

Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03.

Printing date 03/12/2015

Reviewed on 03/12/2015

* **1 Identification**

- **Product identifier**
- **Trade name: Sennosides and Docusate Tablets**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Product description** 8.6 mg and 50 mg, Micro-Coated, Round, Bi-Convex: 192R, 209R & 243R
- **Application of the substance / the mixture** Sennosides and Docusate Tablets
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
 Time-Cap Labs, Inc.
 7 Michael Avenue
 Farmingdale, NY 11735
 Phone: (631) 753-9090
 Fax: (631) 753-2220
- **Emergency telephone number:** (631) 753-9090

* **2 Hazard(s) identification**

- **Classification of the substance or mixture**



Skin Irrit. 2 H315 Causes skin irritation.
 Eye Irrit. 2A H319 Causes serious eye irritation.
 STOT SE 3 H335 May cause respiratory irritation.

- **Label elements**
- **GHS label elements**
 The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



- **Signal word** Warning
- **Hazard-determining components of labeling:**
 Docusate Sodium
 Calcium Phosphate Dibasic Dihydrate
 Sodium Benzoate
 Magnesium Stearate
- **Hazard statements**
 Causes skin irritation.
 Causes serious eye irritation.
 May cause respiratory irritation.
- **Precautionary statements**
 Avoid breathing dust/fume/gas/mist/vapors/spray
 Use only outdoors or in a well-ventilated area.
 Wear protective gloves.
 Wear eye protection / face protection.
 Wash thoroughly after handling.

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If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 Specific treatment (see on this label).
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 Call a poison center/doctor if you feel unwell.
 If skin irritation occurs: Get medical advice/attention.
 If eye irritation persists: Get medical advice/attention.
 If on skin: Wash with plenty of water.
 Take off contaminated clothing and wash it before reuse.
 Store locked up.
 Store in a well-ventilated place. Keep container tightly closed.
 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Unknown acute toxicity:**

36.4 percent of the mixture consists of ingredient(s) of unknown toxicity.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMS-ratings (scale 0 - 4)**



· **Other hazards** None known

*** 3 Composition/information on ingredients**

81-27-6	Sennoside A		5.45-10.89%
128-57-4	Sennoside B		5.45-10.89%
8015-86-9	Carnauba Wax		Proprietary%
9004-65-3	Hypromellose	Combustible Dust	Proprietary%
9004-34-6	Microcrystalline Cellulose		Proprietary%
112945-52-5	Amorphous Silica		Proprietary%
15790-07-5	FD&C Yellow #6 Aluminum Lake	Eye Irrit. 2B, H320; Combustible Dust	Proprietary%
68814-04-0	FD&C Yellow #10 Lake	Eye Irrit. 2B, H320; Combustible Dust	Proprietary%
25322-68-3	Polyethylene Glycol		Proprietary%
68583-95-9	FD&C Red #40 Aluminum Lake	Eye Irrit. 2B, H320; Combustible Dust	Proprietary%

· **Chemical characterization: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous Components:**

CAS: 7789-77-7	Calcium Phosphate Dibasic Dihydrate	Proprietary%
	⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	
CAS: 577-11-7	Docusate Sodium	13.62%
RTECS: WN 0525000	⚠ Eye Dam. 1, H318; ⚠ Skin Irrit. 2, H315; H402	

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CAS: 74811-65-7	Croscarmellose Sodium ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2B, H320; Combustible Dust	Proprietary%
CAS: 532-32-1	Sodium Benzoate ⚠ Acute Tox. 4, H302; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%
CAS: 557-04-0	Magnesium Stearate ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%
CAS: 13463-67-7	Titanium Dioxide ⚠ Carc. 2, H351; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	Proprietary%
CAS: 16521-38-3	FD&C Blue #2 Aluminum Lake ⚠ Eye Irrit. 2A, H319; Combustible Dust	Proprietary%
CAS: 57-11-4 RTECS: WI 2800000	Stearic Acid, pure ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%

· **Additional information:**

- 192R: Only product version colored Orange.
- 209R: Only product version colored Red.
- 243R: Only product version colored Burgandy.

192R: Only product version that include the following ingredients: FD&C Yellow #6 Aluminum Lake, FD&C Yellow #10 Aluminum Lake.

209R & 342R: Only product versions that include the following ingredients: FD&C Red #40 Aluminum Lake.

243R: Only product version that include the following ingredient: FD&C Blue #2 Aluminum Lake.

*Sodium Benzoate is a minor ingredient of the Docusate Sodium major ingredient.

* 4 First-aid measures

· **Description of first aid measures**

· **General information:**

First aid is generally not required if product is used correctly and according to the recommended dosages established by this manufacturer.

· **After inhalation:**

Product generally does not present an inhalation hazard unless it is in powder form. Take care not to crush tablet and inhale powder.

In case of unconsciousness, place patient securely on side position for transportation.

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:**

Rinse opened eye for at least 15 minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:**

Product generally does not present an ingestion hazard is used correctly and according to the recommended dosages established by this manufacturer.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

* 5 Fire-fighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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

If incinerated, product may release the following toxic gases: Oxides of Carbon, Silicon, Sodium, Nitrogen (NOx), Calcium and Titanium.

· **Advice for firefighters**

Product has a combustible dust hazard. Avoid generating dust while extinguishing any fires.

· **Protective equipment:**

As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

*** 6 Accidental release measures**

· **Personal precautions, protective equipment and emergency procedures** Avoid breathing dust.

· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

· **Methods and material for containment and cleaning up:**

Avoid the formation of dust

Ensure adequate ventilation.

Dispose of the collected material according to regulations.

· **Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

*** 7 Handling and storage**

· **Handling:**

· **Precautions for safe handling** No special precautions are necessary if used correctly.

· **Information about protection against explosions and fires:**

Dust can combine with air to form an explosive mixture.

· **Conditions for safe storage, including any incompatibilities**

Store away from strong acids, strong bases, strong oxidizing agents and strong reducing agents.

· **Storage:**

· **Requirements to be met by storerooms and receptacles:** No special requirements.

· **Information about storage in one common storage facility:** Not required.

· **Further information about storage conditions:** Keep receptacle tightly sealed.

· **Specific end use(s)** No further relevant information available.

*** 8 Exposure controls/personal protection**

· **Additional information about design of technical systems:** No further data; see section 7.

· **Control parameters**

· **Components with occupational exposure limits:**

9004-34-6 Microcrystalline Cellulose

PEL	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
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REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
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TLV	Long-term value: 10 mg/m ³
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557-04-0 Magnesium Stearate

TLV	Long-term value: 10 mg/m ³
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· **Additional information:** The lists that were valid during the creation were used as basis.

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- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Breathing equipment:** Not necessary under normal conditions.
- **Protection of hands:** Not necessary under normal conditions.
- **Eye protection:** Not necessary under normal conditions.

* 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Tablet

Color: Orange, Red or Burgandy

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/Melting range: Not determined.

Boiling point/Boiling range: Not determined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not determined.

· **Ignition temperature:**

Decomposition temperature: Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

· **Vapor pressure:** Not applicable.

· **Density:**

Relative density Not determined.

Vapour density Not applicable.

Evaporation rate Not applicable.

· **Solubility in / Miscibility with**

Water: Partly soluble.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

Dynamic: Not applicable.

Kinematic: Not applicable.

· **Solvent content:**

Organic solvents: 0.0 %

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- **Solids content:** 100.0 %
- **Other information** No further relevant information available.

* 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** Strong acids, strong bases, strong oxidizing agents and strong reducing agents.
- **Hazardous decomposition products:**
Oxides of Carbon, Silicon, Sodium, Nitrogen (NOx), Calcium and Titanium.

* 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

577-11-7 Docusate Sodium

Oral	LD50	1900 mg/kg (rat)
Dermal	LD50	>10000 mg/kg (rabbit)
Inhalative	LC50/96 hours	>2000 mg/l (rat)

112945-52-5 Amorphous Silica

Oral	LD50	10000 mg/kg (rat)
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9004-65-3 Hypromellose

Oral	LD50	2000 mg/kg (rat)
	Intravenous	5200 mg/kg (rat)

9004-34-6 Microcrystalline Cellulose

Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)

532-32-1 Sodium Benzoate

Oral	LD50	1600 mg/kg (mouse)
		4070 mg/kg (rat)
		2000 mg/kg (rabbit)

57-11-4 Stearic Acid, pure

Dermal	LD50	>5000 mg/kg (rabbit)
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13463-67-7 Titanium Dioxide

Oral	LD50	>10000 mg/kg (rat)
Dermal	LD50	>10000 mg/kg (rabbit)
Inhalative	LC50/4 h	>6.82 mg/l (rat)

- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:**
Irritating effect.
Causes serious eye irritation.

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Trade name: Sennosides and Docusate Tablets

· **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

- Group 1 - Carcinogenic to humans
- Group 2A - Probably carcinogenic to humans
- Group 2B - Possibly carcinogenic to humans
- Group 3 - Not classifiable as to its carcinogenicity to humans
- Group 4 - Probably not carcinogenic to humans

13463-67-7	Titanium Dioxide	2B
112945-52-5	Amorphous Silica	3

· **NTP (National Toxicology Program)**

None of the ingredients are listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients are listed.

*** 12 Ecological information**

· **Toxicity**

· **Aquatic toxicity:**

577-11-7 Docusate Sodium

EC50 10.3 mg/l (daphnia)

13463-67-7 Titanium Dioxide

EC50 >1000 mg/l (Water flea)

· **Persistence and degradability** No further relevant information available.

· **Behavior in environmental systems:**

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

· **Additional ecological information:**

· **General notes:**

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

*** 13 Disposal considerations**

· **Waste treatment methods**

· **Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

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* 14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** Non-Regulated Material
- **Packing group**
- **DOT, ADR, IMDG, IATA** Non-Regulated Material
- **Environmental hazards:** Not applicable.
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **UN "Model Regulation":** -

* 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**

9004-34-6	Microcrystalline Cellulose
577-11-7	Docusate Sodium
9004-65-3	Hypromellose
532-32-1	Sodium Benzoate
557-04-0	Magnesium Stearate
68583-95-9	FD&C Red #40 Aluminum Lake
57-11-4	Stearic Acid, pure
25322-68-3	Polyethylene Glycol
13463-67-7	Titanium Dioxide
15790-07-5	FD&C Yellow #6 Aluminum Lake
68814-04-0	FD&C Yellow #10 Lake
112945-52-5	Amorphous Silica
16521-38-3	FD&C Blue #2 Aluminum Lake
8015-86-9	Carnauba Wax

· **Proposition 65**

· **Chemicals known to cause cancer:**

13463-67-7 Titanium Dioxide

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

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· Chemicals known to cause reproductive toxicity for males:		
None of the ingredients are listed.		
· Chemicals known to cause developmental toxicity:		
None of the ingredients are listed.		
· Carcinogenic categories		
· EPA (Environmental Protection Agency)		
None of the ingredients are listed.		
· TLV (Threshold Limit Value established by ACGIH)		
13463-67-7	Titanium Dioxide	A4
· NIOSH-Ca (National Institute for Occupational Safety and Health)		
13463-67-7	Titanium Dioxide	

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**

- Docusate Sodium
- Calcium Phosphate Dibasic Dihydrate
- Sodium Benzoate
- Magnesium Stearate

· **Hazard statements**

- Causes skin irritation.
- Causes serious eye irritation.
- May cause respiratory irritation.

· **Precautionary statements**

- Avoid breathing dust/fume/gas/mist/vapors/spray
- Use only outdoors or in a well-ventilated area.
- Wear protective gloves.
- Wear eye protection / face protection.
- Wash thoroughly after handling.
- If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- Specific treatment (see on this label).
- IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- Call a poison center/doctor if you feel unwell.
- If skin irritation occurs: Get medical advice/attention.
- If eye irritation persists: Get medical advice/attention.
- If on skin: Wash with plenty of water.
- Take off contaminated clothing and wash it before reuse.
- Store locked up.
- Store in a well-ventilated place. Keep container tightly closed.
- Dispose of contents/container in accordance with local/regional/national/international regulations.

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<p>· National regulations:</p> <p>The product is subject to be labeled according with the prevailing version of the regulations on hazardous substances.</p>		
<p>· State Right to Know</p>		
CAS: 9004-34-6	Microcrystalline Cellulose	Proprietary%
CAS: 7789-77-7	Calcium Phosphate Dibasic Dihydrate ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%
CAS: 577-11-7 RTECS: WN 0525000	Docusate Sodium ⚠ Eye Dam. 1, H318; ⚠ Skin Irrit. 2, H315; H402	13.62%
CAS: 81-27-6	Sennoside A	5.45-10.89%
CAS: 128-57-4	Sennoside B	5.45-10.89%
CAS: 74811-65-7	Croscarmellose Sodium ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2B, H320; Combustible Dust	Proprietary%
<p>All ingredients are listed.</p>		
<p>· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.</p>		

16 Other information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

· **Date of preparation / last revision** 03/12/2015 / -

· **Abbreviations and acronyms:**

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road
 ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
 IMDG: International Maritime Code for Dangerous Goods
 DOT: US Department of Transportation
 IATA: International Air Transport Association
 ACGIH: American Conference of Governmental Industrial Hygienists
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 NFPA: National Fire Protection Association (USA)
 HMIS: Hazardous Materials Identification System (USA)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 Acute Tox. 4: Acute toxicity, Hazard Category 4
 Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
 Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
 Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
 Eye Irrit. 2B: Serious eye damage/eye irritation, Hazard Category 2B
 Carc. 2: Carcinogenicity, Hazard Category 2
 STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
 : Hazardous to the aquatic environment - AcuteHazard, Category 3

· *** Data compared to the previous version altered.**

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