# Safety Data Sheet

## SECTION 1: Identification

**Contact information**

**General**

Leucadia Pharmaceuticals, Inc.
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Carlsbad, CA, 92011
Main: +1-(844) 538-2231 (Monday through Friday 8am – 6 pm Central Time)
E-mail: info.sds@leucadiapharma.com

**Emergency telephone number**

Chemtrec (24-895): +1 (800) 424-9300 (USA and Canada) +1 (703) 527-3887 (International; collect calls accepted)

**Product identifier**

Acetaminophen Injection, 10 mg/mL

**Synonyms**

For acetaminophen: N-(4-hydroxyphenyl)-Acetamide, 4'-Hydroxyacetanilide, Paracetamol, p-Hydroxyacetanilide, 4-hydroxyacetanilide, p-acetaminophenol, p-acetamidiophenol, N-acetyl-p-aminophenol

**Trade name**

Acetaminophen Injection

**Chemical family**

Mixture - contains a p-aminophenol derivative

**Recommended uses and restrictions**

Formulated pharmaceutical product/mixture packaged in final form for patient use; used for the treatment of pain and fever.

**Note**

This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product/mixture. Workers manufacturing this product/mixture should consult the SDS of each hazardous ingredient for hazard information and handling recommendations. This SDS will be revisited if more data become available.

## SECTION 2: Hazard(s) identification

**Classification of the substance or mixture**

Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada. Consult prescribing/packaging information. The classification and labeling listed below is for bulk drug product.

**Specific target organ toxicity (repeated exposure) Category 2**
May cause damage to organs (liver, kidneys) through prolonged or repeated exposure

**Label elements**

**GHS Hazard pictograms**

**GHS Signal word**

Warning

**GHS Hazard statements**

H373 - May cause damage to organs (liver, kidneys) through prolonged or repeated exposure

**GHS Precautionary statements**

P260 - Do not breathe mist, spray, vapors. P314 - Get medical advice/attention if you feel unwell. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

**Other hazards**

Acetaminophen has analgesic and antifever properties. The most commonly reported adverse effects associated with therapeutic use include nausea, vomiting, headache, and insomnia.

Based on animal studies and its mechanism of action, a potential for acetaminophen to adversely affect a developing fetus, or to impair fertility, cannot be excluded in the absence of definitive data.

**Note**

This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA).

## SECTION 3: Composition/Information on ingredients

| Ingredient | CAS number | EINECS/ELINCS# | Amount | GHS classification |
|---|---|---|---|---|
| Acetaminophen | 103-90-2 | 232-674-9 | ≤ 1 % | Acute Tox. 4 (Oral), H302<br>STOT RE 2, H373 |

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| **Note** | The substance(s) listed above are considered hazardous. The remaining components are not hazardous and/or present at amounts below reportable limits. The primary ingredient is sterile water for injection. Amounts are listed as ranges; the exact percentage of composition is withheld as a trade secret. See Section 16 for full text of GHS classifications. |

## SECTION 4: First-aid measures

**Description of first aid measures**

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| **Immediate medical attention and special treatment, if necessary** | Yes. |
| **Inhalation** | Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor. |
| **Skin contact** | Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor. |
| **Eye contact** | If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor. |
| **Ingestion** | If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor. |
| **Most Important Symptoms/Effects** | Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively. |
| **Expected Symptoms/Effects, Acute and Delayed** | See Sections 2 and 11 |

## SECTION 5: Fire-fighting measures

**Suitable (and unsuitable) extinguishing media**

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| **Suitable extinguishing media** | Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials. |
| **Specific hazards arising from the chemical** | No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen and other nitrogen-containing compounds. |
| **Fire hazard** | No information identified. As product is an aqueous solution, it is not expected to be flammable. |
| **Explosion hazard** | No information identified. As product is an aqueous solution, it is not expected to be explosive. |

**Special protective equipment and precautions for fire-fighters**

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| **Firefighting instructions** | In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use. |

## SECTION 6: Accidental release measures

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

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| **Protective equipment** | If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. |
| **Emergency procedures** | Do not breathe vapors/mist/spray. |
| **Environmental precautions** | Do not empty into drains. Avoid release to the environment. |

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

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| **Methods for cleaning up** | DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g, paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent (see Section 9). |
| **Other information** | Dispose of materials or solid residues at an authorized site. |
| **Reference to other sections** | See Sections 8 and 13 for more information. |

## SECTION 7: Handling and storage

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| **Precautions for safe handling** | Follow recommendations for handling pharmaceutical agents (i.e, use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Do not breathe vapor/mist/spray. |

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

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| **Storage conditions** | Store locked up. Store in a closed container. Do not freeze. Keep/Store away from incompatible materials. Keep only in original container. Do not store near food, foodstuffs, drugs, or potable water supplies. |
| **Storage temperature** | 15 – 30 °C |
| **Specific end use(s)** | Pharmaceuticals. |

## SECTION 8: Exposure controls/personal protection

**Note** Dispose of broken vials in a sharps container.

**Control parameters/Occupational Exposure Limits**

| Name | Issuer | Value |
|---|---|---|
| **Acetaminophen** | No data available | No data available |

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| **Appropriate engineering controls** | None required for normal handling of packaged product. If vials are crushed or broken, or if handling bulk formulation: Control exposures to below the OEL (for the active ingredient(s) if available). Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Solutions can be handled outside a containment system or without local exhaust ventilation (LEV). Use engineered LEV and/or enclosure for high-energy operations such as spraying. All containers for solutions and slurries must be covered while being transferred. |
| **Respiratory protection** | None required for normal handling of packaged product. If vials are crushed or broken, or if handling bulk formulation: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. Respirators are generally not required. At minimum, a tight-fitting full-face respirator with HEPA filters is required for spill cleanup. |
| **Hand protection** | None required for normal handling of packaged product. If vials are crushed or broken, or if handling bulk formulation: Wear nitrile or other impervious gloves if skin contact is possible. When the material is diluted in an organic solvent, wear gloves that provide protection against the solvent. |
| **Eye protection** | None required for normal handling of packaged product. If vials are crushed or broken, or if handling bulk formulation: Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available. |
| **Skin and body protection** | None required for normal handling of packaged product. If vials are crushed or broken, or if handling bulk formulation: Wear disposable coveralls appropriate to the task, booties, and safety glasses with side shields. Ensure gloves are protective against solvents in use. Protective garments (coveralls, disposable coveralls, lab coats) are not to be worn in common areas (e.g., cafeterias) or out-of-doors. Employees must be trained in proper gowning and degowning practices |
| **Other protective measures** | None required for normal handling of packaged product. If vials are crushed or broken, or if handling bulk formulation: Wash hands in the event of contact with material, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). |
| **Environmental exposure controls** | Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel. |

## SECTION 9: Physical and chemical properties

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| **Physical state** | Liquid |
| **Appearance** | Liquid, packaged in glass vial |
| **Formula** | Mixture - Not applicable |
| **Molecular mass** | Not applicable |
| **Color** | Colorless or slightly yellow, clear |
| **Odor** | No data available |
| **pH** | 5 – 6.2 |
| **Melting point** | -2 °C |
| **Freezing point** | No data available |
| **Boiling point** | Approx. to water |
| **Flash point** | No data available |
| **Relative evaporation rate (butyl acetate=1)** | No data available |
| **Flammability (solid, gas)** | No data available |
| **Vapor pressure** | Approx. to water |
| **Relative vapor density at 20 °C** | No data available |
| **Relative density** | 1.015 |

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| **Solubility** | Miscible with water in any proportion. |
| **Log Kow** | No data available |
| **Auto-ignition temperature** | No data available |
| **Decomposition temperature** | No data available |
| **Viscosity, kinematic** | No data available |
| **Viscosity, dynamic** | No data available |
| **Explosion limits** | No data available |
| **Explosive properties** | No data available |
| **Oxidizing properties** | No data available |

## SECTION 10: Stability and reactivity

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| **Reactivity** | The product is non-reactive under normal conditions of use, storage and transport. |
| **Chemical stability** | Stable under normal conditions. |
| **Possibility of hazardous reactions** | No dangerous reactions known under normal conditions of use. |
| **Conditions to avoid** | (See section 7: Handling and Storage). |
| **Incompatible materials** | No data available |
| **Hazardous decomposition products** | Under normal conditions of storage and use, hazardous decomposition products should not be produced. |

## SECTION 11: Toxicological information

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| **Note** | No data on product formulation. The following information is for acetaminophen and other ingredients, where applicable. |
| **Likely routes of exposure** | May be absorbed by inhalation, skin contact and ingestion. |

**Toxicological information**

**Acute toxicity**

| Component | Type | Dose |
|---|---|---|
| **Acetaminophen** | LD50 oral rat | 1944 -2400 mg/kg |

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| **Serious eye damage/irritation** | Rabbit: moderate irritation |
| **Skin corrosion/irritation** | No data available |
| **Sensitization** | No data available |
| **STOT-single exposure** | No data available |
| **STOT-repeated exposure** | Male rats (13-wk), oral LOAEL: 8,000 ppm; oral NOAEL: 2,350 ppm (152.8 mg/kg/day)<br>Effects: decreased body weights, increased serum cholesterol and relative liver weights, and liver changes.<br><br>Male rats (13-wk), oral LOAEL: 800 ppm (100 mg/kg/day)<br>Effects: lesions in liver, kidney, male and female reproductive organs, thymus, and lymph nodes.<br><br>Mice (13-wk), oral NOAEL: 1,600 ppm (400 mg/kg/day)<br>Effects: lesions in livers.<br><br>Rat (28-d), IV NOAEL: 400 mg/kg/day (highest dose tested)<br>Effects: none reported. |
| **Reproductive toxicity** | Rats, oral LOAEL: 400 mg/kg/day<br>Effects: decreased testicular weights, reduced spermatogenesis, reduced fertility, and reduced implantation sites.<br><br>Mice, oral LOAEL: 1430 mg/kg/day<br>Effects: reduction in the number of mating pairs, abnormal sperm in males. |
| **Developmental toxicity** | Mice (developmental)<br>Maternal, oral NOAEL:50 mg/kg/day<br>Fetal, oral LOAEL:50 mg/kg/day<br>Effects: reduced number of follicles (female offspring), percentage of full-term pregnancies, and number of pups.<br><br>Rat (developmental)<br>Maternal oral NOAEL: 350 mg/kg/day<br>Fetal oral LOAEL: 350 mg/kg/day<br>Effects: reduced number of germ cells in the fetal ovary, decreased ovary weight, and reduced the number of pups per litter in female offspring.<br><br>Mice (developmental)<br>Maternal oral NOAEL: 1430 mg/kg/day<br>Fetal oral LOAEL: 1430 mg/kg/day<br>Effects: reduced neonatal survival and offspring weights. |
| **Genotoxicity** | *In vitro:*<br>Bacterial reverse mutation assay (e.g. Ames test): negative<br>Chromosomal aberration assay (peripheral human lymphocytes, Chinese hamster ovary cells): positive<br>Sister chromatid exchange assay (Chinese hamster ovary cells: positive<br>Mouse lymphoma assay: positive<br><br>*In vivo:*<br>Clastogenicity assay in rats (1500 mg/kg, NOAEL: 750 mg/kg): positive |
| **Carcinogenicity** | Mice, oral NOAEL: 6,000 ppm<br>Effect: none reported<br><br>Rats, oral LOAEL: 6,000 ppm (females), oral NOAEL: 6,000 ppm (males)<br>Effect: mononuclear cell leukemia (females) |
| **Aspiration hazard** | No data available |
| **Experience with humans** | See "Section 2 - Other Hazards". |

## SECTION 12: Ecological information

**Toxicity**

| Component | Type | Concentration |
|---|---|---|
| **Acetaminophen** | LC50 fish 1 | 814 mg/l (96-h, Fathead minnow) |
| | LC50 fish 2 | 160 mg/l (96-h, Japanese Medaka) |
| | EC50 Daphnia 2 | 9.2 mg/l (48-h, Daphnia magna) |
| | EC50 72h algae 1 | 200 mg/l (Duckweed) |

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| **Persistence and degradability** | No data available |
| **Bioaccumulative potential** | No data available |
| **Mobility in soil** | No data available |
| **Results of PBT assessment** | No data available |
| **Other adverse effects** | No data available |
| **Note** | The environmental characteristics of this mixture have not been fully investigated. Releases to the environment should be avoided. |

## SECTION 13: Disposal considerations

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| **Waste treatment methods** | Used product should be disposed of according to local, state, and federal regulations. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g, appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g, appropriately permitted municipal or on-site wastewater treatment facility. |

## SECTION 14: Transport information

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| **Transport** | Based on the available data, this mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG. |
| **UN number** | None assigned. |
| **UN proper shipping name** | None assigned. |
| **Transport hazard class(es) (DOT)** | None assigned. |
| **Packing group** | None assigned. |
| **Marine pollutant** | Based on the available data, this mixture is not regulated as an environmental hazard or a marine pollutant. |
| **Special transport precautions** | Avoid release to the environment. |
| **Transport in bulk according to Annex II of Marpol and the IBC Code** | Not applicable |

## SECTION 15: Regulatory information

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| **Safety, health and environmental regulations/legislation specific for the substance or mixture** | This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information. |
| **Chemical safety assessment** | No chemical safety assessment has been carried out |
| **TSCA** | Drugs are exempt from TSCA. |
| **SARA Section 313 - Emission Reporting** | This substance or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372. |
| **California Proposition 65** | California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm |
| **Additional information** | No additional information available |

## SECTION 16: Other information

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| **Full text of H phrases and GHS classification** | Acute Tox. 4 (Oral) - Acute toxicity (oral) Category 4.<br>STOT RE 2 - Specific target organ toxicity (repeated exposure) Category 2.<br>H302 - Harmful if swallowed.<br>H373 - May cause damage to organs through prolonged or repeated exposure. |
| **Data sources** | Information from published literature and internal company data. |

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| **Abbreviations and acronyms** | ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PBT - Persistent, Bioaccumulative, and Toxic; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System |
| **Issue date** | 18 August 2020 |
| **Current revision** | 1.0 |
| **Indication of changes** | This is the first version of this SDS. |
| **Disclaimer** | The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel. |