



SAFETY DATA SHEET

122000005944

Jaydess - Skyla

Version 1.0

Revision Date 01/31/2013

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**Product information**

Product Name: Jaydess - Skyla
MSDS Number: 122000005944

Use : Medical Product

Company

BAYER HEALTHCARE LLC
Bayer HealthCare Pharmaceuticals Inc.
6 West Belt
Wayne, NJ 07470
USA
1888-84-BAYER

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

2. HAZARDS IDENTIFICATION**Emergency Overview**

ATTENTION! Form: solid **Odour:** odourless.

This a pharmaceutical product available only with a prescription, for use only as directed.

Hazard Communication (29CFR 1910.1200)

No Carcinogenic substances as defined by IARC, NTP and/or OSHA

3. COMPOSITION/INFORMATION ON INGREDIENTS

Weight percent	Components	CAS-No.
3 - 7%	Levonorgestrel	797-63-7

Inactive Ingredients: Polydimethylsiloxane various forms; Barium sulfate; Ferric oxide black;

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4. FIRST AID MEASURES

If inhaled: Not an expected entry route.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water. If skin reactions occur, contact a physician.

If swallowed: Not an expected entry route.

Contact Number: Use the Bayer Emergency Number in Section 1

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Any

Specific hazards during firefighting: Fire may cause evolution of: Carbon monoxide Carbon dioxide (CO₂)

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

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

6. ACCIDENTAL RELEASE MEASURES

Environmental precautions: Should not be released into the environment.

7. HANDLING AND STORAGE**Handling:**

Take measures to prevent the build up of electrostatic charge. Keep away from open flames, hot surfaces and sources of ignition.

Storage:

Storage temperature: 59 - 86 °F (15 - 30 °C)
Do not use after expiration date.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Levonorgestrel (797-63-7)

Respiratory protection:

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Recommended Filter type: HEPA

Hand protection:

Chemically resistant gloves.

Eye protection:

Safety glasses

Other protective measures:

Wear suitable protective equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	solid
Odour:	odourless
Water solubility:	insoluble

10. STABILITY AND REACTIVITY

Conditions to avoid: no data available

Materials to avoid: Oxidizing agents

Hazardous reactions: None known.

Thermal decomposition:

no data available

Hazardous decomposition products:

Carbon monoxide, 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.

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Acute oral toxicity:

Levonorgestrel

LD50 rat: > 4,000 mg/kg

LD50 mouse: > 4,000 mg/kg

Genotoxicity in vitro:

Levonorgestrel

Ames test Salmonella typhimurium

Result: negative

Genotoxicity in vivo:

Levonorgestrel

In vivo tests did not show mutagenic effects

Levonorgestrel

Suspected of causing cancer.

Reproductive toxicity:

Levonorgestrel

Result: May damage fertility.

Teratogenicity:

Levonorgestrel

Result: May damage the unborn child.

Pharmaceutic effects:Contraceptive

12. ECOLOGICAL INFORMATION**General advice:**

Do not allow to enter surface waters or groundwater.

Toxicity to fish:

Levonorgestrel

LC50 > 100 mg/l

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

Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:

Levonorgestrel

EC50 > 1.3 mg/l

Test species: Daphnia Duration of test: 48 h

saturated aqueous solution

Biodegradability:

Levonorgestrel

Not readily biodegradable.

Not toxic to the microbes of activated sludge.

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13. DISPOSAL CONSIDERATIONS

If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

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

14. TRANSPORT INFORMATION**Land transport (CFR)****Non-Regulated****Sea transport (IMDG)****Non-Regulated****Air transport (ICAO / IATA cargo aircraft only)****Non-Regulated****Air transport (ICAO / IATA passenger and cargo aircraft)****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

California Prop. 65

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 Hazardous

16. OTHER INFORMATION**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.