

Safety Data Sheet (SDS)

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

Issue date 06/17/2019

Reviewed on 06/17/2019

1 Identification

- **Product Identifier**
- **Trade Name: Aspirin Tablets, USP**
- **Relevant identified uses of the substance or mixture and uses advised against:**
- **Product Description:** 325 mg and 500 mg, Micro-Coated, Round, Bi-Convex: 11R & 382R
- **Application of the substance / the mixture:** Aspirin Tablets, USP
- **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:**



Acute Tox. 4 H332 Harmful if inhaled.
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:**
- **Hazard pictograms:**



- **Signal word:** Warning
- **Hazard-determining components of labeling:**
Aspirin
Croscarmellose Sodium
- **Hazard statements:**
H332 Harmful if inhaled.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
- **Precautionary statements:**

P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P264	Wash thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves / eye protection / face protection.
P302+P352	If on skin: Wash with plenty of water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a poison center/doctor if you feel unwell.
P321	Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).

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P362+P364 Take off contaminated clothing and wash it before reuse.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P403+P233 Store in a well-ventilated place. Keep container tightly closed.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Unknown acute toxicity:

This value refers to knowledge of known, established toxicological or ecotoxicological values.
3.4 % of the mixture consists of component(s) of unknown toxicity.

Classification system: NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme

NFPA ratings (scale 0 - 4)

 Health = 2
Fire = 0
Reactivity = 0

HMIS-ratings (scale 0 - 4)

 HEALTH 2 Health = 2
FIRE 0 Fire = 0
REACTIVITY 0 Physical Hazard = 0

Hazard(s) not otherwise classified (HNOC): None known

* 3 Composition/Information on Ingredients

Chemical characterization: Mixtures

Description: Mixture of substances listed below with non-hazardous additions.

Dangerous Components:

CAS: 50-78-2 RTECS: VO 0700000	Aspirin ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	86%
CAS: 9004-34-6	Microcrystalline Cellulose	Proprietary%
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: 65996-62-5	Corn Starch Combustible Dust	Proprietary%
CAS: 9004-65-3	Hypromellose Combustible Dust	Proprietary%
CAS: 13463-67-7	Titanium Dioxide ⚠ Carc. 2, H351	Proprietary%

Additional information:

The exact percentages of the ingredients of this mixture are considered to be proprietary and are withheld in accordance with the provisions of paragraph (i) of §1910.1200 of 29 CFR 1910.1200 Trade Secrets.

11R: Only product version that is 325 mg

382R: Only product version that is 500 mg

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* 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 stably in the side position for transportation.

- **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation occurs, consult a doctor.

- **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**

Treatment of Aspirin (Salicylate) overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as a slurry. Multiple doses may be beneficial. Perform gastric lavage, unless contraindicated, soon after ingestion. Protect airway and control seizures first. Correct dehydration with sodium chloride until good urine flow is obtained. Do not over hydrate. Add potassium to subsequent fluid. Monitor pulmonary status, urine output, urine pH, and serum potassium. Alkalinize urine with sodium bicarbonate to achieve a urine pH greater than 7.5. Additional potassium chloride may be required. For acidosis, administer sodium bicarbonate intravenously. Monitor ABGs. Treat hyperthermia with external cooling. Early treatment with hemodialysis may be useful if blood salicylate levels are high or if symptoms of salicylism persist. Hemodialysis rapidly increases salicylate clearance and corrects acid-base, fluid, and electrolyte disturbances. For seizures, administer a benzodiazepine intravenously. If seizures recur, consider phenobarbital or propofol. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte imbalances, and hypoxia. For active bleeding or coagulation disorders, give blood or blood platelets if needed. Vitamin K may improve prothrombin time. [Poisindex]

- **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:**

Use fire fighting measures that suit the environment.

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

- **For safety reasons unsuitable extinguishing agents:** No further relevant information.

- **Special hazards arising from the substance or mixture:**

If incinerated, product may release the following toxic gases: Oxides of Carbon, Sodium, and Titanium.

- **Advice for firefighters**

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

- **Special protective equipment for firefighters:**

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.

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* 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
Dispose contaminated material as waste according to section 13.
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.
- **Protective Action Criteria for Chemicals**

· PAC-1:

13463-67-7	Titanium Dioxide	30 mg/m ³
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· PAC-2:

13463-67-7	Titanium Dioxide	330 mg/m ³
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· PAC-3:

13463-67-7	Titanium Dioxide	2,000 mg/m ³
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* 7 Handling and Storage

- **Handling**
- **Precautions for safe handling:**
Avoid creating and breathing dust/fume/gas/mist/vapors/spray.
Ensure good ventilation/exhaustion at the workplace.
- **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 and strong oxidizing agents.
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store in the original container.
- **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:**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

50-78-2 Aspirin

REL	Long-term value: 5 mg/m ³
TLV	Long-term value: 5 mg/m ³

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9004-34-6 Microcrystalline Cellulose	
PEL	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	Long-term value: 10 mg/m ³
13463-67-7 Titanium Dioxide	
PEL	Long-term value: 15* mg/m ³ *total dust
REL	See Pocket Guide App. A
TLV	Long-term value: 10 mg/m ³

· **Additional information:** The lists that were valid during the creation of this SDS were used as basis.

· **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:**

Protective gloves recommended in manufacturing.



Protective gloves

· **Material of gloves:**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material:**

The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.

· **Eye protection:** Not necessary under normal conditions.

· **Limitation and supervision of exposure into the environment:** None

* 9 Physical and Chemical Properties

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

· **General Information**

· **Appearance:**

Form:

Tablet

Color:

White

· **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.

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Trade Name: Aspirin Tablets, USP

- **Flash point:** None
- **Flammability (solid, gaseous):** Not determined.
- **Ignition temperature:** $\geq 340^{\circ}\text{C}$ ($\geq 644^{\circ}\text{F}$)
- **Decomposition temperature:** Not determined.
- **Auto igniting:** Product is not self-igniting.
- **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.
 - Vapor 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:**
 - VOC content:** 0.00 %
 - Solids content:** 99.8 %
- **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 and strong oxidizing agents.
- **Hazardous decomposition products:** Oxides of Carbon, Sodium and Titanium.

* 11 Toxicological Information

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

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

50-78-2 Aspirin

Oral	LD50	1,500 mg/kg (Rat)
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9004-34-6 Microcrystalline Cellulose

Oral	LD50	>5,000 mg/kg (Rat)
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Dermal	LD50	>2,000 mg/kg (Rabbit)
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Trade Name: Aspirin Tablets, USP

9004-65-3 Hypromellose		
Oral	LD50	2,000 mg/kg (Rat)
	Intravenous	5,200 mg/kg (Rat)
13463-67-7 Titanium Dioxide		
Oral	LD50	>10,000 mg/kg (Rat)
Dermal	LD50	>10,000 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.

· **Additional toxicological information:**

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

Harmful

Irritant

· **Carcinogenic categories:**

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

(a) Although IARC has classified titanium dioxide as possible carcinogenic to human (2B), their summary concludes: "No significant exposure to titanium dioxide is thought to occur during the use of products which titanium dioxide is bound to other materials, such as in cosmetics or in paints."

(b) OSHA does not regulate Titanium Dioxide as a carcinogen. However, under 29 CFR 1910.1200 the SDS must convey the fact that Titanium Dioxide is a potential carcinogen to rats.

13463-67-7	Titanium Dioxide	2B
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· **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:**

50-78-2 Aspirin	
EC50	>100 mg/l (Water flea)
13463-67-7 Titanium Dioxide	
EC50	>1,000 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 undiluted product or product that has not been neutralized to reach ground water, water course or sewage system.

· **Results of PBT and vPvB assessment:**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

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- **Other adverse effects:** No further relevant information available.

* 13 Disposal Considerations

- **Waste treatment methods**
- **Recommendation:**
Observe all federal, state and local environmental regulations when disposing of this material.
- **Uncleaned packaging**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport Information

- **UN-Number:**
- **DOT, ADR/ADN, ADN, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name:**
- **DOT, ADR/ADN, ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es):**
- **DOT, ADR/ADN, ADN, IMDG, IATA**
- **Class:** Non-Regulated Material
- **Packing group:**
- **DOT, ADR/ADN, 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":** Non-Regulated Material

* 15 Regulatory Information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture:**
- **SARA (Superfund Amendments and Reauthorization):**

· **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):**

50-78-2	Aspirin	ACTIVE
9004-34-6	Microcrystalline Cellulose	ACTIVE
65996-62-5	Corn Starch	ACTIVE
9004-65-3	Hypromellose	ACTIVE
8042-47-5	White mineral oil, petroleum	ACTIVE
13463-67-7	Titanium Dioxide	ACTIVE

· **Hazardous Air Pollutants**

None of the ingredients are listed.

· **California Proposition 65:**

· **Chemicals known to cause cancer:**

13463-67-7 Titanium Dioxide

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

50-78-2 Aspirin

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· Chemicals known to cause reproductive toxicity for males:		
None of the ingredients are listed.		
· Chemicals known to cause developmental toxicity:		
50-78-2	Aspirin	
· New Jersey Right-to-Know List:		
9004-34-6	Microcrystalline Cellulose	
13463-67-7	Titanium Dioxide	
· New Jersey Special Hazardous Substance List:		
None of the ingredients are listed.		
· Pennsylvania Right-to-Know List:		
50-78-2	Aspirin	
9004-34-6	Microcrystalline Cellulose	
13463-67-7	Titanium Dioxide	
· Pennsylvania Special Hazardous Substance List:		
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:**



· **Signal word:** Warning

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

Aspirin
Croscarmellose Sodium

· **Hazard statements:**

H332 Harmful if inhaled.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

· **Precautionary statements:**

P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
P264 Wash thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves / eye protection / face protection.
P302+P352 If on skin: Wash with plenty of water.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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Trade Name: Aspirin Tablets, USP

- P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P312 Call a poison center/doctor if you feel unwell.
- P321 Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P332+P313 If skin irritation occurs: Get medical advice/attention.
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P403+P233 Store in a well-ventilated place. Keep container tightly closed.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

• **National regulations:**

None of the ingredients are listed.

• **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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 last revision/ revision number:** 06/17/2019 / 1

• **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)
 VOC: Volatile Organic Compounds (USA, EU)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 NIOSH: National Institute for Occupational Safety and Health
 OSHA: Occupational Safety & Health Administration
 TLV: Threshold Limit Value
 PEL: Permissible Exposure Limit
 REL: Recommended Exposure Limit
 Acute Tox. 4: Acute toxicity – Category 4
 Skin Irrit. 2: Skin corrosion/irritation – Category 2
 Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
 Eye Irrit. 2B: Serious eye damage/eye irritation – Category 2B
 Carc. 2: Carcinogenicity – Category 2
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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

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