

**CellCiphr Cytotoxicity Assay, Human HepG2 cells
Paclitaxel Solution**

**SECTION 1 – IDENTIFICATION OF THE SUBSTANCE/PREPARATION and of
THE COMPANY/UNDERTAKING -
CHEMICAL PRODUCT & COMPANY IDENTIFICATION**

Identification of the substance or preparation

Trade Name **CellCiphr Cytotoxicity Assay, Human HepG2 cells
Paclitaxel Solution**

Catalogue Number: **2007510**

Chemical Name: A solution of Paclitaxel in Dimethyl Sulfoxide.

Product Use: Liquid reagent used in cytotoxicity assay research

Other trade names and
synonyms Component in Millipore Product Number **CSB100**

Manufacturer/Distributor: **Millipore Corporation** **Millipore S.A.S.**
(Corporate Headquarters) **(European Headquarters)**

Postal Address: **290 Concord Road** **Boite Postale 116**
Billerica MA **67124 Molsheim Cedex**
USA **France**
978-533-2988 Telephone Number: **33(0)3 90 46 90 00**

CHEMTREC Emergency Telephone Number:

International 1-703-527-3887 (collect)
North America 1 800-424-9300

MSDS/SDS Number: **M118,004ae**

Issue Date: 27 July 2007

Rev. Date: --

Revision: --

SECTION 2 – COMPOSITION/INFORMATION ON INGREDIENTS

| Component | EINECS or ELINCS No. | CAS No. | Content (weight percent) | Symbol letters* | R-phrases** |
|--------------------|----------------------|------------|--------------------------|-----------------|--|
| Dimethyl Sulfoxide | 200-664-3 | 67-68-5 | 90 | None | None |
| Paclitaxel | Unlisted | 33069-62-4 | 10 | Xn | R48/20/21/22, R68/20/21/22 R40 R37/38, R42/43 R41, R62, |

*Symbol letters and categories of danger: **T+**=Very toxic, **T**=Toxic, **C**=Corrosive, **Xn**=Harmful, **Xi**=Irritant, **E**=Explosive, **O**=Oxidising, **F+**=Extremely flammable, **F**=Very flammable, **N**=Dangerous for the environment
** The full text of the phrase is listed under heading 16.

SECTION 3 - HAZARD IDENTIFICATION

EMERGENCY OVERVIEW

Appearance: Clear, colorless solution

Classification: This product (preparation) is classified as Toxic Xn according to European Community Directive 1999/45/EC.

Adverse human health effects

Route of Entry

Potential Health Effects and Symptoms of Exposure

Eyes: Possible transient eye irritant. May cause blurred vision with redness and pain.

Ingestion: Possible gastrointestinal irritant. May cause nausea, vomiting, diarrhea, and cause central nervous system effects. Ingestion may cause garlic smell on the breath and body.

Inhalation: Possible respiratory tract irritant.

Short Term and Long-Term Exposure: Inhalation of misted or heated liquid may cause coughing, shortness of breath and an allergic reaction in sensitive individuals.

Skin: Possible skin irritant. Dimethyl sulfoxide readily penetrates skin and may significantly enhance the absorption of Paclitaxel and other chemicals. This absorption may lead to increased toxicity effects, such as anaphylactic reactions..

Target Organs: Dimethyl sulfoxide - Central nervous system, eyes and skin.
Paclitaxel – No information found.

Medical conditions aggravated by exposure: Persons with impaired liver or kidney function, and pre-existing skin disorders or eye problems may be more susceptible to the effects of dimethyl sulfoxide. Dermal absorption of Paclitaxel and many other chemicals, including drugs and allergens of moderate molecular weight will be enhanced by the presence of dimethyl sulfoxide..

Adverse environmental effects: Dimethyl sulfoxide has low toxicity to aquatic species, but the ecotoxicity of Paclitaxel has not been studied.

Adverse physicochemical effects: Dimethyl sulfoxide is a combustible material and its liquid and vapors may present a fire hazard, especially if heated.

SECTION 4 - FIRST AID MEASURES

- Eyes: In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Seek immediate medical attention.
- Ingestion: If swallowed, seek immediate medical assistance, and then wash out mouth with water provided person is conscious. Do not induce vomiting unless directed to do so by a health care provider.
- Inhalation: Remove victim to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention if irritation persists.
- Skin: In case of contact, immediately wash skin with soap and copious amounts of water. If irritation or redness occurs, seek medical attention. Dimethyl sulfoxide will facilitate the transport of Paclitaxel and other substances through the skin, and speed the onset of any potential anaphylactic reaction

SECTION 5 - FIRE FIGHTING MEASURES

- | | | |
|---|--|-----------------------|
| Flash point and method | Estimated 90°C (closed cup) | |
| Autoignition Temperature | 215°C (pure dimethyl sulfoxide) | |
| Flammability Limits: | Lower explosive limit | Upper explosive limit |
| | 2.6% | 42% |
| Suitable extinguishing media: | Water spray, dry chemical, carbon dioxide, or appropriate foam | |
| Unsuitable extinguishing media: | None reported. | |
| Special protective equipment for fire fighters: | In a fire, large quantities of this product may generate significant quantities of toxic sulfur-containing combustion products. Self contained breath apparatus is required. | |
| Special exposure hazards: | Unprotected exposure to sulfur-containing combustion products may cause serious respiratory irritation. | |

SECTION 6 - ACCIDENTAL RELEASE MEASURES

- Personal precautions Avoid skin contact. Isolate spill and reduce unnecessary traffic in the area of the spill. Remove sources of ignition such as flames, sparking equipment and heated surfaces.
- Small Spills: Clean up spills immediately. Wear appropriate protective nitrile or other resistant gloves. Collect residues and place in labeled containers. Avoid breathing mists and contact with skin and eyes.
- Large Spills: In addition to Small Spill precautions, clear area of all unnecessary personnel and move upwind, if mist formation is possible..
- Environmental precautions Discharge this solution to industrial waste water systems only if waste containing dimethyl sulfoxide and cytotoxins, such as Camptothecin is permitted by the authority have jurisdiction. Collect and dispose according to federal, state and local regulations.
- Clean up measures: Absorb spills with media, such as sand, calcined clay or carbon. Store clean-up debris in closed labeled containers pending final disposition (See section 13). Wash spill area with detergent and water to remove residual contamination. This water should be disposed of in a manner consistent with the site use license and wastewater regulations.

SECTION 7- HANDLING AND STORAGE

Handling:

- Avoid contact with eyes and skin. Wear gloves. Dimethyl sulfoxide facilitates the absorption of toxins and allergens into the skin
- Do not inhale mists.
- May be harmful if swallowed, or inhaled..
- Use personal protective equipment outlined in section 8.
- Wash thoroughly after handling
- Use with adequate ventilation

Storage

- Store tightly closed in original container in a cool, dry place.

SECTION 8 - EXPOSURE CONTROL AND PERSONAL PROTECTION

| Specific Protection | Normal Handling Conditions | Emergency Response Conditions |
|------------------------|---------------------------------------|---|
| Respiratory protection | Not normally required for normal use. | If mists are present - air purifying respirator with HEPA filtration and organic cartridges |
| Ventilation | General room ventilation | If mists are present, provide exhaust ventilation |
| Eye protection | Safety glasses with side shields | Chemical splash goggles. |
| Skin protection | Nitrile gloves and laboratory coat. | Chemically resistant jacket, pants, gloves, boots and head covering |

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

| | |
|--|---|
| Appearance: | Clear, colorless liquid |
| Odour: | Garlic-like |
| Odour threshold: | No data have been found |
| pH (product dissolved in water): | Not applicable |
| Melting point: | 15-17°C |
| Boiling point | 190-191 °C |
| Flash point: | 90°C estimated (closed cup) |
| Explosive properties: | All combustible liquids pose a slight explosion hazard if heated to a high temperature under confined conditions. |
| Oxidising properties: | Not considered to have oxidising properties. |
| Vapor pressure, 20 °C: | 0.3-0.4 mm Hg |
| Specific Gravity (Water = 1.0): | 1.1 |
| Water solubility 20 °C: | Miscible in water |
| Vapor Density | 2.7 (dimethyl sulfoxide) |
| Viscosity | 1.1 cps @ 27°C - dimethyl sulfoxide Not available – Paclitaxel solution |
| Partition coefficient: n-octanol/water | 0.009 |

SECTION 10 - STABILITY AND REACTIVITY

- Chemical Stability: Stable under normal temperatures and pressures. The product is hygroscopic and will absorb water from moist air.
- Conditions to avoid Elevated temperatures, ignition sources, exposed to moist air.
- Incompatible with: Strong oxidizing agents, acid chlorides, strong acids, and strong bases
- Hazardous Decomposition Products: Oxides of sulfur, carbon monoxide, carbon dioxide, formaldehyde and dimethyl sulfide.
- Hazardous Polymerization Will not occur

SECTION 11 - TOXICOLOGICAL INFORMATION

Dangerous to health effects and symptoms relating to:

- Eye contact: May cause transient eye irritation accompanied by blurred vision, redness and pain.
- Ingestion: May cause gastrointestinal irritation with nausea, vomiting, and diarrhea: central nervous system effects are also possible.
- Inhalation: May cause respiratory tract irritation. Inhalation of misted or heated liquid may cause coughing, shortness of breath and an allergic reaction in sensitive individuals.
- Skin contact: May cause skin irritant. Dimethyl sulfoxide readily penetrates skin and may significantly enhance the absorption of Paclitaxel and other chemicals. This absorption may lead to increased toxicity effects, such a anaphylactic reactions..
- Carcinogenicity: Neither Dimethyl sulfoxide nor Paclitaxel are listed by ACGIH, IARC, NTP, or the State of California as known or suspected carcinogens.
- Reproductive Toxicity Paclitaxel is known to the State of California to cause male and female developmental toxicity
- Chronic toxicity In long term skin exposure trials, dimethyl sulfoxide has produced central nervous system effects, such as fatigue, nausea, vomiting, sedation, dizziness and headache, and dermatitis with redness, dryness and scaling. It is expected the enhanced transdermal transport of solutes by the dimethyl sulfoxide would increase the toxic effects of Paclitaxel.

Toxicology Data

No toxicological data is available for this product as an entity.

Selected RTECS data for components

| | |
|---|--------------------------|
| Compound: Paclitaxel | RTECS#: DA8340700 |
| No RTECS data applicable to intended product use were found. | |
| Compound: Dimethyl sulfoxide | RTECS#: PV6210000 |
| LD ₅₀ , oral, rat: | 14,500 mg/kg |
| LD ₅₀ , oral, mouse: | 7,929 mg/kg |
| LD ₅₀ , skin, rat: | 40 mg/kg |
| Standard Draize test, skin, rabbit, 500 mg/24 hr. | Mild |
| Standard Draize test, eye, rabbit, 500 mg/24 hr. | Mild |
| Dimethyl sulfoxide has been investigated as a human primary irritant, tumorigen, mutagen and reproductive effector. | |
| Paclitaxel has been investigated as a reproductive effector.. | |

SECTION 12 - ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data is available for the product as an entity.

Data for dimethyl sulfoxide:

LC₅₀, *Pimephales promelas*, (freshwater fish) 96 hr. 34 grams/liter

LC₅₀, *Oryzias latipes*, (freshwater fish) 48 hr. 33 grams/liter

Environmental Fate: Aquatic fate: Sunlight catalyzes the conversion of dimethyl sulfoxide to dimethyl sulfone and dimethyl sulfide. Dimethyl sulfoxide is not easily biodegraded.

SECTION 13- DISPOSAL INFORMATION

Small quantities of this product may be discharged to industrial wastewater systems with the approval of the facility manager. Some facilities limit the disposal of cytotoxic type substances.

Otherwise, dispose in accordance with federal, state and local regulations.

European Community:

When disposal is required, this product should be considered according to the European Waste catalogue (European commission decision of 03/05/01 modifying directives 94/3/CE and 75/442/CE) as part of the following category:

18 01 08 - Cytotoxic and cytostatic medicines

United States:

The components of this product are not regulated as USEPA RCRA hazardous wastes.

SECTION 14 - TRANSPORTATION INFORMATION

The transportation of this product is not regulated by IMDG (sea), ADR (road), RID (rail), ICAO/IATA (air), or USDOT as a dangerous goods or hazardous material.

SECTION 15 - REGULATORY INFORMATION

Canada:

This product has WHMIS classifications of **D2B, B3**.

European Community:

Label health, safety and environmental information (Directives: 67/548/EEC and 1999/45/EC)

| | |
|--------------------|---|
| Symbols: | Xn |
| Category of danger | Harmful |
| Risk phrases: | R37/38 Irritating to respiratory system and skin. R40 Possible risk of cancer. R41 Risk of serious damage to eyes R42/43 May cause sensitisation by inhalation and skin contact R48/20/21/22 Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed R62 Possible risk of impaired fertility |
| Safety Phrases | S28 After contact with skin, wash immediately with plenty of soap and water. S36/37 Wear suitable protective clothing and gloves. S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). |

Section 15 – Regulatory Information (continued)

Japan:

Dimethyl sulfoxide and Paclitaxel are not listed under the Poisonous and Deleterious Substances Control Law

United States

EPA Toxic Substances Control Act (TSCA) Inventory Status:

Dimethyl sulfoxide Listed
Paclitaxel Not Listed

In the United States, the use of this product is restricted to research and development activities, and activities under the regulation of the Food and Drug Administration.

Occupational Exposure Limits:

Exposure limits have not been established by OSHA, ACGIH, NIOSH or the European Community for the substances in this product.

SECTION 16- ADDITIONAL INFORMATION

Risk phrases referred to under Section 2:

| | | | |
|---------------------|---|---------------|--|
| R 20/21/22 | Harmful by inhalation, in contact with skin and if swallowed | R41 | Risk of serious damage to eyes |
| R48/20/21/22 | Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed | R42/43 | May cause sensitisation by inhalation and skin contact |
| R37/38 | Irritating to respiratory system and skin | R62 | Possible risk of impaired fertility |
| R40 | Limited evidence of a carcinogenic effect | R68 | Possible risk of irreversible effects |

Abbreviations used:

| | |
|------------------|---|
| ACGIH | American Conference of Government Industrial Hygienists |
| ADR | European agreement on the international carriage of dangerous goods on road |
| C | Ceiling exposure value |
| CAS | Chemical Abstract Service |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of Notified Chemical Substances |
| EPA | United States Environmental Protection Agency |
| HEPA | High Efficiency Particulate (Air) |
| IARC | International Agency for Research in Cancer. |
| IATA | International Air Transport Association |
| ICAO | International Civil Aviation Organization |
| IMDG | Regulations regarding the transportation of dangerous goods on ocean-going vessels issued by the International Maritime Organization. |
| kBq | Kilobecquerel |
| LC ₅₀ | Lethal Concentration 50% is the concentration of a chemical which kills 50% of a sample population |
| LD ₅₀ | Lethal Dose 50% is the dose of a chemical which kills 50% of a sample population. |
| MAK | Maximum Concentration Values in the Workplace (Austria, Germany, Switzerland) |
| µC | Microcurie |
| NIOSH | National Institute of Occupational Health & Safety (US) |
| OSHA | United States Occupational Safety and Health Administration |
| REL | Recommended exposure limit (NIOSH) |
| RID | International regulations concerning the international carriage of dangerous goods by rail. |
| RTECS | Registry of Toxic Effects of Chemical Substances (US) |
| STEL | Short term exposure limit (15 minute) |

| | |
|-------|---|
| TGV | 15 minute short term exposure limit (Sweden) |
| TLV | Threshold Limit Value |
| VLE | 15 minute short term exposure limit (France) |
| WHMIS | Workplace Hazardous Materials Information System (Canada) |

Section 16 Additional Information (continued)

This safety data sheet is compliant with the requirements of EC Directive 2001/58/EC and ANSI Z400.1-1998.

The physical, chemical and toxicological properties of this product have not been thoroughly investigated.

Millipore is a registered trademark of Millipore Corporation. CellCiphr is a trademark, registration pending of Cellumen Corporation.

©2007 Millipore Corporation. All rights reserved. The above information is believed to be current and accurate; however, Millipore makes no warranty with respect to such information and assumes no liability for any loss or injury which may result from the use of this information. Users should conduct their own investigations to determine the suitability of the information.