



MATERIAL SAFETY DATA SHEET

Date of preparation: June 16, 2010

1. PRODUCT IDENTIFICATION

Product Name(s): JEVTANA®

Synonym(s): Cabazitaxel, XRP6258

**sanofi-aventis U.S.
55 Corporate Drive
Bridgewater, NJ 08807**

| | |
|--|-----------------------|
| 24-Hour Transport Emergency, US (Chemtrec): | (800) 424-9300 |
| 24-Hour Transport Emergency, outside US (Chemtrec): | (703) 527-3887 |
| US Customer Service | (800) 207-8049 |
| 24-Hour Emergency, sanofi-aventis US: | (908) 981-5550 |

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

This product consists of cabazitaxel/polysorbate 80 solution in glass vials. If the integrity of the vial is maintained, there is no hazard in handling. If the vials are broken, clean-up personnel should wear Solvex nitrile NBR gloves and eye protection. If the potential exists for splashing, impervious clothing and face protection is advised.

POTENTIAL HEALTH HAZARDS

Eye: Irritating to the eyes in the event of an inadvertent splash.

Skin: Irritating to the skin. May be absorbed and made available systemically.

Ingestion: Moderately toxic if inadvertently ingested.

Inhalation: Compound is supplied in solution therefore this is not an expected route of exposure.

Chronic Effects: This is an antineoplastic (taxoid) compound. No chronic studies have been conducted. The compound was negative in the Ames test but positive in the in vitro micronucleus test. If the compound is bioavailable via the route of exposure and exposure occurs for prolonged periods of time, due to the pharmacological activity it is presumed that potentially adverse and irreversible effects could occur, including limited carcinogenic and reprotoxic effects.

Product Name: Jevtana®

3. COMPOSITION/INFORMATION ON INGREDIENTS

| <u>INGREDIENT</u> | <u>CAS NUMBER</u> |
|----------------------------------|------------------------------|
| Cabazitaxel (XRP6258) | 183133-96-2 |
| Polysorbate 80 | 9005-55-6 |

4. FIRST AID MEASURES

Eyes: Immediately flush eyes with plenty of water for fifteen minutes. Seek medical attention.

Skin: Wash with copious amounts of soap and water. Seek medical attention.

Ingestion: Seek medical attention. Induce only as directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: If mist is inhaled, remove to fresh air and seek medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Note to Physicians: Treat symptomatically and supportively.

5. FIRE FIGHTING MEASURES

Hazardous Combustion Products: CO, CO₂ and oxides of nitrogen may be generated in a fire.

Extinguishing Media: Packaging material fires may be extinguished with water, carbon dioxide, or dry chemical.

Firefighting Instructions: Firefighting in confined spaces requires full protective gear and supplied air respiratory protection.

6. ACCIDENTAL RELEASE MEASURES

Small Spill: Don Solvex nitrile NBR gloves and eye protection. Absorb liquid. Clean area with commercial bleach solution.

Large Spill: Don Solvex nitrile NBR gloves, Tyvek outer clothing and face protection. Absorb liquid. Clean area with commercial bleach solution.

7. HANDLING AND STORAGE

Handling: Protect package from damage.

Storage: Keep away from light and heat.

Product Name: Jevtana®

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold Limit Values:

Cabazitaxel: sanofi-aventis US Occupational Exposure Band 5 (0.1 – 1.0 mcg/m³).
Polysorbate 80: Not established.

Engineering Controls: Operations should be designed to offer no significant exposure to the liquid.

Respiratory Protection: Recommended to protect against aerosols for manufacturing operations without local exhaust ventilation or when cleaning up a very large spill.

Skin Protection: Solvex nitrile NBR gloves are recommended if potential exists for significant hand/wrist exposure.

Eye Protection: Safety glasses recommended. Full-face protection recommended for spill cleanup if potential exists for splashing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Data for Cabazitaxel:

Form: Solid.

Color: White.

Empirical formula: C₄₅ H₅₇ N O₁₄, C₃ H₆ O

Molecular weight: 894.03.

Melting point: 157⁰ C.

Solubility: 0.006 g/L; practically insoluble in water.
Soluble in ethanol.

Log Kow: 3.88 (computed value).

Data for Polysorbate 80:

Form: Liquid.

Color: Yellow.

Flash point: 113⁰C (235⁰F) – closed cup.

Boiling point: 100⁰C (212⁰F).

Density: 1.064 g/cm³.

Vapor pressure: < 1 mm Hg at 20⁰C (68⁰F).

10. STABILITY AND REACTIVITY

Incompatibility: Direct light and heat.

Hazardous Decomposition Products: No data.

Hazardous Polymerization: Will not occur.

Product Name: Jevtana®

11. TOXICOLOGICAL INFORMATION

Information for the active ingredient cabazitaxel:

Acute oral toxicity LD50 (rat): 500 mg/kg

Genotoxicity: Negative in the Ames test. Positive in the in vitro micronucleus test.

Irritation: Strong dermal irritant.

Information for the ingredient Polysorbate 80:

Acute oral toxicity LD50 (rat): 25,000 mg/kg

Irritation: Mild eye irritant. Mild skin irritant.

12. ECOLOGICAL INFORMATION

No data available for the formulation. The active ingredient is currently under evaluation.

13. DISPOSAL CONSIDERATIONS

Waste must be disposed of in accordance with all federal, state, and local regulations. Incineration is the preferred method.

14. TRANSPORT INFORMATION

No classification currently assigned.

15. REGULATORY INFORMATION

TSCA Status: N0

CERCLA Section 103: No

SARA Section 302: No

SARA Section 304: No

SARA Section 313: No

16. OTHER INFORMATION

Report to the manufacturer any allegations of adverse effects related to handling or accidental contact with this material.

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