

MATERIAL SAFETY DATA SHEET

Revision History

Revision	Date	Description of changes
00	2016.05.02	Established Material safety data sheet of SD MultiCareAnalyzer TF.

Written by	Reviewed by		Approved by

1. MATERIAL SAFETY DATA SHEET

(1) Analyzer

1) Product and company identification	
Product Name	SD MultiCare™ Analyzer
Product code	03MA10 / 03MA20
Manufacturer Information	
Name	SD BIOSENSOR, INC.
Address	Head office: C-4th&5th, 16, Deogyong-daero, 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 443-813, KOREA Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Cheongwon-gun, Chungcheongbuk-do, 363-951, KOREA
Telephone	+82 31 300 0400
Fax	+82 31 300 0499
Emergency phone number	+82 31 300 0400
2) Hazards identification	
Emergency Overview	
All information within the MSDS is based on hazards of the lithium battery that is either installed with the analyzer or shipped with the analyzer. The risk of exposure occurs only if the battery is mechanically or electrically abused. Most likely risk is an acute exposure when the gas release vent works. Organic solvent released has slight toxicity and can irritate skin and eyes. Lithium salt is irritating to skin, eyes, and mucous membranes and should be avoided. All information is based on manufacturer information.	
NEPA Ratings	Health=0, Flammability=0, Reactivity=0
Principle routes of exposure	Ingestion, inhalation, skin/eye contact
Inhalation	May cause irritation of respiratory tract
Ingestion	Harmful if swallowing, ingestion of strips or other solid pieces may cause choking
Skin contact	May cause irritation in contact with skin
Eye contact	Contact with eyes may cause irritation
Medical conditions aggravated by exposure	None Known
Additional information	None
3) Composition/Information on ingredients	
6V capacity (1.5V alkaline four batteries (type AA)) or AC adapter packaged with analyzer	
All other components of this product	
• Components	No hazardous components >1%, >0.1% carcinogen

• CAS Number	None
• Weight %	<0.01
• OSHA PEL	N/A
• OSHA STEL	N/A
• ACGIH TLV	N/A
• ACGIH STEL	N/A

4) First aid measures	
Inhalation	Consult a physician. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen
Skin contact	Rinse with plenty of water. If skin irritation persists, call a physician. Remove and wash contaminated clothing before re-use
Ingestion	Consult a physician. Do not induce vomiting without medical advice
Eye contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice
Notes to physician	None determined

5) Fire-Fighting measures	
Suitable extinguishing media	Use dry chemical, CO ₂ , water spray or `alcohol` foam
Unusual hazards	Batteries may explode or cause burns if disassembled, crushed, or exposed to fire or high temperatures. Do not short or install with incorrect polarity
Special protective equipment for firefighters	Wear self-contained breathing apparatus for firefighting if necessary

6) Accidental release procedures	
Personal precautions	Use personal protective equipment. Evacuate personnel to safe area
Environmental precautions	Prevent further leakage or spillage if safe to do so. Prevent product from entering drains
Methods for cleaning up	Never return spills in original containers for re-use. Sweep up or vacuum (if powder) or soak up with inert absorbent material (if liquid), then place into a suitable clean, dry, closed container, and label for disposal

7) Handling and storage	
Handling	Avoid mechanical or electrical abuse
Storage	No special precautions required

8) Exposure controls & personal protection	
Engineering measures	Not applicable
Personal Protective equipment	
Respiratory	Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow the OSHA regulation, 29CFR1910.134. Always use a NIOSH approved respirator when necessary
Hand	Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly
Skin and body	Wear appropriate body protection to prevent skin contact
Eye	Wear appropriate eye protection to prevent eye contact
Hygiene measures	Avoid contact with skin, eyes and clothing
9) Physical and chemical properties	
Physical state	Solid
10) Stability and reactivity	
Stability	Stable under the recommended storage conditions
Polymerization	Not applicable
Hazardous decomposition products	None
Materials to avoid	Do not heat, disassemble or overcharge
11) Toxicological information	
Inhalation	No additional data available
Skin	No additional data available
Oral	No additional data available
Mutagenic effects	No data is available on the product itself
Reproductive toxicity	No data is available on the product itself
Carcinogenic effects	No data is available on the product itself
12) Ecological information	
Bioaccumulation	No data available
Aquatic toxicity	Not applicable
Eco-toxicity effects	No data is available on the product itself
13) Disposal considerations	
Waste from residues / unused products	Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised

by your local hazardous waste regulatory authority. Residue from fires extinguished with this material may be hazardous

14) Transport information

Is product hazardous to ship? This product is not hazardous to ship. Any lithium battery is shipped with or installed in an analyzer. Any lithium battery shipped with this analyzer meets Special Provision A45 for IATA and is not regulated by DOT.

DOT		ICAO/IATA	
Proper shipping name	None	Proper shipping name	No shipping name is necessary
UN number	Not applicable	UN number	Not applicable
Hazard class	Not applicable	Hazard class	Not applicable
Subsidiary risks	Not applicable	Subsidiary risks	Not applicable
Packing group	Not applicable	Packing group	Not applicable

15) Regulatory information

U.S Regulations

U.S CERCLA/SARA/TSCA Information The following chemicals are listed under the following TSCA/SARA/CERCLA lists. Refer to TSCA regulation if you need a definition for acronyms that may be shown in the TSCA Inventory field in the table below

U.S. Clean Water Act (CWA)/ California The following chemicals are listed under the CWA and/or

Proposition 65 California Proposition 65

Canadian Regulations

Canada DSL Inventory List This product does not comply with DSL

Canada NDSL Inventory List This product does not comply with NDSL

16) Other information

Reason for revision Not applicable

Additional device None

(2) Test Kit

1) Product and company identification	
Product Name	SD MultiCare™ HbA1c Test Kit SD MultiCare™ CRP Test Kit SD MultiCare™ U-Albumin Test Kit
Product code	M-HbA1c M-CRP M-UALB
Manufacturer Information	
Name	SD BIOSENSOR, INC.
Address	Head office: C-4th&5th, 16, Deogyong-daero, 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 443-813, KOREA Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Cheongwon-gun, Chungcheongbuk-do, 363-951, KOREA
Telephone	+82 31 300 0400
Fax	+82 31 300 0499
Emergency phone number	+82 31 300 0400
2) Hazards identification	
NEPA Ratings	Health=0, Flammability=0, Reactivity=0
Principle routes of exposure	Ingestion, inhalation, skin/eye contact
Inhalation	May cause irritation of respiratory tract
Ingestion	Harmful if swallowing, ingestion of strips or other solid pieces may cause choking
Skin contact	May cause irritation in contact with skin
Eye contact	Contact with eyes may cause irritation
Medical conditions aggravated by exposure	None Known
Additional information	None
3) Composition/Information on ingredients	
Pursuant to United States OSHA Regulations 29 CFR Part 1910.1200, This Product Is Not Considered To Contain Hazardous Materials.	
EU classification <small>(1999/45/EC)</small>	Not applicable
EU risk and safety phrases	None

4) Emergency first aid measures	
Inhalation	Consult a physician. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen
Skin contact	Rinse with plenty of water. If skin irritation persists, call a physician.
Ingestion	Consult a physician. Do not induce vomiting without medical advice
Eye contact	In the case of contact with eyes, rinse immediately with plenty of water. Do not rub eyes
Notes to physician	None determined
5) Fire-Fighting measures	
Flash Point(Method used)	None
Flammable limits	Not applicable
Extinguishing media	Use whatever is required for the surrounding area
Special firefighting procedures	It is always best to wear a self-contained breathing apparatus.
Unusual fire and explosion hazard	None determined
6) Spill or Leak procedures	
Steps to be taken in case material is released or spilled	Pick up and place in a disposal container
7) Handling and storage	
Store the test kits at temperatures and conditions as indicated on the product label. See product test kit package or insert for instructions on handling product	
8) Personal protection	
Ventilation	Use general room ventilation, there is no special respiratory protection required
Protective gloves and other protective equipment	Not required
Eye protective	Not needed or required to use this product
9) Physical data	
Appearance and odor	Plastic strips with applied chemicals and desiccant bead
pH	Not applicable
Solubility in water	Not soluble
Physical Characteristics	Not significant
10) Reactivity data	

Stability	This product is stable as sold if used as directed. There are no specific conditions to avoid.
11) Toxicological information	
Chronic effect of over exposure	None currently known. None of the components are listed as a carcinogen or suspected carcinogen
Inhalation, Skin Contact and Eye Contact	Not considered health risks
Ingestion	If ingestion should occur the patient may feel uncomfortable. Treat as indicated
Acute toxicity values	Not applicable
12) Ecological information	
Ecological effects of the product strips have not been determined	
13) Disposal considerations	
Primary Container Type	Aluminum pouch in a fiberboard box. Plastic panels are polystyrene with applied chemicals.
Waste Disposal Method	Each disposal facility must determine proper disposal methods to comply with Local, State and Federal Environmental Regulations. Incineration of the product could produce trace amounts of toxic gasses. Check your local regulations before incineration
14) Transport information (JATA regulation)	
Proper shipping name	Not regulated
UN number	Not applicable
Hazard class	Not applicable
Subsidiary risks	Not applicable
Packing group	Not applicable
Label(s)	Not applicable
Packing instruction _(Passenger aircraft)	Not applicable
Packing instruction _(cargo aircraft)	Not applicable
Unit volume	See products labels
Primary container type	Aluminum pouch in a fiberboard box
Sales unit	1 package including 20 test kits
15) Regulatory information	
SARA 311/312	Hazard categories for SARA section 311/312
Reporting	Not hazardous

Canadian WHMIS classification	Not a controlled products
EU classification <small>(1999/45/EC)</small>	Not applicable
EU risk and safety phrases	None
16) Other information	
None	

(3) Control

1) Product and company identification	
Product Name	SD A1C Control SD CRP Control SD U-Albumin Control
Product code	C-A1C C-CRP C-UALB
Manufacturer Information	
Name	SD BIOSENSOR, INC.
Address	Head office: C-4th&5th, 16, Deogyong-daero, 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 443-813, KOREA Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Cheongwon-gun, Chungcheongbuk-do, 363-951, KOREA
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2) Hazards identification	
NEPA Ratings	Health=0, Flammability=0, Reactivity=0
Principle routes of exposure	Ingestion, inhalation, skin/eye contact
Inhalation	May cause irritation of respiratory tract
Ingestion	Harmful if swallowing, ingestion of strips or other solid pieces may cause choking
Skin contact	May cause irritation in contact with skin
Eye contact	Contact with eyes may cause irritation
Medical conditions aggravated by exposure	None Known
Additional information	None
3) Composition/Information on ingredients	
Pursuant to United States OSHA Regulations 29 CFR Part 1910.1200, This Product Is Not Considered To Contain Hazardous Materials.	
EU classification <small>(1999/45/EC)</small>	Not applicable
EU risk and safety phrases	None
4) Emergency first aid measures	
Inhalation	Consult a physician. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen
Skin contact	Rinse with plenty of water. If skin irritation persists, call a

	physician.
Ingestion	Consult a physician. Do not induce vomiting without medical advice
Eye contact	In the case of contact with eyes, rinse immediately with plenty of water. Do not rub eyes
Notes to physician	None determined
5) Fire-Fighting measures	
Flash Point(Method used)	None
Flammable limits	Not applicable
Extinguishing media	Use whatever is required for the surrounding area
Special firefighting procedures	No special procedures are necessary
Unusual fire and explosion hazard	None determined
6) Spill or Leak procedures	
Steps to be taken in case material is released or spilled	Pick up and place in a disposal container
7) Handling and storage	
Store the control solution at temperatures and conditions as indicated on the product label. See product package or insert for instructions on handling product	
8) Personal protection	
Engineering measures	Not applicable
Personal Protective Equipment	
Respiratory protection	Respiratory protection is not required under normal use of this product.
Skin and body protection	None required in normal product use. Should circumstances occur where prolonged or repeated skin contact may occur, then it is recommended that protective gloves be worn
Eye protection	None required in normal product use. If large quantities of the product are handled in bulk, and there is a change of splashing, then it is recommended that safety glasses, or face shield be worn.
Hygiene measures	Avoid contact with skin, eyes and clothing
9) Physical data	

Physical state	Liquid
Appearance	White bottle
Color	Red
Odor	Odorless
10) Reactivity data	
Stability	Stable under recommended storage conditions
Incompatible materials	None
Hazardous decomposition products	None
Hazardous polymerization	Will not occur
Materials to avoid	Refer to the insert for this product about the storage condition.
11) Toxicological information	
Inhalation	No additional data available
Skin	No additional data available
Oral	No additional data available
Mutagenic effects	No data is available on the product itself
Reproductive toxicity	No data is available on the product itself
Carcinogenic effects	No data is available on the product itself
12) Ecological information	
Bioaccumulation	No data available
Aquatic toxicity	Not applicable
Ecotoxicity effects	No data is available on the product itself
13) Disposal considerations	
Primary Container Type	Aluminum pouch in a fiberboard box. Plastic spoit contains a latex-tablet consisting of chemicals.
Waste from residues / unused products	Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority.
14) Transport information (JATA regulation)	
Proper shipping name	Not regulated
UN number	Not applicable
Hazard class	Not applicable

Subsidiary risks	Not applicable
Packing group	Not applicable
Label(s)	Not applicable
Packing instruction _(Passenger aircraft)	Not applicable
Packing instruction _(cargo aircraft)	Not applicable
Unit volume	See products labels
Primary container type	Aluminum pouch in a fiberboard box
Sales unit	1 package including 10 control materials for level 1 and 2
15) Regulatory information	
No data given	
16) Other information	
None	