



## SAFETY DATA SHEET

Rev. Date 09/12/2018

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product Identifier/Name: **Collagel® Kit**

Product Number: COLKIT-100A (Patent Nos. 8,663,988; 8,877,500; 8,993,325; 9,018,009)

Company: Flexcell® International Corp.

Address: 2730 Tucker Street, Suite 200  
Burlington, NC 27215

Telephone Number: 1-919-732-1591  
1-800-728-3714

Emergency Telephone Number: (919) 732-1591

Recommended Use: For *in vitro* research use only

### 2. HAZARDS IDENTIFICATION

Component	GHS Classification	GHS Label Elements	Hazards not Otherwise Classified (HNOC) or not covered by GHS
<b>Collagel®</b> (Type I Collagen 3 mg/ml in 0.01 M HCl)	Not a hazardous substance or mixture	Not a hazardous substance or mixture	None
<b>Reagent A</b> (5X MEM)	Not a hazardous substance or mixture	Not a hazardous substance or mixture	None
<b>Reagent B</b> (Fetal Bovine Serum)	Not a hazardous substance or mixture	Not a hazardous substance or mixture	None
<b>Reagent C</b> (1M HEPES)	Not a hazardous substance or mixture	Not a hazardous substance or mixture	None

*Culturing Cells in a Mechanically Active Environment™*

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## 2. HAZARDS IDENTIFICATION

Component	GHS Classification	GHS Label Elements	Hazards not Otherwise Classified (HNOC) or not covered by GHS
<b>Reagent D</b> (0.1 M NaOH in 5X MEM)	Skin irritation (Category 3)	<b>Signal Word: WARNING</b>	None
	Eye Irritation (Category 2B)	<p><b>Hazard Statements</b> Causes mild skin irritation Causes eye irritation</p> <p><b>Precautionary Statements:</b> Wash skin thoroughly after handling. Wear protective gloves/ eye protection/ face protection.</p> <p>IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs, get medical advice/ attention. Take off contaminated clothing and wash before reuse.</p> <p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present. Continue rinsing.</p> <p>Immediately call a POISON CENTER or doctor/ physician.</p>	

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Substance	Formula	Molecular weight	%	CAS-No.	EC-No.
<b>CollageI®</b>	Bovine Collagen – Calf Skin			2.9 - 3.2	9007-34-5	
	<i>This kit component contains no substances which at their given concentration, are considered to be hazardous to health. We recommend handling all chemicals with caution.</i>					
<b>Reagent A</b>	Minimum Essential Medium (MEM)			47.5		
	Sodium Bicarbonate	CHNaO <sub>3</sub>	84.01 g/mol	18.5	144-55-8	205-633-8
	Water			34	7732-18-5	231-791-2
	<i>This kit component contains no substances, which at their given concentration, are considered to be hazardous to health. We recommend handling all chemicals with caution.</i>					
<b>Reagent B</b>	Fetal Bovine Serum					
	<i>This kit component contains no substances which at their given concentration, are considered to be hazardous to health. We recommend handling all chemicals with caution.</i>					

Component	Substance	Formula	Molecular weight	%	CAS-No.	EC-No.
<b>Reagent C</b>	HEPES (4-(2-Hydroxyethyl)-1-piperazineethanesulphonic acid), 1 M Solution			>/=23.8 - </=23.9	7365-45-9	230-907-9
	Water			>/=76.1 - </=76.2	7732-18-5	231-791-2
	<i>This kit component contains no substances which at their given concentration, are considered to be hazardous to health. We recommend handling all chemicals with caution.</i>					
<b>Reagent D</b>	Sodium hydroxide	NaOH	40.0 g/mol		1310-73-2	215-185-5
	Minimum Essential Medium (MEM)					
	Sodium Bicarbonate	CHNaO <sub>3</sub>	84.01 g/mol		144-55-8	205-633-8
	Water				7732-18-5	231-791-2

#### 4. FIRST AID MEASURES

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##### **Skin Contact**

Wash off with soap and rinse with plenty of water. Consult a physician as needed.

##### **Eye Contact**

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Continue rinsing eyes during transport to hospital, if needed.

##### **Inhalation**

Move to fresh air. If symptoms persist, call a physician. If not breathing, give artificial respiration.

##### **Ingestion**

Never give anything by mouth to an unconscious person. Rinse mouth with water. If symptoms persist, call a physician. Do not induce vomiting without medical advice.

#### 5. FIRE FIGHTING MEASURES

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##### **Suitable extinguishing media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

##### **Special protective equipment for firefighters**

Wear self-contained breathing apparatus and protective suit for firefighting if necessary. Prevent contact with skin and eyes.

##### **Special hazards arising from the substance or mixture**

**CollageI®:** As with any organic material, this product may produce toxic carbon monoxide and dioxide fumes if heated to decomposition and airborne dust may present an explosion hazard.

**Reagent A & D:** Sodium oxides, Carbon oxides

**Reagent B:** Not data available

#### 6. ACCIDENTAL RELEASE MEASURES

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##### **Personal precautions, protective equipment and emergency procedures**

Avoid breathing vapors, mist or gas. Avoid dust formation.

For personal protection see section 8.

**Environmental precautions**

Prevent further leakage or spillage if safe to do so. Do not let product enter drains

**Methods and materials for containment and cleaning up**

Wear protective clothing and gloves in section 8. Take up mechanically and collect in suitable container for disposal. Avoid dust formation. Avoid breathing vapors, mist, or gas. Ensure adequate ventilation. Wash contaminated clothing before reuse. Do not let product enter drains.

**Waste Disposal**

Dispose of waste in accordance with all applicable federal, state, and local regulations. See Section 13 for additional information.

**7. HANDLING AND STORAGE**

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**Precautions for Safe Handling**

To ensure sterility of product, handle in an aseptic environment. Always wear recommended Personal Protective Equipment. Avoid contact with skin and eyes. Avoid inhalation of vapor or mist.

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.

**Conditions for safe storage**

Keep containers tightly closed in a dry and well-ventilated place. Some reagents are light sensitive. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Store CollageI® and vials A, B, C, and D in a darkened environment at 4 °C.

- CollageI® 4 °C in darkened environment.
- Reagent A 4 °C in darkened environment.
- Reagent B 4 °C in darkened environment.
- Reagent C 4 °C in darkened environment. Light sensitive.
- Reagent D 4 °C in darkened environment.

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

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**Components with Workplace Control Parameters**

Component	CAS-No.	Value	Control parameters	Basis
Sodium hydroxide (NaOH) in Reagent D	1310-73-2	CEIL	2 mg/m <sup>3</sup>	USA. ACGIH Threshold Limit Values (TLV)
		C	2 mg/m <sup>3</sup>	USA. OSHA - TABLE Z-1 Limits for Air Contaminants -1910.1000
		TWA	2 mg/m <sup>3</sup>	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		C	2 mg/m <sup>3</sup>	USA. NIOSH Recommended Exposure Limits

**Specific Engineering Controls**

Use general industrial hygiene practice. Ensure adequate ventilation, especially in confined areas.

**Personal Protective Equipment**

*Respiratory protection*- In case of insufficient ventilation wear suitable respiratory equipment. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

*Hand protection*- Impervious 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.

*Eye protection*- Safety glasses with side-shields. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

*Skin and body protection*- Lightweight protective impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

*Hygiene measures*- Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

**Control of Environmental Exposure:** Prevent product from entering drains.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Component	Collagel®	Reagent A	Reagent B	Reagent C	Reagent D
<b>Appearance</b>	Liquid, clear to opaque, white to tan, typical enzyme odor	Liquid	Liquid	Liquid, Clear	Liquid
<b>pH</b>			No data available	7.2 +/- 0.2 @ 20-25C	
<b>Melting Point/ Freezing Point</b>		300 °C (572 °F) for CHNaO <sub>3</sub>	No data available		300 °C (572 °F) for CHNaO <sub>3</sub>
<b>Boiling Point</b>	Decomposes		No data available		
<b>Specific Gravity</b>	Varies		No data available		
<b>Solubility in Water</b>	Immiscible in water	50 g/l for CHNaO <sub>3</sub>	No data available		50 g/l for CHNaO <sub>3</sub>
<b>Density</b>		2.160 g/cm <sup>3</sup> for CHNaO <sub>3</sub>	No data available	1.070 g/cm <sup>3</sup>	2.160 g/cm <sup>3</sup> for CHNaO <sub>3</sub>

**10. STABILITY AND REACTIVITY**

Component	Collagel®	Reagent A	Reagent B	Reagent C	Reagent D
<b>Reactivity</b>	No data available				
<b>Chemical stability</b>	Stable under recommended storage conditions				
<b>Possibility of hazardous reactions</b>	No data available				
<b>Conditions to avoid</b>	No data available				
<b>Incompatible Materials</b>	No data available	Strong acids, Strong oxidizing agents	Strong oxidizing agents		Strong oxidizing agents, Strong acids, Organic materials

Component	Collagel®	Reagent A	Reagent B	Reagent C	Reagent D
<b>Hazardous Decomposition Products</b>	As with any organic material, this product may produce toxic carbon monoxide and dioxide fumes if heated to decomposition and airborne dust may present an explosion hazard	No data available			Sodium oxides

## 11. TOXICOLOGICAL INFORMATION

### Effects of Exposure to Chemicals in Reagents A and D

	Sodium Bicarbonate (CHNaO3)	Sodium Hydroxide Solution (NaOH)
<b>Acute Toxicity</b>	<b>Oral LD50:</b> LD50 Oral - rat - 4,220 mg/kg <b>Inhalation:</b> no data available <b>Dermal:</b> no data available	<b>Sodium Hydroxide, 0.1N (0.1M)</b> LD50 dermal rabbit 337500 mg/kg <b>Sodium Hydroxide (1310-73-2)</b> LD50 dermal rabbit 1350 mg/kg (Rabbit; Literature)
<b>Skin Corrosion/Irritation</b>	Skin - Human - Mild skin irritation - 3 d	No data available
<b>Serious Eye Damage/Eye Irritation</b>	Eyes - rabbit - Mild eye irritation - 30 s	No data available
<b>Respiratory or skin sensitization</b>	No data available	No data available
<b>Germ Cell Mutagenicity</b>	No data available	No data available
<b>Carcinogenicity-IARC</b>	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.	No component of this product presents at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
<b>Carcinogenicity - ACGIH</b>	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
<b>Carcinogenicity-NTP</b>	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP	
<b>Carcinogenicity-OSHA</b>	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.	
<b>Reproductive toxicity</b>	No data available	No data available

**Sodium Bicarbonate (CHNaO3)****Sodium Hydroxide Solution (NaOH)****Additional Information**

Exposure to large amounts can cause: gastrointestinal disturbance, heavy or prolonged skin exposure may result in the absorption of harmful amounts of material. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

**12. ECOLOGICAL INFORMATION**

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**Toxicity**

Collagel, Reagent A, B, C: No data available

**In Reagent D, Sodium Hydroxide, 0.1N (0.1M)**

LC50 fishes 1 11350 mg/l

EC50 Daphnia 1 10125 mg/l

**Persistence and degradability**

In Reagent A, MEM is inherently biodegradable

Collagel, Reagent B, C, D: Not established

**Bioaccumulative potential**

In Reagent A, MEM does not bioaccumulate; No data available for Sodium Bicarbonate (CHNaO<sub>3</sub>)

Collagel, Reagent B, C, D: Not established

**Mobility in soil**

No data available

**Results of PBT and vPvB assessment**

No data available

**Other adverse effects**

No data available

**13. DISPOSAL CONSIDERATIONS**

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**Product**

Dispose of waste in accordance with all federal, state and local environmental regulations.

Offer surplus, non-recyclable solutions, and contaminated packaging to a licensed disposal company.

**Contaminated Packaging**

Dispose of unused product

**14. TRANSPORT INFORMATION**

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Not classified as dangerous in the meaning of transport regulations

**15. REGULATORY INFORMATION**

	<i>U.S. Federal Regulations</i>	<i>U.S. State Regulations</i>	<i>International Regulations</i>
<b>Collagel®</b>	Material(s) listed are exempt from the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory when supplied for research and development purposes or used under the Supervision of a technically qualified individual as defined by 40 CFR720.3.  The health risks have not been fully determined.	Based upon available information, material(s) listed are not known to be regulated by any state or listed on any "Right To Know" Hazardous Substance List.	EC: Harmful; R42/43, May cause sensitization by inhalation and skin contact.  S36, Wear suitable protective clothing.
<b>Reagent A, B, C, D</b>	<b>SARA 302 Components:</b> No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302. <b>SARA 313 Components:</b> This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313. <b>SARA 311/312 Hazards:</b> No SARA Hazards	<b>Massachusetts Right To Know Components:</b> No components are subject to the Massachusetts Right to Know Act. <b>Pennsylvania Right To Know Components:</b> Sodium hydrogencarbonate CAS-No. 144-55-8; Fetal bovine serum; Water CAS-No. 7732-18-5; Sodium hydroxide CAS-No. 1310-73-2 <b>New Jersey Right To Know Components:</b> Sodium hydrogencarbonate CAS-No. 144-55-8; Fetal bovine serum; Water CAS-No. 7732-18-5; Sodium hydroxide CAS-No. 1310-73-2 <b>California Prop. 65 Components:</b> This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm	

**16. OTHER INFORMATION**

**HMIS Rating**

Health: 1  
Flammability: 0  
Physical: 0

**NFPA Rating**

NFPA health hazard: 1  
NFPA fire hazard: 0  
NFPA reactivity: 0

*The information contained in this SDS is believed to be accurate and represents the best information available to date. The information contained in this SDS relates only to the material(s) designated and does not relate to uses(s) in combination with any other materials, process(es), and/or chemical reactions(s).*

*Flexcell International Corp. makes no warranty nor assumes liability for its usage. Users should make their own investigations to determine the suitability of the product for specific applications. Flexcell International Corp. provides this information in good faith, from sources believed to be accurate, however, assumes no liability for its accuracy or completeness.*