

GHS Classification

ID537

5,5-Diphenyl-2,4-imidazolidinedione

CAS 57-41-0

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 and chlorine (but not fluorine), with the oxygen and chlorine bound to carbon and hydrogen respectively (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 1,635mg/kg (IUCLID (2000)). |
| 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 |
| 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 positive data on multi-generation mutagenicity tests (dominant lethal tests), described in NTP DB (Access on June, 2006), NTP TR404 (1993) and IARC 66 (1996). |
| 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 (1996). |
| 7 Toxic to reproduction | Category 1A | Health hazard | Danger | May damage fertility or the unborn child | Based on the human evidence of reproductive toxicity, described in IARC 66 (1996) and NTP TR404 (1993). |
| 8 Specific target organs/systemic toxicity following single exposure | Category 1 (nervous system) | Health hazard | Danger | Causes damage to organs (nervous system) | Based on the human evidence: "acute oral overexposure to the material causes irreversible cerebellar atrophy, according to some studies" (IARC 66 (1996)). |

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| 9 | Specific target organs/systemic toxicity following repeated exposure | Category 1 (nervous system, gingiva, liver, lymph node) | Health hazard | Danger | Causes damage to organs through prolonged or repeated exposure (nervous system, gingiva, liver, lymph node) | Based on the human evidence (patients receiving doses over a long period of time): "Gingival hyperplasia is a major disorder associated with phenytoin. In addition, hepatic necrosis and a decrease in peripheral blood lymphocyte counts have been reported; hyperplasia of heterotype cells of lymph node has also been noted" (IARC 13 (1973)). "long-term ingestion of phenytoin adversely affects the nervous system," "clinically significant gingival growth was noted" (IARC 66 (1996)). Also based on the evidence from animal studies including "dose dependent hypertrophy of centrolobular hepatocytes was observed" (NTP TR404 (1993)). 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 |