

SAFETY DATA SHEET

SECTION 1. IDENTIFICATION

1.1 Product identifiers

Product name	: Endoxifen 20 mg Tablets
Product Number	: ENDOX-TAB
Brand	: 4AminoLabs
CAS-No. (active)	: 112093-28-4 ((Z)-endoxifen)
Reference batch	: ENDX-2026-001 (see container label)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses	: Laboratory research and analytical reference use.
Uses advised against	: Not for human or veterinary use. Not a drug, dietary supplement, food, or cosmetic. Supplied under the TSCA R&D Exemption (40 CFR Section 720.36); it is the recipient's responsibility to comply with the requirements of the R&D exemption.

1.3 Details of the supplier of the safety data sheet

Company	: 4AminoLabs 1001 S. Main Street, STE 600 Kalispell, MT 59901 UNITED STATES
Telephone	: +1 (256) 472-1983
E-mail	: sales@4aminolabs.com
Website	: www.4aminolabs.com

1.4 Emergency telephone number

Emergency Phone #	: Poison Control Center (US): 1-800-222-1222 (24 hours/day, 7 days/week)
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SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Carcinogenicity	: Category 1A
Reproductive toxicity	: Category 1B
Long-term (chronic) aquatic hazard	: Category 2

Classification is based on the actual concentration of the active ingredient in the finished product (GHS mixture rules; approx. 7.7 % w/w, tablet weight 260 mg). Substance classification of (Z)-endoxifen: Carc. 1A, Repr. 1B, Aquatic Acute 1, Aquatic Chronic 1.

GHS label elements

Hazard pictograms	:  
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Signal word	: Danger
Hazard statements	: H350 May cause cancer. H360 May damage fertility or the unborn child. H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:
P203 Obtain, read and follow all safety instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P318 IF exposed or concerned, get medical advice.
P391 Collect spillage.
Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

Limited test data available for hazard assessment; handle with caution. Crushing or grinding tablets may generate airborne dust. Persons who are pregnant, breast-feeding, or may become pregnant should not handle this product. Hormonally active substance (selective estrogen receptor modulator).

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration
Endoxifen ((Z)-4-hydroxy-N-desmethyltamoxifen) Synonyms: Z-endoxifen; N-desmethyl-4-hydroxytamoxifen; 4-hydroxy-N-desmethyltamoxifen Formula: C ₂₅ H ₂₇ NO ₂ Molecular weight: 373.49 g/mol	112093-28-4	approx. 20 mg/tablet approx. 7.7 % w/w
Microcrystalline cellulose	9004-34-6	Balance
Dicalcium phosphate	7757-93-9	Balance
Magnesium stearate	557-04-0	Balance
Silicon dioxide (amorphous)	7631-86-9	Balance

Excipients are not classified as hazardous. Individual excipient percentages are withheld as trade secret.

SECTION 4. FIRST AID MEASURES

General advice : Show this safety data sheet to the doctor in attendance.
If inhaled : After inhalation: fresh air. Call in physician if symptoms develop.
In case of skin contact : Take off immediately all contaminated clothing. Rinse skin with water/ shower. Consult a physician.
In case of eye contact : After eye contact: rinse out with plenty of water for at least 15 minutes. Remove contact lenses.
If swallowed : After swallowing: rinse mouth, make victim drink water (two glasses at most). Do not induce vomiting. Consult a physician.
Most important symptoms and effects, both acute and delayed : Hormonal effects possible with significant exposure, including hot flushes, effects on the endometrium, thromboembolic effects, and effects on fertility. See also section 11.
Protection of first-aiders : For personal protection see section 8.
Notes to physician : Treat symptomatically. Endoxifen is a selective estrogen receptor modulator (SERM) and the principal active metabolite of tamoxifen.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray, dry powder, foam, carbon dioxide (CO₂).
Unsuitable extinguishing media : For this substance/mixture no limitations of extinguishing agents are given.
Specific hazards during firefighting : Combustible. Finely divided dust may form explosive mixtures in air.
Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
Phosphorus oxides
Further information : Suppress (knock down) gases/vapours/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Advice for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact. Evacuate the danger area, observe emergency procedures, consult an expert. Advice for emergency responders: For personal protection see section 8.

Environmental precautions : Do not let product enter drains. Prevent release to the environment. Collect spillage.

Methods and materials for containment and cleaning up : Collect intact tablets by hand. Take up broken tablets and powder dry, avoiding generation of dusts; a HEPA vacuum may be used. Place in a closed, labeled container. Decontaminate surfaces with alcohol followed by soap and water. Dispose of properly (see section 13).

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : For precautions see section 2. Obtain special instructions before use. Handle only by qualified personnel in a laboratory setting. Crush, split, or weigh tablets only in a fume hood or ventilated enclosure. Avoid contact with skin and eyes.

Hygiene measures : Change contaminated clothing. Wash hands after working with substance. Do not eat, drink, or smoke in work areas.

Further information on storage conditions : Tightly closed. Dry. Protect from light (light sensitive). Store locked up or in an area accessible only to qualified or authorized persons.

Storage class : 6.1C, Combustible acute toxic Cat. 3 / toxic compounds or compounds which cause chronic effects

Recommended storage temperature : 2 - 8 °C (36 - 46 °F) for long-term storage; brief excursions to room temperature are acceptable

Materials to avoid : Strong oxidizing agents, strong acids and bases.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Component	CAS-No.	Value type	Control parameter	Basis
Endoxifen	112093-28-4	-	No established limit	-
Particulates not otherwise regulated (excipient dust)	-	TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable)	5 mg/m3	
Engineering measures	: Use a fume hood or ventilated balance enclosure when tablets are crushed, split, or weighed. Provide an eyewash station and safety shower.			

Personal protective equipment

Respiratory protection : Required when dusts are generated. Use a NIOSH-approved N95 or P100 particulate respirator. Maintenance, cleaning, and testing of respiratory protective devices must be carried out according to the manufacturer's instructions and documented.

Hand protection : Material: Nitrile rubber
Glove thickness: minimum 0.11 mm
Protective index: full contact and splash contact
Remarks: Handle with impervious gloves; double-gloving recommended. Inspect before use and dispose of after contamination.

Eye protection : Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU). Safety glasses with side shields.

Skin and body protection : Laboratory coat. Impervious clothing as needed for the task.

Hygiene measures : Change contaminated clothing. Wash hands after working with substance.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Solid, tablet

Color : White

Odor : No data available

Odor Threshold : No data available

pH : No data available



Melting point	: 127 - 129 °C (261 - 264 °F) ((Z)-endoxifen)
Boiling point/boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: Dust may be combustible
Upper/lower explosion limit	: No data available
Vapor pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Water solubility	: endoxifen: practically insoluble in water (< 0.1 mg/mL); soluble in DMSO and ethanol
Partition coefficient: n-octanol/water	: No data available
Autoignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: Not applicable
Explosive properties	: No data available
Oxidizing properties	: No data available
Molecular weight	: 373.49 g/mol (endoxifen)
Particle size	: Not applicable (tablet)

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No data available
Chemical stability	: The product is chemically stable under recommended storage conditions. Light and heat may promote Z/E isomerization of endoxifen.
Possibility of hazardous reactions	: No data available
Conditions to avoid	: Heat, moisture, direct light, dust formation.
Incompatible materials	: Strong oxidizing agents, strong acids, strong bases, strong reducing agents.
Hazardous decomposition products	: In the event of fire: see section 5

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

No data available for the tablets. No validated LD50 data for endoxifen.

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

May cause cancer (Carc. 1A, based on supplier classification of (Z)-endoxifen). Endoxifen is the principal active metabolite of tamoxifen; IARC classifies tamoxifen as Group 1 (carcinogenic to humans), associated with endometrial cancer.

IARC: Endoxifen is not individually evaluated by IARC.

NTP: Tamoxifen is listed by NTP as a known human carcinogen; endoxifen is not individually listed.

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

Reproductive toxicity

May damage fertility or the unborn child. Endoxifen acts on estrogen receptors (ER-alpha and ER-beta) and the hypothalamic-pituitary-gonadal axis.

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

Not applicable

11.2 Additional Information

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Substance ((Z)-endoxifen) is classified Aquatic Acute 1 and Aquatic Chronic 1: very toxic to aquatic life with long lasting effects.

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

Hormonally active substance; avoid release to the environment. This product neither contains, nor was manufactured with, a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App. A + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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|------------------------|---|---|
| Waste from residues | : | Waste material must be disposed of in accordance with national, state, and local regulations using a licensed waste disposal contractor. Leave chemicals in original containers. No mixing with other waste. Do not dispose of in household trash or sewer. |
| Contaminated packaging | : | Handle uncleaned containers like the product itself. |

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR: Not regulated as a dangerous good in this packaging (excepted quantity of solid in tablet form; verify against current regulations for bulk shipments).

IMDG-Code: Not regulated as a dangerous good in this packaging.

National Regulations

49 CFR (DOT): Not regulated as a dangerous good

Poison Inhalation Hazard : No

Special precautions for user : Not classified as dangerous in the meaning of transport regulations for retail-size containers.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 302 / 304 Extremely Hazardous Substances

This material does not contain any components with a section 302 EHS TPQ or section 304 EHS RQ.

SARA 311/312 Hazards : Carcinogenicity, Reproductive toxicity

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP) as defined by the U.S. Clean Air Act Section 112 (40 CFR 61), nor any Class I or Class II ODS.

Clean Water Act

This product does not contain any Hazardous Substances listed under Section 311, Table 116.4A, or toxic or priority pollutants under Section 307.

US State Regulations

Massachusetts Right To Know : No components are subject to the Massachusetts Right to Know Act.



Pennsylvania Right To Know	: No components are subject to the Pennsylvania Right to Know Act.
New Jersey Right To Know	: No components are subject to the New Jersey Right to Know Act.
California Prop. 65	: Endoxifen is not individually listed under Proposition 65. Its parent compound, tamoxifen and its salts, is listed as known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov .

Inventories

TSCA	: Product contains substance(s) not listed on the TSCA inventory. Supplied for research and development use only under 40 CFR 720.36.
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SECTION 16. OTHER INFORMATION

Full text of other abbreviations

CAS - Chemical Abstracts Service; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; DOT - Department of Transportation; GHS - Globally Harmonized System; HEPA - High-Efficiency Particulate Air; IARC - International Agency for Research on Cancer; IATA-DGR - International Air Transport Association Dangerous Goods Regulations; IMDG - International Maritime Dangerous Goods; LD50 - Lethal Dose to 50% of a test population; NIOSH - National Institute for Occupational Safety and Health; NTP - National Toxicology Program; ODS - Ozone Depleting Substance; OSHA - Occupational Safety and Health Administration; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; SERM - Selective Estrogen Receptor Modulator; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average.

For research use only. Not for human or veterinary use. The information is believed to be correct but is not exhaustive and shall be used solely as a guideline, based on current knowledge of the chemical substance or mixture, and is applicable to appropriate safety precautions for the product. It does not represent any guarantee of the properties of the product. 4AminoLabs shall not be held liable for any damage resulting from handling or from contact with the above product. The burden of safe use rests with the user.

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