

GHS Classification

ID527

2,2-Dichloro-N-[2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]acetamide; Chloramphenicol

CAS 56-75-7

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	Classification not possible	—	—	—	Classification not possible due to lack of data on the kick-off temperature and decomposition energy (though the substance contains nitro groups with its oxygen budget calculated at -114).
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	Classification not possible	—	—	—	Classification not possible due to lack of data, though containing nitro groups with explosive 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	Classification not possible	—	—	—	Classification not possible due to lack of data, though being organic compounds containing oxygen bound to the elements other than carbon and hydrogen.
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 5	—	Warning	May be harmful if swallowed	Based on the rat LD50 (oral route) value of 2,500mg/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	—	—	—	Insufficient 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 negative data on multi-generation mutagenicity tests (dominant lethal tests), positive data on germ cell mutagenicity tests in vivo (chromosome aberration tests) and somatic cell mutagenicity tests in vivo (chromosome aberration tests), and the absence of data on germ cell genotoxicity tests in vivo, described in IARC 50 (1990) and IARC 10 (1976).
6 Carcinogenicity	Category 1B	Health hazard	Danger	May cause cancer	Due to the fact that the substance is classified as Category R by NTP (2005) and Group 2A by IARC (1990).
7 Toxic to reproduction	Category 2	Health hazard	Warning	Suspected of damaging fertility or the unborn child	Based on the evidence of pup malformation including hydrocephalus and cleft palate observed in rat teratogenicity studies, described in IARC 10 (1976) (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 (bone marrow, nervous system, digestive organs) Category 2 (heart)	Health hazard	Danger	Causes damage to organs through prolonged or repeated exposure (bone marrow, nervous system, digestive organs) May cause damage to organs through prolonged or repeated exposure (heart)	Based on the human evidence: "a case report of a 5-yr-old child who developed aplastic anemia and died of acute myeloblastic leukemia 1 year after chloramphenicol was therapeutically administered," "a case of a 63-yr-old man who developed bone marrow suppression 4 months after chloramphenicol was administered at a dose of 12g" (IARC 10 (1976)), "other adverse effects of prolonged administration included skin eruption, gastrointestinal disorder and nervous system damage" (IARC 50 (1990)), "there is symmetrical loss of ganglion cells from retina and atrophy of fibers in optic nerve," "cardiovascular collapse with cardiomyopathic changes and impaired left ventricular function was documented by echocardiography" (HSDB (2005)). Since the priority rating of the referenced study reporting the effects on the heart in humans is 2, these effects are classified into 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)	Not classified	—	—	—	It was classified into Not classified from 48 hours EC50=34500microg/L of the crustacea (Daphnia magna) (AQUIRE, 2003).
11 Hazardous to the aquatic environment (chronic)	Not classified	—	—	—	Since it was not water-insolubility (the water-solubility =2500mg/L (PHYSPROP Database, 2005)), and acute toxicity was low, it was classified into Not classified.