

Safety Data Sheet (SDS)

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

Printing date 02/19/2015

Reviewed on 02/19/2015

* 1 Identification

- **Product identifier**
- **Trade name: Aspirin Delayed-Release Tablets, USP**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Product description** 81 mg, Enteric-Coated, Round, Bi-Convex: 328 R, 377R, 381R, 387R, 390R & 481R
- **Application of the substance / the mixture** Delayed-Release Aspirin 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**



GHS07

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**
- **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:**
Methacrylic Acid and Ethyl Acrylate Copolymer
Aspirin
Triethyl Citrate
Talc
- **Hazard statements**
Harmful if inhaled.
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.

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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.

· **Unknown acute toxicity:**

1.3 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

CAS: 9004-65-3	Hypromellose Combustible Dust	Proprietary%
CAS: 63-42-3	Lactose	Proprietary%
CAS: 8015-86-9	Carnauba Wax	Proprietary%
CAS: 65996-62-5	Corn Starch Combustible Dust	Proprietary%
CAS: 68583-95-9	FD&C Red #40 Aluminum Lake Eye Irrit. 2B, H320; Combustible Dust	Proprietary%
CAS: 15790-07-5	FD&C Yellow #6 Aluminum Lake Eye Irrit. 2B, H320; Combustible Dust	Proprietary%
CAS: 68814-04-0	FD&C Yellow #10 Lake Eye Irrit. 2B, H320; Combustible Dust	Proprietary%
CAS: 9004-34-6	Microcrystalline Cellulose	Proprietary%
CAS: 8042-47-5	Mineral Oil	Proprietary%
CAS: 57-55-6 RTECS: TY 2000000	Propylene Glycol	Proprietary%
CAS: 9000-59-3	Shellac	Proprietary%
CAS: 8050-81-5	Simethicone	Proprietary%
CAS: 112945-52-5	Amorphous Silica	Proprietary%

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- **Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous 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	44 or 66%
CAS: 25212-88-8	Methacrylic Acid and Ethyl Acrylate Copolymer ⚠ Acute Tox. 3, H331; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2B, H320; Combustible Dust	Proprietary%
CAS: 77-93-0	Triethyl Citrate ⚠ Acute Tox. 4, H332	Proprietary%
CAS: 14807-96-6	Talc ⚠ Carc. 2, H351; ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%
CAS: 51274-00-1	Iron Oxide Ochre ⚠ Eye Irrit. 2A, H319	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: 9005-65-6	Polysorbate 80 ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%
CAS: 151-21-3 RTECS: WT 1050000	Sodium Lauryl Sulfate ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317; STOT SE 3, H335	Proprietary%
CAS: 13463-67-7	Titanium Dioxide ⚠ Carc. 2, H351; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	Proprietary%
CAS: 1310-58-3 RTECS: TT 2102000	Potassium Hydroxide ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302	Proprietary%
CAS: 1310-73-2	Sodium Hydroxide	Proprietary%
CAS: 1309-37-1 RTECS: NO 7400000	Iron Oxide (Brown & Black) ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	Proprietary%

Additional information:

328R, 377R, 387R & 390R: Only product versions that include the following ingredient: 44% Aspirin.

381R & 481R: Only product versions that include the following ingredient: 66% Aspirin.

328R: Only product version colored Peach.

377R, 387R, 390R, 381R & 481R: Only product versions colored Yellow.

387R & 390R: Only product versions that include the following ingredient: Carnauba Wax.

381R & 481R: Only product versions that include the following ingredients: FD&C Red #40 Aluminum Lake and FD&C Yellow #6 Aluminum Lake.

377R, 381 R and 481R: Only product versions that include the following ingredients: Iron Oxide (Brown & Black), Hypromellose, Mineral Oil, Propylene Glycol and Shellac.

328R: Only product version that includes the following ingredient: Corn Starch.

*Polysorbate 80 & Sodium Lauryl Sulfate are minor ingredients of the Methacrylic Acid and Ethyl Acrylate Copolymer major ingredient.

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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.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· **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.

Supply fresh air. If required, provide artificial respiration. Consult doctor if symptoms persist.

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.

Immediately call a doctor.

· **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:**

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

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

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

· **Advice for firefighters**

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

· **Protective equipment:**

Mouth respiratory protective device.

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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
 Pick up mechanically.
 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.

*** 7 Handling and storage**

- **Handling:**
- **Precautions for safe handling**
 Thorough dedusting.
 Ensure good ventilation/exhaustion at the workplace.
- **Information about protection against explosions and fires:**
 Dust can combine with air to form an explosive mixture.
 No special measures required.
- **Conditions for safe storage, including any incompatibilities**
 Store away from strong acids, strong bases, strong oxidizing agents, Alkali Hydroxides and Carbonates.
- **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:	
Aspirin	
REL	Long-term value: 5 mg/m ³
TLV	Long-term value: 5 mg/m ³
Talc	
PEL	Long-term value: 20 mppcf ppm (containing <1% Quartz)
REL	Long-term value: 2* mg/m ³ *respirable dust
TLV	Long-term value: 2* mg/m ³ *as respirable fraction; E

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- **Additional information:** The lists that were valid during the creation 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:** 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: Peach or Yellow

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **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.

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- **Solvent content:**
- **Organic solvents:** 0.0 %
- **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, Alkali Hydroxides and Carbonates.
- **Hazardous decomposition products:**
Oxides of Carbon, Iron, Silicon, Sodium, Nitrogen (NO_x), Potassium, Calcium and Titanium.

* 11 Toxicological information

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

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

Oral	LD50	1500 mg/kg (rat)
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Methacrylic Acid and Ethyl Acrylate Copolymer

Oral	LD50	>2000 mg/kg (rat)
Inhalative	LC50/4 h	1.03 mg/l (rat)

77-93-0 Triethyl Citrate

Oral	LD50	5900 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rabbit)

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

Talc	2B - Applies to Inhalative Exposure Only
Proprietary	3 - Applies to Inhalative Exposure Only

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<ul style="list-style-type: none"> · NTP (National Toxicology Program)
None of the ingredients are listed.
<ul style="list-style-type: none"> · OSHA-Ca (Occupational Safety & Health Administration)
None of the ingredients are listed.

12 Ecological information

<ul style="list-style-type: none"> · Toxicity
<ul style="list-style-type: none"> · Aquatic toxicity:
Aspirin
EC50 >100 mg/l (Water flea)
<ul style="list-style-type: none"> · 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: Not known to be hazardous to water. · Results of PBT and vPvB assessment · PBT: Not applicable. · vPvB: Not applicable. · Other adverse effects No further relevant information available.

13 Disposal considerations

<ul style="list-style-type: none"> · 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.

* 14 Transport information

<ul style="list-style-type: none"> · UN-Number · DOT, ADR, ADN, IMDG, IATA · UN proper shipping name · DOT, ADR, ADN, IMDG, IATA · Transport hazard class(es) 	<p>Non-Regulated Material</p> <p>Non-Regulated Material</p>
<ul style="list-style-type: none"> · DOT, ADR, ADN, IMDG, IATA · Class · Packing group · DOT, ADR, IMDG, IATA · Environmental hazards: · Special precautions for user · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code · UN "Model Regulation": 	<p>Non-Regulated Material</p> <p>Non-Regulated Material</p> <p>Not applicable.</p> <p>Not applicable.</p> <p>Not applicable.</p> <p>-</p>

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* 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):**

All ingredients are listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients are listed.

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

Aspirin

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed.

- **Chemicals known to cause developmental toxicity:**

Aspirin

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients are listed.

- **TLV (Threshold Limit Value established by ACGIH)**

Talc

A4

Proprietary

A4

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients are listed.

- **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:**

Methacrylic Acid and Ethyl Acrylate Copolymer

Aspirin

Triethyl Citrate

Talc

- **Hazard statements**

Harmful if inhaled.

Causes skin irritation.

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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.

National regulations:

The product is subject to be labeled according with the prevailing version of the regulations on hazardous substances.

State Right to Know

CAS: 50-78-2 RTECS: VO 0700000	Aspirin ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	66%
CAS: 9004-65-3	Hypromellose Combustible Dust	Proprietary%
CAS: 25212-88-8	Methacrylic Acid and Ethyl Acrylate Copolymer ⚠ Acute Tox. 3, H331; Skin Irrit. 2, H315; Eye Irrit. 2B, H320; Combustible Dust	Proprietary%
CAS: 63-42-3	Lactose	Proprietary%
CAS: 77-93-0	Triethyl Citrate ⚠ Acute Tox. 4, H332	Proprietary%
CAS: 14807-96-6	Talc ⚠ Carc. 2, H351; ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%

All 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 preparation / last revision 02/19/2015 / -

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

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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
Acute Tox. 3: Acute toxicity, Hazard Category 3
Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
Eye Irrit. 2B: Serious eye damage/eye irritation, Hazard Category 2B
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
Carc. 2: Carcinogenicity, Hazard Category 2
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

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

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