REACH

Hydrogen chloride

EC number: 231-595-7 | CAS number: 7647-01-0

Toxicological information

Toxicological Summary

Administrative data

Workers - Hazard via inhalation route

Systemic effects

Long term exposure

Hazard assessment conclusion:	no hazard identified

Acute/short term exposure

Hazard assessment conclusion:	no hazard identified

DNEL related information

Local effects

Long term exposure

Hazard assessment conclusion:	DNEL (Derived No Effect Level)
Value:	8 mg/m³
Most sensitive endpoint:	irritation (respiratory tract)

DNEL related information

DNEL derivation method:	other: Existing EU IOEL

Acute/short term exposure

Hazard assessment conclusion:	DNEL (Derived No Effect Level)
Value:	15 mg/m³
Most sensitive endpoint:	irritation (respiratory tract)

DNEL related information

DNEL derivation method:	other:

Workers - Hazard via dermal route

Systemic effects

Long term exposure

Hazard assessment conclusion:	no hazard identified

Acute/short term exposure

Hazard assessment conclusion:	no hazard identified

DNEL related information

Local effects

Long term exposure

Hazard assessment conclusion:	high hazard (no threshold derived)
Most sensitive endpoint:	skin irritation/corrosion

Acute/short term exposure

Hazard assessment conclusion:	high hazard (no threshold derived)
Most sensitive endpoint:	skin irritation/corrosion

Workers - Hazard for the eyes

Local effects

Hazard assessment conclusion:	medium hazard (no threshold derived)

Additional information - workers

Toxicologicol information (hydrogen chloride gas and hydrochloric acid):

Endpoint data are partly based on studies with hydrochloric acid, partly based on studies with hydrogen chloride gas. Hydrogen chloride gas, in contact with water in air, on skin or mucous membranes and in biological media will immediately dissociate to form hydrochloric acid, with a pH dependent on the concentration. Therefore, studies with hydrogen chloride gas and studies with hydrochloric acid are believed to be mutually exchangeable for toxicological hazard identification. Quantitative assessments are based on the actual dose of HCl or, where appropriate, on the worst-case assumption that HCl gas will be absorbed in water or biological media to the highest possible concentration of hydrochloric acid.

Health

The substance only causes local dermal and/or pulmonary effects and no systemic effects.

Inhalation exposure:

Pulmonary uptake is very unlikely to happen, as the substance will immediately start to irritate when it enters the respiratory tract.

Dermal exposure:

Dermal absorption is unlikely. It is most likely that anyone exposed via the skin will react to the burning/itching skin sensation and will automatically start to wear PPE. Concentrated hydrogen chloride is corrosive to skin. At concentrations lower than those that cause corrosion, hydrogen chloride will have no effect on systemic toxicity. Dermal exposures should be regulated on the basis of risk to local effects (irritation, corrosion) on the skin.

Further tests on this compound are therefore not necessary; this data requirement is not triggered.

Use of the IOEL in place of developing a DNEL

In Appendix R.8-13 of the Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health (v.2.1, Nov.2012, ECHA) it is noted that:

'When an EU IOEL exists the registrant may, under conditions as described below, use the IOEL in place of developing a DNEL. A registrant is allowed to use an IOEL as a DNEL for the same exposure route and duration, unless new scientific information that he has obtained in fulfilling his obligations under REACH does not support the use of the IOEL for this purpose. This could be because the information obtained is more recent than the information that was used to support setting the IOEL at EU level and because it leads to another value being derived which requires different risk management measures (RMMs) and operational conditions (OCs)'.

The SCOEL has derived a STEL and an 8 hour TWA for Hydrogen chloride (SCOEL/SEG/SUM/49, 1994).

Health Significance:

Hydrogen chloride gas and solution aerosols when absorbed from the respiratory tract, forms chloride ions and becoming indistinguishable from chloride derived from dietary sources.

The acute toxicity of hydrogen chloride gas and aerosol is high: 30 minute LC50 values of 4701 ppm (7051 mg/m3) and 5666 ppm (8500 mg/m3) have been determined for the gas and aerosol respectively, in rats and mice (Darmer et al, 1974). The principal effects seen in acute toxicity studies were irritation of the eyes, upper respiratory tract and exposed areas of skin. When inhaled at high concentrations, the gas caused necrosis of the epithelial lining of the naso-tracheal passages as well as alveolar emphysema, atelectasis and lung oedema. Repeated exposure of rabbits and guinea pigs to hydrogen chloride gas at 100 ppm (152 mg/m3) for 6h/d for 5 days resulted in only slight respiratory difficulties and eye and nasal irritation (Jones, 1972). Blood haemoglobin levels were slightly reduced.

Exposure of a monkey, rabbits and guinea pigs to 30 ppm (46 mg/m3), 6h/d for 4 weeks caused no adverse effects or morphological changes (Machle et al, 1942).

No data are available on genotoxicity of hydrogen chloride. In a well-conducted inhalation carcinogenicity study, rats were exposed to 10 ppm (15 mg/m3) hydrogen chloride gas, 6h/d 5d/w for their lifetime (Albert et al, 1982; Sellakumar et al, 1985).No serious irritating effects in the nasal epithelium were observed. None of the treated animals developed any pre-neoplastic or neoplastic lesions indicating a lack of carcinogenic activity.

No data on reproductive toxicity or teratogenicity are available.

Data on the human health effects are generally limited to poorly reported secondary sources. Exposure of male volunteers to 50 - 100 ppm (76 - 152 mg/m3) hydrogen chloride gas for 1 hour was claimed to be barely tolerable (Henderson and Haggard, 1943). Irritation of the throat resulted from brief exposure to 35 ppm (53 mg/m3) and 10 ppm (15 mg/m3) was considered to be the maximal acceptable concentration for prolonged exposure.

Recommendation:

The well-conducted carcinogenicity study reported by Albert et al (1982) and Sellakumar et al (1985), establishing that no serious irritating effects were observed in rats exposed to 10 ppm (15 mg/m3) hydrogen chloride, was considered to be the best available basis for proposing occupational exposure limits. An uncertainty factor of 2 was applied to allow for the absence of controlled human data. The recommended 8-hour TWA is 5 ppm (8 mg/m3). A STEL (15 mins) of 10 ppm (15 mg/m3) was proposed to limit peaks of exposure which could result in irritation.

No "skin" notation was considered necessary.

At the levels recommended, no measurement difficulties are foreseen.

No evidence of adverse effects on health has been found at the workplace following occupational exposure concentrations of about 5 ppm (8 mg/m3) over several years. Experimental studies appear consistent with this figure.

DNEL for acute exposure

Inhalation exposure

The STEL derived by the SCOEL will be used as DNEL for acute inhalation exposure: 10 ppm (15 mg/m3) for an exposure duration of 15 min.

DNEL for long-term exposure

Inhalation exposure

The 8 hours TWA derived by the SCOEL will be used as DNEL for long-term inhalation exposure: 5 ppm (8 mg/m3).

Skin and eye corrosive (due to classification)

Hydrogen chloride is proposed to be classified as a skin corrosive substance. However, it is not possible to derive a DNEL based on the available data. According to the REACH guidance on information requirements and chemical safety assessment, Part E: Risk Characterisation, a qualitative risk characterisation should be performed for this endpoint. In order to guarantee 'adequately control of risks', it is necessary to stipulate risk management measures that prevent dermal exposure that will cause skin irritation.

Eye corrosive (due to classification)

The substance is classified as an eye irritant. The available human and animal data do not allow a quantitative approach. According to the REACH guidance on information requirements and chemical safety assessment, Part E: Risk Characterisation, a qualitative risk characterisation should be performed for this endpoint. In order to guarantee 'adequately control of risks', it is necessary to stipulate risk management measures that prevent eye irritation, i.e. goggles are considered to be adequate risk management measures for worker protection.

General Population - Hazard via inhalation route

Systemic effects

Long term exposure

Hazard assessment conclusion:	no hazard identified

Acute/short term exposure

Hazard assessment conclusion:	no hazard identified

DNEL related information

Local effects

Long term exposure

Hazard assessment conclusion:	DNEL (Derived No Effect Level)
Value:	8 mg/m³
Most sensitive endpoint:	irritation (respiratory tract)

Acute/short term exposure

Hazard assessment conclusion:	DNEL (Derived No Effect Level)
Value:	15 mg/m³
Most sensitive endpoint:	irritation (respiratory tract)

DNEL related information

DNEL derivation method:	other: Based on existing EU IOEL

General Population - Hazard via dermal route

Systemic effects

Long term exposure

Hazard assessment conclusion:	no hazard identified

Acute/short term exposure

Hazard assessment conclusion:	no hazard identified

DNEL related information

Local effects

Long term exposure

Hazard assessment conclusion:	high hazard (no threshold derived)
Most sensitive endpoint:	skin irritation/corrosion

Acute/short term exposure

Hazard assessment conclusion:	high hazard (no threshold derived)
Most sensitive endpoint:	skin irritation/corrosion

General Population - Hazard via oral route

Systemic effects

Long term exposure

Hazard assessment conclusion:	no hazard identified

Acute/short term exposure

Hazard assessment conclusion:	no hazard identified

DNEL related information

General Population - Hazard for the eyes

Local effects

Hazard assessment conclusion:	medium hazard (no threshold derived)

Additional information - General Population

In the OECD SIDS 2002 Hydrogen Chloride SIAR it was concluded for human health:

Hydrogen chloride will rapidly dissociate and its effects are thought to be a result of pH change (local deposition of H^+) rather than effects of hydrogen chloride/hydrochloric acid. The acute oral LD50 values were determined to be 238-277 mg/kg bw for female rats, and the inhalation LC50 values were determined to be 23.7-60.9 mg/L/5min, 5.7-7.0 mg/L/30min and 4.2-4.7 mg/L/60min for rats, 20.9 mg/L/5min, 3.9 mg/L/30min and 1.7 mg/L/30min for mice.

Hydrogen chloride is corrosive to the skin and severe effects can be expected from exposure to the eyes. No skin sensitisation has been reported. There are few detailed studies reported for human exposure. The irritation of hydrogen chloride to mucous is so severe that workers evacuate from the work place shortly after detecting its odor. A relation between concentrations from accidental exposure and health effects have not been reported in detail.

For repeated dose toxicity, local irritation effects were observed in the groups of 10 ppm and above in a 90-day inhalation study in compliance with FDA-GLP. The NOAEL for systemic toxicity has been determined to be 20 ppm for rats and mice. For genetic toxicity, a negative result has been shown in the Ames test. A positive result, which is considered to be an artefact due to the low pH, has been obtained in a chromosome aberration test using Hamster ovary cells. The effects of low pH in in vitro studies are not a problem in vivo as the proton level is regulated systemically. For carcinogenicity, no pre-neoplastic or neoplastic nasal lesions were observed in a 128-week inhalation study with SD male rats at 10 ppm hydrogen chloride gas. No evidence of treatment related carcinogenicity was observed either in other animal studies performed by inhalation, oral or dermal administration. In humans, no association between hydrogen chloride exposure and tumour incidence was observed. No reliable studies have been reported regarding toxicity to reproduction and development in animals after oral, dermal or inhalation exposure to hydrogen chloride/hydrochloric acid. Because protons and chloride ions are normal constituents in the body fluid of animal species, low concentrations of hydrogen chloride gas/mist or solution do not seem to cause adverse effects to animals. In fact, the cells of gastric glands secrete hydrochloric acid into the cavity of the stomach and orally administered sulphuric acid, which results in pH change as well, did not cause developmental toxicity to laboratory animals. These facts indicate that hydrogen chloride/hydrochloric acid is not expected to have developmental toxicity. In addition, no effects on the gonads were observed in a good quality 90 -day inhalation study up to 50 ppm.