




# Chemical Safety Practices Recommendations

## Gemcitabine (2'-Deoxy-2',2'-difluorocytidine, dFdC)

### Exposure Hazards (1)

<p>Category 1B Danger</p>  <p>Toxic to Reproduction</p> <p>May Damage Fertility and/or the Unborn Child</p>	<p>Category 4 Warning Toxic</p>  <p>May be Harmful if Swallowed</p>
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### Response to Exposure

Oral	Dermal	Inhalation	Injection
Rinse mouth; do not induce vomiting. Report to OHS.	Wash skin with soap and water for 15 minutes. Rinse eyes for 15 minutes. Report to OHS.	Leave area; go to clean air. Report to OHS.	Report to OHS.
<b>Special Precautions</b>	Pregnant women should be extra cautious when working with dFdC. (2) Discard garments as hazardous if contaminated with dFdC.		
<b>Personal Protective Equipment</b>	Gloves (Double glove) (Latex or Nitrile) Skin Protection (Suit or Scrubs or Lab Coat) Eye Protection (Safety-glasses or Goggles) Closed-toe shoes Use N100 respirator if engineering controls are not available.		
<b>Engineering Controls</b>	dFdC powder- Chemical Fume Hood (CFH) (3) dFdC solution- CFH or Biosafety Cabinet (Class II, B2 BSC if aerosolized)		
<b>Animal Handling</b>	Avoid exposure to animal urine until two days after last treatment. (4, 5) Animal waste and bedding until 2 days after last treatment- CFH or Class II, B2 		
<b>Bedding Disposal</b>	Dispose of bedding as hazardous material until two days after last treatment.		
<b>Work Practices</b>	Empty dFdC containers and unused dFdC must be disposed of as hazardous. Follow LASP SOPs for preparation, handling, dosing, and disposal of dFdC.		

**References:**

1. Gemcitabine MSDS Sigma 12312014 [Internet]. Sigma Aldrich. [cited 11/04/2014]. Available from: <http://www.sigmaaldrich.com/united-states.html>.
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3. National Research Council Committee on Prudent Practices in the L. The National Academies Collection: Reports funded by National Institutes of Health. Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards: Updated Version. Washington (DC): National Academies Press (US) National Academy of Sciences.; 2011.
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5. Peters GJ, Clavel M, Noordhuis P, Geysen GJ, Laan AC, Guastalla J, et al. Clinical phase I and pharmacology study of gemcitabine (2', 2'-difluorodeoxycytidine) administered in a two-weekly schedule. Journal of chemotherapy (Florence, Italy). 2007;19(2):212-21.

Questions or concerns: Please contact EHS, Ted Witte, [theodore.witte@nih.gov](mailto:theodore.witte@nih.gov) or 301-846-5860  
 Reviewed 01/02/2015 *These recommendations are not final and may be updated.*

# Chemical Safety Practices Recommendations

## Gemcitabine (2'-Deoxy-2',2'-difluorocytidine, dFdC)

Gemcitabine (dFdC) is a nucleoside analog and antimetabolite, similar to BrdU or 5-FU, used to treat breast, ovary, pancreas, and lung cancer by inhibiting DNA elongation and the synthesis of deoxyribonucleotides. Like many anti-neoplastic drugs Gemcitabine may have toxic effects on rapidly regenerating/growing tissues such as the bone marrow, skin, or developing fetuses.

dFdC is quickly deaminated to dFdU by the liver and gut, but if taken in high doses can also be excreted in the urine as unchanged drug and the active metabolite dFdC-MP. dFdU, previously considered an inactive metabolite, also inhibits DNA and RNA formation and is actively excreted in the urine with a much longer half life than dFdC. Previous NCI-Frederick recommendations to treat waste and bedding as hazardous for 24 hours reflect the complete clearance of dFdC and almost total clearance of the metabolites within 24 hours. The recommendation has been increased to 2 days (48 hours) because of the small fraction of metabolites which may be excreted after 24 hours, and because there is currently a research effort to modulate/slow the deamination of Gemcitabine, and therefore it is not unlikely that there may be projects at NCI-Frederick where the animals will continue to excrete dFdC metabolites in their urine past 24 hours.