



SAFETY DATA SHEET

122000005219

Natazia™

Version 3.0

Revision Date 07/18/2016

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product information

Product Name: Natazia™
SDS Number: 122000005219

Use : Medicinal products

Company

Bayer HealthCare, LLC
Pharmaceuticals
100 Bayer Boulevard PO Box 915
Whippany, NJ 07981-0915
UNITED STATES OF AMERICA
1888-84-BAYER

In case of emergency: 1888-84-BAYER
Chemtrec: (800) 424-9300

2. HAZARDS IDENTIFICATION

Emergency Overview

Colour: red, yellow, white **Form:** tablet **Odour:** odourless.

GHS Classification:

Carcinogenicity : Category 2
Reproductive toxicity : Category 1A
Effects on or via lactation :

GHS label elements:

Hazard pictograms :



Signal word : Danger

Hazard statements : H351 Suspected of causing cancer.
H360FD May damage fertility. May damage the unborn child.
H362 May cause harm to breast-fed children.

Precautionary statements : **Prevention:**

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust or mist.
P263 Avoid contact during pregnancy/ while nursing.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification:

Risk of dust explosion in fine crystalline powder form.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Weight percent	Components	CAS-No.
3.6%	Estradiol valerate	979-32-8
3.6%	Dienogest	65928-58-7

Other Ingredients

Weight percent	Components	CAS-No.
11.9%	Starch	9005-25-8
0.6%	Titanium oxide	13463-67-7
0.4%	Polyethyleneglycol	25322-68-3

4. FIRST AID MEASURES

General advice: No hazards which require special first aid measures.

If inhaled: Not an expected entry route.

In case of skin contact: Not considered a health risk.

In case of eye contact: Not considered a health risk.

If swallowed: In case of overdose, contact your regional poison control center or physician immediately. Contact U.S. Poison Control Center at 1-800-222-1222.

Contact Number: Use the Bayer Emergency Number in Section 1

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Any

Specific hazards during firefighting: Fire may cause the release of: Carbon monoxide (CO)
Carbon dioxide (CO₂)

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

Further information: Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment.

Methods for cleaning up: Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

Additional advice: Avoid dust formation.

Further Accidental Release Notes Avoid dust formation.

7. HANDLING AND STORAGE

Handling:

No special handling advice required.

No special protective measures against fire required.

Storage:

Storage temperature: 59 - 86 °F (15 - 30 °C)

Do not use after expiration date.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Starch (9005-25-8)

US. ACGIH Threshold Limit Values

Time Weighted Average (TWA): 10 mg/m³

US. NIOSH: Pocket Guide to Chemical Hazards

Recommended exposure limit (REL): 10 mg/m³ (Total)

US. NIOSH: Pocket Guide to Chemical Hazards

Recommended exposure limit (REL): 5 mg/m³ (Respirable.)
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)
Permissible exposure limit: 15 mg/m³ (Total dust.)
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)
Permissible exposure limit: 5 mg/m³ (Respirable fraction.)

Titanium oxide (13463-67-7)

US. ACGIH Threshold Limit Values
Time Weighted Average (TWA): 10 mg/m³
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)
Permissible exposure limit: 15 mg/m³ (Total dust.)

Polyethyleneglycol (25322-68-3)

US. OARS. WEELs Workplace Environmental Exposure Level Guide
Time Weighted Average (TWA): 10 mg/m³ (Particulate.)

Respiratory protection:

Recommended Filter type: HEPA

None required for consumer use of this product.

Hand protection:

Chemically resistant gloves.

None required for consumer use of this product.

Other protective measures:

No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff or patients.

Wear suitable protective equipment.

For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet.

Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	tablet
Colour:	red, yellow, white
Odour:	odourless
Odour Threshold:	No applicable information is available
Melting point:	No applicable information is available
Boiling point/boiling range:	No applicable information is available
Density:	No applicable information is available
Bulk density:	No applicable information is available
Vapour pressure:	No applicable information is available
Viscosity, dynamic:	No applicable information is available
Viscosity, kinematic:	No applicable information is available
Flow time:	No applicable information is available
Surface tension:	No applicable information is available

Miscibility with water:	No applicable information is available
Water solubility:	No applicable information is available
pH:	No applicable information is available
Relative density:	No applicable information is available
Partition coefficient:	No applicable information is available
Solubility(ies):	No applicable information is available
Flash point:	No applicable information is available
Flammability (solid, gas):	No applicable information is available
Ignition temperature:	No applicable information is available
Explosion limits:	No applicable information is available

10. STABILITY AND REACTIVITY

Conditions to avoid: No data available

Materials to avoid: No data available

Hazardous reactions: No data available

Thermal decomposition:

No data available

Volume resistivity:

4.400000E+12 Ohm.m at 21 °C

Relative humidity: 29 %

Measuring voltage: 100 V

Method: DIN EN 61241-2-2 (VDE 0170/0171 Part 15-2-2)

Sample tested as delivered (dust)., High specific resistance., Non-conductive dust.

8.100000E+12 Ohm.m at 21 °C

Relative humidity: 29 %

Measuring voltage: 500 V

Method: DIN EN 61241-2-2 (VDE 0170/0171 Part 15-2-2)

Sample tested as delivered (dust)., High specific resistance., Non-conductive dust.

Hazardous decomposition products:

Carbon monoxide (CO), Carbon dioxide (CO₂)

Oxidizing properties:

No statements available.

Impact sensitivity:

No data available

11. TOXICOLOGICAL INFORMATION**Other information on toxicity:**

No data is available on the product itself.

Acute oral toxicity:

Estradiol valerate

LD50 Rat: > 4,000 mg/kg

Dienogest

LD50 Rat: > 2,000 mg/kg

Starch

No adverse effect has been observed in acute toxicity tests.

Titanium oxide

LD50 Rat: > 10,000 mg/kg

Starch

No adverse effect has been observed in acute toxicity tests.

Acute inhalation toxicity:

Titanium oxide

LC50 Rat: > 6.8 mg/l, 4 h

Acute dermal toxicity:

Titanium oxide

LD50 Rabbit: > 10,000 mg/kg

Acute toxicity (other routes of administration):

Starch

LD50 intraperitoneal Mouse: 6,600 mg/kg

Starch

LD50 intraperitoneal Mouse: 6,600 mg/kg

Skin irritation:

Starch

Rabbit

Result: Mild skin irritation

Method: Draize Test

Titanium oxide

Result: No skin irritation

TiO₂ pigments are not irritant but as with all fine powders can adsorb moisture and natural oils from the surface of the skin during prolonged exposure.

Starch

Rabbit

Result: Mild skin irritation

Method: Draize Test

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Eye irritation:

Titanium oxide

Result: No eye irritation

Possibly mechanical irritation

Genotoxicity in vitro:

Estradiol valerate

Ames test

Result: Negative.

Dienogest

Result: Negative.

Genotoxicity in vivo:

Estradiol valerate

Micronucleus test, Rat

Result: No indication of clastogenic effects.

Dienogest

Result: Negative.

Estradiol valerate

Suspected of causing cancer.

Sex steroids may stimulate the growth of hormone-dependent tissue and tumors.

Dienogest

Sex steroids may stimulate the growth of hormone-dependent tissue and tumors. Suspected of causing cancer.

Reproductive toxicity:

Estradiol valerate

Result: May damage fertility.

Dienogest

Result: May damage fertility.

Teratogenicity:

Estradiol valerate

Result: May damage the unborn child.

May cause harm to breast-fed children.

Dienogest

Result: May damage the unborn child.

May cause harm to breast-fed children.

Pharmaceutic effects:

Contraceptive

CMR classification:

Carcinogenicity: Suspected of causing cancer.

Teratogenicity: May damage fertility. May damage the unborn child.

Reproductive toxicity: Effects on or via lactation

Carcinogenicity:

Estradiol valerate

Talcum

Titanium oxide

STOT - single exposure:

No data available

STOT - repeated exposure:No data available

12. ECOLOGICAL INFORMATION**General advice:**

Do not allow to enter surface waters or groundwater.

Toxicity to fish:

Dienogest

LC50 > 22.2 mg/l

Test species: Pimephales promelas (fathead minnow) Duration of test: 96 h

Method: OECD 203

saturated aqueous solution

Titanium oxide

Acute Fish toxicity: LC50 240 - 370 mg/l

Test species: Cyprinodon sp. (minnow) Duration of test: 96 h

Toxicity to daphnia and other aquatic invertebrates:

Estradiol valerate

EC50 > 100 mg/l

Test species: Daphnia pulex (Water flea) Duration of test: 48 h

Method: OECD 202

saturated aqueous solution

Dienogest

EC50 > 21.5 mg/l

Test species: Daphnia (water flea) Duration of test: 48 h

Method: OECD 202

saturated aqueous solution

Titanium oxide

LC50 300 - 400 mg/l

Test species: Mysidopsis almyra (Opposum shrimp) Duration of test: 96 h

Toxicity to algae:

Estradiol valerate

EC50 > 100 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Method: OECD 201

saturated aqueous solution

Dienogest

> 100 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Method: OECD 201

saturated aqueous solution

saturated aqueous solution

Biodegradability:

Estradiol valerate

2 - 14 %, 28 d Readily biodegradable

Not toxic to the microbes of activated sludge.

Dienogest

2.7 %, 29 d Not rapidly biodegradable

Not toxic to the microbes of activated sludge.

Titanium oxide

Pigments are practically not biodegradable.

Bioaccumulation:

Titanium oxide

Bioaccumulation is unlikely.

13. DISPOSAL CONSIDERATIONS

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

14. TRANSPORT INFORMATION

Land transport (CFR)

non-regulated

US Sea transport (IMDG)

non-regulated

US Air transport (ICAO / IATA cargo aircraft only)

non-regulated

US Air transport (ICAO / IATA passenger and cargo aircraft)

non-regulated

International IATA

IMDG

non-regulated

non-regulated

15. REGULATORY INFORMATION

Other regulations: No statements available.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A)

Components

None

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required

Components

None

US. EPA CERCLA Hazardous Substances (40 CFR 302)Components

None

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists

Weight percent	Components	CAS-No.
10 - 30%	Starch	9005-25-8

New Jersey Environmental Hazardous Substances List and/or New Jersey RTK Special Hazardous Substances Lists

Weight percent	Components	CAS-No.
0.5 - 1%	Titanium oxide	13463-67-7

California Prop. 65

Weight percent	Components	CAS-No.
1.2 - 3.6%	Estradiol valerate	979-32-8

To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard Rating Not subject to OSHA

16. OTHER INFORMATION

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

Further information

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.