbiosys.com

1.4 Emergency telephone number

(925) 484-3350 (9AM-6PM, Monday - Friday, Pacific Standard Time)

SECTION 2: Hazards identification

General hazard statement
For Professional Users Only

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

- Acute toxicity, inhalation (chapter 3.1), Cat. 5, H333
- Carcinogenicity (chapter 3.6), Cat. 1B, H350
- Germ cell mutagenicity (chapter 3.5), Cat. 1B, H340
- Skin corrosion/irritation (chapter 3.2), Cat. 2, H315
- Specific target organ toxicity following repeated exposure (chapter 3.9), Cat. 2, H373
- Specific target organ toxicity following single exposure (chapter 3.8), Cat. 3, H335, H336
- Toxic to reproduction (chapter 3.7), Cat. 2, H361

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For the full text corresponding to the "H"-codes displayed in this section, refer to Section 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms



1. Health hazard; 2. Exclamation mark

Signal word

Danger

Hazard statements

H315	Causes skin irritation
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H340	May cause genetic defects
H350	May cause cancer
H361	Suspected of damaging fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure

Precautionary statements

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust/fume/gas/mist/vapors/spray.
P264	Wash hands thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P312	Call a POISON CENTER/doctor if you feel unwell.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container to a licensed disposal company.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

1. Toluene

Concentration < 35 % (volume)

Other names / synonyms

ANTISAL 1A; Benzene, methyl-; METHACIDE; METHANE, PHENYL-; METHYLBENZENE; METHYLBENZOL; NCI-C07272; PHENYLMETHANE; RCRA WASTE NUMBER U220; TOLU-SOL; Toluene ; TOLUOL; UN 1294

EC no.

203-625-9

CAS no.

108-88-3

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Index no. 601-021-00-3

- Flammable liquids (chapter 2.6), Cat. 2
- Reproductive toxicity (chapter 3.7), Cat. 2
- Aspiration hazard (chapter 3.10), Cat. 1
- Specific target organ toxicity, single exposure (chapter 3.8), Cat. 3
- Specific target organ toxicity, repeated exposure (chapter 3.9), Cat. 2
- Skin corrosion/irritation (chapter 3.2), Cat. 2

H225 Highly flammable liquid and vapor
H304 May be fatal if swallowed and enters airways
H315 Causes skin irritation
H336 May cause drowsiness or dizziness
H373 May cause damage to organs through prolonged or repeated exposure

2. Solvent naphtha (petroleum), light arom

Concentration < 30 % (volume)

Other names / synonyms Naphtha (petroleum), light, C5-rich, sweetened; Naphtha (petroleum), sweetened light; Solvent naphtha (petroleum), light arom.

EC no. 292-695-4
CAS no. 90989-39-2
Index no. 649-403-00-9

- Carcinogenicity (chapter 3.6), Cat. 1B
- Germ cell mutagenicity (chapter 3.5), Cat. 1B
- Aspiration hazard (chapter 3.10), Cat. 1

H304 May be fatal if swallowed and enters airways
H340 May cause genetic defects
H350 May cause cancer

3. Resin

Concentration < 35 % (volume)

EC no. N/A
CAS no. N/A
Index no. N/A

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes Consult a physician. Show this safety data sheet to the doctor in attendance.

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Following inhalation	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Following skin contact	Rinse with plenty of water. Get medical attention if irritation develops and persists.
Following eye contact	Rinse thoroughly with plenty of water for at least 15 minutes. Get medical attention if symptoms occur.
Following ingestion	Call a poison center or doctor if you feel unwell. If vomiting occurs naturally, have victim lean forward to reduce the risk of aspiration. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Acute and delayed symptoms and effects: May cause gastrointestinal irritation. Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.
Self-protection of the first aider	Ensure adequate ventilation. Use personal protective equipment. For personal protection see section 8.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Use extinguishing media appropriate for surrounding fire.

5.2 Special hazards arising from the substance or mixture

No data available.

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

Further information

No data available.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas. For personal protection see section 8.

Ensure adequate ventilation. Use personal protective equipment. For personal protection see section 8.

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Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas. For personal protection see section 8.

6.2 Environmental precautions

Should not be released into the environment. See Section 12 for additional ecological information.

6.3 Methods and material for containment and cleaning up

Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Further processing of solid materials may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

CAS: 108-88-3

Toluene

ACGIH: 20 ppm (75 mg/m³) TLV® inhalation; See Annotated Z-2 TLV® inhalation; Cal/OSHA: See Annotated Z-2 PEL inhalation; 500 ppm Ceiling PEL-C inhalation; 150 ppm (560 mg/m³) - SKIN PEL-ST inhalation; 10 ppm (37 mg/m³) TWA inhalation; NIOSH: 100 ppm (375 mg/m³) REL inhalation; See Annotated Z-2 REL inhalation; 150 ppm (560 mg/m³) STEL inhalation; OSHA: See Annotated Z-2 mg/m³ PEL inhalation; 300 ppm PEL-C inhalation; 500 ppm (10 minutes) PEL-Peak inhalation; 200 ppm PEL-TWA inhalation; 150 ppm STEL inhalation

8.2 Exposure controls

Appropriate engineering controls

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Individual protection measures, such as personal protective equipment

Pictograms



Eye and face protection

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Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Thermal hazards

No data available

Control banding approach

No data available.

Environmental exposure controls

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Appearance	Pen
Colour	Not Applicable
Odour	Odorless
Odour threshold	No data available.
pH	No data available
Melting point/freezing point	No data available.
Boiling point or initial boiling point and boiling range	No data available.
Flash point	No data available.
Evaporation rate	No data available.
Flammability	No data available.
Lower and upper explosion limit/flammability limit	No data available.
Vapor pressure	No data available.
Relative vapor density	No data available.
Density and/or relative density	No data available.
Solubility	No data available.
Partition coefficient n-octanol/water (log value)	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
Kinematic viscosity	No data available.
Explosive properties	No data available.
Oxidizing properties	No data available.

Particle characteristics

No data available.

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9.2 Other information

9.2.1 Information with regard to physical hazard classes

No data available.

9.2.2 Other safety characteristics

No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

None under normal use conditions.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

None under normal use conditions.

10.4 Conditions to avoid

Exposure to moisture.

Avoid storing in direct sunlight and avoid extremes of temperature.

Heat, flames and sparks.

10.6 Hazardous decomposition products

Other decomposition products - No data available In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

The ATE (gas inhalation) of the mixture is: 30000 ppmV

Toluene

LD50 Oral - Rat - > 5,580 mg/kg

Skin corrosion/irritation

Toluene

LD50 Skin - Rabbit - 12,196 mg/kg

Toluene

Skin - Rabbit - 24 h

Serious eye damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitization

Based on available data, classification data are not met

Germ cell mutagenicity

Based on available data, classification data are not met

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Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

Based on available data, classification data are not met

STOT-single exposure

No data available.

STOT-repeated exposure

No data available.

Aspiration hazard

No data available.

11.2 Information on other hazards

Endocrine disrupting properties

No data available.

Other information

No data available.

SECTION 12: Ecological information

12.1 Toxicity

Toluene

EC50 - *Pseudokirchneriella subcapitata* (green algae) - 10 mg/l - 24 h

Toluene

LC50 - *Oncorhynchus mykiss* (rainbow trout) - 7.63 mg/l - 96 h

Toluene

EC50 - *Daphnia magna* (water flea) - 6 mg/l - 48 h

Toluene

EC50 - *Chlorella vulgaris* (fresh water algae) - 245 mg/l - 24 h

Toluene

NOEC - *Pimephales promelas* (fathead minnow) - 5.44 mg/l - 7 d

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

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12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

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

12.6 Endocrine disrupting properties

No data available.

12.7 Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product disposal

Offer surplus and non-recyclable solutions to a licensed disposal company.

Packaging disposal

Dispose of as unused product.

Waste treatment

No data available

Sewage disposal

Do not let product enter drains

Other disposal recommendations

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

SECTION 14: Transport information

14.1 UN Number	None
14.2 UN Proper Shipping Name	None
14.3 Transport hazard class(es)	None
14.4 Packing group	None
14.5 Environmental hazards	None
14.6 Special precautions for user	None
14.7 Maritime transport in bulk according to IMO instruments	None

SECTION 15: Regulatory information

15.2 Chemical Safety Assessment

The supplier of this product has not conducted any Chemical Safety Assessment

SECTION 16: Other information

Full text of hazard statements referenced in Section 2

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H361
H373

Suspected of damaging fertility or the unborn child
May cause damage to organs through prolonged or repeated exposure

SDS-0054, Rev. E

Further information/disclaimer

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