SAFETY DATA SHEETS

This SDS packet was issued with item:

078942067

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078942037 078942038 078942055 078942056 078942057 078942058 078942059 078942060 078942061 078942062 078942063 078942064 078942065 078942066 078942068 078942069 078942070

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Thyrocryn™ (Levothyroxine Sodium Tablets)

SECTION 1: Identification

Product identifier

Product name: Thyrocryn™ (Levothyroxine Sodium Tablets)
Product code: 21303828, 21303885, 21303829, 21303889, 21303910, 21303890, 21303911, 21303891, 21303912, 21303892, 21303913, 21303893, 21303914, 21303894, 21303915, 21303895, 21303916, 21303896
Additional information: NADA 141-539

Recommended use of the product and restriction on use

Relevant identified uses: For animal use only. Permitted for use only by and under the supervision of licensed veterinarians.
Uses advised against: Uses other than those recommended above.
Reasons why uses advised against: Not determined or not applicable.

Manufacturer or supplier details

Supplier:
United States
Aspen Veterinary Resources, LTD.
3155 W. Heartland Drive
Liberty, MO 64068
1-800-792-1238

Emergency telephone number:

United States
CHEMTREC
Within USA and Canada: 1-800-424-9300 (24 hours)
Outside USA and Canada: +1-703-527-3887 (24 hours)

SECTION 2: Hazard(s) identification

GHS classification:

Specific target organ toxicity - repeated exposure, category 1

Label elements

Hazard pictograms:



Signal word: Danger

Hazard statements:

H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary statements:

P260 Do not breathe dust/fume/gas/mist/vapors/spray
P264 Wash hands thoroughly after handling
P270 Do not eat, drink or smoke when using this product
P314 Get medical advice/attention if you feel unwell
P501 Dispose of contents/container in accordance with local, regional, national and international regulations.

Hazards not otherwise classified:

Combustible dust. May form combustible dust concentrations in air.

SECTION 3: Composition/information on ingredients

Identification	Name	Weight %
CAS number: 9004-34-6	Microcrystalline cellulose (Cellulose)	60-70
CAS number: 25416-65-3	Levothyroxine sodium, USP	0.1-1

Additional Information:

Concentrations listed are not product specifications.

SECTION 4: First aid measures

Description of first aid measures

General notes:

Show this Safety Data Sheet to the doctor in attendance.

After inhalation:

If inhaled, remove person to fresh air and place in a position comfortable for breathing. Keep person at rest. If breathing is difficult, administer oxygen. If breathing has stopped, provide artificial respiration. If experiencing respiratory symptoms, seek medical advice/attention.

After skin contact:

Remove contaminated clothing and shoes. Rinse skin with copious amounts of water [shower] for several minutes. Launder contaminated clothing before reuse. If symptoms develop or persist, seek medical advice/attention.

After eye contact:

Rinse eyes with plenty of water for several minutes. Remove contact lenses if present and easy to do so. Protect unexposed eye. If symptoms develop or persist, seek medical advice/attention.

After swallowing:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Most important symptoms and effects, both acute and delayed

Acute symptoms and effects:

Product presents an explosion hazard when suspended in air under certain conditions. Inhalation of large amounts of dust may cause inflammation and irritation of the nose and throat. Symptoms may include cough, sore throat, tightness of the chest, chest pain and lightheadedness.

Delayed symptoms and effects:

Causes damage to organs through prolonged or repeated exposure. Effects are dependent on exposure (dose, concentration, contact time).

Immediate medical attention and special treatment

Specific treatment:

Not determined or not applicable.

Notes for the doctor:

Treat symptomatically.

SECTION 5: Firefighting measures

Extinguishing media

Suitable extinguishing media:

Dry chemical, sand and carbon dioxide.

Unsuitable extinguishing media:

Do not use water, halogenated extinguishing agents and alcohol-based foam.

Specific hazards during fire-fighting:

May form combustible dust concentrations in air. Reacts with water and alcohols. Reacts violently with oxidants, strong acids and bases and chlorinated hydrocarbons. This generates a fire and explosion hazard. Thermal decomposition may produce irritating/toxic fumes/gases.

Special protective equipment for firefighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full-face piece operated in positive pressure mode. Use shielding to protect against bursting containers.

Special precautions:

Violent reactions may result from the use of a water jet or halogenated extinguishing agents. When using extinguishers, avoid dispersing combustible dust into the air. Aim extinguishers directly at the base of the flames and apply the agent as gently as possible. Overall, give preference to using medium to wide spray patterns rather than solid streams. Use only non-sparking tools. Fire fight from a protected location or maximum possible distance. Use water spray/fog for cooling fire exposed containers. Avoid unnecessary run-off of extinguishing media which may cause pollution.

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Evacuate unnecessary personnel. Extinguish any sources of ignition. Do not ventilate area as this may spread dust. Wear recommended personal protective equipment including suitable respiratory protection (see Section 8). Ensure no sources of electric discharge or ignition are on your person before entering area. Do not get on skin, eyes or on clothing. Avoid breathing dust, fumes. Wash thoroughly after handling. Remove contaminated clothing and launder before reuse.

Environmental precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

Methods and material for containment and cleaning up:

Avoid dust generation or stirring up of dust. Use only non-sparking tools. Ground all equipment used for recovery and clean up. Vacuum up and place in suitable containers for future disposal. Only use vacuum cleaners approved for dust collection. Dispose of in accordance with all applicable regulations (see Section 13).

Reference to other sections:

For personal protective equipment see Section 8. For disposal see Section 13.

SECTION 7: Handling and storage

Precautions for safe handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Use dust explosion proof electrical equipment and lighting. Avoid dust generation and dispersal of dust in air. Dust deposits should not be allowed to accumulate on surfaces. Clean dust residues at regular intervals. Do not use brooms or compressed air hoses to clean surfaces. Only use vacuums approved for dust collection. Use only non-sparking tools. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions such as electrical grounding and bonding or inner atmospheres. Keep containers tightly closed and grounded when not in use. Workers whose clothing may have been contaminated should change into non-contaminated clothing before leaving the work premises. Contaminated clothing should be segregated in such a manner so that there is no direct personal contact by personnel who handle, dispose or clean the clothing. Contaminated clothing should not be allowed out of the workplace. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10).

Conditions for safe storage, including any incompatibilities:

Store in cool, dry, well-ventilated location out of direct sunlight. Keep away from food and beverages. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed. Outside or detached storage is preferred. Inside storage should be in a standard flammable storage cabinet. Store away from incompatible materials (See Section 10).

SECTION 8: Exposure controls/personal protection

Only those substances with limit values have been included below.

Occupational Exposure limit values:

Country (Legal Basis)	Substance	Identifier	Permissible concentration
ACGIH	Microcrystalline cellulose (Cellulose)	9004-34-6	8-Hour TWA: 10 mg/m³
NIOSH	Microcrystalline cellulose (Cellulose)	9004-34-6	REL: 10 mg/m³ (10-Hours, Total)
	Microcrystalline cellulose (Cellulose)	9004-34-6	REL: 5 mg/m³ (10-Hours, Respirable)
OSHA	Microcrystalline cellulose (Cellulose)	9004-34-6	TWA: 5 mg/m³ (Respirable fraction)
	Microcrystalline cellulose (Cellulose)	9004-34-6	TWA: 15 mg/m³ (Total Dust)

Biological limit values:

No biological exposure limits noted for the ingredient(s).

Information on monitoring procedures:

Not determined or not applicable.

Appropriate engineering controls:

This product is a combustible material which may be ignited by friction, heat, sparks or flames. It is recommended that all dust control equipment (such as local exhaust ventilation and material transport systems) involved in handling this product contain explosion relief vents or an explosion suppression system. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area. Keep static electricity under control, which includes the bonding and grounding of equipment. Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

Personal protection equipment

Eye and face protection:

Use safety glasses with side shields or goggles. Do not wear contact lenses when handling or processing this product. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

Skin and body protection:

Chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

Respiratory protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn. Use a positive pressure air supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air purifying respirators may not provide adequate protection.

General hygienic measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Contaminated clothing should be removed and separated for decontamination. Do not allow contaminated work clothing out of the workplace. Perform routine housekeeping.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Tablet of various colors
Odor	Odorless/slight
Odor threshold	Not determined or not available.
pH	Not determined or not available.
Melting point/freezing point	Not determined or not available.
Initial boiling point/range	Not determined or not available.
Flash point (closed cup)	Not determined or not available.
Evaporation rate	Not determined or not available.
Flammability (solid, gas)	Not determined or not available.
Upper flammability/explosive limit	Not determined or not available.
Lower flammability/explosive limit	Not determined or not available.
Vapor pressure	Not determined or not available.
Vapor density	Not determined or not available.
Density	Not determined or not available.
Relative density	Not determined or not available.
Solubilities	Soluble in water
Partition coefficient (n-octanol/water)	Not determined or not available.
Auto/Self-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.
Dynamic viscosity	Not determined or not available.

Kinematic viscosity	Not determined or not available.
Explosive properties	Not determined or not available.
Oxidizing properties	Not determined or not available.

Other information

Color-coded and potency-embossed tablets	0.1 mg, Yellow. 0.2 mg, Pink. 0.3 mg, Green. 0.4 mg, Light pink. 0.5 mg, White. 0.6 mg, Dark blue, Violet. 0.7 mg, Orange, Pink. 0.8 mg, Light blue. 1.0 mg, Beige.

SECTION 10: Stability and reactivity

Reactivity:

Not reactive under recommended handling and storage conditions.

Chemical stability:

Stable under recommended handling and storage conditions.

Possibility of hazardous reactions:

Hazardous reactions are not anticipated under recommended conditions of handling and storage.

Conditions to avoid:

Extreme heat, open flames, hot surfaces, sparks, static discharge, ignition sources, dust generation and accumulation and incompatible materials.

Incompatible materials:

None known.

Hazardous decomposition products:

Carbon oxides.

SECTION 11: Toxicological information

Acute toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Route	Result
Microcrystalline cellulose (Cellulose)	dermal	LD50 Rabbit: > 2000 mg/kg
	inhalation	LC50 Rat: > 5.8 mg/L (4 hr)
	oral	LD50 Rat: > 5000 mg/kg

Skin corrosion/irritation

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Serious eye damage/irritation

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Respiratory or skin sensitization

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Carcinogenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

International Agency for Research on Cancer (IARC): None of the ingredients are listed.

National Toxicology Program (NTP): None of the ingredients are listed.

OSHA Carcinogens: Not applicable

Germ cell mutagenicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Reproductive toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Specific target organ toxicity (single exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Specific target organ toxicity (repeated exposure)

Assessment:

Causes damage to organs through prolonged or repeated exposure.

Product data:

No data available.

Substance data:

Name	Result
Levothyroxine sodium, USP	Causes damage to organs through prolonged or repeated exposure.

Aspiration toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Information on likely routes of exposure:

No data available.

Symptoms related to the physical, chemical and toxicological characteristics:

Refer to Section 4 of this SDS.

Other information:

No data available.

SECTION 12: Ecological information

Acute (short-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Chronic (long-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Persistence and degradability

Product data: No data available.

Substance data: No data available.

Bioaccumulative potential

Product data: No data available.

Substance data: No data available.

Mobility in soil

Product data: No data available.

Substance data: No data available.

Results of PBT and vPvB assessment

Product data:

PBT assessment: This product does not contain any substances that are assessed to be a PBT.

vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

Substance data:

PBT assessment: This product does not contain any substances that are assessed to be a PBT.

vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

Other adverse effects: No data available.

SECTION 13: Disposal considerations

Disposal methods:

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory entities

Contaminated packages:

Not determined or not applicable.

SECTION 14: Transport information

United States Transportation of dangerous goods (49 CFR DOT)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Maritime Dangerous Goods (IMDG)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None

Special precautions for user	None

International Air Transport Association Dangerous Goods Regulations (IATA-DGR)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

SECTION 15: Regulatory information

United States regulations

Inventory listing (TSCA): All ingredients are listed-active or exempt.

Significant New Use Rule (TSCA Section 5): None of the ingredients are listed.

Export notification under TSCA Section 12(b): None of the ingredients are listed.

SARA Section 302 extremely hazardous substances: None of the ingredients are listed.

SARA Section 313 toxic chemicals: None of the ingredients are listed.

CERCLA: None of the ingredients are listed.

RCRA: None of the ingredients are listed.

Section 112(r) of the Clean Air Act (CAA): None of the ingredients are listed.

Massachusetts Right to Know:

9004-34-6	Microcrystalline cellulose (Cellulose)	Listed

New Jersey Right to Know:

9004-34-6	Microcrystalline cellulose (Cellulose)	Listed

New York Right to Know: None of the ingredients are listed.

Pennsylvania Right to Know:

9004-34-6	Microcrystalline cellulose (Cellulose)	Listed

California Proposition 65: None of the ingredients are listed.

SECTION 16: Other information

Abbreviations and Acronyms: None

Disclaimer:

This product has been classified in accordance with OSHA HCS 2012 guidelines. The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation and disposal 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, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

NFPA: 3-0-0

HMIS: 3*-0-0

Initial preparation date: 04.06.2021

Additional information:

Approved by the Food and Drug Administration (FDA). The labeling requirements of the Federal Food, Drug, and Cosmetic Act differ from the classification criteria and hazard information required for safety data sheets and for workplace labels under the OSHA Hazard Communication Standard 29 CFR 1910.1200.

Following is the hazard information as required on the drug label:
User Safety Warnings: Not for human use. Keep out of reach of children. In case of accidental ingestion, seek medical advice immediately and show the product label to the physician. Wash hands after handling the product.
Animal Safety Warnings: Keep away from children, domestic animals, and pets.

End of Safety Data Sheet