

# **Phosgene Safety Practices**

## **for design, production and processing**

### **Part 3**

#### **Related information and special Safety Practices**

#### **Section 4: Regulatory levels and limits for phosgene**

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#### **III caveat**

The information herein is presented in good faith, is believed to be accurate and reliable, but may well be incomplete and /or not applicable to all conditions or situations that may be encountered.

No representation, guarantee or warranty is made as to the accuracy, reliability or completeness of this report, or that the application or use of any of the information, analysis, methods and recommendations herein will avoid, reduce or ameliorate hazard, accidents, losses, damages or injury of any kind to persons or property. Readers are therefore cautioned to satisfy themselves as to the applicability and suitability of said information, for the purposes intended, prior to use.

# **1. Emergency response levels, workplace limits and community Limits**

## **1.1 Introduction**

Given the potential for serious and large-scale effects, there is a need for scientifically based risk assessments for determining appropriate on-site control measures, as well as off-site emergency contingency plans and land-use development decisions.

There are multiple national regulatory authorities with the statutory responsibility for providing land-use planning advice in the vicinity of major accident hazard sites. The advice given in the vicinity of sites, which have toxic substances in their inventory, is based on a quantified assessment of the individual risk of receiving a specified amount of the toxic substance. This requires a consistent, reliable and transparent understanding of the major hazard toxicology of the substance concerned. With regard to phosgene several harmonised approaches to Emergency Planning have been made.

In this context, Acute Exposure Guideline Levels (AEGLs) or the evolving European Acute Exposure Threshold Levels (EU AETLs) have to be addressed in case of accidental chemical release. These levels can be adapted to the various national regulations addressing land use planning and emergency situations.

These procedures have in common that they represent thresholds exposure levels for the general population. They are applicable to exposure periods ranging from 10 to 480 minutes. They categorize the following levels, defined by the degree of the severity of toxic effect:

- Level 1: notable discomfort and irritation;
- Level 2: irreversible or other serious long-lasting health effects, including an impairment of escape;
- Level 3: life-threatening health effects or death.

EU-AETLs address in addition a Level of Distinct Sensory Awareness (LDSA). The paradigms used for these derivations are detailed elsewhere (NRC, 2001).

Recent derivations are the US-AEGL values, the EU-AETL values and the ERPG (Emergency Response Planning Guidelines). The derivation of the NIOSH-IDLH (National Institute of Occupational Safety and Health - Immediately Dangerous to Life or Health) values received a substantially less detailed scrutiny. The IDLH values are limited to workers and not the general public. IDLHs and ERPGs are based on the effects that might occur as a consequence of a 30-minute and 1-hour exposure respectively, whereas the AEGL- and AETL-values range from 10-minutes to 8-hours. A summary of the more recently derived emergency limit values of phosgene is provided later in Table 1.

## 1.2 US Acute Exposure Guideline Levels (AEGL)

Briefly, AEGLs represent threshold exposure limits for the general public and are applicable to emergency exposure periods of 10 and 30 minutes, 1 hour, 2 hours, 4 hours and 8 hours. The AEGL-2 and AEGL-3 levels and AEGL-1 levels as appropriate will be developed for each of the exposure periods and will be distinguished by varying degrees of severity of toxic effects. It is believed that the recommended exposure levels are applicable to the general population, including infants and children and other individuals who may be sensitive and susceptible. The three AEGLs have been defined as follows:

- AEGL-1 is the airborne concentration (expressed as ppm or mg/m<sup>3</sup>) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic, non-sensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.
- AEGL-2 is the airborne concentration (expressed as ppm or mg/m<sup>3</sup>) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects, or an impaired ability to escape.
- AEGL-3 is the airborne concentration (expressed as ppm or mg/m<sup>3</sup>) of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.

Airborne concentrations below the AEGL-1 represent exposure levels that could produce mild and progressively increasing odour, taste and sensory irritation, or certain non-symptomatic, non-sensory effects.

With increasing airborne concentrations above each AEGL level, there is a progressive increase in the likelihood of occurrence and the severity of effects described for each corresponding AEGL level.

Although the AEGL values represent threshold levels for the general public, including sensitive sub-populations, it is recognised that certain individuals, subject to unique or idiosyncratic responses, could experience the effects described at concentrations below the corresponding AEGL level.

### 1.3 EU Acute Exposure Threshold Levels (AETL)

In the context of the harmonised implementation of the SEVESO II Directive on the control of major-accident hazards involving dangerous substances, phosgene has been re-evaluated in the ACUTEX project.

One objective of ACUTEX is to develop a Technical Guidance Document (TGD) for establishing European Acute Exposure Threshold Levels (EU-AETLs) in case of accidental chemical release. The TGD is used as a supportive tool to derive at AETLs, which can be adapted to the various national situations for land use planning or emergency situations. AETLs represent thresholds exposure levels for the general population and are applicable to exposure periods ranging from 10 to 240 minutes. Three levels (AETL-1, -2, -3) and a Level of Distinct Sensory Awareness (LDSA) are proposed for six exposure periods (10, 30, 60, 120, 240 and 480 minutes). They are defined as follow:

- AETL-3b is the maximum airborne concentration at which it is predicted the general population could be exposed up to a specified exposure time without experiencing life threatening health effects or death. With the distinction of AETL-3a: concentration at which it is predicted that a certain percent of the general population will die.
- AETL-2 is the maximum airborne concentration at which it is predicted the general population could be exposed up to a specified exposure time without experiencing or developing irreversible or other serious adverse health effects including symptoms that could lead to impairment to escape.
- AETL-1 is the maximum airborne concentration at which it is predicted the general population could be exposed up to a specified exposure time without experiencing more than mild and reversible adverse health effects.
- LDSA: the maximum airborne concentration at which it is predicted the general population could be exposed up to a specified exposure time without experiencing sensory stimuli (e.g. odour) that may lead to complaints, concerns or even panic.

AETLs are developed to protect the general population that is considered to contain all persons in the general public that may be potentially exposed (e.g. the elderly, the young, the pregnant and the diseased). This includes susceptible but excludes hyper-susceptible (persons that are in a very unstable health situation or do have a very specific pre-conditions (e.g. allergic to a specific respiratory sensitizer).

## 1.4 Summary of AEGL and AETL values

The derived AEGL and AETL values, including the major workplace limit values for a work-daily exposure of 8-hours, for the various levels of effects and different durations of exposure are summarised in Table 1.

Data were insufficient for deriving AEGL-1 values, although in the EU an LSDA was derived based on odour perception. Chemical pneumonia in rats was used as the basis for AEGL-2 (Gross study) and a no-effect-level for death in rats and mice was used for AEGL-3 and AETL-3, respectively.

**Table 1:** Summary of Emergency Response Guidance Levels (all concentrations in ppm)

	10-min	30-min	60-min	2-hour	4-hour	8-hour
AEGL – 1 <sup>a</sup> (Non disabling)	NR	NR	NR	NA	NR	NR
AEGL - 2 (Disabling)	2.0	0.67	0.33	NA	0.07	0.033
AEGL - 3 (Lethal)	5.0	1.7	1.3	NA	0.33	0.16
ERPG - 1 (Non disabling)	NA	NA	NR	NA	NA	NA
ERPG -2 (Disabling)	NA	NA	0.5	NA	NA	NA
ERPG - 3 (Lethal)	NA	NA	1.5	NA	NA	NA
LDSA	16					
AETL – 1 <sup>b</sup> (Non disabling)	2.5	0.73	0.34	0.16	0.072	0.033
AETL -2 (Disabling)	4.5	1.3	0.62	0.29	0.13	0.061
AETL-3a (@01/ 05/50)	22/ 28/53	6.4/ 8.3/15	2.9/ 3.8/7.1	1.3/ 1.7/3.2	0.62/ 0.80/1.5	0.28/ 0.37/0.68
AETL -3b (Lethal)	7.3	2.1	0.97	0.43	0.21	0.093
NIOSH-IDLH	2					

*For Abbreviations / Acronyms see also §5.*

<sup>a</sup> Revised in 2009 (document status: draft),

<sup>b</sup> Non-binding draft status

NA: Not applicable, NR: Not recommended due to insufficient data

**AEGL:** Last updated March 3, 2006. The US National Research Council has developed guidelines as to how AEGLs are derived. Documents are published by the US EPA Office of Pollution Prevention and Toxics (OPPT).

**AETL:** non-legally binding European limit, last updated October 2005.

**AETL-3b** maximum airborne concentration at which it is predicted the general population could be exposed up to a specified exposure time without experiencing life threatening health effects or death. With the distinction of AETL-3a: concentration at which it is predicted that a certain percent of the general population will die. ##/## represents the respective percentage at 0.1%/5%/50%.

**ERPG:** by AHIA (American Industrial Hygiene Association) last updated in March 2002.

**NIOSH-IDLH** NIOSH recommended exposure limit to ensure that a worker can escape from an exposure condition that is likely to cause death or immediate or delayed permanent adverse health effects or prevent escape from the environment. IDLHs were based on the effects that might occur as a consequence of a 30-minute exposure

## 1.5 Provisional Advisory Levels (PALs) for phosgene

PALs are provisional values that will not be promulgated, nor have been formally issued as regulatory guidance. Rather, they are intended to be used at the discretion of risk managers in emergency situations based on site-specific conditions. As provisional estimates, they may be continually updated as new data or information become available.

The Provisional Advisory Level (PAL) protocol was applied to estimate inhalation exposure limits for phosgene (CG). Three levels (PAL 1, 2 and 3), distinguished by severity of toxic effects, are developed for 24-hour, 30-day, 90-day and 2-year durations of potential drinking water and inhalation exposures for the general public. For background on the PAL program and a description of the methodology used in deriving PALs, the reader is referred to an accompanying paper (Glass et al., 2009).

Data on humans are limited to occupational exposures or accounts from the use of phosgene as a chemical warfare agent in World War I. Animal studies with phosgene show a steep dose-response curve for pulmonary oedema and mortality, with little species variability in effects. Although immediately upon exposure lacrimation and upper respiratory irritation can occur, the main effect in the target organ, a progressive pulmonary oedema, occurs after a latency period of 1–24 hours.

PAL estimates were approved by the Expert Consultation Panel for Provisional Advisory Levels in May 2007. Exposure limits for oral exposure to phosgene are not developed due to insufficient data. PAL estimates for inhalation exposure to phosgene are presented as follows:

**Table 2:** Summary of Provisional Advisory Levels (PALs) for Phosgene (CG)  
(all concentrations are in ppm)

Severity level <sup>a</sup>	24 hour	30 day	90 day	2 year <sup>b</sup>
PAL-1 (Non disabling)	0.0017	0.0006	0.006	0.0006
PAL-2 (Disabling)	0.0033	0.0012	0.0012	0.0012
PAL-3 (Lethal)	0.0022	NA	NA	NA

*For Abbreviations / Acronyms see also §5.*

<sup>a</sup> The PAL severity levels 1, 2 and 3 are similar to the categorisation system as for AEGL values.

<sup>b</sup> The 30- and 90-day PAL values were also accepted as the 2-year PAL 1 and 2 values because severity of lesions in the key study did not increase when exposures were extended from 4 weeks to 12 weeks.

**NA:** Data were not available for deriving 30-day, 90-day and 2-year PAL 3 values.

## 2. Working place limits

Occupational exposure limits represent the time-weighted average (TWA) concentration for a conventional 8-hour workday and a 40-hour workweek to which healthy, adult workers are day-by-day exposed to.

In the US the legally binding limit is the TLV (Threshold Limit Value). Short-term exposures are regulated by STELs (Short-Term Exposure Limits) which is defined as a 15-minute TWA exposure which should not be exceeded any time during a workday even if the 8-hour TWA is within the TLV-TWA. There should be at least 1 hour between successive exposures in this range with maximal 4 excursions per shift.

Workplace limits for the U.S., EU and Germany are summarised in Table 3.

*Table 3: Summary of Occupational Exposure Limits (all concentrations are in ppm)*

Organisation	Designation	Value
ACGIH	TLV (TWA)	0.1
EU-SCOEL	IOELV (TWA)	0.1 <sup>a</sup>
EU-SCOEL	IOELV (STEL)	0.41 <sup>a</sup>
DFG-MAK	MAK (TWA)	0.1
DFG-MAK	MAK (STEL)	0.41

<sup>a</sup> Revised in 2009 (document status: draft)

For Abbreviations / Acronyms see also §5.

<b>ACGIH</b>	<i>American Conference of Governmental Industrial Hygienists</i>
<b>DFG-MAK:</b>	<i>German Research Foundation (Deutsche Forschungsgemeinschaft) Maximal Workplace Concentrations, List of MAK and BAT values</i>
<b>IOELV</b>	<i>Indicative Occupational Exposure Limit Values. IOELVs are European legal limits which are set to protect workers in the European Union. For phosgene the IOELV was published in the Directive 2000/39/EEC (98/24/EEC) as of June 8, 2000.</i>
<b>SCOEL</b>	<i>Scientific Committee on Occupational Exposure Limits</i>
<b>STEL</b>	<i>Short-Term Exposure Limit which is specified as follows: the concentration to which it is believed that workers can be exposed continuously for a short period of time without suffering from 1) irritation, 2) chronic or irreversible tissue damage, or 3) narcosis of sufficient degree to increase the likelihood of accidental injury, impair self-rescue or materially reduce work efficiency. A STEL is defined as a 15-minute TWA exposure which should not be exceeded any time during a workday even if the 8-hour TWA is within the TLV-TWA. There should be at least 1 hour between successive exposures in this range with maximal 4 excursions per shift.</i>
<b>TLV (TWA)</b>	<i>Threshold Limit Value (Time Weighted Average) is specified as follows: the time-weights-average concentration for a conventional 8-hour workday and a 40-hour workweek, to which it is believed that nearly all workers may be repeatedly exposed, day after day, with adverse effect.</i>



### 3. Community exposure limits

Community exposure limits (Inhalation Reference Concentrations, RfCs) have been derived for phosgene for continuous, lifetime exposure of the general public (for details see Gift et al., 2008). Permissible intermittent exposure excursions for maximal 1-hour have been defined by the Acute Reference Level (Acute REL). The acute REL is an exposure that is not likely to cause adverse effects in a human population, including sensitive subgroups, exposed to that concentration for one hour on an intermittent basis.

They are shown in Table 4.

*Table 4: Summary of Community Exposure Limits (all concentrations are in ppm)*

Organisation	Exposure Limit	Value (in ppm)
US-EPA IRIS	RfC	$7.5 \cdot 10^{-5}$
OEHHA	CalEPA-Acute REL	$1 \cdot 10^{-3}$

*For Abbreviations / Acronyms see also §5.*

**US-EPA IRIS** *Integrated Risk Information System, By EPA,  
last update January 31, 2006.*

**OEHHA** *California EPA / Office of Environmental Health Hazard Assessment*

**Acute REL** *Air-Hot Spots-Acute Reference Levels (last update March 1999).*

*The health-based acute REL is applicable to risk characterisation of air releases, defined in Health and Safety Code 44303.*



#### 4. Links to regulatory websites

AEGL:	<a href="http://www.epa.gov/oppt/aegl/results7.htm">http://www.epa.gov/oppt/aegl/results7.htm</a> ; <a href="http://www.nap.edu">www.nap.edu</a>
AETL:	<a href="http://www.acutex.info/">http://www.acutex.info/</a>
CalEPA:	<a href="http://www.oehha.ca.gov/air/acute_rels/allAcRELs.html">http://www.oehha.ca.gov/air/acute_rels/allAcRELs.html</a>
EPA-IRIS:	<a href="http://www.epa.gov/iris/subst/0487.htm">http://www.epa.gov/iris/subst/0487.htm</a>
NIOSH-IDLH:	<a href="http://www.cdc.gov/niosh/idlh/intridl4.html">http://www.cdc.gov/niosh/idlh/intridl4.html</a>

#### 5. Abbreviations and acronyms

ACGIH	American Conference of Governmental Industrial Hygienists
ACUTEX	(Acute Exposure) project a subsidiary of CEFIC aimed at the development of innovative approaches to define AETLs
AEGL	Acute Exposure Guideline Level The US National Research Council has developed guidelines as to how AEGLs are derived. Documents are published by the UE Environmental Protection Agency (EPA), Office of Pollution Prevention and Toxics (OPPT).
AETL	Acute Exposure Threshold Level (EU) non-legally binding European limit,
BAT	German Biological Tolerance Values (Biologische Arbeitsstoffoleranzwerte)
CalEPA	California USA EPA
CEFIC	European Chemical Industry Council
DFG	German Research Foundation (Deutsche Forschungsgemeinschaft)
EPA	Environmental Protection Agency (US)
ERPG	Emergency Response Planning Guide AHIA (American Industrial Hygiene Association) last updated in March 2002
EU	European
IDLH	Immediately Dangerous to Life or Health NIOSH recommended exposure limit to ensure that a worker can escape from an exposure condition that is likely to cause death or immediate or delayed permanent adverse health effects or prevent escape from the environment. IDLHs were based on the effects that might occur as a consequence of a 30-minute exposure.
IOELV	Indicative Occupational Exposure Limit Values European legal limits which are set to protect workers in the European Union. For phosgene the IOELV was published in the Directive 2000/39/EEC (98/24/EEC) as of June 8, 2000.
IRIS	Integrated Risk Information System, By EPA.
LDSA	Level of Distinct Sensory Awareness
MAC	Maximum Allowable Concentrations
MAK	German Maximum Allowable Concentrations (Maximale Arbeitsplatzkonzentrationen)
mg/m <sup>3</sup>	concentration in milligram per cubic meter
NIOSH	National Institute of Occupational Safety and Health (US)
OEHHA	Office of Environmental Health Hazard Assessment (California USA EPA)
OPPT	Office of Pollution prevention and Toxics
PAL	Provisional Advisory Levels
PPM	Parts per Million
REL	Recommended Exposure Limit

RfC	Inhalation Reference Standard lifetime continuous exposure of the general public
SCOEL	Scientific Committee on Occupational Exposure Limits (EU)
SEVESO II	Council Directive 96/82/EC of 9 December 1996 known as the SEVESO II Directive on the control of major-accident hazards involving dangerous substance
STEL	Short-Term Exposure Limits (US) The concentration to which it is believed that workers can be exposed continuously for a short period of time without suffering from 1) irritation, 2) chronic or irreversible tissue damage, or 3) narcosis of sufficient degree to increase the likelihood of accidental injury, impair self-rescue or materially reduce work efficiency. It is defined as a 15-minute TWA exposure which should not be exceeded any time during a workday even if the 8-hour TWA is within the TLV-TWA.
TGD	Technical Guidance Document Methodology with associated software tools.
TLV	Threshold Limit Value (legally binding limit in US)
TWA	Time Weighted Average
TLV (TWA)	Threshold Limit Value (Time Weighted Average) Specified as the time-weights-average concentration for a conventional 8-hour workday and a 40-hour workweek, to which it is believed that nearly all workers may be repeatedly exposed, day after day, with adverse effect.