


MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 005 Rev. AD	
Control Strip Activation Solution	EFFECTIVE DATE 06/28/2013	

Section 1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Control Strip Activation Solution
Product Number: 100121
Business Area: Point of Care
Product Line: Coagulation monitoring
Instrument Type: Coag-Sense® PT/INR Meter

PHONE NUMBERS

Supplier

CoaguSense, Inc
48377 Fremont Blvd, STE 113
Fremont, CA USA 94538
Phone: 510-270-5442
Fax: 510-226-6540

In Case of Emergency:

911 or local authority
CHEMTREC
Phone: 800-424-9300 USA and Canada
Phone 703-527-3887 International


Section 2 COMPOSITION / INFORMATION ON INGREDIENTS

The Control Strip Activation Solution is a 2 ml vial of 14.1 mM (milli-Molar) CaCl solution, which is used in conjunction with the Coag-Sense® Low and High Control Strips.

Components	CAS Number	Weight%	OSHA PEL	ACGIH TLV	ACGIH STEL
Calcium chloride dihydrate	10035-04-8	0.2 %			
Water	7732-18-5	balance			

Section 3 HAZARDS IDENTIFICATION (Emergency Overview)

NFPA Ratings:	Health = 1 (estimated) Flammability = 0 Reactivity = 0
Special Definitions:	A=Allergen CA=Carcinogen CO=corrosive F=Flammable H=Harmful I=Irritant Ox=Oxidizer PB=Potential Bio-Hazard R=Reproductive S=Sensitizer T=Toxic TH= Highly Toxic W=Water Reactive
Principle routes of exposure:	Ingestion, skin, and/or eye contact
Inhalation:	Low hazard for usual industrial / clinic handling.
Ingestion:	Low hazard for usual industrial / clinic handling.
Skin Contact:	Low hazard for usual industrial / clinic handling.
Eye Contact:	Contact with eyes may cause irritation
Sensitization or Odor Threshold:	The following chemicals may cause sensitization, be absorbed via skin, and/or has an odor threshold for detection: none known
Medical conditions aggravated by exposure:	None known
Additional Information:	None

MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 005 Rev. AD	
Control Strip Activation Solution	EFFECTIVE DATE 06/28/2013	

Section 4 FIRST AID MEASURES

Inhalation:	Consult a physician. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical aid.
Skin contact	Rinse with plenty of water and soap. Remove and wash contaminated clothing. If skin irritation persists, call a physician. Wash clothing before re-use.
Ingestion:	If swallowed, do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical aid.
Eye Contact:	In the case of contact with eyes, rinse immediately with plenty of water for at least 15 minutes and seek medical advice.
Notes to Physician	Treat symptomatically and supportively.

Section 5 FIRE FIGHTING MEASURES

Suitable extinguishing media	Substance is non-flammable. Use dry chemical, CO2, water spray, or alcohol foam.
Unusual Hazards	None known
Special protective equipment for firefighters	Wear self contained breathing apparatus for fire-fighting if necessary. During a fire, irritating and highly toxic gases may be generated by decomposition or combustion

Section 6 ACCIDENTAL RELEASE MEASURES


Personal precautions:	Use personal protective equipment. Evacuate personnel to safe areas
Environmental precautions:	Prevent further leakage or spillage if safe to do so. Prevent product from entering drains
Methods for cleaning up:	Never return spill in original containers for re-use. Sweep up or vacuum (if powder) or soak up with inert absorbent material (if liquid) using vermiculite, sand, or earth), then place into suitable clean, dry, closed container, and label for disposal. Clean up spills immediately, observing precautions in Section 8.

Section 7 HANDLING AND STORAGE

Handling:	Protect from contamination. Wear personal protective equipment. Wash thoroughly after handling. Use with adequate ventilation. Avoid contact with eyes, skin, and clothing. Keep container tightly closed. Avoid ingestion, or inhalation.
Storage:	Store in a tightly closed container. Store in a cool, dry, well-ventilated area, away from combustible substances.

Section 8 EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Measures:	Not applicable
Personal Protective Equipment	
Respiratory Protection	Respiratory protection is not required under normal use in a ventilated area for this product. If respiratory protection is needed, follow the OSHA regulation 20CFR1910.134. Always use a NIOSH approved respirator when necessary.
Hand Protection	Wear appropriate gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Skin and Body Protection	Wear appropriate body protection to prevent skin contact
Eye Protection	Wear appropriate eye protection to prevent eye contact
Hygiene Protection	Avoid contact with skin, eyes, and clothing

MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 005 Rev. AD	
Control Strip Activation Solution	EFFECTIVE DATE 06/28/2013	

Section 9 PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Color, Odor, pH, Vapor Pressure, Vapor Density, Evaporation rate, Viscosity, Boiling point, freezing/melting, de composition temperature, solubility in water, specific gravity / density, molecular weight	No information found
Molecular formula:	Solution

Section 10 STABILITY AND REACTIVITY


Chemical Stability:	Stable under recommended storage conditions
Conditions to avoid:	No specific conditions to avoid noted.
Hazardous Polymerization:	Will not occur
Hazardous decomposition products:	None
Incompatibilities with other materials:	None reported.

Section 11 TOXOLOGICAL INFORMATION

RTECS	CAS# 10035-04-8: EV9810000 CAS# 7732-18-5: ZC 0110000
LD50 / LC 50	CAS# 10035-04-8: No information found. CAS# 7732-18-5: oral, rat: LD50=>90 ml/KG
Carcinogenic effects:	CAS# 10035-04-8; not listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, OSHA or CA Prop 65 CAS# 7732-18-5 not listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, OSHA or CA Prop 65
Epidemiology	No information found.
Teratogenicity	No information found.
Neurotoxicity	No information found.
Mutagenic effects:	No information found.
Reproductive toxicity:	No information found.
Inhalation:	No information available.
Skin:	No information available.
Oral:	No information available.

Section 12 ECOLOGICAL INFORMATION

Bioaccumulation	No information found.
Aquatic toxicity	No information found.
Eco toxicity effects	No information found.

MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 005 Rev. AD	
Control Strip Activation Solution	EFFECTIVE DATE 06/28/2013	

Section 13 DISPOSAL INFORMATION

Waste from residues / unused product	Chemical Waste Generators must determine whether a discarded chemical is classified as a hazardous waste US EPA guideline for the classification determination are listed in 40CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.
RCRA P series Wastes	None of the components are on this list
RCRA U series Wastes	None of the components are on this list

Section 14 TRANSPORTATION INFORMATION

Is this product hazardous to ship?	No.
US DOT	
Proper shipping name	Not regulated as a hazardous material
UN Number Not applicable.	Hazard Class: Not applicable Subsidiary Risk: Not applicable Packing group: Not applicable
ICAO / IATA	
Proper shipping name	None
UN Number Not applicable	Hazard Class: Not applicable Subsidiary Risk: Not applicable Packing group: Not applicable

Section 15 REGULATORY INFORMATION

U.S. Regulations:

U.S. CERCLA / SARA / TSCA Regulatory information: the following chemicals are listed under the CERCLA / SARA / TSCA lists (Refer to the TSCA regulation if you need a definition for acronyms that may be shown in the TSCA inventory filed in the table below):


TSCA: CAS 10035-04-8 is not on the TSCA inventory because it is a hydrate. It is considered to be listed if the CAS for the anhydrous form is on the inventory (40CFR720.3 (u) (2)).
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U.S. Clean Water Act (CWA / California Proposition 65: The following chemicals are listed under the CWA and/or California Proposition 65:

There are no substances to report.


Section 16 OTHER INFORMATION

- All information in this MSDS is has been derived from the sources outlined below, and is believed to be correct. It is provided as a guide to proper use, storage, transportation and disposal of this product. CoaguSense Inc. has not performed any independent testing of this product, and in no way warranties the accuracy or completeness of this information. CoaguSense Inc. shall not be held liable for any damages incurred as a result of handling, contact, use or disposal of this product.
- A complete listing of the main ingredients in this product is given on the accompanying product data sheet.
- Hazard identification is based on information on known hazardous ingredients at the time of this documents creation. Since no information is available on some components of this mixture, precautions should be taken to avoid contact with this product.
- Although this product contains biological components considered to be non-hazardous, standard safety precautions for handling biological materials are recommended.
- References used to prepare this document.
 - Manufacturers MSDS for individual components used to prepare this product.

MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 005 Rev. AD	
Control Strip Activation Solution	EFFECTIVE DATE 06/28/2013	

Document History

Rev.	DCO #	Effective Date	Originator	Description of Change
AA	424	02/27/2007	D. Gyorke	Initial Release
AB	539	04/24/2009	M. Acosta	Revised for CoaguSense Inc use.
AC	808	08/11/2010	M. Acosta	Update with current company information.
AD	1035	06/25/2013	N. Bhatnagar	Update with current address and product name.

MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 001 Rev. AD	
	EFFECTIVE DATE 06/28/2013	
Coag-Sense® Patient Test Strip		

Section 1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Coag-Sense® Patient Test Strip
Product Number: 100209
Business Area: Point of Care
Product Line: Coagulation monitoring
Instrument Type: Coag-Sense® PT/INR Meter

PHONE NUMBERS

Supplier

CoaguSense, Inc
48377 Fremont Blvd, STE 113
Fremont, CA USA 94538
Phone: 510-270-5442
Fax: 510-226-6540

In Case of Emergency:

911 or local authority

CHEMTREC
Phone: 800-424-9300 USA and Canada
Phone 703-527-3887 International

Section 2 COMPOSITION / INFORMATION ON INGREDIENTS


The Coag-Sense® Patient Test Strip is a dry test strip, comprised primarily of a polycarbonate substrate, plastic rotating wheel, with proprietary chemistry applied and dried onto the strip area where, when used with a patient, a patient's blood is intermixed by the Coag-Sense Meter.

Components	CAS Number	Weight%	OSHA PEL	ACGIH TLV	ACGIH STEL
Dry Test Strip: No hazardous components >1%; No carcinogen components >0.1%	NONE	N/A	N/A	N/A	N/A
Recombinant Animal Tissue Base Reagent < 0.1%	Not available	N/A	N/A	N/A	N/A

Additional information: Contains animal sourced and/or potentially infectious components.

Section 3 HAZARDS IDENTIFICATION (Emergency Overview)

NFPA Ratings:	Health = 0 Flammability = 0 Reactivity = 0
Special Definitions:	A=Allergen CA=Carcinogen CO=corrosive F=Flammable H=Harmful I=Irritant Ox=Oxidizer PB=Potential Bio-Hazard R=Reproductive S=Sensitizer T=Toxic TH= Highly Toxic W=Water Reactive
Principle routes of exposure:	Ingestion, skin, and/or eye contact
Inhalation:	None
Ingestion:	Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea
Skin Contact:	None
Eye Contact:	Contact with eyes may cause irritation
Sensitization or Odor Threshold:	The following chemicals may cause sensitization, be absorbed via skin, and/or has an odor threshold for detection: none known
Medical conditions	None known

MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 001 Rev. AD	
Coag-Sense® Patient Test Strip	EFFECTIVE DATE 06/28/2013	

aggravated by exposure:	
Additional Information:	None

Section 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 and soap. If skin irritation persists, call a physician. Remove and wash contaminated clothing.
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.

Section 5 FIRE FIGHTING MEASURES

Suitable extinguishing media	Use dry chemical, CO2, water spray, or alcohol foam
Unusual Hazards	None known
Special protective equipment for firefighters	Wear self contained breathing apparatus for fire fighting if necessary.

Section 6 ACCIDENTAL RELEASE MEASURES

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

Section 7 HANDLING AND STORAGE


Handling:	Protect from contamination. Wear personal protective equipment
Storage:	No special precautions required.

Section 8 EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Measures:	Not applicable
Personal Protective Equipment	
Respiratory Protection	Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow the OSHA regulation 20CFR1910.134. Always use a NIOSH approved respirator when necessary.
Hand Protection	Wear appropriate gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Skin and Body Protection	Wear appropriate body protection to prevent skin contact
Eye Protection	Wear appropriate eye protection to prevent eye contact
Hygiene Protection	Avoid contact with skin, eyes, and clothing

Section 9 PHYSICAL AND CHEMICAL PROPERTIES

Not applicable.	
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MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 001 Rev. AD	
Coag-Sense® Patient Test Strip	EFFECTIVE DATE 06/28/2013	

Section 10 STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions
Polymerization:	Not applicable
Hazardous decomposition products:	Carbon dioxide
Materials to avoid:	Strong acids and strong bases. Strong oxidizing agents.

Section 11 TOXOLOGICAL 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.

Section 12 ECOLOGICAL INFORMATION

Bioaccumulation	No data available
Aquatic toxicity	Not applicable
Ecotoxicity effects	No data available on the product itself

Section 13 DISPOSAL INFORMATION

Waste from residues / unused product	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 you local hazardous waste regulatory authority.
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Section 14 TRANSPORTATION INFORMATION

Is this product hazardous to ship?	No.
DOT	
Proper shipping name	None
UN Number Not applicable.	Hazard Class: Not applicable Subsidiary Risk: Not applicable Packing group: Not applicable
ICAO / IATA	
Proper shipping name	None
UN Number Not applicable	Hazard Class: Not applicable Subsidiary Risk: Not applicable Packing group: Not applicable

Section 15 REGULATORY INFORMATION


U.S. Regulations:

U.S. CERCLA / SARA / TSCA Regulatory information: the following chemicals are listed under the CERCLA / SARA / TSCA lists (Refer to the TSCA regulation if you need a definition for acronyms that may be shown in the TSCA inventory filed in the table below):

There are no substances to report.

U.S. Clean Water Act (CWA / California Proposition 65: The following chemicals are listed under the CWA and/or California Proposition 65:

There are no substances to report.


MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 001 Rev. AD	
	EFFECTIVE DATE 06/28/2013	
Coag-Sense® Patient Test Strip		

Section 16 OTHER INFORMATION

- All information in this MSDS is has been derived from the sources outlined below, and is believed to be correct. It is provided as a guide to proper use, storage, transportation and disposal of this product. CoaguSense Inc. has not performed any independent testing of this product, and in no way warranties the accuracy or completeness of this information. CoaguSense Inc. shall not be held liable for any damages incurred as a result of handling, contact, use or disposal of this product.
- A complete listing of the main ingredients in this product is given on the accompanying product data sheet.
- Hazard identification is based on information on known hazardous ingredients at the time of this documents creation. Since no information is available on some components of this mixture, precautions should be taken to avoid contact with this product.
- Although this product contains biological components considered to be non-hazardous, standard safety precautions for handling biological materials are recommended.
- References used to prepare this document.
 - Manufacturer's MSDS for individual components used to prepare this product.
 - MSDS for GE Plastics synthetic thermoplastic polymers (CASRN 111211-39-3).
 - MSDS for DuPont engineering polymer resin (DEL 007).

Document History

Rev.	DCO #	Effective Date	Originator	Description of Change
AA	424	02/27/2007	D. Gyorke	Initial Release
AB	539	04/24/2009	M. Acosta	Revised for CoaguSense use.
AC	808	08/11/2010	M. Acosta	Update with current company information.
AD	1035	06/28/2013	N. Bhatnagar	Update with current address and product name.

MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 002 Rev. AD	
	EFFECTIVE DATE 06/28/2013	
Coag-Sense® Low Control Strip		

Section 1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Coag-Sense® Low Control Strip
Product Number: 100211
Business Area: Point of Care
Product Line: Coagulation monitoring
Instrument Type: Coag-Sense® PT/INR Meter

PHONE NUMBERS

Supplier
CoaguSense, Inc
48377 Fremont Blvd, STE 113
Fremont, CA USA 94538
Phone: 510-270-5448
Fax: 510-226-6540

In Case of Emergency:
911 or local authority

CHEMTREC
Phone: 800-424-9300 USA and Canada
Phone 703-527-3887 International

Section 2 COMPOSITION / INFORMATION ON INGREDIENTS


The Coag-Sense® Low Control Test Strip is dry test control strip, comprised primarily of a polycarbonate substrate with proprietary chemistry applied and dried onto the area where, when used with CoaguSense calcium chloride, is mixed by the Coag-Sense Meter.

Components	CAS Number	Weight%	OSHA PEL	ACGIH TLV	ACGIH STEL
Dry Test Strip: No hazardous components >1%; No carcinogen components >0.1%	NONE	N/A	N/A	N/A	N/A
Recombinant Animal Tissue Base Reagent < 0.1%	Not available	N/A	N/A	N/A	N/A
Lyophilized human citrated plasma < 0.1%	Not available	N/A	N/A	N/A	N/A

Additional information: Contains human/animal sourced and/or potentially infectious components.

Section 3 HAZARDS IDENTIFICATION (Emergency Overview)

NFPA Ratings:	Health = 0 Flammability = 0 Reactivity = 0
Special Definitions:	A=Allergen CA=Carcinogen CO=corrosive F=Flammable H=Harmful I=Irritant Ox=Oxidizer PB=Potential Bio-Hazard R=Reproductive S=Sensitizer T=Toxic TH= Highly Toxic W=Water Reactive
Principle routes of exposure:	Ingestion, skin, and/or eye contact
Inhalation:	None
Ingestion:	Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea
Skin Contact:	None
Eye Contact:	Contact with eyes may cause irritation

MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 002 Rev. AD	
Coag-Sense® Low Control Strip	EFFECTIVE DATE 06/28/2013	

Sensitization or Odor Threshold:	The following chemicals may cause sensitization, be absorbed via skin, and/or has an odor threshold for detection: none known
Medical conditions aggravated by exposure:	None known
Additional Information:	None

Section 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 and soap. If skin irritation persists, call a physician. Remove and wash contaminated clothing.
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.

Section 5 FIRE FIGHTING MEASURES

Suitable extinguishing media	Use dry chemical, CO2, water spray, or alcohol foam
Unusual Hazards	None known
Special protective equipment for firefighters	Wear self contained breathing apparatus for fire fighting if necessary.

Section 6 ACCIDENTAL RELEASE MEASURES


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

Section 7 HANDLING AND STORAGE

Handling:	Protect from contamination. Wear personal protective equipment
Storage:	No special precautions required.

Section 8 EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Measures:	Not applicable
Personal Protective Equipment	
Respiratory Protection	Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow the OSHA regulation 20CFR1910.134. Always use a NIOSH approved respirator when necessary.
Hand Protection	Wear appropriate gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Skin and Body Protection	Wear appropriate body protection to prevent skin contact
Eye Protection	Wear appropriate eye protection to prevent eye contact
Hygiene Protection	Avoid contact with skin, eyes, and clothing

MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 002 Rev. AD	
Coag-Sense® Low Control Strip	EFFECTIVE DATE 06/28/2013	

Section 9 PHYSICAL AND CHEMICAL PROPERTIES

Not applicable.	
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Section 10 STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions
Polymerization:	Not applicable
Hazardous decomposition products:	Carbon dioxide
Materials to avoid:	Strong acids and strong bases. Strong oxidizing agents.

Section 11 TOXOLOGICAL 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.

Section 12 ECOLOGICAL INFORMATION

Bioaccumulation	No data available
Aquatic toxicity	Not applicable
Ecotoxicity effects	No data available on the product itself

Section 13 DISPOSAL INFORMATION

Waste from residues / unused product	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 you local hazardous waste regulatory authority.
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Section 14 TRANSPORTATION INFORMATION


Is this product hazardous to ship?	No.
DOT	
Proper shipping name	None
UN Number Not applicable.	Hazard Class: Not applicable Subsidiary Risk: Not applicable Packing group: Not applicable
ICAO / IATA	
Proper shipping name	None
UN Number Not applicable	Hazard Class: Not applicable Subsidiary Risk: Not applicable Packing group: Not applicable

Section 15 REGULATORY INFORMATION

U.S. Regulations:

U.S. CERCLA / SARA / TSCA Regulatory information: the following chemicals are listed under the CERCLA / SARA / TSCA lists (Refer to the TSCA regulation if you need a definition for acronyms that may be shown in the TSCA inventory filed in the table below):

There are no substances to report.

MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 002 Rev. AD	
	EFFECTIVE DATE 06/28/2013	
Coag-Sense [®] Low Control Strip		

U.S. Clean Water Act (CWA / California Proposition 65: The following chemicals are listed under the CWA and/or California Proposition 65:


There are no substances to report.

Section 16 OTHER INFORMATION

- All information in this MSDS is has been derived from the sources outlined below, and is believed to be correct. It is provided as a guide to proper use, storage, transportation and disposal of this product. CoaguSense Inc. has not performed any independent testing of this product, and in no way warranties the accuracy or completeness of this information. CoaguSense Inc. shall not be held liable for any damages incurred as a result of handling, contact, use or disposal of this product.
- A complete listing of the main ingredients in this product is given on the accompanying product data sheet.
- Hazard identification is based on information on known hazardous ingredients at the time of this documents creation. Since no information is available on some components of this mixture, precautions should be taken to avoid contact with this product.
- Although this product contains biological components considered to be non-hazardous, standard safety precautions for handling biological materials are recommended.
- References used to prepare this document.
 - Manufacturers MSDS for individual components used to prepare this product.
 - MSDS for Beckman Coulter HemosIL Recombiplastin
 - MSDS for GE Plastics synthetic thermoplastic polymers (CASRN 111211-39-3)
 - MSDS for DuPont engineering polymer resin (DEL 007)

Document History

Rev.	DCO #	Effective Date	Originator	Description of Change
AA	424	02/27/2007	D. Gyorke	Initial Release
AB	539	04/24/2009	M. Acosta	Revised for CoaguSense use.
AC	808	08/11/2010	M. Acosta	Update with current company information.
AD	1035	06/25/2013	N. Bhatnagar	Update with current address and product name.

MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 003 Rev. AD	
	EFFECTIVE DATE 06/28/2013	

Section 1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Coag-Sense ® High Control Strip
Product Number: 100210
Business Area: Point of Care
Product Line: Coagulation monitoring
Instrument Type: Coag-Sense PT/INR Meter

PHONE NUMBERS

Supplier

CoaguSense, Inc
48377 Fremont Blvd, STE 113
Fremont, CA USA 94538
Phone: 510-270-5442
Fax: 510-226-6540

In Case of Emergency:

911 or local authority

CHEMTREC
Phone: 800-424-9300 USA and Canada
Phone 703-527-3887 International

Section 2 COMPOSITION / INFORMATION ON INGREDIENTS


The Coag-Sense ® High Control Strip is dry test control strip, comprised primarily of a polycarbonate substrate with proprietary chemistry applied and dried onto the area where, when used with CoaguSense calcium chloride, is mixed by the Coag-Sense Meter.

Components	CAS Number	Weight%	OSHA PEL	ACGIH TLV	ACGIH STEL
Dry Test Strip: No hazardous components >1%; No carcinogen components >0.1%	NONE	N/A	N/A	N/A	N/A
Recombinant Animal Tissue Base Reagent < 0.1%	Not available	N/A	N/A	N/A	N/A
Lyophilized human citrated plasma < 0.1%	Not available	N/A	N/A	N/A	N/A

Additional information: Contains human/animal sourced and/or potentially infectious components.

Section 3 HAZARDS IDENTIFICATION (Emergency Overview)

NFPA Ratings:	Health = 0 Flammability = 0 Reactivity = 0
Special Definitions:	A=Allergen CA=Carcinogen CO=corrosive F=Flammable H=Harmful I=Irritant Ox=Oxidizer PB=Potential Bio-Hazard R=Reproductive S=Sensitizer T=Toxic TH= Highly Toxic W=Water Reactive
Principle routes of exposure:	Ingestion, skin, and/or eye contact
Inhalation:	None
Ingestion:	Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea
Skin Contact:	None
Eye Contact:	Contact with eyes may cause irritation

MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 003 Rev. AD	
Coag-Sense ® High Control Strip	EFFECTIVE DATE 06/28/2013	

Sensitization or Odor Threshold:	The following chemicals may cause sensitization, be absorbed via skin, and/or has an odor threshold for detection: none known
Medical conditions aggravated by exposure:	None known
Additional Information:	None

Section 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 and soap. If skin irritation persists, call a physician. Remove and wash contaminated clothing.
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.

Section 5 FIRE FIGHTING MEASURES

Suitable extinguishing media	Use dry chemical, CO2, water spray, or alcohol foam
Unusual Hazards	None known
Special protective equipment for firefighters	Wear self contained breathing apparatus for fire fighting if necessary.

Section 6 ACCIDENTAL RELEASE MEASURES


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

Section 7 HANDLING AND STORAGE

Handling:	Protect from contamination. Wear personal protective equipment
Storage:	No special precautions required.

Section 8 EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Measures:	Not applicable
Personal Protective Equipment	
Respiratory Protection	Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow the OSHA regulation 20CFR1910.134. Always use a NIOSH approved respirator when necessary.
Hand Protection	Wear appropriate gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Skin and Body Protection	Wear appropriate body protection to prevent skin contact
Eye Protection	Wear appropriate eye protection to prevent eye contact
Hygiene Protection	Avoid contact with skin, eyes, and clothing

MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 003 Rev. AD	
Coag-Sense ® High Control Strip	EFFECTIVE DATE 06/28/2013	

Section 9 PHYSICAL AND CHEMICAL PROPERTIES

Not applicable.	
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Section 10 STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions
Polymerization:	Not applicable
Hazardous decomposition products:	Carbon dioxide
Materials to avoid:	Strong acids and strong bases. Strong oxidizing agents.

Section 11 TOXOLOGICAL 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.

Section 12 ECOLOGICAL INFORMATION

Bioaccumulation	No data available
Aquatic toxicity	Not applicable
Ecotoxicity effects	No data available on the product itself

Section 13 DISPOSAL INFORMATION

Waste from residues / unused product	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 you local hazardous waste regulatory authority.
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Section 14 TRANSPORTATION INFORMATION

Is this product hazardous to ship?	No.
DOT	
Proper shipping name	None
UN Number	Not applicable
	Hazard Class: Not applicable Subsidiary Risk: Not applicable Packing group: Not applicable
ICAO / IATA	
Proper shipping name	None
UN Number	Not applicable
	Hazard Class: Not applicable Subsidiary Risk: Not applicable Packing group: Not applicable


Section 15 REGULATORY INFORMATION

U.S. Regulations:

U.S. CERCLA / SARA / TSCA Regulatory information: the following chemicals are listed under the CERCLA / SARA / TSCA lists (Refer to the TSCA regulation if you need a definition for acronyms that may be shown in the TSCA inventory filed in the table below):

There are no substances to report.

U.S. Clean Water Act (CWA / California Proposition 65): The following chemicals are listed under the CWA and/or California Proposition 65:

MATERIAL SAFETY DATA SHEET	DOCUMENT NUMBER MSDS 003 Rev. AD	
Coag-Sense ® High Control Strip	EFFECTIVE DATE 06/28/2013	

There are no substances to report.

Section 16 OTHER INFORMATION

- All information in this MSDS is has been derived from the sources outlined below, and is believed to be correct. It is provided as a guide to proper use, storage, transportation and disposal of this product. CoaguSense Inc. has not performed any independent testing of this product, and in no way warranties the accuracy or completeness of this information. CoaguSense Inc. shall not be held liable for any damages incurred as a result of handling, contact, use or disposal of this product.
- A complete listing of the main ingredients in this product is given on the accompanying product data sheet.
- Hazard identification is based on information on known hazardous ingredients at the time of this documents creation. Since no information is available on some components of this mixture, precautions should be taken to avoid contact with this product.
- Although this product contains biological components considered to be non-hazardous, standard safety precautions for handling biological materials are recommended.
- References used to prepare this document.
 - Manufacturers MSDS for individual components used to prepare this product.
 - MSDS for Beckman Coulter HemosIL Recombiplastin
 - MSDS for GE Plastics synthetic thermoplastic polymers (CASRN 111211-39-3)
 - MSDS for DuPont engineering polymer resin (DEL 007)

Document History

Rev.	DCO #	Effective Date	Originator	Description of Change
AA	424	02/27/2007	D. Gyorke	Initial Release
AB	539	04/24/2009	M. Acosta	Revised for CoaguSense use.
AC	808	08/11/2010	M. Acosta	Update with current company information.
AD	1035	06/25/2013	N. Bhatnagar	Update with current address and product name.