

Scientific Documentation

Estradiol, Hemihydrate, Soy Base, Micronized, USP

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300



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Specification for Estradiol, Hemihydrate, Soy Base, Micronized, USP (E2918)

Item Number	E2918
Item	Estradiol, Hemihydrate, Soy Base, Micronized, USP
CAS Number	35380-71-3
Molecular Formula	$C_{18}H_{24}O_2 \cdot 1/2 H_2O$
Molecular Weight	281.39
MDL Number	
Synonyms	Oestradiol ; 17-Beta-Estradiol ; Estra-1,3,5(10)-triene-3,17Beta-diol

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	97.0	103.0%
MELTING RANGE	173°	179°C
SPECIFIC ROTATION $[\alpha]_D^{25}$	+76° to +83°	
PARTICLE SIZE (THROUGH 20 micron)	92%	
WATER DETERMINATION		3.5%
CHROMATOGRAPHIC PURITY :		
INDIVIDUAL IMPURITY		0.5 %
TOTAL IMPURITIES		1.0 %
ELEMENTAL IMPURITIES:		
LITHIUM (Li)	AS REPORTED	
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)		3.0 %
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

Spectrum Chemical Mfg Corp

Corporate Headquarters: West Coast Facility:

769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

Certificate Of Analysis

Item Number	E2918	Lot Number	4MK0014
Item	Estradiol, Hemihydrate, Soy Base, Micronized, USP	Manufacturer Lot	QC014-230902
CAS Number	35380-71-3	Manufacturer Code	13524
Molecular Formula	C ₁₈ H ₂₄ O ₂ •1/2H ₂ O	Molecular Weight	281.39

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS BASIS)	97.0	103.0%	100.5 %
MELTING RANGE	173°	179°C	173.3 - 175.8 °C
SPECIFIC ROTATION [α] _D 25	+76° to +83°		+ 82 °
PARTICLE SIZE (THROUGH 20 micron)	92%		96.66%
WATER DETERMINATION		3.5%	3.0 %
CHROMATOGRAPHIC PURITY :			.
INDIVIDUAL IMPURITY		0.5 %	0.05 %
TOTAL IMPURITIES		1.0 %	0.1 %
ELEMENTAL IMPURITIES:			.
LITHIUM (Li)	AS REPORTED		< 0.5 µg/g
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)		3.0 %	< 3.0 %
EXPIRATION DATE			09-SEP-2028
DATE OF MANUFACTURE			09-SEP-2023
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS		AS REPORTED	.
CLASS 2 (SOLVENT) / METHANOL			< 3000 ppm
CLASS 3 (solvent) / ETHANOL			< 5000 ppm
MONOGRAPH EDITION (USP)			USP 2023

Certificate of Analysis Results Entered By:

CMARIN
Catherine Marin
27-FEB-24 07:49:03

Certificate of Analysis Results Approved By:

MCAMACHO
Matheu Camacho
28-FEB-24 06:02:05

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Zhejiang Xianju Pharmaceutical Co., Ltd. (Yangfu API) at 15 West Fengxi Road, Modern Industrial Park, Xianju, Taizhou, Zhejiang 317300, China (CHN). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

spectrum®



Revision date 24-August-2022

Revision Number 2

1. Identification

Product identifier

Product Name ESTRADIOL, SOY BASE, MICRONIZED, USP

Other means of identification

Product Code(s) E2918

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

Carcinogenicity	Category 1A
Reproductive toxicity	Category 1A
Effects on or via lactation	Yes

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

May cause cancer
May damage fertility or the unborn child
Effects on or via lactation



Appearance Powder or Fine granules or Crystalline powder

Physical state Solid

Odor No information available

Precautionary Statements - Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

Precautionary Statements - Storage

Store locked up.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
ESTRADIOL, SOY BASE, MICRONIZED, USP	50-28-2	100	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

General advice	IF exposed or concerned: Get medical advice/attention. Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
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	Clean mouth with water and drink afterwards plenty of water.

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	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	No information available.
Hazardous combustion products	Carbon dioxide (CO ₂).
Explosion data	
Sensitivity to mechanical impact	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.
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. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.
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Conditions for safe storage, including any incompatibilities

Storage Conditions	Store locked up.
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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.
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Engineering controls	Showers
	Eyewash stations
	Ventilation systems.

Eye/face protection	No special protective equipment required.
Hand protection	Wear suitable gloves.
Skin and body protection	Wear suitable protective clothing.
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	Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Powder or Fine granules or Crystalline powder
Color	White to Yellow
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	> 170 °C / 338 °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 limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	Practically insoluble in water	None known
Solubility(ies)	Slightly soluble in Dimethyl sulfoxide (DMSO)	None known
	Very slightly soluble in acetone	
	Very slightly soluble in Ethanol	
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

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
Liquid Density	No information available

Bulk density 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.

Conditions to avoid None known based on information supplied.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

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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.

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 No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity Contains a known or suspected carcinogen. Classification based on data available for ingredients. May cause cancer.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
ESTRADIOL, SOY BASE, MICRONIZED, USP 50-28-2	-	Supplement 7 [1987] Estrogens steroidal	-	-

Legend

Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May damage fertility or the unborn child.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard	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	No information available.
Bioaccumulation	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

<u>DOT</u>	not regulated
<u>TDG</u>	not regulated
<u>MEX</u>	not regulated
<u>ICAO (air)</u>	not regulated
<u>IATA</u>	not regulated
<u>IMDG</u>	not regulated
<u>RID</u>	not regulated
<u>ADR</u>	not regulated
<u>ADN</u>	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	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:

IECSC
KECL
PICCS
AICS

This product complies with China:
Does not Comply
Complies
All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - 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 contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
ESTRADIOL, SOY BASE, MICRONIZED, USP - 50-28-2	carcinogen

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
ESTRADIOL, SOY BASE, MICRONIZED, USP 50-28-2	-	Present	Special hazardous substance

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 -
HMIS

Health hazards * 1
Flammability 0
Physical hazards 0
Personal protection X
Chronic Hazard Star Legend

** = Chronic Health Hazard*

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value		

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) (AELG(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 (IUCSID)
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 24-August-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



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
E2918	Estradiol, Hemihydrate, Soy Base, Micronized, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

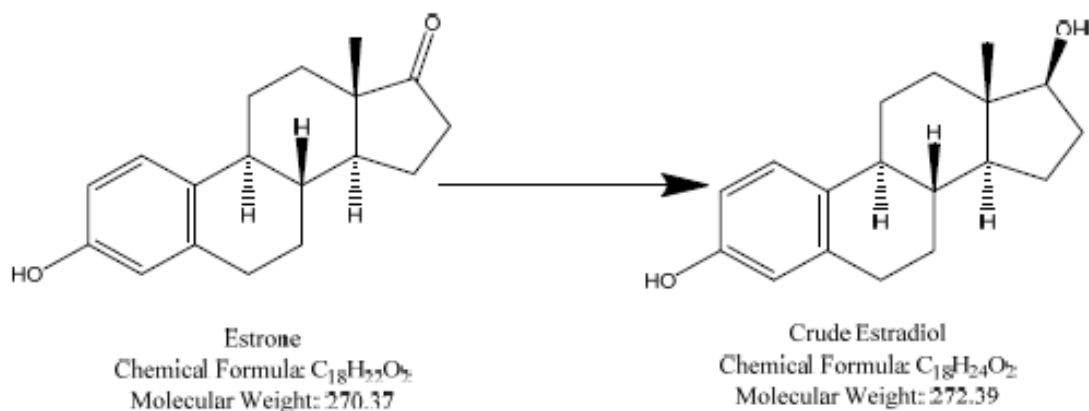
A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

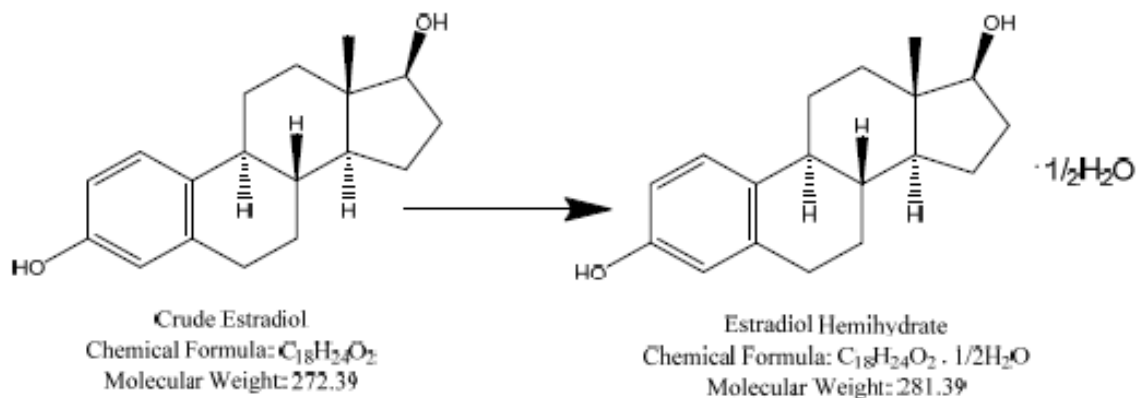
Manufacturing Process Flowchart Estradiol, Hemihydrate, Soy Base, Micronized, USP (E2918)

Synthetic Route of Estradiol Hemihydrate

Stage 1: Reduction Reaction



Stage 2: Purification



CORPORATE HEADQUARTERS

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14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

E2918, Estradiol, Hemihydrate, Soy Base, Micronized, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis using plant derived raw material from soy. No animal derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above-mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- | | |
|---------------------|-----------------|
| • Aflatoxins | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Estradiol, Hemihydrate, Soy Base, Micronized, USP (Cat# E2918)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Mercury	Hg	1	< 3 ppm
Nickel	Ni	2A	< 20 ppm
Thallium	Tl	2B	Not tested
Gold	Au	2B	Not tested
Palladium	Pd	2B	Not tested
Iridium	Ir	2B	Not tested
Osmium	Os	2B	Not tested
Rhodium	Rh	2B	Not tested
Ruthenium	Ru	2B	Not tested
Selenium	Se	2B	Not tested
Silver	Ag	2B	Not tested
Platinum	Pt	2B	Not tested
Antimony	Sb	3	Not tested
Barium	Ba	3	Not tested
Molybdenum	Mo	3	Not tested
Copper	Cu	3	Not tested
Tin	Sn	3	Not tested
Chromium	Cr	3	Not tested

Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

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This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

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RE: Residual Solvents - Estradiol, Hemihydrate, Soy Base, Micronized, USP (Cat# E2918)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Methanol	2	< 3000 ppm
Ethanol	3	< 5000 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

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Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

Exp. Date: 00-00-0000



DANGER
 • May cause cancer • May damage fertility or the unborn child • May cause harm to breast-fed children.
 • Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Wear protective gloves, protective clothing, eye protection, face protection • Do not eat, drink or smoke when using this product • Do not breathe dust • Avoid contact during pregnancy or while nursing • Wash face, hands and any exposed skin thoroughly after handling.
FIRST AID: If exposed or concerned: Get medical attention.
KEEP FROM CHILDREN



E2918

SIZ SY

Estradiol
 [17-β-Estradiol; Estra-1,3,5(10)-triene-3,17β-diol; Oestradiol]
 Hemihydrate
 Soy Base, Micronized, USP
 CAS 35380-71-3

CAUTION: For manufacturing, processing, repacking, or for prescription compounding. Rx only.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300
www.SpectrumChemical.com

$C_{18}H_{24}O_2 \cdot \frac{1}{2}H_2O$ F.W. 281.39

Manufacturer/Supplier Code ?
 Manufacturer Lot Number ?

Assay (Anhydrous Basis) 97.0-103.0%
 Melting Range 173°-179°C
 Specific Rotation, $[\alpha]_D^{25}$ +76° to +83°
 Particle Size (Through 20 Microns) Min. 92%

MAXIMUM LIMITS

Water Determination 3.5%
 Chromatographic Purity To pass test
 Elemental Impurities As reported
 Residual Solvents To pass test

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.

WARNING: Cancer-
www.P65Warnings.ca.gov

Repackaged by Spectrum as:
 Lot No. XQ####

G 3/16GHS-A ?

Spectrum Chemical Mfg Corp

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