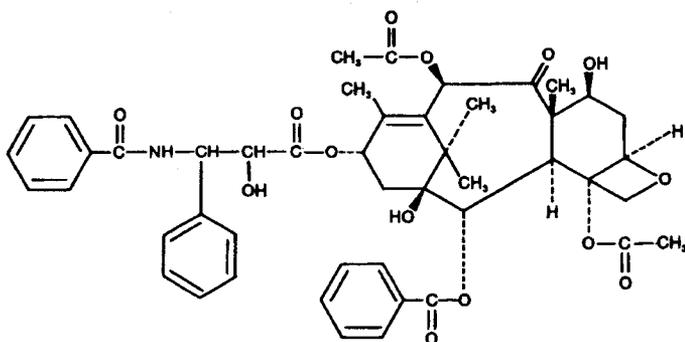


# TAXOL

NSC - 125973



**Chemical Name:**  $\beta$ -(Benzoylamino)- $\alpha$ -hydroxy-benzenepropanoic acid, 6,12b-bis(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-4,11-dihydroxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, [2aR-[2 $\alpha\alpha$ ,4 $\beta$ ,4a $\beta$ ,6 $\beta$ ,9 $\alpha$ ( $\alpha$ R\*, $\beta$ S\*)],11 $\alpha$ ,12 $\alpha$ ,12a $\alpha$ ,12b $\alpha$ ]]-

**Other Names:** Taxol<sup>®</sup>, Paclitaxel

**CAS Registry Number:** 33069-62-4

**Molecular Formula:** C<sub>47</sub>H<sub>51</sub>NO<sub>14</sub>

**M.W.:** 853.9

**Description:** Taxol is a poorly soluble plant product isolated from *Taxus brevifolia*.

**How Supplied:** Injection, 30 mg, ampule/vial: 6 mg/mL, 5 mL, in polyethoxylated castor oil (Cremophor EL<sup>®</sup>) 50%, and dehydrated alcohol, USP, in 5 mL flint ampules/vials.

**Solution Preparation:** Taxol concentrations from 0.3 mg/mL to 1.2 mg/mL may be obtained by diluting the solution with either 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP.

**CAUTION:** PVC bags and sets should be avoided due to appreciable leaching of DEHP(1,2,3). This solution must be diluted before use and given by slow intravenous infusion.

**NOTE:** A small number of fibers (within acceptable levels of the USP Particulate Matter Test for LVPs) have been observed after dilution. Therefore, inline filtration is necessary with all taxol infusions. Solutions exhibiting excessive particulate formation should not be used. Analyses of solutions filtered through IVEX-2<sup>®</sup> and IVEX-HP<sup>®</sup>(Abbott) 0.2  $\mu$ m filters showed no appreciable loss of potency.

**Storage:** Refrigerate the intact ampules and vials (2-8 °C).

**Stability:** Shelf-life surveillance of the ampules and vials is ongoing. Three lots have maintained stability for at least 18 months at room temperature (22-25 °C). The intact vials were unstable at elevated temperature (50 °C).

Solutions of taxol diluted to the above concentrations are both chemically and physically stable for at least 27 hours at room temperature. All solutions exhibit a slight haze which is common to all products containing nonionic surfactants.

**Route of Administration:** Intravenous (slow infusion over one hour or more)

**References:**

1. Waugh, W.N., Trissel, L.A., Stella, V.J. Stability, Compatabilty, and Plasticizer Extraction of Taxol (NSC-125973) Injected Diluted in Infusion Solutions and Stored in Various Containers. *Am J Hosp Pharm* 48:1520-1524, 1991.
2. Harris, G.W. Di(2-ethylhexyl) phthalate (DEHP) in Medical Products. Proceedings of the Conference on Phthalates, National Toxicology Program/Interagency Regulatory Liaison Group, June 9, 1981. pp 179-195
3. Jaeger, R.J., Rubin, R.J. Migration of a Phthalate Ester Plasticizer from Polyvinyl Chloride Blood Bags into Stored Human Blood and Its Localization in Human Tissues. *N.Engl J Med* 287:1114-1118, 1972.