

---

## Iron Dextran Complex

### CAS No. 9004-66-4

Reasonably anticipated to be a human carcinogen  
First Listed in the *Second Annual Report on Carcinogens* (1981)

#### Carcinogenicity

Iron dextran complex is *reasonably anticipated to be a human carcinogen* based on sufficient evidence of carcinogenicity in experimental animals (IARC 1973, 1982). When administered by subcutaneous injection, iron dextran complex induced local sarcomas in mice and hamsters of both sexes and male rats. When administered by intramuscular injection, iron dextran complex induced local sarcomas in rats and rabbits of both sexes.

There is inadequate evidence for the carcinogenicity of iron dextran complex in humans (IARC 1987). There have been case reports of cancers associated with injections of iron dextran in human subjects. Tumors appeared at the probable sites of injection, and the similarity of the local effect in humans and animals was noted by an IARC Working Group.

#### Properties

Iron dextran is a complex of ferric hydroxide with dextran, a polysaccharide. Iron dextran complex is very soluble in water and insoluble in most organic solvents. Iron dextran decomposes in 95% ethanol and acetone. A typical product contains 5% weight/volume iron and 20% weight/volume dextran. The product for human use is a sterile, dark brown, colloidal solution in saline; the products designed for use in animals are more concentrated (IARC 1973, HSDB 2000).

#### Use

Iron dextran complex is used for parenteral treatment of iron-deficiency anemia, but it is used only in special cases such as when oral treatment has failed. It also is used in veterinary medicine to treat baby pigs (IARC 1973, HSDB 2000).

#### Production

Iron dextran complex is not currently produced commercially in the United States (HSDB 2000). No data on imports or exports were available. In 1980, pharmacists dispensed 30,000 prescriptions for iron dextran. Iron dextran complex was introduced in the United States in 1957 (IARC 1973). Chem Sources (2001) lists one U.S. supplier of iron dextran.

#### Exposure

The primary routes of potential human exposure to iron dextran complex are deep intramuscular injection, inhalation, and dermal contact. The therapeutic dose of iron dextran for humans is 1 to 5 mL (50 to 250 mg of iron) daily (IARC 1973). Use is advised solely for those patients who do not respond to oral administration of iron. Warning of potential injection site sarcoma is included with the physician's package insert. The National Occupational Exposure Survey (1981-1983) estimated that 1,157 total workers, including 573 women, potentially were exposed to iron dextran complex in the workplace (NIOSH 1984). Potential occupational exposure to iron dextran complex may occur during the production, formulation, packaging, or administration of the pharmaceuticals. Exposure during production may be site-limited because the compound is produced by a single manufacturer.

#### Regulations

##### FDA

Iron Dextran Complex is a prescription drug subject to labeling and other requirements

#### REFERENCES

- ChemSources. 2001. Chemical Sources International, Inc. <http://www.chemsources.com>.  
HSDB. 2000. Hazardous Substances Data Base. National Library of Medicine. <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB>.

- IARC. 1973. Some Inorganic and Organometallic Compounds. IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans, vol. 2. Lyon, France: International Agency for Research on Cancer. 181 pp.  
IARC. 1982. Chemicals, Industrial Processes and Industries Associated with Cancer in Humans. IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans, Supplement 4. Lyon, France: International Agency for Research on Cancer. 292 pp.  
IARC. 1987. Overall Evaluations of Carcinogenicity. IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans, Supplement 7. Lyon, France: International Agency for Research on Cancer. 440 pp.  
NIOSH. 1984. National Occupational Exposure Survey (1981-83). Cincinnati, OH: U. S. Department of Health and Human Services. <http://www.cdc.gov/noes/noes3/empl0003.html>.
-