

GHS Classification

ID533

CAS 51-52-5

Physical Hazards

2,3-Dihydro-6-propyl-2-thioxo-4(1H)-pyrimidinone; Propylthiouracil

Date Classified: Sep. 20, 2006 (Environmental Hazards: Mar. 31, 2006)

Reference Manual: GHS Classification Manual (Feb. 10, 2006)

Hazard class	Classification	symbol	signal word	hazard statement	Rational for the classification
1 Explosives	Not applicable	—	—	—	Containing no chemical groups with explosive properties
2 Flammable gases	Not applicable	—	—	—	Classified as "solid" according to GHS definition
3 Flammable aerosols	Not applicable	—	—	—	Not aerosol products
4 Oxidizing gases	Not applicable	—	—	—	Classified as "solid" according to GHS definition
5 Gases under pressure	Not applicable	—	—	—	Classified as "solid" according to GHS definition
6 Flammable liquids	Not applicable	—	—	—	Classified as "solid" according to GHS definition
7 Flammable solids	Classification not possible	—	—	—	No data available
8 Self-reactive substances and mixtures	Not applicable	—	—	—	Containing no chemical groups with explosive or self-reactive properties
9 Pyrophoric liquids	Not applicable	—	—	—	Classified as "solid" according to GHS definition
10 Pyrophoric solids	Classification not possible	—	—	—	No data available
11 Self-heating substances and mixtures	Classification not possible	—	—	—	No data available
12 Substances and mixtures, which in contact with water, emit flammable gases	Not applicable	—	—	—	Containing no metals or metalloids (B, Si, P, Ge, As, Se, Sn, Sb, Te, Bi, Po, At)
13 Oxidizing liquids	Not applicable	—	—	—	Classified as "solid" according to GHS definition
14 Oxidizing solids	Not applicable	—	—	—	Organic compounds containing oxygen (but not fluorine and chlorine), with the oxygen bound to carbon and hydrogen (but not to other elements)
15 Organic peroxides	Not applicable	—	—	—	Organic compounds containing no "O-O-" structure
16 Corrosive to metals	Classification not possible	—	—	—	Test methods applicable to solid substances are not available

Health Hazards

Hazard class	Classification	symbol	signal word	hazard statement	Rational for the classification
1 Acute toxicity (oral)	Category 4	Exclamation mark	Warning	Harmful if swallowed	Based on the rat LD50 (oral route) value of 1,250mg/kg (RTECS (2006)).
1 Acute toxicity (dermal)	Classification not possible	—	—	—	No data available
1 Acute toxicity (inhalation: gas)	Not applicable	—	—	—	Due to the fact that the substance is "solid" according to the GHS definition and inhalation of its gas is not expected.
1 Acute toxicity (inhalation: dust, mist)	Classification not possible	—	—	—	No data available
1 Acute toxicity (inhalation: dust, mist)	Classification not possible	—	—	—	No data available
2 Skin corrosion / irritation	Classification not possible	—	—	—	No data available
3 Serious eye damage / eye irritation	Classification not possible	—	—	—	No data available
4 Respiratory/skin sensitization	Respiratory sensitization: Classification not possible Skin sensitization: Classification not possible	(Respiratory sensitization) — (Skin sensitization) —	(Respiratory sensitization) — (Skin sensitization) —	(Respiratory sensitization) — (Skin sensitization) —	Respiratory sensitization: No data available Skin sensitization: No data available
5 Germ cell mutagenicity	Classification not possible	—	—	—	Classification is not possible due to the insufficiency of data. No data are available on multi-generation mutagenicity tests and germ cell mutagenicity tests in vivo, whereas a somatic cell mutagenicity study in vivo (chromosome aberration test) showed negative results (NTP DB (Access on June 2006) and IARC 79 (2001)). However, the latter test was exceptional in that it was conducted ex vivo using the thyroid gland and therefore cannot serve as an adequate basis for the classification.
6 Carcinogenicity	Category 2	Health hazard	Warning	Suspected of causing cancer	Due to the fact that the substance is classified as Category R by NTP (2005) and Group 2B by IARC (2001).
7 Toxic to reproduction	Category 2	Health hazard	Warning	Suspected of damaging fertility or the unborn child	Based on the evidence of reduced cerebral neocortex volume and abnormal behaviour in the pups observed in rat teratogenicity studies, described in IARC 79 (2001) (though no data are available regarding parental toxicity).
8 Specific target organs/systemic toxicity following single exposure	Classification not possible	—	—	—	No data available

9	Specific target organs/systemic toxicity following repeated exposure	Category 1 (thyroid gland, blood system, liver, cardiovascular system, skin)	Health hazard	Danger	Causes damage to organs through prolonged or repeated exposure (thyroid gland, blood system, liver, cardiovascular system, skin)	Based on the human evidence (patients given doses of propylthiouracil): "Agranulocytosis is the most common side effect; rare but severe side effects include hepatitis, angitis and drug induced lupus syndrome," "Propylthiouracil has been widely used in the treatment of hyperthyroidism; patients tend to develop hypothyroidism due to inappropriate management of dosage regimens" (IARC 79 (2001)). Also based on the evidence from animal studies: "Both serum T3 and T4 levels are decreased; hyperplasia of the follicular epithelial cells has been reported" (IARC 79 (2001)). The effects on experimental animals were observed at dosing levels within the guidance value ranges for Category 2.
10	Aspiration hazard	Classification not possible	—	—	—	No data available

Environmental Hazards

Hazard class	Classification	symbol	signal word	hazard statement	Rational for the classification
11 Hazardous to the aquatic environment (acute)	Classification not possible	—	—	—	Classification not possible due to lack of data
11 Hazardous to the aquatic environment (chronic)	Classification not possible	—	—	—	Classification not possible due to lack of data