SAFETY DATA SHEET

Revision date 28-October-2022

| 1. Identification | | |
|--|-----------------------------------|--|
| Product identifier | | |
| Product Name | HYDROCODONE BITARTRATE (CII), USP | |
| Other means of identification | | |
| Product Code(s) | H1067 | |
| Synonyms | None | |
| Recommended use of the chemical and restrictions on use | | |
| Recommended use | No information available | |
| Restrictions on use | No information available | |
| Details of the supplier of the safety data sheet | | |
| Supplier Address Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000 | | |
| Emergency telephone number | | |

Emergency Telephone

Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

| Acute toxicity - Oral | Category 4 |
|--|------------|
| Specific target organ toxicity (single exposure) | Category 3 |

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Harmful if swallowed May cause drowsiness or dizziness



Revision Number 2



Physical state Solid

Odor No information available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling Do not eat, drink or smoke when using this product Avoid breathing dust/fume/gas/mist/vapors/spray Use only outdoors or in a well-ventilated area

Precautionary Statements - Response

IF INHALED: Remove person to fresh air and keep comfortable for breathing Call a POISON CENTER or doctor if you feel unwell IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell Rinse mouth

Precautionary Statements - Storage

Store in a well-ventilated place. Keep container tightly closed Store locked up.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

May be habit forming.

3. Composition/information on ingredients

Substance

| Chemical name | CAS No | Weight-% |
|------------------------|------------|----------|
| Hydrocodone Bitartrate | 34195-34-1 | 100 |

4. First-aid measures

Description of first aid measures

| General advice | Show this safety data sheet to the doctor in attendance. |
|----------------|--|
| Inhalation | Remove to fresh air. IF exposed or concerned: Get medical advice/attention. |
| Eye contact | Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician. |
| Skin contact | Wash skin with soap and water. |
| Ingestion | Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician. |

Most important symptoms and effects, both acute and delayed

Symptoms

No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

| 5. Fire-fighting measures | | |
|---|---|--|
| Suitable Extinguishing Media Large Fire | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. CAUTION: Use of water spray when fighting fire may be inefficient. | |
| Large File | | |
| Unsuitable extinguishing media | Do not scatter spilled material with high pressure water streams. | |
| Specific hazards arising from the chemical | No information available. | |
| Explosion data Sensitivity to mechanical impac | ct none. | |
| Sensitivity to static discharge | none. | |
| Special protective equipment for fire-fighters | Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment. | |
| 6. Accidental release measures | | |
| Personal precautions, protective equipment and emergency procedures | | |
| Personal precautions | Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. | |
| Other information | Refer to protective measures listed in Sections 7 and 8. | |
| Methods and material for containment and cleaning up | | |
| Methods for containment | Prevent further leakage or spillage if safe to do so. | |
| Methods for cleaning up | Pick up and transfer to properly labeled containers. | |
| | | |

| 7. Handling and storage | | |
|--|---|--|
| Precautions for safe handling | | |
| Advice on safe handling | Handle in accordance with good industrial hygiene and safety practice. | |
| Conditions for safe storage, including any incompatibilities | | |
| Storage Conditions | Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Protect from light. | |

8. Exposure controls/personal protection

Control parameters

Exposure Limits

The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure

limits from the sources listed here.

| Engineering controls | Showers Eyewash stations Ventilation systems. | |
|---|--|--|
| Individual protection measures, such as personal protective equipment | | |
| Eye/face protection | No special protective equipment required. | |
| | | |
| Skin and body protection | No special protective equipment required. | |
| Respiratory protection | No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required. | |
| General hygiene considerations | Handle in accordance with good industrial hygiene and safety practice. | |

Appropriate engineering controls

9. Physical and chemical properties

| Information on basic physical and | chemical properties | |
|-----------------------------------|------------------------------------|------------------|
| Physical state | Solid | |
| Appearance | Crystals or Crystalline powder | |
| Color | White | |
| Odor | No information available | |
| Odor threshold | No information available | |
| | | |
| Property_ | Values | Remarks • Method |
| рН | no data available | None known |
| Melting point / freezing point | 118 - 128 °C / 244.4 - 262.4 °F | None known |
| Boiling point / boiling range | no data available | None known |
| Flash point | no data available | None known |
| Evaporation rate | no data available | None known |
| Flammability (solid, gas) | no data available | None known |
| Flammability Limit in Air | | None known |
| Upper flammability or explosive | No data available | |
| limits | | |
| Lower flammability or explosive | No data available | |
| limits | | |
| Vapor pressure | No data available | None known |
| Vapor density | no data available | None known |
| Relative density | no data available | None known |
| Water solubility | Soluble in water | None known |
| Solubility(ies) | Partially soluble in methanol | None known |
| | Slightly soluble in Acetone | |
| | Insoluble in Ether | |
| | Insoluble in Chloroform | |
| Partition coefficient | No data available | None known |
| Autoignition temperature | no data available | None known |
| Decomposition temperature | | None known |
| Kinematic viscosity | no data available | None known |
| Dynamic viscosity | No data available | None known |
| _ y | | |
| Other information | | |
| Explosive properties | No information available | |
| Oxidizing properties | No information available | |
| Softening point | No information available | |
| Molecular weight | No information available | |
| VOC Content (%) | No information available | |
| | | |

10. Stability and reactivity

| Reactivity | No information available. |
|--|---|
| Chemical stability | Stable under normal conditions. |
| Possibility of hazardous reactions | None under normal processing. |
| Hazardous polymerization | Hazardous polymerization does not occur. |
| Conditions to avoid | None known based on information supplied. |
| Incompatible materials | Alkali. Oxidizing agent. |
| Hazardous decomposition products None known based on information supplied. | |

11. Toxicological information

Information on likely routes of exposure

| oduct Information | |
|-------------------|--|
| Inhalation | Specific test data for the substance or mixture is not available. |
| Eye contact | Specific test data for the substance or mixture is not available. |
| Skin contact | Specific test data for the substance or mixture is not available. |
| Ingestion | Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components). |

Symptoms related to the physical, chemical and toxicological characteristics

| Symptoms | No information available. |
|----------|---------------------------|
|----------|---------------------------|

Acute toxicity

Numerical measures of toxicity No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

| Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization Germ cell mutagenicity | No information available. No information available. No information available. No information available. |
|---|--|
| Reproductive toxicity | No information available. |
| STOT - single exposure STOT - repeated exposure Aspiration hazard | No information available. No information available. No information available. |
| Other adverse effects | No information available. |
| Interactive effects | No information available. |

12. Ecological information

| Ecotoxicity | The environmental impact of this product has not been fully investigated. |
|--|---|
| Persistence and degradability Bioaccumulation | No information available. Inherently biodegradable. |
| Other adverse effects | No information available. |

13. Disposal considerations

| Waste treatment methods | |
|--|---|
| Waste from residues/unused products | Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. |
| Contaminated packaging | Do not reuse empty containers. |

14. Transport information

| DOT | not regulated |
|------------|---------------|
| TDG | not regulated |
| <u>MEX</u> | not regulated |
| ICAO (air) | not regulated |
| IATA | not regulated |
| IMDG | not regulated |
| RID | not regulated |
| ADR | not regulated |
| ADN | not regulated |

15. Regulatory information

International Inventories

| TSCA | Not listed |
|---|--|
| Note | *Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements |
| DSL/NDSL EINECS/ELINCS ENCS IECSC KECL PICCS AICS | Does not Comply Does not Comply This product complies with ENCS: This product does not comply with china: Does not Comply Does not Comply This product does not comply with AICS |

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances **ENCS** - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA Health hazards 0 Flammability 0 Instability 0 Physical and chemical properties -<u>HMIS</u> Health hazards 0 Flammability 0 Physical hazards 0 Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheetLegend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTIONTWATWA (time-weighted average)CeilingSTELMaximum limit valueSTEL

STEL (Short Term Exposure Limit)

Key literature references and sources for data used to compile the SDS Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization **Revision date** 28-October-2022

Revision Note

No information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet