BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: AUH1014-75 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 Low Serum Standard

Part Number AUH1014

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)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

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

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

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

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Hazardous Ingredients

Formaldehyde

Pictogram

None

Signal Word

None

Hazard Statements

EUH208 May produce an allergic reaction.

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**	
Formaldehyde CAS # 50-00-0 EINECS # 200-001-8 Index # 605-001-00-5	< 0.1	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	15, 8

15 - May produce an allergic reaction.
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.

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Section 4 First Aid Measures (Continued)

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

This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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.

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 — No special precautions are necessary. Use good laboratory procedures.
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.

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Section 7 Handling and Storage

7.1 Precautions for safe handling No special precautions are necessary; use good laboratory procedures.

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.

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)

ACGIH

Formaldehyde CAS # 50-00-0	0.3 ppm Ceiling

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)

Ireland

Formaldehyde CAS # 50-00-0	2 ppm TWA; 2.5 mg/m3 TWA; 2 ppm STEL; 2.5 mg/m3 STEL

IOELVs None established

NIOSH

Formaldehyde CAS # 50-00-0	20 ppm IDLH; 0.016 ppm TWA

Japan

Formaldehyde CAS # 50-00-0	0.1 ppm OEL; 0.12 mg/m3 OEL

8.2 Exposure controls

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

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.

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Section 8 Exposure Controls and Personal Protection (Continued)

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.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.01 @20°C
Color	Colorless	**Solubility**	
Transparency	Clear	**Water**	Fully miscible
Odor	Odorless	**Organic**	Not determined
pH	Not determined	**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.

10.3 Possibility of hazardous reactions

No further relevant information available.

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Section 10 Stability and Reactivity (Continued)

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

Primary Routes of Exposure

Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation

No data available.

Serious eye damage/eye irritation

No data available.

Respiratory/skin sensitization

This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

Carcinogenicity

This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

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.

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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]
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	No information available.

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

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.

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Section 15 Regulatory Information (Continued)

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.
Sodium Sulfate is listed.

New Jersey Dept. of Health RTK List

Formaldehyde is listed.

Pennsylvania RTK

Formaldehyde is listed.
Sodium Sulfate is listed.

EU Regulations

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

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)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN

Not applicable

Ingredients on Ingredient Disclosure List

Formaldehyde

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: 1** **Reactivity with Water: 0** **Contact: 1**	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

Carc. Cat. 3 - Carcinogen Category 3
T - Toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.

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Section 16 Other Information (Continued)

R40 Limited evidence of a carcinogenic effect
R43 May cause sensitization by skin contact.
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Carc. 1B - Carcinogenicity Category 1B
Eye Dam. 1 - Eye Damage Category 1
Muta. 2 - Germ Cell Mutagenicity Category 2
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
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%

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Section 16 Other Information (Continued)

LD50 - Lethal Dose, 50%

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

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