GHS Classification

ID519 5-Ethyl-5-phenyl-2,4,6(1H,3H,5H)-pyrimidinetrione; Phenobarbital

CAS 50-06-6 Date Classified: Sep. 20, 2006 (Environmental Hazards: Mar. 31, 2006)

Physical Hazards 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 3	Skull and crossbones	Danger	Toxic if swallowed	Based on the rat LD50 (oral route) value of 162mg/kg (IARC 79 (2001)).
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:	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	Category 1B	Health hazard	Danger	May cause genetic defects	Based on the absence of data on multi-generation mutagenicity tests and positive data on germ cell mutagenicity tests in vivo (chromosome aberration tests), described in IARC 79 (2001) and NTP DB (Access on May 2006).
6	Carcinogenicity	Category 2	Health hazard	Warning	Suspected of causing cancer	Due to the fact that the substance is classified as 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 cleft palate and abnormal behaviour of the offspring observed in teratogenicity studies with mice and rats, described in IARC 79 (2001) (though no data are available regarding parental toxicity).
8	Specific target organs/systemic toxicity following single exposure	Category 3 (narcotic effects)	Exclamation mark	Warning	(Narcotic effects) May cause drowsiness or dizziness	Based on the evidence from animal studies including "somnolence" (RTECS (2006)).

9	Specific target organs/systemic toxicity following repeated exposure	Category 1 (nervous system, thyroid gland) Category 2 (liver, kidneys)	Health hazard	Danger	Causes damage to organs through prolonged or repeated exposure (nervous system, thyroid gland) May cause damage to organs through prolonged or repeated exposure (liver, kidneys)	Based on the human evidence: "Sedation is the most common side effect of exposure to phenobarbital in humans. Overdosage of phenobarbital leads to nystagmus and ataxia," "In the patient, T4 level was decreased whereas T3 and TSH responses to thyrotropin-releasing hormone were within the normal range" (IARC 79 (2003)), "A 2-yr-old child developed massive hepatic necrosis caused by an unusual hypersensitivity response to phenobarbital that was prescribed for presumed febrile seizures," "phenobarbital induced a hypersensitivity state consisting of tubulointerstitial nephritis, exfoliative dermatitis and hepatitis" (HSDB (2002)). Also based on the evidence from animal studies: "the liver of the test animal showed an occurrence of moderate to severe hypertrophy of centrolobular hepatocytes," "serum T4 and T3 levels were decreased, whereas TSH production was increased," "mild to moderate follicular hypertrophy of the thyroid gland and moderate hepatocellular hypertrophy occurred" (IARC 79 (2003)). The effects on experimental animals were observed at dosing levels within the guidance value ranges for Category 2. Since the priority rating of the
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)	Not classified	-	-	-	It was classified into Not classified from 96 hours LC50=484mg/L of the fish (Fathead Minnows) (HSDB, 2004).
11	Hazardous to the aquatic environment (chronic)	Not classified	-	-	-	Since it was not water-insolubility (the water-solubility =1110mg/L (PHYSPROP Database, 2005)), and acute toxicity was low, it was classified into Not classified.