Safety Data Sheet
SITVue /DAB Detection System (EU)

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

1.1 Product identifier

Product name	SITVue /DAB Detection System (EU)
Product number	SIT-25D, SIT-100D, SIT-1000D
Brand	SITVue /DAB Detection System

Other means of identification
Component 1: K029
Component 2: Stable DAB/Plus Chromogen
Component 3: Stable DAB/Plus Substrate Buffer

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, oral (chapter 3.1), Cat. 4, H302
- Carcinogenicity (chapter 3.6), Cat. 1B, H350

- Germ cell mutagenicity (chapter 3.5), Cat. 2, H341
- Specific target organ toxicity following repeated exposure (chapter 3.9), Cat. 2, H373
- Toxic to reproduction (chapter 3.7), Cat. 1B, H360

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. Exclamation mark; 2. Health hazard

Signal word **Danger**

Hazard statements

H302	Harmful if swallowed
H317	May cause an allergic skin reaction
H332	Harmful if inhaled
H341	Suspected of causing genetic defects
H350	May cause cancer
H360	May damage 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.
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell,
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.
P314	Get medical advice/attention if you feel unwell.
P330	Rinse mouth.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P405	Store locked up.
P501	Dispose of contents/container to a licensed disposal company.

2.3 Other hazards

No other hazards identified

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Component 1.
1. Glycol

Concentration	<= 25 % (volume)
Other names / synonyms	1,2-DIHYDROXYETHANE; 1,2-ETHANDIOL; 1,2-Ethanediol; DOWTHERM SR 1; ETHANE-1,2-DIOL; Ethane-1,2-diol, Ethylene glycol; ethanediol; ETHYLENE ALCOHOL; ETHYLENE DIHYDRATE; Ethylene glycol; Ethylene glycol (ingested); ETHYLENEGLYCOL; GLYCOL ALCOHOL; LUTROL-9; M.E.G.; MACROGOL 400 BPC; MONOETHYLENE GLYCOL; NCI-C00920; NORKOOL; TESCOL; UCAR 17
EC no.	203-473-3
CAS no.	107-21-1
Index no.	603-027-00-1

- Acute toxicity, oral (chapter 3.1), Cat. 4
- Specific target organ toxicity, repeated exposure (chapter 3.9), Cat. 2

H302	Harmful if swallowed
H373	May cause damage to organs [organs] through prolonged or repeated exposure [route]

2. 2-[[]4-(2,4,4-trimethylpentan-2-yl)phenoxy]ethanol

Concentration	<= 0.1 % (volume)
EC no.	618-344-0
CAS no.	9002-93-1

3. Tromethamine

Concentration	<= 1.5 % (weight)
Other names / synonyms	1,3-Propanediol, 2-amino-2-(hydroxymethyl)-; Tris; Trometamol;
CAS no.	77-86-1

4. Methylchloroisothiazolinone

Concentration	<= 0.1 % (volume)
Other names / synonyms	3(2H)-Isothiazolone, 5-chloro-2-methyl-; 5-Chloro-2-methyl-2H-isothiazol-3-one; 5-chloro-2-methyl-3(2H)-isothiazolone; Proclin 300
EC no.	247-500-7
CAS no.	26172-55-4

- Acute toxicity, dermal (chapter 3.1), Cat. 3
- Acute toxicity, oral (chapter 3.1), Cat. 3
- Skin corrosion/irritation (chapter 3.2), Cat. 1B
- Sensitization - skin (chapter 3.4), Cat. 1

- Eye damage/irritation (chapter 3.3), Cat. 1
- Hazardous to the aquatic environment, short-term (acute) (chapter 4.1), Cat. 1

Component 2.
1. 3,3'-Diaminobenzidine tetrahydrochloride hydrate

Concentration	1 - 5 % (weight)
Other names / synonyms	[1,1'-Biphenyl]-3,3',4,4'-tetramine; biphenyl-3,3',4,4'-tetrayltetraamine; diaminobenzidine
EC no.	231-018-8
CAS no.	868272-85-9

- Eye damage/irritation (chapter 3.3), Cat. 2
- Acute toxicity, oral (chapter 3.1), Cat. 4
- Carcinogenicity (chapter 3.6), Cat. 1B
- Germ cell mutagenicity (chapter 3.5), Cat. 2

H341	Suspected of causing genetic defects [route]
H350	May cause cancer [route]

Component 3.
1. Imidazole

Concentration	0.1 - 0.5 % (weight)
Other names / synonyms	1H-Imidazole;
EC no.	206-019-2
CAS no.	288-32-4
Index no.	613-319-00-0

- Reproductive toxicity (chapter 3.7), Cat. 1B
- Acute toxicity, oral (chapter 3.1), Cat. 4
- Skin corrosion/irritation (chapter 3.2), Cat. 1C

H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H360D	May damage the unborn child

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.
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

Ethylene glycol: No data available.

5-chloro-2-methyl-3(2H)-isothiazolone: carbon dioxide, carbon monoxide, hydrogen sulfide, nitrogen oxides, phosgene

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3,3'-Diaminobenzidine: Carbon oxides, Nitrogen oxides (NOx)

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.

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: 107-21-1 (EC: 203-473-3)
Glycol
ACGIH (USA): 100 mg/m3 PEL-C inhalation; 100 mg/m3 PEL-C inhalation; 100 mg/m3 PEL-C inhalation;
Cal/OSHA (USA): 40 ppm, 100 mg/m3 PEL-C 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
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	Liquid
Appearance	Clear
Colour	Not Applicable
Odour	Not Applicable
Odour threshold	No data available.
pH	7.6
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.

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.

10.5 Incompatible materials

Ethylene glycol: Strong acids, Strong oxidizing agents, Strong bases, Aldehydes, Aluminum

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5-chloro-2-methyl-3(2H)-isothiazolone: strong oxidizing agents

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

Ethylene glycol: Hazardous decomposition products formed under fire conditions. - Carbon oxides
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 (oral) of the mixture is: 1639.34 mg/kg bw

3,3'-Diaminobenzidine
LD50 Oral - Mouse - 1,834 mg/kg

Ethylene glycol
LD50 Oral - Rat - 4,700 mg/kg

Skin corrosion/irritation
Ethylene glycol

LD50 Skin - Rabbit - 10,626 mg/kg

Serious eye damage/irritation
No Data Available

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

Carcinogenicity
3,3'-Diaminobenzidine
Oral - Rat
Result: Tumorigenic:Equivocal tumorigenic agent by RTECS criteria. Skin and Appendages: Other: Tumors.
Presumed to have carcinogenic potential for humans

Reproductive toxicity
Based on available data, classification data are not met

STOT-single exposure
Ethylene glycol
LD50 Skin - Rabbit - 10,626 mg/kg

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

5-chloro-2-methyl-3(2H)-isothiazolone
EC50 - Pseudokirchneriella subcapitata (green algae) - 0.11 - 0.16 mg/l - 72 h

5-chloro-2-methyl-3(2H)-isothiazolone
LC50 - Oncorhynchus mykiss (rainbow trout) - 1.6 mg/l - 96 h

5-chloro-2-methyl-3(2H)-isothiazolone
EC50 - Daphnia magna (water flea) - 4.7 mg/l - 48 h

Ethylene glycol
LC50 - Oncorhynchus mykiss (rainbow trout) - 18,500 mg/l - 96 h

Ethylene glycol
LC50 - Leuciscus idus (golden orfe) - >10,000 mg/l - 48 h
Result: Bioconcentration factor (BCF): 0.60

Ethylene glycol
NOEC - Pimephales promelas (fathead minnow) - 32,000 mg/l - 7 d

Ethylene glycol
NOEC - Pimephales promelas (fathead minnow) - 39,140 mg/l - 96 h

Ethylene glycol
EC50 - Daphnia magna (water flea) - 74,000 mg/l - 24 h

Ethylene glycol
NOEC - Daphnia magna (water flea) - 24,000 mg/l - 48 h

Ethylene glycol
LC50 - Daphnia magna (water flea) - 41,000 mg/l - 48 h

12.2 Persistence and degradability
Ethylene glycol

Result: Ratio BOD/ThBOD 0.78 %

12.3 Bioaccumulative potential
Ethylene glycol
- other fish - 50 mg/l - 61 d

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

H302	Harmful if swallowed
H341	Suspected of causing genetic defects
H350	May cause cancer
H360	May damage fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure

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Further information/disclaimer

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