


**SECTION 1: PRODUCT IDENTIFICATION**

|                        |  |
|------------------------|--|
| <b>PRODUCT NAME</b>    | <b>ACETAMINOPHEN, USP</b>  |
| <b>PRODUCT CODE</b>    | <b>0409</b>  |
| <b>SUPPLIER</b>        | <b>MEDISCA Inc.</b><br>Tel.: 1.800.932.1039   Fax.: 1.855.850.5855<br>661 Route 3, Unit C, Plattsburgh, NY, 12901<br>6641 N. Belt Line Road, Suite 130, Irving, TX, 75063<br><b>MEDISCA Pharmaceutique Inc.</b><br>Tel.: 1.800.665.6334   Fax.: 514.338.1693<br>4509 Rue Dobrin, St. Laurent, QC, H4R 2L8<br>21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2<br><b>MEDISCA Australia PTY LTD</b><br>Tel.: 1.300.786.392   Fax.: 61.2.9700.9047<br>Unit 7, Heritage Business Park<br>5-9 Ricketty Street, Mascot, NSW 2020 |
| <b>EMERGENCY PHONE</b> | CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300<br>NSW Poisons Information Centre: 131 126<br>National Chemical Emergency Centre 44(0)1235239670   |
| <b>USES</b>            | Manufacturing and Compounding  |

**SECTION 2: HAZARDS IDENTIFICATION**

|   |   |  |                              |
|---|---|--|------------------------------|
| <b>GHS CLASSIFICATION</b>   | Acute Toxicity - Oral (Category 4)<br>Acute Aquatic Toxicity (Category 2)           |  |                              |
| <b>PICTOGRAM</b>  |  |  |                              |
| <b>SIGNAL WORD</b>  | Warning   |  |                              |
| <b>HAZARD STATEMENT(S)</b>  | Harmful if swallowed.<br>Toxic to aquatic life.                                     |  |                              |
| <b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b> | Repeated exposure may cause skin dryness or cracking.                               |  |                              |
| <b>PRECAUTIONARY STATEMENT(S)</b>                                     | <b>Prevention</b>   | Wash thoroughly after handling.<br>Do not eat, drink or smoke when using this product.<br>Avoid release to the environment.              |                              |
|   | <b>Response</b>   | IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.<br>Get medical advice/attention if you feel unwell. |                              |
|   | <b>Storage</b>  | Not applicable   |                              |
|   | <b>Disposal</b>   | Dispose of contents and/or container in accordance with local regulations.   |                              |
| <b>HMS CLASSIFICATION</b>   | <b>Health Hazard</b>  | 1  | <b>Flammability</b> 0        |
|   | <b>Reactivity</b>   | 0  | <b>Personal Protection</b> E |

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

|                      |   |
|----------------------|---|
| CHEMICAL NAME        | N-(4-hydroxyphenyl) acetamide                 |
| BOTANICAL NAME       | Not applicable                                |
| SYNONYM              | Paracetamol                                   |
| CHEMICAL FORMULA     | C <sub>8</sub> H <sub>9</sub> NO <sub>2</sub> |
| CAS NUMBER           | 103-90-2                                      |
| ALTERNATE CAS NUMBER | Not applicable                                |
| MOLECULAR WEIGHT     | 151.1641                                      |

| CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT |
|---------------|------------|-----------|-------------|
| ACETAMINOPHEN | 103-90-2   | 203-157-5 | 100         |

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES  
Chemical family: Aniline derivative; para-aminophenol

**SECTION 4: FIRST-AID MEASURES**

|                         |   |
|-------------------------|---|
| IN CASE OF EYE CONTACT  | Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid. |
| IN CASE OF SKIN CONTACT | Wash with soap & water for 15 minutes. If irritation persists seek medical aid.   |
| IF SWALLOWED            | Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.                                   |
| IF INHALED              | Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician  |
| SYMPTOMS AND EFFECTS    | Not expected to present a significant hazard under anticipated conditions of normal use.                                      |

**SECTION 5: FIREFIGHTING MEASURES**

|   |  |
|---|--|
| SPECIFIC HAZARDS ARISING FROM THE CHEMICAL            | Not applicable   |
| FLAMMABLE PROPERTIES                                  | May be combustible at high temperature   |
| HAZARDOUS COMBUSTION PRODUCTS                         | Under fire conditions, hazardous fumes will be present.  |
| SUITABLE & UNSUITABLE EXTINGUISHING MEDIA             | <b>Small fire:</b> dry chemical, CO <sub>2</sub> or water spray. <b>Large fire:</b> dry chemical, CO <sub>2</sub> , alcohol resistant foam or water spray. Do not get water inside containers. |
| PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS | Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.   |

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

|                      |   |
|----------------------|---|
| PERSONAL PRECAUTIONS | Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. |
|----------------------|---|

**METHODS & MATERIAL FOR CONTAINMENT**

On land, sweep or shovel into suitable containers. Minimize generation of dust.

**CLEANUP PROCEDURE**

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

**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.

**SECTION 7: HANDLING AND STORAGE**
**PRECAUTIONS FOR SAFE HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**CONDITIONS FOR SAFE STORAGE**

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**STORAGE CONDITIONS**

Store in original container at room temperature, tightly sealed, protected from direct sunlight and moisture. Short term excursions up to 40°C are acceptable.

**SPECIFIC END USE(S)**

See Section 1

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**

Chemical Name: ACETAMINOPHEN CAS #: 103-90-2

|        | Country   | Limit value-8 hours |                   | Limit value-Short Term |                   | IDLH | REL | Advisory | Notes |
|--------|-----------|---------------------|-------------------|------------------------|-------------------|------|-----|----------|-------|
|        |           | ppm                 | mg/m <sup>3</sup> | ppm                    | mg/m <sup>3</sup> |      |     |          |       |
| OSHA   | USA       | N/L                 | N/L               | N/L                    | N/L               | N/L  | N/L | N/A      | N/A   |
| ACGIH  | USA       | N/L                 | N/L               | N/L                    | N/L               | N/L  | N/L | N/A      | N/A   |
| NIOSH  | USA       | N/L                 | N/L               | N/L                    | N/L               | N/L  | N/L | N/A      | N/A   |
| WEEL   | USA       | N/L                 | N/L               | N/L                    | N/L               | N/L  | N/L | N/A      | N/A   |
| HSIS   | Australia | N/L                 | N/L               | N/L                    | N/L               | N/L  | N/L | N/A      | N/A   |
| HSE    | UK        | N/L                 | 10                | N/L                    | N/L               | N/L  | N/L | N/A      | N/A   |
| GESTIS | Ireland   | N/L                 | 10                | N/L                    | N/L               | N/L  | N/L | N/A      | N/A   |

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

**EXPOSURE GUIDELINES**

 Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>.

**PERSONAL PROTECTIVE EQUIPMENT**

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

**SPECIFIC ENGINEERING CONTROLS**

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

**NOTES**

USP: ELV: Industrial Use: TWA: 5 mg/m<sup>3</sup>  
 Manufacturer: Occupational: 4 mg/m<sup>3</sup> (8 hrs)

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

|                                     |  |   |                       |   |                                |
|-------------------------------------|--|---|-----------------------|---|--------------------------------|
| <b>PHYSICAL STATE</b>               | Solid  |   |                       |   |                                |
| <b>DESCRIPTION</b>                  | White, odorless, crystalline powder.   |   |                       |   |                                |
| <b>SOLUBILITY</b>                   | Freely soluble in alcohol; soluble in boiling water and in 1 N sodium hydroxide. |   |                       |   |                                |
| <b>ODOR</b>                         | Odorless   |   |                       |   |                                |
| <b>FLAMMABILITY</b>                 | May be combustible at high temperature   |   |                       |   |                                |
| <b>AUTO-IGNITION TEMPERATURE</b>    | >180 °C, > 356 °F  | <b>BOILING POINT</b>                      | > 500 °C, 932 °F      | <b>DECOMPOSITION TEMPERATURE</b>          | Not available                  |
| <b>EVAPORATION RATE</b>             | Not available  | <b>EXPLOSIVE LIMIT</b>                    | Not available         | <b>FLASH POINT</b>                        | Not available                  |
| <b>log P (OCTANOL-WATER)</b>        | 0.46 - 0.51  | <b>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</b> | Not available         | <b>MELTING/FREEZING POINT</b>             | (168 - 172)°C, (334.4-341.6)°F |
| <b>ODOR THRESHOLD</b>               | Not available  | <b>OXIDIZING PROPERTY</b>                 | Not available         | <b>pH</b>                                 | 5.5 - 6.5 (10%) (20°C)         |
| <b>RELATIVE DENSITY (WATER = 1)</b> | 5.2  | <b>SPECIFIC GRAVITY</b>                   | 1.293 (21 °C)         | <b>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</b> | Not available                  |
| <b>VAPOR DENSITY (AIR = 1)</b>      | 5.2  | <b>VAPOR PRESSURE</b>                     | 0.0000003 kPa (25 °C) | <b>VISCOSITY</b>                          | Not available                  |

The physical data presented above are typical values and should not be construed as a specification.

**SECTION 10: STABILITY AND REACTIVITY**

|   |   |
|---|---|
| <b>REACTIVITY</b>                       | Not established   |
| <b>CHEMICAL STABILITY</b>               | Stable under recommended storage conditions   |
| <b>INCOMPATIBLE MATERIALS</b>           | Strong oxidants. Strong acids. Strong bases. Amides.                                      |
| <b>HAZARDOUS DECOMPOSITION PRODUCTS</b> | Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur |
| <b>HAZARDOUS POLYMERIZATION</b>         | Will not occur  |

**POSSIBILITY OF HAZARDOUS REACTION** Not established

**CONDITIONS TO AVOID** Moisture, sunlight and extreme temperatures

## SECTION 11: TOXICOLOGICAL INFORMATION

|   |  |
|---|--|
| <b>ACUTE TOXICITY</b>                                     | Oral: Rat: LD50: (mg/kg): 1944<br>Dermal: Rabbit LD50: (mg/kg): Not available<br>Inhalation: Rat: LC50: (mg/L/4hr): Not available  |
| <b>SKIN CORROSION/IRRITATION</b>                          | Based on available data, the classification criteria are not met.<br>Rabbit skin irritancy test (OECD 404). Result: Not irritant.  |
| <b>SERIOUS EYE DAMAGE/EYE IRRITATION</b>                  | Based on available data, the classification criteria are not met.<br>Rabbit eye irritancy test (OECD 405). Result: Not irritant.   |
| <b>RESPIRATORY SENSITIZATION</b>                          | Due to lack of data the classification is not possible.  |
| <b>SKIN SENSITIZATION</b>                                 | Based on available data, the classification criteria are not met.<br>Skin rashes and other hypersensitivity reactions occur occasionally.  |
| <b>GERM CELL MUTAGENICITY</b>                             | Based on available data, the classification criteria are not met.<br>Ames test (Salmonella typhimurium; E. coli); Result: Negative.<br>Drosophila SLRL test; Result: Negative.<br>In vitro tests in human cells; Result: Induced sister chromatid exchange and chromosomal aberrations.<br>In vitro tests in mammalian cells; Result: Induced chromosomal aberrations, micronuclei, and sister chromatid exchange; did not induce gene mutation.<br>In vivo cytogenetic test in mice; Result: Induced DNA single-strand breaks.<br>In vivo cytogenetic tests in human cells; Result: Induced sister chromatid exchange.<br>In vivo cytogenetic tests in mammalian cells; Result: Aneugenic; induced chromosomal aberrations; did not induce micronuclei. |
| <b>CARCINOGENICITY</b>                                    | <p><b>OSHA</b> ACETAMINOPHEN is listed.</p> <p><b>NTP</b> ACETAMINOPHEN is not listed.</p> <p><b>IARC</b> ACETAMINOPHEN is listed in group 3 (not classifiable as to its carcinogenicity to humans).</p> <p><b>California Proposition 65</b> This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</p>  |
| <b>ADDITIONAL CARCINOGENICITY INFORMATION</b>             | Based on available data, the classification criteria are not met.<br>600 - 6000 ppm 2-year Feed studies. Result: No evidence of carcinogenic activity in males; equivocal evidence of carcinogenic activity in females based on increased incidences of mononuclear cell leukemia.<br>Species: Rat<br>600 - 6000 ppm 2-year Feed studies. Result: No evidence of carcinogenic activity in males and females.<br>Species: Mouse   |
| <b>REPRODUCTIVE TOXICITY</b>                              | Based on available data, the classification criteria are not met.<br>Epidemiological studies have not shown an association between therapeutic use of this material during pregnancy and an increased incidence of birth defects.<br>Mouse: 0 - 250 mg/kg/day Reproductivity, administered orally during gestation; Result: Dose-dependent increase in malformations.<br>Rat: 0 - 250 mg/kg/day Reproductivity, administered orally during gestation; Result: No fetal or embryo toxicity; no maternal toxicity; no teratogenicity.<br>Mouse: 0.25 - 1 % Reproductivity, administered in diet; Result: No effect on fertility endpoints; reduced growth and birth weights; increased incidence of sperm abnormalities.                                   |
| <b>SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE</b>   | Based on available data, the classification criteria are not met.  |
| <b>SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE</b> | Based on available data, the classification criteria are not met.  |
| <b>ASPIRATION HAZARDS</b>                                 | Based on available data, the classification criteria are not met.  |

**SIGNS AND SYMPTOMS OF EXPOSURE**

Not expected to present a significant hazard under anticipated conditions of normal use. Adverse effects of paracetamol are rare and usually mild, although haematological reactions including thrombocytopenia, leucopenia, pancytopenia, neutropenia, and agranulocytosis have been reported. Overdosage with can result in severe liver damage and sometimes acute renal tubular necrosis.

Symptoms related to the physical, chemical, and toxicological characteristics  
Nausea. Vomiting. Diarrhea. Abdominal pain. Loss of appetite. Sweating. Behavior, mood, or mental changes. Irritability. Jaundice. Convulsions. Skin rash.

Delayed and immediate effects of exposure  
Liver damage. Kidney damage. Irregular heartbeat. Cardiovascular collapse. Swelling or fluid in the brain. Hypoglycemia. Metabolic acidosis. Blood disorders. Coma.

Cross sensitivity  
Rarely, persons sensitive to aspirin may be sensitive to this material as well.

Medical conditions aggravated by exposure  
Active alcoholism. Impaired liver function. Viral hepatitis. Impaired kidney function. Malnutrition. Glucose-6-phosphate dehydrogenase deficiency.

**POTENTIAL HEALTH EFFECTS**

|                   |  |
|-------------------|--|
| <b>Inhalation</b> | May be harmful if inhaled. May cause respiratory tract irritation.                               |
| <b>Ingestion</b>  | May be harmful if swallowed.   |
| <b>Skin</b>       | May be harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction. |
| <b>Eyes</b>       | May cause serious eye irritation.  |

**SECTION 12: ECOLOGICAL INFORMATION**
**TOXICITY**

EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): 6.1 - 14  
 LC50: 96 Hr: Fish: Pimephales promelas: (mg/L): 814  
 EC50: 72 Hr: Algae: Scenedesmus subspicatus: (mg/L): 134

**PERSISTENCE AND DEGRADABILITY**

Readily biodegradable (100%)

**BIOACCUMULATIVE POTENTIAL**

LogPow: 0.46 - 0.51

**MOBILITY IN SOIL**

Solubility in water: 1.40E+04 mg/L (25°C)  
 Henry's Law Constant: 6.42E-13 atm·m<sup>3</sup>/mole (25°C)

**OTHER ADVERSE EFFECTS**

Not available  
 This product is not intended to be released into the environment

**SECTION 13: DISPOSAL CONSIDERATIONS**
**WASTE DISPOSAL**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

**SECTION 14: TRANSPORT INFORMATION**
**UN PROPER SHIPPING NAME**

Not dangerous good

**UN NUMBER**

Not applicable

**CLASS**

Not applicable

**PACKING GROUP**

Not applicable

**AUSTRALIA**
**HAZCHEM**

Not Applicable

**EU**
**TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE**

Not Listed

**ENVIRONMENTAL HAZARDS**

Not available

**SPECIAL SHIPPING INFORMATION**

Not applicable

**SECTION 15: REGULATORY INFORMATION**
**UNITED STATES REGULATIONS**

| Chemical Name & CAS    | CERCLA<br>40 CFR<br>Part 302.4 | SARA (Title III)<br>40 CFR<br>Part 372.65 | EPA 40 CFR Part 355 |            | Pennsylvania | Right-to-know |               | California<br>Prop 65 |
|------------------------|--------------------------------|---|---------------------|------------|--------------|---------------|---------------|-----------------------|
|                        |                                |   | Appendix A          | Appendix B |              | New Jersey    | Massachusetts |                       |
| ACETAMINOPHEN 103-90-2 | N/L                            | N/L                                       | N/L                 | N/L        | N/L          | N/L           | N/L           | N/L                   |

N/L = Not Listed; X = Listed

**AUSTRALIAN REGULATIONS**

| Chemical Name & CAS    | Poisons and Therapeutic Goods Regulation | Therapeutic Goods Act | Code of Practices - Illicit Drug Precursors |
|------------------------|--|-----------------------|---|
| ACETAMINOPHEN 103-90-2 | N/L                                      | Listed as Schedule 4  | N/L   |

N/L = Not Listed

**EU REGULATIONS**

| Chemical Name & CAS    | REACH ANNEX XVII | REACH ANNEX XIV | EC 1005/2009 | EC 850/2004 | EC 1107/2009 | EC 649/2012 | EC 2012/118 |
|------------------------|------------------|-----------------|--------------|-------------|--------------|-------------|-------------|
| ACETAMINOPHEN 103-90-2 | N/L              | N/L             | N/L          | N/L         | N/L          | N/L         | N/L         |

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

**SECTION 16: OTHER INFORMATION**
**REFERENCES**

Available upon request

**ABBREVIATIONS AND ACRONYMS**

**ACGIH** - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

**LAST REVISION**

04/2021

**SUPERSEDES**

12/2020

For a list of changes to the SDS since the last version, please communicate with MEDISCA at [www.medisca.com](http://www.medisca.com)

**DISCLAIMER**

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

**SUPPLEMENTARY INFORMATION**

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.