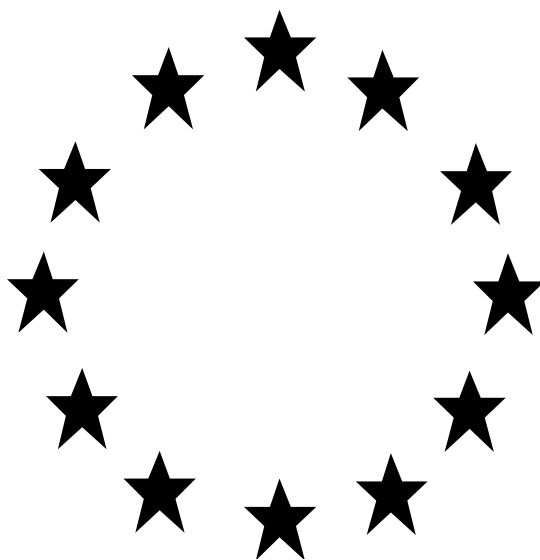




Draft Assessment Report (DAR)

- public version -

**Initial risk assessment provided by the rapporteur Member State
Portugal for the existing active substance**

CALCIUM CARBIDE

**of the fourth stage of the review programme
referred to in Article 8(2) of Council Directive 91/414/EEC**

Volume 3, Annex B, part 2, B.6

August 2008

B.6 Toxicology and metabolism

The Notifier presented the toxicological dossier based on “calcium carbide” as notified active substance.

In the use of technical calcium carbide as a repellent against voles and moles, the granulate is introduced into the animal’s burrows where it is decomposed to calcium hydroxide and acetylene by ground humidity. Additionally, odour-intensive phosphine gas arises from hydrolysis of the very small amounts of calcium phosphide present.

As stated by the Notifier, pure calcium carbide is odourless. The technical product activity is based on its garlic-like odour, which arises from the small amount of impurity present in calcium carbide (calcium phosphide, ca. 0.025% by weight) which liberates the odour-intensive gas phosphine in the presence of ambient humidity. Acetylene itself, which is released during the reaction, has no unpleasant odour when pure, but has disagreeable odour due to the same impurity phosphine (*Merck Index*, 8th edition).

Considering the above, the a.s. is considered to be, actually calcium phosphide, present as an impurity in the technical calcium carbide, although the mode of action might also be related to acetylene formation as a vector agent of the odour. Taking in consideration the concentration of a.s. present in the technical product, for the intended use as repellent – and not rodenticide – for moles and voles, RMS considers that the toxicity of the whole technical product, as manufactured, has to be evaluated under the Annex II requirements, and not the a.s. calcium phosphide pure, which is not relevant in this case due to its type of use and was evaluated under the 3rd stage (3B) of the EU review program by Germany. The repellent toxicological profile of the whole technical product is considered for this product under the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC.

B.6.1 Absorption, distribution, excretion and metabolism in mammals (toxicokinetics)

The Notifier presented the following justification for non-submission of data regarding this end-point:

Studies on the absorption, distribution, metabolism and excretion of calcium carbide in mammals do not exist.

Detailed investigations of calcium carbide metabolism based on the hydrolysis to calcium hydroxide and acetylene were not considered to be required, since dietary exposure of humans does not occur in view of the lack of appreciable residues according to the use of the substance as repellent.

As stated above, in the use of technical calcium carbide as a repellent against voles and moles, the granulate is introduced into the animal’s burrows where it is decomposed to calcium hydroxide and acetylene by ground humidity. Additionally, odour-intensive phosphine gas arises from hydrolysis of the very small amounts of calcium phosphide present on the technical material.

In the prescribed use of calcium carbide, there is no contact with plant roots above the soil surface. The uptake of acetylene by plant roots cannot be demonstrated due to the high volatility of acetylene. According to “American Chemistry Council, HPV Challenge, Acetylene Panel, Report n. ° 201-15005A of December 30, 2003”, acetylene is a gas, and 99.9% partitions to the air, 0.104% partitions to the water, 0.0101% partitions to the soil and 0.000177 partitions to the sediment were estimated.

Table 6.1 – Environmental fate parameters for acetylene

Environmental transport of acetylene (fugacity level III mass percentages ^a)	
Air	99.9
Water	0.104
Soil	0.0101
Sediment	0.000177

^a : Estimated using EPIWIN model

The calcium hydroxide remaining in the ground binds with carbon dioxide in the air and forms calcium bicarbonate in the first stage, which later partly changes into calcium carbonate. Both substances do not possess any toxic properties. From the facts presented it follows that the calcium carbide itself, as well as its decomposition product acetylene, calcium hydroxide and phosphine do not enter into the food chain.

Besides this, the Notifier mentioned that calcium hydroxide and calcium carbides' impurity calcium oxide are food additives specified by EC regulations (SCF-Scientific Committee for Food) and by FAO/WHO (JECFA – Joint Expert Committee on Food Additives). The use of food additives in the European Union is regulated by a framework directive of December 1988 concerning food additives for use in foodstuffs intended for human consumption (Council Directive 89/107/EEC of December 21, 1988). An ADI (Acceptable Daily Intake) is not specified based the fact that these substances are normal constituents of the diet and can not be distinguished from the same ions already present in food from other sources when used according to good manufacturing practice.

B.6.1.1 Toxicokinetic studies – Single dose, oral route, in rats

No study is available, for explanation see above.

B.6.1.2 Toxicokinetic studies – Second single dose, oral route, in rats

No study is available, for explanation see above.

B.6.1.3 Toxicokinetic studies – Repeated dose, oral route, in rats

No study is available, for explanation see above.

B.6.2 Acute toxicity including irritancy and skin sensitization

B.6.2.1 Acute oral toxicity

“Calcium Carbide”: Acute Oral Toxicity Study with Rats (Acute Toxic Class Method)

Wolf, T. (February 17, 2006) – Report No. ARC—L-1913 (internal study code WUE2); performed by ARC Seibersdorf research GmbH, A-2444 Seibersdorf, Austria.

Guidelines and GLP

The study was performed according to OECD-Principles of GLP (1998) and Federal Ministry of Agriculture, Forestry, Environment and Water Management, Vienna, Austria (2004); and Directive 2004/73/EC method B.1 tris and OECD-Guideline 423 (2001).

The study is acceptable.

Materials and methods

Test substance: Technical Calcium carbide / Prontox Wühlmausgas (75 - 80% w/w); Batch No. 120405 (Certificate of Analysis of Chemische Fabrik Wülfel GmbH & Co. KG dated May 30, 2005).

The aim of the study was to investigate acute toxic effects of the test substance after a single peroral administration to rats.

Results

On the basis of the measured pH of 12.48 (1% solution in deionised water w/v, at 20°C, determined with a pH-Meter Inolab Level 2), the test substance was classified as corrosive. In contact with water, test substance undergoes hydrolysis forming acetylene and calcium hydroxide under heating.

According to the guidelines, dosing test substances in a way known to cause marked pain and distress due to corrosive or irritating properties need not be carried out and administered to animals.

Therefore and for animal welfare reasons the test was not performed experimentally.

Conclusions

The oral LD₅₀ of calcium carbide was not determined due to corrosive properties of the substance in contact with water.

Calcium carbide

Hinkamp, D.L., Alkaline material, in Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4th edition, Volume 4, Part XVIII, 104 Guide do Chemicals, Table 104.18, 1998.

Summary

Symptoms upon ingestion of calcium carbide are abdominal cramps, burning sensation, vomiting and weakness.

Main impurity calcium oxide

No data on acute oral toxicity is available.

RMS Comment:

Calcium oxide liberates heat on contact with water and is a strong caustic agent that may cause severe irritation of skin and mucous membranes (*Gangolli, S., The Dictionary of Substances and their Effects, 2nd edition, Royal Society of Chemistry, UK, 1999, Volume 2, p. 64; Deichmann, W.B. and Gerarde, H.W., Toxicology of Drugs and Chemicals, Academic Press New York and London, 1969, p. 353*).

B.6.2.2 Acute percutaneous toxicity

“Calcium Carbide”: Acute Dermal Toxicity Study with Rats

Bernat, E. (February 17, 2006) – Report No. ARC—L-1931 (internal study code WUE3); performed by ARC Seibersdorf research GmbH, A-2444 Seibersdorf, Austria.

Guidelines and GLP

The study was performed according to OECD-Principles of GLP (1998) and Federal Ministry of Agriculture, Forestry, Environment and Water Management, Vienna, Austria (2004); and Directive 92/69/EEC method B.3 and OECD-Guideline 402 (1987).

The study is acceptable.

Materials and methods

Test substance: Technical Calcium carbide / Prontox Wühlmausgas (75 - 80% w/w); Batch No. 120405 (Certificate of Analysis of Chemische Fabrik Wülfel GmbH & Co. KG dated May 30, 2005).

The aim to the study was to investigate acute toxic effects of the test substance after a single dermal administration to rats.

Results

On the basis of the measured pH of 12.48 (1% solution in deionised water w/v, at 20°C, determined with a pH-Meter Inolab Level 2), the test substance was classified as corrosive. In contact with water, test substance undergoes hydrolysis forming acetylene and calcium hydroxide under heating.

According to the guidelines, dosing test substances in a way known to cause marked pain and distress due to corrosive or irritating properties need not be carried out and administered to animals.

Therefore and for animal welfare reasons the test was not performed experimentally.

Conclusions

The dermal LD₅₀ of calcium carbide was not determined due to corrosive properties of the substance in contact with water.

Calcium carbide

Hinkamp, D.L., Alkaline material, in Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4th edition, Volume 4, Part XVIII, 104 Guide do Chemicals, Table 104.18, 1998.

Summary

Calcium carbide exerts a pronounced irritant effect due to the formation of calcium hydroxide upon reaction with moist air or sweat. Dry carbide in contact with skin may cause dermatitis. Contact with moist skin and mucous membranes leads to ulceration and scarring. A peculiar type of melanoderma with strong hyperpigmentation and numerous telangiectases is often observed. Burns caused by hot calcium carbide are common. The tissues are generally damaged in depths of 1 to 5 mm; the burns evolve very slowly, are difficult to treat, and often require excision. Injured workers may resume work only after the burnt skin surface is completely scarred.

Persons exposed to calcium carbide frequently suffer from cheilitis characterized by dryness, swelling and hyperaemia of the lips, intense desquamation, and deep radial fissures; erosive lesions with tendency to suppuration can be observed in the mouth angles. Workers with a long professional history often suffer from nail lesions –that is occupational onychia and paronychia.

Conclusions

In contact with skin, calcium carbide produces redness, skin burns and pain.

Gosselin, R.E., Smith, R.P., Hodge, H.C., Clinical Toxicology of Commercial Products, 5th edition Baltimore, Williams and Wilkins, 1984, p.II-105.

Summary

In contact with moist skin calcium carbide gives rise to severe thermal and caustic burn. Systemic effects do not occur.

Main impurity calcium oxide

Hinkamp, D.L., in Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4th edition, Volume 4, Part XVIII, 104 Guide do Chemicals, Table 104.18, 1998; and,

Gosselin, R.E., Smith, R.P., Hodge, H.C., Clinical Toxicology of Commercial Products, 5th edition Baltimore, Williams and Wilkins, 1984, p.II-105.

Summary

Calcium oxide (unslaked lime, quicklime) reacts with water with the evolution of heat, to form calcium hydroxide. This reaction on the skin or in the mouth produces both a thermal and a caustic burn.

B.6.2.3 Acute inhalation toxicity

Calcium carbide

Hinkamp, D.L., Alkaline materials, in Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4th edition, Volume 4, Part XVIII, 104 Guide do Chemicals, Table 104.18, 1998.

Summary

Inhalation risk: evaporation at 20°C is negligible; a harmful concentration of airborne particles can however, be reached quickly especially if powdered, causing cough, laboured breathing, shortness of breath and sore throat.

Main impurity calcium oxide

ACGIH, calcium oxide, in Documentation of the threshold limit values and biological exposure indices, 6th edition Cincinnati, OH, American Conference of Governmental Industrial Hygienists, pp. 200-201, 1991.

Summary

Strong nasal irritation has been reported to result from exposures to about 25 mg/m³, but exposures to 9 to 10 mg/m³ resulted in no observable irritation.

Richardson, M.L., Gangolli, S., The Dictionary of Substances and their Effects, Royal Society of Chemistry, UK, 1993, Volume 2, p. 59.

Summary

Repeated exposure study by inhalation to rats at 413 mg/m³ or a single exposure of 1026 mg/m³ (duration not specified) caused no deaths, and no marked changes in behaviour, body weight or food intake. No significant difference in haematological results and serum biochemical analysis or urine analysis was noted.

B.6.2.4 Skin irritation

“Calcium Carbide”: Acute Dermal Irritation/Corrosion Study with Rabbits

Wolf, T. (February 17, 2006) – Report No. ARC—L-1914 (internal study code WUE4), performed by ARC Seibersdorf research GmbH, A-2444 Seibersdorf, Austria.

Guidelines and GLP

The study was performed according to OECD-Principles of GLP (1998) and Federal Ministry of Agriculture, Forestry, Environment and Water Management, Vienna, Austria (2004); and Directive 2004/73/EC method B.4 and OECD-Guideline 404 (2002).

The study is acceptable.

Materials and methods

Test substance: Technical Calcium carbide / Prontox Wühlmausgas (75 - 80% w/w); Batch No. 120405 (Certificate of Analysis of Chemische Fabrik Wülfel GmbH & Co. KG dated May 30, 2005).

The aim to the study was to investigate possible irritation or corrosion by the test substance following a single application to the intact skin of rabbits.

Results

On the basis of the measured pH of 12.48 (1% solution in deionised water w/v, at 20°C, determined with a pH-Meter Inolab Level 2), the test substance was classified as corrosive. In contact with water, test substance undergoes hydrolysis forming acetylene and calcium hydroxide under heating.

According to the guidelines, dosing test substances in a way known to cause marked pain and distress due to corrosive or irritating properties need not be carried out and administered to animals.

Therefore and for animal welfare reasons the test was not performed experimentally.

Conclusions

According to Commission Directive 2001/59/EC a substance or preparation should be considered corrosive if the result can be predicted, for example from strongly acid or alkaline reactions indicated by a pH of 2 or less or 11.5 or greater. On the basis of the measured pH of 12.48 the test substance was classified as corrosive.

Where classification is based upon consideration of extreme pH alone, R35, “causes severe burns” should be applied.

Hinkamp, D.L., Alkaline materials, in Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4th edition, Volume 4, Part XVIII, 104 Guide to Chemicals, 1998.

Summary

See B.6.2.2 Acute percutaneous toxicity of calcium carbide: Dry carbide in contact with skin may cause dermatitis; contact with moist skin and mucous membranes leads to ulceration and scarring. Symptoms of redness, skin burns and pain are found.

Gosselin, R.E., Smith, R.P., Hodge, H.C., Clinical Toxicology of Commercial Products, 5th edition Baltimore, Williams and Wilkins, 1984, p.II-105.

Summary

Contact of calcium carbide with the moist mucous membranes, would probably result in a severe thermal and caustic burn. Systemic effects do not occur.

Main impurity calcium oxide

See B.6.2.2 Acute percutaneous toxicity of calcium oxide.

B.6.2.5 Eye Irritation

“Calcium Carbide”: Acute Eye Irritation/Corrosion Study with Rabbits

Wolf, T. (February 17, 2006) – Report No. ARC—L-1915 (internal study code WUE5); performed by ARC Seibersdorf research GmbH, A-2444 Seibersdorf, Austria.

Guidelines and GLP

The study was performed according to OECD-Principles of GLP (1998) and Federal Ministry of Agriculture, Forestry, Environment and Water Management, Vienna, Austria (2004); and Directive 2004/73/EC method B.5 and OECD-Guideline 405 (2002).

The study is acceptable.

Materials and methods

Test substance: Technical Calcium carbide / Prontox Wühlmausgas (75 - 80% w/w); Batch No. 120405 (Certificate of Analysis of Chemische Fabrik Wülfel GmbH & Co. KG dated May 30, 2005).

The aim to the study was to investigate possible irritating or corrosive effects of the undiluted test substance following a single application into the conjunctival sac of rabbit's eye.

Results

On the basis of the measured pH of 12.48 (1% solution in deionised water w/v, at 20°C, determined with a pH-Meter Inolab Level 2), the test substance was classified as corrosive. In contact with water, test substance undergoes hydrolysis forming acetylene and calcium hydroxide under heating.

According to the guidelines, dosing test substances in a way known to cause marked pain and distress due to corrosive or irritating properties need not be carried out and administered to animals.

Therefore and for animal welfare reasons the test was not performed experimentally.

Conclusions

The test substance is corrosive, therefore the risk of a severe damage to eyes (R41, “risk of serious damage to eyes”) is considered implicit, according to Commission Directive 2001/59/EC and Directive 1999/45/EC.

Hinkamp, D.L., Alkaline materials, in Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4th edition, Volume 4, Part XVIII, 104 Guide do Chemicals, 1998.

Summary

Calcium carbide is particularly hazardous to the eyes. Workers with a long professional history often show eye lesions with pronounced hyperaemia of the lids and conjunctiva, often accompanied by mucopurulent secretions. In heavy cases the sensitivity of the conjunctiva and cornea is strongly reduced. While the keratitis and keratoconjunctivitis evolve first without symptoms, they may later degenerate into corneal opacities.

Symptoms of short-term exposure of the eyes are redness, pain, blurred vision, severe deep burns.

Grant, W.M., 1986, Toxicology of the eye – Effects on the Eyes and Visual System from Chemicals, Drugs, Metals and Minerals, Plants, Toxins and Venoms; also, Systemic Side Effects from Eye Medications, Charles C Thomas Publisher, Springfield Illinois, USA, 3rd Edition, p.166.

Summary

In several instances burns of the eye resulting in opacity and scarring have been caused by contact with particles of calcium carbide or with strongly alkaline residues from its reaction with water. The clinical character of the burns is the same as those produced by calcium hydroxide. If particles of calcium carbide are removed promptly, healing may be rapid.

Conclusions

The published data confirm the proposed classification of calcium carbide/Prontox Wühlmausgas as severe eye irritant (R41, “risk of serious damage to eyes”).

Main impurity calcium oxide

Hinkamp, D.L., Alkaline materials, in Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4th edition, Volume 4, Part XVIII, 104 Guide do Chemicals, Table 104.18, 1998.

Summary

Short-term exposure symptoms from contact with calcium oxide on eyes are redness, pain and blurred vision.

Gosselin, R.E., Smith, R.P., Hodge, H.C., Clinical Toxicology of Commercial Products, 5th edition Baltimore, Williams and Wilkins, 1984, p.II-103.

Summary

Calcium oxide (quicklime) tends to form clumps in the conjunctival sac, which are dangerous and difficult to wash out.

B.6.2.6 Skin sensitization

“Calcium Carbide”: Skin Sensitisation Study (Guinea Pig Maximisation Test)

Sattler, K. (January 30, 2006) – Report No. ARC—L-1891 (internal study code WUE6); performed by ARC Seibersdorf research GmbH, A-2444 Seibersdorf, Austria.

Guidelines and GLP

The study was performed according to OECD-Principles of GLP (1998) and Federal Ministry of Agriculture, Forestry, Environment and Water Management, Vienna, Austria (2004); and Directive 96/54/EC method B.6 and OECD-Guideline 406 (1992), Guinea Pig Maximisation Test.

The study is acceptable.

Materials and methods

Test substance: Technical Calcium carbide / Prontox Wühlmausgas (75 - 80% w/w); Batch No. 120405 (Certificate of Analysis of Chemische Fabrik Wülfel GmbH & Co. KG dated May 30, 2005).

The aim to the study was to investigate possible skin sensitizing properties of the test substance. A search on the possible sensitizing properties of the test substance and its components was performed first.

Calcium carbide and also calcium oxide, which are contained in the test substance, will react with water to give calcium dihydroxide. This reaction will occur on or in the skin if the test substance would be applied epicutaneously and intradermally, as would be performed in a Guinea Pig Maximization Test. Therefore not only the 4 relevant components (>1% in test substance – calcium carbide, calcium oxide, silicon dioxide and carbon) of the test substance, but also calcium dihydroxide were considered as a possible sensitizing component/degradation product of the test substance.

RMS comment: although the content of aluminium oxide in the Chemische Fabrik Wülfel GmbH & Co. KG origin is below 1% in test substance, and so was not taken into account in this study, in the Detia Freyberg GmbH origin, the content of aluminium oxide is slightly above 1%, so the sensitizing properties of this compound has also to be included in this assessment.

Results

The following information was obtained:

Name	CAS No.	Classification by EU	IUCLID	Skin sensitization and method, according to IUCLID
Calcium carbide (calcium acetylide)	75-20-7	F; R15	available	Not sensitizing (open epicutaneous test in humans)
Calcium oxide	1305-78-8	Not classified	available	Not sensitizing (open epicutaneous test in humans)
Silicon dioxide	7631-86-9	Not classified	available	Not sensitizing (GPMT)
Carbon	7440-44-0	Not classified	available	No data available, considered to be not sensitizing
Calcium dihydroxide	1305-62-0	Not classified	available	Not sensitizing (no method stated) but has been reported to cause dermatitis in humans*
Aluminium oxide	1344-28-1	Not classified	available	No data available

* Gangolli, S., The Dictionary of Substances and their Effects, 2nd edition, Royal Society of Chemistry, UK, 1999, Volume 2, p. 59

Calcium carbide is also contained in the IPCS INCHEM database of the WHO, UN and ILO, where possible skin burns are mentioned but no sensitizing potential is mentioned.

Based on these results, it was anticipated that the test substance is not a skin sensitizer.

Considering animal welfare issues, it was therefore decided not to verify the results by an experimental test.

Conclusions

Based on the known composition of the test substance and available results on the possible skin sensitizing properties of the test substance and its components it was anticipated that the test substance is not a skin sensitizer.

B.6.2.7 Potentiation/interactions of multiple active substances or products

According to the notifier, potentiation of activity and interaction of the active substance with their impurities is not observable.

RMS comment: Pure calcium carbide is odourless. The technical product activity is based on its garlic-like odour, which arises from the small amount of impurity present in calcium carbide (calcium phosphide, ca. 0.025% by weight) which liberates the odour-intensive gas phosphine in the presence of ambient humidity. Acetylene itself, which is released during the reaction, has no unpleasant odour when pure, but has disagreeable odour due to the same impurity phosphine (*Merck Index*, 8th edition).

Although calcium phosphide is classified as “T+; R28: very toxic by ingestion”, and “R15/29: contact with water liberates toxic, extremely flammable gas” by EU, its concentration in technical product doesn’t influence the overall classification of calcium carbide. When phosphine liberates from calcium phosphide, the reaction occurs slowly underground within the burrows or tunnels that should be closed after application, so the exposure of operators is expected to be negligible (see point B.6.8.3 Acute inhalation toxicity on metabolite phosphine).

B.6.3 Short-term toxicity

The Notifier gave the following justification for non-submission:

The complete toxicology data requirements, e.g. short-term toxicity, for a food-use chemical are not required for calcium carbide since little acetylene and phosphine exposure is expected from the use pattern like repellent as such does not enter the human food chain.

Calcium carbide is introduced into the burrows or tunnels and is hydrolysed to acetylene and calcium hydroxide under the influence of soil humidity. Because of the underground application of calcium carbide there is no contact with surface plant components.

B.6.3.1 Oral 28-day toxicity

No study is available, for explanation see above.

B.6.3.2 Oral 90-day toxicity (rodents)

No study is available, for explanation see above.

B.6.3.3 Oral 90-day toxicity (dog)

No study is available, for explanation see above.

B.6.3.4 Oral 1 year toxicity (dog)

No study is available, for explanation see above.

B.6.3.5 28-day inhalation toxicity (rodents)

No study is available, for explanation see above.

B.6.3.6 90-day inhalation toxicity (rodents)

No study is available, for explanation see above.

B.6.3.7 Percutaneous 28-day toxicity (rodents)

No study is available, for explanation see above.

B.6.3.8 Percutaneous 90-day toxicity (rodents)

No study is available, for explanation see above.

B.6.4 Genotoxicity

Justification for non-submission:

See point B.6.3 above.

B.6.4.1 *In vitro* genotoxicity testing – Bacterial assay for gene mutation

No study is available; see the remarks under point B.6.3.

B.6.4.2 *In vitro* genotoxicity testing – Test for clastogenicity in mammalian cells

No study is available; see the remarks under point B.6.3.

B.6.4.3 *In vitro* genotoxicity testing – Test for gene mutation in mammalian cells

No study is available; see the remarks under point B.6.3.

B.6.4.4 *In vivo* genotoxicity testing (somatic cells) – Metaphase analysis in rodent bone marrow, or micronucleus test in rodents

No study is available; see the remarks under point B.6.3.

B.6.4.5 *In vivo* genotoxicity testing (somatic cells) – Unscheduled DNA synthesis or a mouse spot test

No study is available; see the remarks under point B.6.3.

B.6.4.6 *In vivo* studies in germ cells

No study is available; see the remarks under point B.6.3.

B.6.5 Long-term toxicity and carcinogenicity

The Notifier presented the following justification for non-submission:

See point B.6.3 above.

The International Agency for Research on Cancer (IARC) has not evaluated the carcinogenicity of calcium carbide and his metabolites.

The American Conference of Governmental Industrial Hygienists (ACGIH) has not assigned a carcinogenicity designation to calcium carbide and his metabolites.

The US National Toxicology Program (NTP) has not listed calcium carbide and his metabolites in its report on carcinogens.

B.6.5.1 Long-term (2 years) oral toxicity in the rat

No study is available; see the remarks under point B.6.3.

B.6.5.2 Carcinogenicity study in the rat

No study is available; see the remarks under point B.6.3.

B.6.5.3 Carcinogenicity study in the mouse

No study is available; see the remarks under point B.6.3.

B.6.5.4 Mechanism of action and supporting data

No study is available; see the remarks under point B.6.3.

B.6.6 Reproductive toxicity

Justification for non-submission:

See point B.6.3 above.

B.6.6.1 Two generation reproductive toxicity in the rat

No study is available; see the remarks under point B.6.3.

B.6.6.2 Separate male and female studies

No study is available; see the remarks under point B.6.3.

B.6.6.3 Three segment designs

No study is available; see the remarks under point B.6.3.

B.6.6.4 Dominant lethal assay for male fertility

No study is available; see the remarks under point B.6.3.

B.6.6.5 Cross-matings of treated males with untreated females and *vice versa*

No study is available; see the remarks under point B.6.3.

B.6.6.6 Effects on spermatogenesis

No study is available; see the remarks under point B.6.3.

B.6.6.7 Effects on oogenesis

No study is available; see the remarks under point B.6.3.

B.6.6.8 Sperm motility, mobility and morphology

No study is available; see the remarks under point B.6.3.

B.6.6.9 Investigation of hormonal activity

No study is available; see the remarks under point B.6.3.

B.6.6.10 Teratogenicity test by the oral route in the rat

No study is available; see the remarks under point B.6.3.

B.6.6.11 Teratogenicity test by the oral route in the rabbit

No study is available; see the remarks under point B.6.3.

B.6.7 Neurotoxicity

Justification for non-submission:

See point B.6.3 above.

B.6.7.1 Acute neurotoxicity – rat

No study is available; see the remarks under point B.6.3.

B.6.7.2 Delayed neurotoxicity following acute exposure

No study is available; see the remarks under point B.6.3.

B.6.7.3 28-day delayed neurotoxicity

No study is available; see the remarks under point B.6.3.

B.6.7.4 Subchronic neurotoxicity – rat – 90 day

No study is available; see the remarks under point B.6.3.

B.6.7.5 Postnatal developmental neurotoxicity

No study is available; see the remarks under point B.6.3.

B.6.8 Toxicity studies on metabolites

B.6.8.1 Acute oral toxicity on metabolites

Metabolite calcium hydroxide

Richardson, M.L. Gangolli, S., The Dictionary of Substances and their Effects, Royal Society of Chemistry, UK, 1993.

Summary

The oral LD₅₀ in rats for calcium hydroxide is reported to be 7340 mg/kg.

Conclusion:

Calcium hydroxide doesn't require classification relating to acute oral toxicity according to Commission Directive 2001/59/EC.

Patnaik, P., A Comprehensive Guide to the Hazardous Properties of Chemical Substances, Van Nostrand Reinhold, New York, 1992, p.119

Summary

The oral LD₅₀ in mice is reported to be 7300 mg/kg.

Conclusion:

This information confirms the results obtained in rats with calcium hydroxide, that no classification relating to oral toxicity is required.

Metabolite acetylene

RMS comment: Gas formerly used as surgical anaesthetic and for determination of cardiac output, is a moderate anaesthetic and asphyxiant gas (*The Merck Index, 8th edition, Merck & Co., Inc., Rahway, N.J., USA, p. 11*). Oral LD₅₀ is not available due to physical form (gas). Main toxicological concerns are via inhalatory route. No classification related to oral toxicity is attributed by EU.

B.6.8.2 Acute percutaneous toxicity on metabolites

Metabolite calcium hydroxide

Gangolli, S., The Dictionary of Substances and their Effects, 2nd edition, Royal Society of Chemistry, UK, 1999, Volume 2, p. 59.

Summary

Calcium hydroxide is a skin and mucous membrane irritant.

Gosselin, R.E., Smith, R.P., Hodge, H.C., Clinical Toxicology of Commercial Products, 5th edition Baltimore, Williams and Wilkins, 1984, p.II-105.

Summary

Calcium hydroxide (slaked lime) is a simple alkali; because of low solubility and apparently slow penetration into tissues, its aqueous solutions are not corrosive.

Conclusions:

RMS comments: calcium hydroxide seems to be less corrosive than calcium carbide itself (in contact with water), this result may be due to the fact that when calcium hydroxide is formed by hydrolysis of calcium carbide an exothermic reaction occurs that worsen the irritant effects of calcium hydroxide.

Metabolite acetylene

RMS comment: the same comment as in point B.6.2.1: Gas formerly used as surgical anaesthetic and for determination of cardiac output, is a moderate anaesthetic and asphyxiant gas (*Stecher, P.G., The Merck Index, 8th edition, Merck & Co., Inc., Rahway, N.J., USA, p. 11*). Dermal LD₅₀ is not available due to physical form (gas). Main toxicological concerns are via inhalatory route. No classification related to dermal toxicity is attributed by EU.

B.6.8.3 Acute inhalation toxicity on metabolites

Metabolite calcium hydroxide

Hinkamp, D.L., Alkaline materials, in Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4th edition, Volume 4, Part XVIII, 104 Guide do Chemicals, Table 104.18, 1998.

Summary

Inhalation of calcium hydroxide causes burning sensation and cough.

Richardson, M.L., Gangolli, S., The Dictionary of Substances and their Effects, Royal Society of Chemistry, UK, 1993, Volume 2, p. 54.

Summary

Calcium hydroxide is a respiratory system irritant.

Metabolite acetylene

American Chemistry Council, Acetylene Panel, High Production Volume Challenge, Test Plan for Acetylene CAS No. 74-86-2; Report No. 201-15005A, December 30, 2003.

Introduction

The Acetylene Panel of the American Chemistry Council (ACC) has agreed to supply screening level hazard and use information under the U.S. EPA High Production Volume (HPV) Challenge Program for Acetylene. This plan identifies existing data of adequate quality for this chemical, and how the data serve to address the HPV Challenge screening endpoints.

All identified available studies were reviewed and assessed for the adequacy according to the standards of Klimisch *et al.* (1997). Studies receiving a Klimisch rating of 1 or 2 were considered to be adequate.

Summary

In humans, acetylene is not acutely toxic below its lower explosive limit of 2.5 % (25'000 ppm).

Inhalation of 10% acetylene (100'000 ppm) for 1 hour does not cause acute toxicity. Inhalation of 33% or 35% has caused unconsciousness within 7 and 5 minutes, respectively (Davidson, 1952). Two deaths and a near fatality occurred after inhalation of 40% acetylene during manufacture with calcium carbide (Carreün, 2000; Jones, 1960). The cause of these deaths was attributed to the phosphate and arsine impurities in crude acetylene and carbon monoxide present in the work area.

In rats, a concentration of 78% acetylene (780'000 ppm) produced anaesthesia in 15 minutes, and inhalation of 90% for 2 hours caused respiratory failure (Riggs, 1952). Inhalation of 850'000 ppm caused increased respiratory volume and frequency and induced anaesthesia in dogs, with rapid recovery (Heymans and Bouckaert, 1952). Therefore, the LC₅₀ in this study was greater than 850'000 ppm.

It has been established that acetylene behaves in mammalian systems primarily as a central nervous depressant and asphyxiant at high dose levels (100,000 ppm in air or above). It produces varying degrees of temporary and reversible narcosis when administered with oxygen in concentrations of 100'000 ppm (10% in air) and higher. Repeated exposures of rats, mice, guinea pigs, rabbits and dogs to concentrations up to 800'000 ppm showed no evidence of cellular injury to the parenchymatous cells of the heart, lungs, liver, kidneys, or spleen (Franklin and Miklos, 1933).

Limited data reported in the literature indicate that Acetylene is rapidly adsorbed and eliminated unchanged in the body (Adriani, 1952, 1962). The blood-gas partition coefficient of acetylene at normal haematocrit and body temperature is 0.833 (Jibelian *et al.*, 1981), indicating, that the material has a greater propensity to be removed from blood than to be retained in it. Schrikker *et al.* (1989) have shown that, in man at rest, the rates of alveolar and mixed venous washout for acetylene calculated from the slopes of the alveolar plateau are 2.6% and 4.8% per second, respectively. Within 10 minutes of inhalation of acetylene for 15 minutes, the end tidal concentration was 8.0% of its initial value. Together, these data support the contention that the lungs rapidly excrete acetylene. The gas also diffuses rapidly from the peritoneal and pleural cavities and diffuses through the skin. Therefore, acetylene is unlikely to persist in the body, even after repeated exposure to low concentrations that may be encountered in the workplace.

Conclusions

Data regarding the acute inhalation toxicity to animals and humans show that acetylene is of very low acute toxicity. Overall, the data support a rat LC₅₀ > 100'000 ppm.

The most meaningful hazard associated with acetylene is fire and explosion that would be life-threatening before toxicological hazard could develop.

Metabolite phosphine

No reference was given, the Notifier justified as follows:

Actually, the active substance of technical calcium carbide is calcium phosphide contained in minor quantities of 0.025 % w/w or 0.25g calcium phosphide/kg calcium carbide, respectively.

The useful recommended mode of application is at a rate of 10g PRONTOX Wühlmausgas (calcium carbide)/tunnel (*Arvicola terrestris*) and at a rate of 20 g PRONTOX Wühlmausgas/burrow (*Talpa europaea* L.).

0.005 g calcium phosphide is contained in 20 g technical calcium carbide. Calcium phosphide decomposes with the moisture of soil or air to the toxic gas phosphine and calcium hydroxide. On the understanding of a complete decomposition 0.005 g calcium phosphide (molecular mass of calcium phosphide: 182.19 g) evolve 0.0019 g phosphine. This corresponds to a gas volume of about 1.3 ml phosphine under the following conditions: temperature: 20°C, atmospheric pressure: 1013 hPa. In the mode of application of PRONTOX Wühlmausgas this small quantity is released over several hours, in the consequence the concentration of phosphine is always in a non-toxic range but is attaining the threshold value of smelling (0.02 ppm).

B.6.8.4 Skin irritation on metabolites

Metabolite calcium hydroxide

See B.6.8.2 Acute percutaneous toxicity of calcium hydroxide.

B.6.8.5 Eye Irritation on metabolites

Metabolite calcium hydroxide

Hinkamp, D.L., *Alkaline materials*, in *Encyclopaedia of Occupational Health and Safety*, International Labour Office, Geneva, Switzerland, 4th edition, Volume 4, Part XVIII, 104 *Guide do Chemicals*, Table 104.18, 1998.

Summary

Short-term exposure of the eyes with calcium hydroxide show the following symptoms: redness, pain and blurred vision.

Gosselin, R.E., Smith, R.P., Hodge, H.C., *Clinical Toxicology of Commercial Products*, 5th edition Baltimore, Williams and Wilkins, 1984, p.II-103.

Summary

Calcium hydroxide (slaked lime) usually produces only superficial opacities of the cornea, apparently because it penetrates corneal epithelium so slowly. In contrast, an aqueous suspension of calcium oxide or dried powdered calcium oxide contains particles that readily adhere to the conjunctiva; they often induce ulcerations of the corneal epithelium and stromal opacities but rarely penetrate to the iris or lens. It is difficult but essential to wash out the conjunctival sac completely.

B.6.8.6 Skin sensitization on metabolites

Data on skin sensitization of the metabolite calcium dihydroxide are given in point B.6.2.6.

B.6.9 Medical data

B.6.9.1 Report on medical surveillance on manufacturing plant personnel

During production, transport, and preparation of raw materials, dust can cause a nuisance in the vicinity of the factory and at the workplace and is therefore removed by air extraction and retained by means of filters.

Calcium carbide and his main impurity calcium oxide can cause ill health mainly by:

- inhalation of dust;
- skin contact;
- manual handling.

All workers involved with the production of calcium carbide are regularly monitored at intervals of 12 months by occupational medical inspections according to the requirements of the German national regulations on hazardous substances (Gefahrstoffverordnung, (GefStoffV), Annex III No. 2, particle-shaped hazardous substances).

In addition to this, special comprehensive health checkups are conducted in intervals of 36 months according to recommendation no. 26 (relevant where protective respiratory devices are used) of the professional trade association (Berufsgenossenschaft).

Skin inspections are done at regular intervals by a doctor competent to recognise the signs and symptoms of substance-related dermatitis, and the results are recorded.

In connection with German national regulations on hazardous substances (GefStoffV) the technical rules on hazardous substances (TRGS 900, Hazardous substances in air) require exposure controls in monitoring limit values at workplaces:

Calcium carbide	MAK 2 mg/m ³ (portion of total dust inhaled)
Calcium oxide	MAK 5 mg/m ³ (portion of total dust inhaled)

Ergenzinger, M. , Calcium carbide – occupational medical statement, Degussa AG, Department of occupational medicine, Trostberg, Germany, May 3, 2005.

Calcium carbide has been produced for decades at the Hart location. Up to date, some 100 people have been exposed to calcium carbide during production. Previously it was significantly more and the production conditions were less favourable. The author himself has been responsible for the factory in Hart since 1997. During these years and in previous years according to the records, no specific effects damaging to health of calcium carbide have been observed.

From time to time skin and eye irritation were apparent among workers. As a rule these were associated with heavy perspiration particularly when working with ovens. No such effects were known during reconditioning and maintenance.

Because of eye irritation, which reduces in a few hours after ocular rinsing and non-specific therapy with Bepanthen eye cream, some 20 treatments were carried out annually. Due to skin irritation, which similarly reduced rapidly following short term topical cortisone therapy, there were ca. 15 treatments annually. The high number results from the urgent requirements of factory management to medically report even such small incidents around the clock. In the years of his practice, two workers were moved by mutual agreement from carbide production, due to recurrent conjunctival inflammation.

Routine occupational medical examinations were offered to workers every three years. The main emphasis being on noise, dust masks, driving ability, working in hot conditions and fully continuous shift work. A specific examination for calcium carbide does not exist naturally. Furthermore, during these comprehensive examinations which include a hearing test, sight test, lung function, ECG under exercise, blood and urine examinations, no dust or carbide-related signs appeared.

NIOSH/OSHA, Occupational Health Guidelines for Chemical Hazards, Occupational Health Guideline for Calcium Oxide, U.S. Department of Health and Human Services and U.S. Department of Labor, January, 1981, pp. 208-211

The guideline is intended as a source of information for employees, employers, physicians, industrial hygienists, and other occupational health and professionals who may have contact with calcium oxide. Calcium oxide is a main impurity of technical calcium carbide.

Summary of toxicology:

Calcium oxide dust irritates the eyes and upper respiratory tract. The irritant effects are probably due primarily to its alkalinity, but dehydrating and thermal effects also may be contributing factors. Inflammation of the respiratory passages, ulceration, perforation of the nasal septum, and pneumonia have been attributed to inhalation of calcium oxide dust. Severe irritation of the upper respiratory tract ordinarily causes persons to avoid serious inhalation exposures. Particles of calcium oxide have caused severe burns of the eyes; prolonged or repeated contact with skin could cause dermatitis.

Permissible Exposure Limit (PEL):

The current OSHA standard for calcium oxide is 5 mg/m³ of air averaged over an eight-hour work shift. The American Conference of Governmental Industrial Hygienists has recommended for calcium oxide a Threshold Limit Value (TLV) of 2 mg/m³.

Recommended medical surveillance:

1. Initial Medical Screening: Employees should be screened for history of certain medical conditions which might place the employee at increased risk from calcium oxide exposure.
 - Chronic respiratory disease: In persons with impaired pulmonary function, especially those with obstructive airway diseases, the breathing of calcium oxide might cause exacerbation of symptoms due to its irritant properties.
 - Skin disease: calcium oxide is a primary skin irritant. Persons with pre-existing skin disorders may be more susceptible to the effects of this agent.
2. Periodic Medical Examination: Any employee developing the above-listed conditions should be referred for further medical examination.

B.6.9.2 Report on clinical cases and poisoning incidents

Begemann, K., Summaries of three cases of health impairment relating to calcium carbide, Federal Institute for Risk Assessment (BfR), Technical group 32: poisoning and product documentation, Poisons Assessment Centre, Berlin, Germany

Information of Federal Institute for Risk Assessment (BfR):

Summaries of three cases of health impairment were reported in the scope of the reporting requirements according to §16e of the Chemical Law.

Case 1:

In the exercise of professional duties, a worker received carbide dust in the eyes. The eyes were immediately rinsed with water and an eye doctor consulted shortly thereafter. There, distinct conjunctival and corneal corrosion were diagnosed in the left eye and conjunctival irritation in the right eye. The casualty was treated with a localized therapy as an out-patient.

Case 2:

In this instance also, a worker received carbide dust in the eyes in the exercise of his professional duties. The eyes were immediately rinsed with water and an eye doctor consulted, who diagnosed conjunctival and corneal corrosion. The casualty was treated as an out-patient and was written off as sick for three days.

Case 3:

A container, filled with calcium carbide, ruptured. While clearing up, the female casualty had breathed in calcium carbide and also received it in the eyes, for ca. ½ an hour. There became apparent burning sensation of the face and mouth area, reddening of the mucous membranes of the nasal passages, dryness of the mouth and strong feeling of thirst, as well as throat ache and tears. The complaints persisted for ca. 14 days.

B.6.9.3 Observations on exposure of the general population and epidemiological studies

In the literature observations on exposure of the general population or epidemiological studies in connection with the substance calcium carbide are not published.

B.6.9.4 Clinical signs and symptoms of poisoning and details of clinical tests

Technical calcium carbide and his main impurity calcium oxide

Technical calcium carbide and his main impurity calcium oxide are dusty alkaline materials. In contact with moist skin and mucous membranes they develop calcium hydroxide, a middle-strong alkaline substance.

The clinical signs and symptoms are dependent on the mode of exposure and concentration of the hazardous substance, and other factors.

- **Ingestion:** Calcium carbide dust may produce burns to the lips, tongue, oropharynx, upper airway, oesophagus and occasionally stomach. Spontaneous vomiting may occur. The absence of visible oral burns does not reliably exclude the presence of oesophageal burns.
- **Inhalation:** Calcium carbide dust can produce upper airway oedema, respiratory failure, wheezing, pulmonary oedema, and pneumonitis.
- **Dermal (skin) contact:** Dry calcium carbide dust may cause irritant dermatitis. If exposure continues over a longer period the condition will get worse and the individual is the more susceptible to allergic dermatitis. The contact with moist skin may produce pain, redness, irritation or full thickness burns.
- **Eye contact (ocular):** The exposure can produce severe conjunctival irritation and chemosis, corneal epithelial defects, limbal ischemia, permanent visual losses and in severe cases perforation.

Bronstein, A.C., Currance, P.L., Emergency Care for Hazardous Materials Exposure, Guideline 49, St. Louis, Mosby, 1988, p. 181-182.

Life threat: Severe irritant to tissue that can cause upper airway burns and oedema, circulatory collapse, and severe skin burns. May cause gastric perforation and peritonitis.

Signs & symptoms by system:

- *Cardiovascular* – Tachycardia and shock.
- *Respiratory* – Dyspnoea and tachypnoea. Burns and oedema in the upper airway. Sneezing, coughing, stridor and pulmonary oedema may be present.
- *CNS* – Apathy, mental confusion, blurred vision and tremors.
- *Gastrointestinal* – Nausea, vomiting and abdominal pain. Painful swallowing, profuse salivation and burns to the mouth, oesophagus, stomach and lower G.I. tract may result.
- *Eye* – Chemical conjunctivitis to severe eye injury.
- *Skin* – Chemical burns and in milder cases a skin rash. Cold and clammy skin with cyanosis or pale colour.

Metabolite acetylene

Bronstein, A.C., Currance, P.L., Emergency Care for Hazardous Materials Exposure, Guideline 72, St. Louis, Mosby, 1988, p. 227-228.

Life threat: Asphyxiation or anaesthetic properties at high concentrations. Cardiac arrhythmias.

Signs & symptoms by system:

- *Cardiovascular* – Cardiovascular collapse and arrhythmias. May aggravate pre-existing cardiac problem.
- *Respiratory* – Narcotic effect may depress respirations. Irritation of the respiratory tract and possibly pulmonary oedema.
- *CNS* – Excitation, headache, disorientation, dizziness, weakness and possible seizures. CNS depression and coma due to anaesthetic effect or hypoxia. Psycho-Organic Syndrome of Solvents (neurobehavioral effects)(see description in “Other” section below).
- *Gastrointestinal* – Nausea, vomiting and abdominal cramps. Excessive salivation.
- *Eye* – Irritation and lacrimation.
- *Skin* – Mild skin irritation and frostbite.
- *Other* – Symptoms may be delayed. Certain products can cause respiratory depression and arrest.

B.6.9.5 First aid measures

- **Inhalation of dust:** Remove source of contamination or have victim move to fresh air. Obtain medical advice immediately.
- **Skin contact:** Avoid direct contact with calcium carbide. Wear chemical protective gloves. Quickly and gently blot or brush away excess chemical. Remove contaminated clothing, shoes and leather goods (e.g. watchbands, belts). Flush contaminated area with lukewarm, gently running water for at least 30 minutes, or until the chemical is removed. If irritation persists, repeat flushing. Do not interrupt flushing. If necessary, keep emergency vehicle

waiting. Transport victim to an emergency care facility immediately. Discard contaminated clothing, shoes and leather goods.

- **Eye contact:** Avoid direct contact with the calcium carbide. Wear tightly sealed goggles. Quickly and gently blot or brush away excess chemical. Immediately flush the contaminated eye(s) with lukewarm, gently flowing water for 30 minutes, or until the chemical is removed while holding the eyelid(s) open. Neutral saline solution may be used as soon as it is available. Do not interrupt flushing. If necessary, keep the emergency vehicle waiting. Take care not to rinse contaminated water into the non-affected eye. If irritation persists, repeat flushing. Quickly transport victim to an emergency care facility.
- **Ingestion:** Never give anything by mouth if victim is rapidly losing consciousness, or is unconscious or convulsing. Have victim rinse mouth thoroughly with water. Do not induce vomiting. Have victim drink about 1'000 ml of water to dilute material in stomach. If milk available, it be administered after the water has been given. If vomiting occurs naturally, repeat administration of water. Quickly transport victim to emergency care facility.

First Aid Comments: Provide general supportive measures (comfort, warmth, rest). Consult a doctor and/or the nearest Poison Control Centre for all exposures except minor instances of inhalation contact.

All first aid procedures should be periodically reviewed by a doctor familiar with calcium carbide and his metabolites and its conditions of use in the workplace.

B.6.9.6 Therapeutic regimes

Technical calcium carbide and his main impurity calcium oxide

Bronstein, A.C., Currance, P.L., Emergency Care for Hazardous Materials Exposure, Guideline 49, St. Louis, Mosby, 1988, p. 181-182.

Summary:

Decontamination: Wear positive pressure self-contained breathing apparatus and special protective equipment. Delay entry until equipment is available. Remove patient from contaminated area. Gently brush away any dry particles and blot, with absorbent material, any excess liquids that are present. Rinse patient with water and remove all clothing, jewellery, and shoes. Wash patient with Tincture of Green Soap and large quantities of water.

Basic treatment: Establish a patent airway. Suction if necessary. Watch for signs of respiratory insufficiency and assist ventilations if necessary. Administer oxygen by non-rebreather mask at 10 to 15 L/min. Monitor for pulmonary oedema and treat if necessary. For eye contamination, flush eyes immediately with water. Irrigate each eye continuously with sterile 0.9 % saline for at least an hour or until the cul-de-sacs are free of particulate matter and returned to neutrality (confirm with pH paper). Do not use emetics. For ingestion, rinse mouth and administer 10 ml/kg up to 1'000 ml of water for dilution if the patient can swallow, has a strong gag reflex, and does not drool. Cover skin burns with dry sterile dressings after decontamination.

Advanced treatment: Consider orotracheal or nasotracheal intubation for airway control in the patient who is unconscious, has severe pulmonary oedema, or is in respiratory arrest. Early intubation, at the first signs of upper airway obstruction, may be necessary. Positive pressure ventilation techniques with a bag valve mask device may be beneficial. Monitor cardiac rhythm and treat arrhythmias if necessary. Use lactated Ringer's if signs of hypovolemia are present. Watch for signs of fluid overload. Consider drug therapy for pulmonary oedema. For hypotension with signs

of hypovolemia, administer fluid cautiously. Treat seizures with diazepam (Valium). Use proparacaine hydrochloride to assist eye irrigation.

In second degree burns cover skin with an ointment containing a dermatocorticoid.

Special considerations: Do not attempt to neutralize product because of exothermic reactions.

Metabolite acetylene

Bronstein, A.C., Currance, P.L., Emergency Care for Hazardous Materials Exposure, Guideline 72, St. Louis, Mosby, 1988, p. 227-228.

Decontamination: Wear positive pressure self-contained breathing apparatus and special protective equipment. Delay entry until equipment is available. Remove patient from contaminated area. Gently blot, with absorbent material, any liquids that are present. Rinse patient with water and remove all clothing, jewellery, and shoes. Wash patient with Tincture of Green Soap and large quantities of water.

Basic treatment: Assist ventilation as needed. Administer oxygen by nonrebreather mask at 6 to 12 L/min. Monitor for pulmonary oedema and treat as necessary. Anticipate seizures and treat as necessary. Flush eye immediately with available water for eye contamination. Irrigate each eye with a minimum of 1000 cc of normal saline. Administer 4 to 8 oz of water for dilution if product was ingested and the patient can swallow, has a good gag reflex and no drooling. Do not use emetics. Treat frostbite with rapid rewarming techniques.

Advanced treatment: Consider orotracheal or nasotracheal intubation for airway control in the unconscious or respiratory arrest patient. Use positive pressure ventilation techniques, they may be beneficial. Monitor cardiac rhythm and treat arrhythmias if necessary. Consider drug therapy for pulmonary oedema. Treat seizures with diazepam (Valium). Use proparacaine hydrochloride to assist eye irrigation.

B.6.9.7 Expected effects and duration of poisoning as a function of the type, level and duration of exposure or ingestion

The effects are described under point B.6.9.4.

B.6.9.8 Expected effects and duration of poisoning as a function of varying time periods between exposure or ingestion and commencement of treatment

According to notifier, dry calcium carbide is capable of causing dermatitis by two mechanisms - irritancy and allergy. Irritant dermatitis is caused by the physical properties of Calcium carbide that irritate the skin mechanically. The fine particles of the dust can abrade the skin and cause irritation resulting in dermatitis. In delaying the commencement of treatment a sensitisation of the skin is possible. Sensitizers penetrate the barrier layer of the skin and cause an allergic reaction (allergic dermatitis).

RMS comment: there is no other source (in the literature) than this statement from the notifier indicating that calcium carbide is a skin sensitiser, so no classification is proposed relating to skin sensitization for calcium carbide.

B.6.9.9 Dermal penetration

Justification for non-submission:

The estimation or the measurement for the dermal penetration of the substance calcium carbide is not possible. Calcium carbide decomposes spontaneously in contact with water or with moist skin

to calcium hydroxide and acetylene. For this reason the estimation for the dermal penetration is in regard of the breakdown product calcium hydroxide as metabolite.

See point B.6.2.2 and B.6.8.2.

B.6.9.10 Other/special studies

Other or special studies are not available.

B.6.10 Summary of mammalian toxicology and proposed ADI, AOEL, ARfD and drinking water limit

Toxicokinetic

Studies on the absorption, distribution, metabolism and excretion of calcium carbide in mammals do not exist.

Detailed investigations of calcium carbide metabolism based on the hydrolysis to calcium hydroxide and acetylene were not considered to be required, since dietary exposure of humans does not occur in view of the lack of appreciable residues according to the use of the substance as repellent.

In the use of technical calcium carbide as a repellent against voles and moles, the granulate is introduced into the animal's burrows where it is decomposed to calcium hydroxide and acetylene by ground humidity. Additionally, odour-intensive phosphine gas arises from hydrolysis of the very small amounts of calcium phosphide present on the technical material.

In the prescribed use of calcium carbide, there is no contact with plant roots above the soil surface. The uptake of acetylene by plant roots cannot be demonstrated due to the high volatility of acetylene. According to "American Chemistry Council, HPV Challenge, Acetylene Panel, Report n. °201-15005A of December 30, 2003", acetylene is a gas, and 99.9% partitions to the air, 0.104% partitions to the water, 0.0101% partitions to the soil and 0.000177 partitions to the sediment were estimated.

The calcium hydroxide remaining in the ground binds with carbon dioxide in the air and forms calcium bicarbonate in the first stage, which later partly changes into calcium carbonate. Both substances do not possess any toxic properties. From the facts presented it follows that the calcium carbide itself, as well as its decomposition product acetylene, calcium hydroxide and phosphine do not enter into the food chain.

Besides this, calcium hydroxide and calcium carbides' impurity calcium oxide are food additives specified by EC regulations (SCF-Scientific Committee for Food) and by FAO/WHO (JECFA – Joint Expert Committee on Food Additives). An ADI (Acceptable Daily Intake) is not specified based on the fact that these substances are normal constituents of the diet and can not be distinguished from the same ions already present in food from other sources when used according to good manufacturing practice.

Acute toxicity

Technical calcium carbide and his main impurity calcium oxide are dusty alkaline materials. In contact with moist skin and mucous membranes they develop calcium hydroxide, a middle-strong alkaline substance. Calcium carbide/calcium oxide dust irritates the eyes and upper respiratory tract. The irritant effects are probably due primarily to its alkalinity, but dehydrating and thermal effects also may be contributing factors.

On the basis of the measured pH of 12.48 of a 1% solution in deionised water of calcium carbide, no experiment was undertaken for humane reasons on live animals. Symptoms upon ingestion of calcium carbide are abdominal cramps, burning sensation, vomiting and weakness from the open

literature. No classification regarding the acute oral, dermal and inhalation toxicity of calcium carbide is required according to Annex I of Directive 67/548/EEC and its amendments.

Dry calcium carbide in contact with skin may cause dermatitis. Contact with moist skin and mucous membranes leads to ulceration and scarring. A peculiar type of melanoderma with strong hyperpigmentation and numerous telangiectases is often observed. Burns caused by hot calcium carbide are common. The tissues are generally damaged in depths of 1 to 5 mm; the burns evolve very slowly, are difficult to treat, and often require excision.

Persons exposed to calcium carbide frequently suffer from cheilitis characterized by dryness, swelling and hyperaemia of the lips, intense desquamation, and deep radial fissures; erosive lesions with tendency to suppuration can be observed in the mouth angles. Workers with a long professional history often suffer from nail lesions –that is occupational onychia and paronychia.

Calcium carbide is particularly hazardous to the eyes. Workers with a long professional history often show eye lesions with pronounced hyperaemia of the lids and conjunctiva, often accompanied by mucopurulent secretions. In heavy cases the sensitivity of the conjunctiva and cornea is strongly reduced. While the keratitis and keratoconjunctivitis evolve first without symptoms, they may later degenerate into corneal opacities. Symptoms of short-term exposure of the eyes are redness, pain, blurred vision, severe deep burns.

Based on the composition of the test substance and available results in the literature on the possible skin sensitizing properties its components, it was anticipated that the test substance is not a skin sensitizer.

Toxicity of metabolites

Calcium hydroxide

The LD₅₀ of the metabolite calcium hydroxide is reported from the literature to be about 7300 mg/kg bw in rats and mice. Because of its low solubility and apparently slow penetration into tissues, its aqueous solutions are not reported to be corrosive. However, inhalation of calcium hydroxide causes burning sensation and cough. It produces severe eye irritation and has been reported to cause dermatitis in humans; it is a skin and mucous membrane irritant.

Acetylene

In humans acetylene is not acutely toxic below its lower explosive limit of 2.5 % (25'000 ppm). It has been established in the literature that acetylene behaves in mammalian systems primarily as a central nervous depressant and asphyxiant at high dose levels (100'000 ppm in air or above). It produces varying degrees of temporary and reversible narcosis when administered with oxygen in concentrations of 100'000 ppm (10% in air) and higher. Repeated exposures of rats, mice, guinea pigs, rabbits and dogs to concentrations up to 800'000 ppm showed no evidence of cellular injury to the parenchymatous cells of the heart, lungs, liver, kidneys, or spleen.

Limited data reported in the literature indicate that Acetylene is rapidly adsorbed and eliminated unchanged in the body. The blood-gas partition coefficient of acetylene indicates that the material has a greater propensity to be removed from blood than to be retained in it. The lungs rapidly excrete acetylene. The gas also diffuses rapidly from the peritoneal and pleural cavities and diffuses through the skin. Therefore, acetylene is unlikely to persist in the body, even after repeated exposure to low concentrations that may be encountered in the workplace. Overall, the data support a rat LC₅₀ > 100'000 ppm.

Phosphine

Actually, the active substance of technical calcium carbide is calcium phosphide contained in minor quantities of 0.025 % w/w or 0.25g calcium phosphide/kg calcium carbide.

In the mode of application of calcium carbide this small quantity is released over several hours, in consequence, according to the Notifier, the concentration of phosphine is always in a non-toxic range but is attaining the threshold value of smelling (0.02 ppm).

Medical data

All workers involved with the production of calcium carbide are regularly monitored at intervals of 12 months by occupational medical inspections according to the requirements of the German national regulations on hazardous substances (Gefahrstoffverordnung (GefStoffV), Annex III No. 2, particle-shaped hazardous substances). In addition to this, special comprehensive health checkups are conducted in intervals of 36 months according to recommendation no. 26 (relevant where protective respiratory devices are used) of the professional trade association (Berufsgenossenschaft).

Skin inspections are done at regular intervals by a doctor competent to recognise the signs and symptoms of substance-related dermatitis, and the results are recorded.

In connection with German national regulations on hazardous substances (GefStoffV) the technical rules on hazardous substances (TRGS 900, Hazardous substances in air) require exposure controls in monitoring limit values at workplaces:

Calcium carbide	MAK 2 mg/m ³ (portion of total dust inhaled)
Calcium oxide	MAK 5 mg/m ³ (portion of total dust inhaled)

Emergency Care for Hazardous Materials:

First aid measures and therapeutic regimes related to poisoning with calcium carbide/calcium oxide/calcium hydroxide were established.

B.6.11 Toxicological studies of the preparation

Calcium carbide technical is identical to the commercial product PRONTOX Wühlmausgas.

B.6.11.1 Acute oral toxicity

See point B.6.2.1.

B.6.11.2 Acute percutaneous (dermal) toxicity

See point B.6.2.2.

B.6.11.3 Acute inhalation toxicity to rats

See point B.6.2.3.

B.6.11.4 Skin irritation

See point B.6.2.4.

B.6.11.5 Eye Irritation

See point B.6.2.5.

B.6.11.6 Skin sensitization

See point B.6.2.6.

B.6.11.7 Supplementary studies for combinations of plant protection products

PRONTOX Wühlmausgas is not applied in combination of other plant protection products.

B.6.11.8 Short-term toxicity studies

Justification for non-submission: see point B.6.3.

B.6.12 Dermal absorption

The estimation or the measurement for the dermal absorption of the substance calcium carbide is not possible. Calcium carbide decomposes spontaneously in contact with water or with moist skin to calcium hydroxide and acetylene. For this reason the estimation for the dermal absorption is in regard of the breakdown product calcium hydroxide as metabolite.

See point B.6.2.2 and B.6.8.2.

B.6.12.1 Dermal absorption, in vivo in the rat

For explanation see above.

B.6.12.2 Comparative dermal absorption, in vitro using rat and human skin

For explanation see above.

B.6.13 Toxicological data on non active substances

PRONTOX Wühlmausgas is identical to technical calcium carbide. It is to be sold and applied unformulated, as the technical material.

B.6.13.1 Material safety data sheet for each formulante

Not applicable. See above for explanation.

B.6.13.2 Available toxicological data for each formulante

Not applicable. See above for explanation.

B.6.14 Exposure data

B.6.14.1 Operator exposure

B.6.14.1.1 Estimation of operator exposure assuming personal protective equipment is not used

If the directions for use (see point B.14.1.2) are not noticed PRONTOX Wühlmausgas can cause ill health mainly by skin contact and inhalation of dust.

Dry PRONTOX Wühlmausgas in contact with skin may cause dermatitis.

In contact with moist skin and mucous membranes PRONTOX Wühlmausgas is developing calcium hydroxide, a medium strong alkaline substance.

Small quantities of PRONTOX Wühlmausgas in contact with moist give rise to redness, and pain.

Small quantities of PRONTOX Wühlmausgas in contact with eyes lead to redness, pain, and blurred vision.

According to the indication of use, minimal exposure is anticipated. However, according to toxicological classification of the a.s./PPP, it is recommended to use protective clothing, gloves and eye/face shield protection.

B.6.14.1.2 Estimation of operator exposure assuming personal protective equipment is used

Köhler, U., PRONTOX Wühlmausgas – Instructions for use, Chemische Fabrik Wülfel GmbH & Co. KG, Hanover, Germany, June 15, 2005.

Summary:

Application

PRONTOX Wühlmausgas (calcium carbide) is introduced into the target animals underground runs and tunnels by means of a spoon or another aid. The spoon should be designed to both an applicator and a dosage measuring system.

Granules can then be introduced one at a time into the tunnels with a simple, clear, accurate measurement of the dosage, whilst at the same time eliminating operator exposure.

Underground, the evolution of acetylene and phosphine is not abrupt, but depends on the progressive absorption of soil moisture. Since phosphine is heavier than air, it remains within the target animals burrows underground, and because the entrances to the burrow system are closed, the gas ultimately diffuses into the surrounding soil, with no more than trace quantities reaching the surface, well away from the respiration zone of operators or bystanders.

Skin contact with PRONTOX Wühlmausgas is prevented by wearing general-purpose protective gloves (plant protection) when applying/handling the product ready for application.

RMS comment: Taking in consideration the classification of the a.s./preparation as corrosive (R35), the use of protective clothing, gloves and eye/face protection is recommended.

B.6.14.1.3 Measurement of operator exposure (mixer/loader/applicator)

Measurement of operator exposure for the product PRONTOX Wühlmausgas is not required, since this plant protection product represents a ready-to-use repellent which is placed underground into target animal runs and tunnels and negligible exposure is expected.

B.6.14.2 Bystander exposure

B.6.14.2.1 Estimation of bystander exposure assuming personal protective equipment is not used

No exposure for bystanders is expected during the use of PRONTOX Wühlmausgas (see point B.14.1.2 above).

B.6.14.2.2 Measurement of bystander exposure

No exposure for bystanders is expected during the use of PRONTOX Wühlmausgas.

B.6.14.3 Worker exposure

As for operators and bystanders, worker exposure is not expected to occur.

B.6.14.3.1 Estimation of worker exposure assuming personal protective equipment is not used

See above for explanation.

B.6.14.3.2 Estimation of worker exposure assuming personal protective equipment is used

See above for explanation.

B.6.14.3.3 Estimation of worker exposure assuming personal protective equipment is used and using data generated on dislogeable residues under the proposed conditions of use

See above for explanation.

B.6.14.3.4 Measurement of worker exposure

See above for explanation.

B.6.15 Dislogeable residues

Not applicable, PRONTOX Wühlmausgas (calcium carbide) is not intended for direct application to growing crops.

B.6.15.1 Dislogeable residues – foliar

Not applicable.

B.6.15.2 Dislogeable residues – soil

Not applicable.

B.6.15.3 Dislogeable residues – indoor surface re-volatilization

Not applicable.

B.6.16 Epidemiology

In the literature observations on exposure of the general population or epidemiological studies in connection with the substance calcium carbide are not available.

B.6.17 Domestic animal/livestock safety

Calcium carbide is placed in tunnels and burrows of target pests in non-crop situations, away from buildings. No exposure of domestic animal/livestock is expected to occur.

B.6.18 Other/special studies

Other or special studies are not available.

B.6.19 References relied on

OECD data point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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