BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: AUH1012-75 Rev. 03
Revised (year/month/day) 2015/03/20

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name ISE Mid Standard Solution

Part Number AUH1012

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

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

e-mail address SDSNT@beckman.com

Further information Contact:
Customer support Unit, Beckman Coulter Ireland Inc.
Technical Service Department Tel. +001-800-854-3633 (PST)
E-mail CC_Support.ie@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1
Carcinogenicity Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

©2015 Beckman Coulter, Inc.

Section 2 Hazards Identification (Continued)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3
Skin Sensitization Category 1
Carcinogenicity Category 1

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Formaldehyde
Triethanolamine

Pictogram



Signal Word

DANGER

Hazard Statements

H316 Causes mild skin irritation.
H317 May cause an allergic skin reaction.
H350 May cause cancer.

Precautionary Statements

P201 Obtain special instructions before use.
P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/national regulations
Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	

©2015 Beckman Coulter, Inc.

Section 3 Composition and Information on Ingredients (Continued)

Triethanolamine CAS # 102-71-6 EINECS # 203-049-8 Index # Not available	1 - 2	Xi;R36/38	Eye Irrit. 2 Skin Irrit. 2 H315; H319	Eye Irrit. 2 Skin Irrit. 2 H315; H319	
Formaldehyde CAS # 50-00-0 EINECS # 200-001-8 Index # 605-001-00-5	0.2 - 0.5	T;R23/24/25-34-40-43 Carc. Cat. 3	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Carc. 1B Eye Dam. 1 Muta. 2 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H318; H331; H341; H350	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Carc. 1B Eye Dam. 1 Muta. 2 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H318; H331; H341; H350	
Phosphoric Acid CAS # 7664-38-2 EINECS # 231-633-2 Index # 015-011-00-6	< 1	C;R34	Acute Tox. Inhal. 2 Acute Tox. Oral 4 Eye Dam. 1 Skin Corr. 1B H302; H314; H318; H330	Acute Tox. Inhal. 2 Acute Tox. Oral 4 Eye Dam. 1 Skin Corr. 1B H302; H314; H318; H330	3, 8

3 - Health hazard
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause cancer.
May cause an allergic skin reaction.
Causes mild skin irritation.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

©2015 Beckman Coulter, Inc.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable aqueous solution.

5.1 Extinguishing Media In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information No further relevant information available.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Observe general safety guidelines for protection; avoid eye and skin contact.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions Contain spill to prevent migration.
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling Avoid inhaling, ingesting, and contact with eyes and skin.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 25°C , as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

©2015 Beckman Coulter, Inc.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

Formaldehyde CAS # 50-00-0	0.75 ppm TWA; 2 ppm STEL (see 29 CFR 1910.1048)
Phosphoric Acid CAS # 7664-38-2	1 mg/m3 TWA

ACGIH

Formaldehyde CAS # 50-00-0	0.3 ppm Ceiling
Triethanolamine CAS # 102-71-6	5 mg/m3 TWA
Phosphoric Acid CAS # 7664-38-2	3 mg/m3 STEL; 1 mg/m3 TWA

DFG MAK

Formaldehyde CAS # 50-00-0	0.6 ppm Peak (no irritation should occur during mixed exposure); 0.74 mg/m3 Peak (no irritation should occur during mixed exposure); 0.3 ppm TWA MAK; 0.37 mg/m3 TWA MAK (no irritation should occur during mixed exposure)
Triethanolamine CAS # 102-71-6	20 mg/m3 Peak; 5 mg/m3 TWA MAK (inhalable fraction)
Phosphoric Acid CAS # 7664-38-2	4 mg/m3 Peak (inhalable fraction); 2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Formaldehyde CAS # 50-00-0	2 ppm TWA; 2.5 mg/m3 TWA; 2 ppm STEL; 2.5 mg/m3 STEL
Triethanolamine CAS # 102-71-6	5 mg/m3 TWA
Phosphoric Acid CAS # 7664-38-2	1 mg/m3 TWA; 2 mg/m3 STEL

IOELVs

Phosphoric Acid CAS # 7664-38-2	1 mg/m3 TWA; 2 mg/m3 STEL

NIOSH

Formaldehyde CAS # 50-00-0	20 ppm IDLH; 0.016 ppm TWA
Phosphoric Acid CAS # 7664-38-2	1000 mg/m3 IDLH; 3 mg/m3 STEL; 1 mg/m3 TWA

Japan

Formaldehyde CAS # 50-00-0	0.1 ppm OEL; 0.12 mg/m3 OEL
Phosphoric Acid CAS # 7664-38-2	1 mg/m3 OEL

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

©2015 Beckman Coulter, Inc.

Section 8 Exposure Controls and Personal Protection (Continued)

Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.0 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	7.9	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Similar to water, approximately 0 °C	**Auto-ignition Temp.**	Product is not selfigniting
Boiling Point	Similar to water, approximately 100 °C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
Flammability (Solid, Gas)	Not applicable	**Viscosity**	Not determined
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Formaldehyde no geometric mean air odor threshold		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity	No further relevant information available.
10.2 Chemical Stability	The product is stable in accordance with recommended storage conditions.

©2015 Beckman Coulter, Inc.

Section 10 Stability and Reactivity (Continued)

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid

Avoid exposure to heat and direct sunlight.

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Formaldehyde CAS # 50-00-0	Dermal LD50 Rabbit 270 mg/kg; Inhalation LC50 Rat 0.578 mg/L 4 h; Oral LD50 Rat 600 mg/kg
Triethanolamine CAS # 102-71-6	Oral LD50 Rat 4190 mg/kg; Dermal LD50 Rabbit >2000 mg/kg; Dermal LD50 Rat >16 mL/kg
Phosphoric Acid CAS # 7664-38-2	Inhalation LC50 Rat >850 mg/m3 1 h; Oral LD50 Rat 1530 mg/kg; Dermal LD50 Rabbit 2730 mg/kg

Primary Routes of Exposure

Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation

Causes mild skin irritation.

Serious eye damage/eye irritation

No data available.

Respiratory/skin sensitization

May cause an allergic skin reaction.

Carcinogenicity

May cause cancer.

Formaldehyde is listed with OSHA as a carcinogen; NTP as known Human Carcinogen; IARC as Group 1 carcinogenic to humans; ACGIH as Group A2 Suspected Human Carcinogen; and 1272/2008 EC as Category 1B carcinogen.

Germ cell mutagenicity

No data available.

Reproductive Toxicity

No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard

No data available.

Other Information

No further relevant information available.

©2015 Beckman Coulter, Inc.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Formaldehyde CAS # 50-00-0	96 h LC50 Pimephales promelas: 22.6 - 25.7 mg/L [flow-through]; 96 h LC50 Lepomis macrochirus: 1510 µg/L [static]; 96 h LC50 Brachydanio rerio: 41 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 0.032 - 0.226 mL/L [flow-through]; 96 h LC50 Oncorhynchus mykiss: 100 - 136 mg/L [static]; 96 h LC50 Pimephales promelas: 23.2 - 29.7 mg/L [static]
Triethanolamine CAS # 102-71-6	96 h LC50 Pimephales promelas: 10600-13000 mg/L [flow-through]; 96 h LC50 Pimephales promelas: >1000 mg/L [static]; 96 h LC50 Lepomis macrochirus: 450-1000 mg/L [static]

Microtox No information available.

Water Flea

Formaldehyde CAS # 50-00-0	48 h LC50 Daphnia magna: 2 mg/L; 48 h EC50 Daphnia magna: 11.3 - 18 mg/L [Static]

Fresh Water Algae

Triethanolamine CAS # 102-71-6	72 h EC50 Desmodesmus subspicatus: 216 mg/L; 96 h EC50 Desmodesmus subspicatus: 169 mg/L

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulation Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other Adverse Effects No further relevant information available.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

13.2 Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

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

©2015 Beckman Coulter, Inc.

Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313
Formaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

CERCLA RG's, 40 CFR 302.4
Formaldehyde is listed.
Phosphoric Acid is listed.

California Proposition 65
Formaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.
WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL
Formaldehyde is listed.
Triethanolamine is listed.
Phosphoric Acid is listed.
Sodium Sulfate is listed.

New Jersey Dept. of Health RTK List

Formaldehyde is listed.
Triethanolamine is listed.
1-Hexanol is listed.
Phosphoric Acid is listed.

Pennsylvania RTK
Formaldehyde is listed.
Triethanolamine is listed.
1-Hexanol is listed.
Phosphoric Acid is listed.
Sodium Sulfate is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi



Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S24 Avoid contact with skin.
S37 Wear suitable gloves.
S60 This material and/or its container must be disposed of as hazardous waste.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

©2015 Beckman Coulter, Inc.

Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

Formaldehyde
Triethanolamine
1-Hexanol
Phosphoric Acid

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive
Carc. Cat. 3 - Carcinogen Category 3
T - Toxic
Xi - Irritant
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R40 Limited evidence of a carcinogenic effect
R43 May cause sensitization by skin contact.
R36/38 Irritating to eyes and skin.
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Carc. 1B - Carcinogenicity Category 1B
Eye Dam. 1 - Eye Damage Category 1
Eye Irrit. 2 - Eye Irritation Category 2
Muta. 2 - Germ Cell Mutagenicity Category 2
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Irrit. 2 - Skin Irritation Category 2
Skin Sens. 1 - Skin Sensitization Category 1
H301 - Toxic if swallowed.
H302 - Harmful if swallowed.
H311 - Toxic in contact with skin.

©2015 Beckman Coulter, Inc.

Section 16 Other Information (Continued)

H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H319 - Causes serious eye irritation.
H330 - Fatal if inhaled.
H331 - Toxic if inhaled.
H341 - Suspected of causing genetic defects.
H350 - May cause cancer.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
EC50 - Effective Concentration, 50%
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

For further information, please contact your local Beckman Coulter, Inc. representative.

WHILE BECKMAN COULTER, INC. BELIEVES THE INFORMATION CONTAINED HEREIN IS VALID AND ACCURATE, MAKES NO WARRANTY OR REPRESENTATION AS TO ITS VALIDITY, ACCURACY, OR CURRENCY. BECKMAN COULTER, INC. SHALL NOT BE LIABLE OR OTHERWISE RESPONSIBLE IN ANY WAY FOR USE OF EITHER THIS INFORMATION OR MATERIALS TO WHICH IT APPLIES. DISPOSAL OF HAZARDOUS MATERIALS MAY BE SUBJECT TO LOCAL LAWS OR REGULATIONS.