

Environmental Assessment Level (EAL) Support Document

## Dossier of substances included within our 2025 EAL Consultation

Date: January 2025

Version: 1

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## Introduction

This document provides a short technical background to the decisions that underpin the derivation of the new Environmental Assessment Levels (EAL) in the Environment Agency’s consultation.

The document briefly summarises the toxicity to human health, primarily via inhalation, of priority substances in air following short-term and long-term exposure. Substances have been prioritised for EAL development based on their hazard to health, the availability of information, and following discussions with Carbon Capture and Storage Association.

Toxicity summaries are provided for each of the seven substances presented in the consultation. Key individual references for each substance are provided at the end of each summary. A list of abbreviations and definitions is provided at the end of the document.

## Practical Compliance Constraints on a Short Term EAL

Depending on the toxicity of a substance, both a short- and long-term EAL may be appropriate, reflecting adverse effects to health over different exposure periods. Notwithstanding the possible differences in the toxicology (dose-response and endpoints) between potential short-term and long-term health effects, there is a practical limit on the value of a short-term EAL if the long-term EAL or statutory value is not to be exceeded. The limit depends on whether the long-term EAL is based on either a threshold or a non-threshold health effect.

**Threshold Effects**

The long-term EAL is usually based on a 24-hour time weighted mean concentration. The highest short-term air concentration that will not exceed the long-term EAL can be estimated by multiplying the long-term value by 24 for a short-term hourly upper limit. There is no short-term daily upper limit.

**Non-thresholded Effects**

The long-term EAL is usually based on the annual mean (either 90% of 1-hour values or all 24-hour values averaged over a year). The highest short-term air concentration that will not exceed the long-term EAL or statutory value can be estimated by multiplying the long-term value by either 365 or 8,760 (24 \* 365) for a short-term daily or hourly upper limit, respectively.

Any proposed short-term EAL should be less than the appropriate daily or hourly upper limit to be useful without any practical constraint imposed by the need to ensure compliance with the long-term EAL or statutory value. If a recommended short-term EAL is equal to or exceeds the upper limit, then it is assumed that compliance with the long-term EAL will be protective of short-term exposures and health effects.

# Aminomethyl propanol (CAS Number 124-68-5)

Aminomethyl propanol or 2-amino-2-methylpropan-1-ol (AMP) is a linear aliphatic alkanolamine with a primary amine group. It is a white solid at room temperature, becoming a liquid above 30-31˚C, and is miscible in water (ECHA 2023). It is used in water treatment products, coating products, adhesives and sealants, inks and toners, laboratory chemicals, metal working fluids, and as a pH regulator in cosmetics and personal care products. New uses include as a solvent in post-combustion carbon capture systems. It is registered for use under EU REACH for ≥ 1 000 to < 10 000 tonnes.

Studies on the effects of inhalation exposure are limited (Burnett et al. 2009, ECHA 2023). Experimental oral animal studies and human clinical studies (where AMP is present in medicines) reported limited adverse effects following exposure. Undiluted, AMP caused corrosion to the eyes and severe skin irritation but was not a sensitiser. After acute and chronic oral exposure using pH adjusted forms such as AMP hydrochloride (AMP-HCl), the liver was the target organ as increased enzyme activity and histopathological alterations were reported. AMP also caused damage and haemorrhage in the gastrointestinal mucosa.

### Recommended Environmental Assessment Level in Air

|  |  |
| --- | --- |
| Long-term EAL | 0.000009 mg/m3 (9 ng/m3) as a 24-hour mean |
| Short-term EAL | None (practical compliance) |

### Supporting Information

While there were uncertainties with respect to the inhalation studies summarised by Burnett et al. (2009) using hairspray formulations, the doses were lower than those estimated by route-to-route extrapolation from oral data. Of the three sub-chronic studies reported (unpublished inhalation study from 1977, unpublished inhalation study from 1980, and unpublished inhalation study from 1981, all cited in Burnett et al. 2009), the high dose in the 1980 study of 0.057 mg/m3 AMP was considered a LOAEC. Due to the order of magnitude dose spacing in the 1980 study, the concentration of 0.026 mg/m3 from the 1977 study, from the group with static air conditions, was considered to provide a suitable POD for derivation of the EAL. This POD was considered protective for the local effects of pulmonary alveolitis reported in the 1980 study and potential systemic effects demonstrated by impacts on decreases in uterine weight and increases in heart and liver weight to bodyweight ratio reported in the 1981 study.

A long-term EAL of 0.000009 mg/m3 (9 ng/m3) as a 24-hour mean is recommended to protect the public. It was derived from the concentration of 0.026 mg/m3 in the 1977 unpublished inhalation study cited by Burnett et al. (2009), which was adjusted for continuous exposure (100 minutes total administration time divided by 1440 minutes per day) to give a value of 0.0018 mg/m3. The modified POD was then divided by a total UF of 200 (a factor of 10 for interspecies variability, a factor of 10 for intraspecies variability, and a factor of 2 for use of a sub-chronic study). This EAL is considered protective of both local and systemic effects.

A short-term EAL was not recommended due to constraints for practical compliance.

### References

[BURNETT C.L., BERGFELD W.F., BELSITO D.V., KLAASSEN C.D, MARKS J.G., SHANK R.C., SLAGA T.J., SNYDER P.W., ANDERSEN A., 2009. Final Amended Report on Safety Assessment on Aminomethyl Propanol and Aminomethyl Propanediol. International Journal of Toxicology, 28(6S), 141S-161S.](https://journals.sagepub.com/doi/pdf/10.1177/1091581809350932#:~:text=The%20Cosmetic%20Ingredient%20Review%20Expert,described%20in%20this%20safety%20assessment.&text=Synonyms%20and%20trade%20names%20for,be%20found%20in%20Table%201.)

[ECHA, 2023. 2-amino-2-methylpropanol. CAS No. 124-68-5. [accessed May 2023]](https://echa.europa.eu/registration-dossier/-/registered-dossier/11767/1/2)

# 2. Diethanolamine (CAS Number 111-42-2)

Diethanolamine or 2-(2-hydroxyethylamino)ethanol (DEA) is a linear aliphatic alkanolamine with one secondary amine group. It is a colourless, crystalline solid in its pure form at room temperature, but its tendency to absorb water leads to it commonly occurring as a white liquid with a mild ammoniacal odour (AICIS 2013). DEA is used as a corrosion inhibitor and a surface-active agent in metal working fluids, fuels, cosmetic formulations, paints, and inks. New uses include as a solvent in post-combustion carbon capture systems (Xue et al. 2017). DEA is registered for use under EU REACH for ≥ 100,000 tonnes.

Acute inhalation exposure in rodents has resulted in lethal and sub-lethal effects, including lethargy, increased breathing rate, increased blood pressure, congestion in the lung and discolouration in the kidney and thymus. Longer term animal studies have shown effects on the kidneys and liver, as well as effects including tremors, extreme weight loss, abnormal posture, and a dose dependent increase in microcytic anaemia (TCEQ 2018, USEPA 2012).

### Recommended Environmental Assessment Level in Air

|  |  |
| --- | --- |
| Long-term EAL | 0.003 mg/m3 as a 24-hour mean |
| Short-term EAL | None (practical compliance) |

### Supporting Information

A long-term EAL of 0.003 mg/m3 as a 24-hour mean was derived from a low concentration 90-day inhalation study in rats (Gamer et al. 2008), from which a NOAEC of 3 mg/m3 was identified for increased liver weight. This was adjusted for continuous exposure (multiplying by (6/24) and (5/7)) to give a POD of 0.54 mg/m3. A total UF of 200 (a factor of 10 for interspecies variability, a factor of 10 for intraspecies variability and a factor of 2 for extrapolation from a sub-chronic to chronic duration) was applied to this. This is considered protective of all potential health effects including respiratory effects and carcinogenicity.

A short-term EAL was not recommended due to constraints for practical compliance.

### References

AICIS, 2013. Ethanol, 2,2’-iminobis-: Human health tier II assessment – IMAP Single Assessment Report. Australia: Australian Industrial Chemicals Introduction Scheme.

GAMER A.O., ROSSBACHER R., KAUFMANN W., VAN RAVENZWAAY B., 2008. The Inhalation toxicity of di- and triethanolamine upon repeated exposure. FOOD AND CHEMICAL TOXICOLOGY, 46, 2173 – 2183.

TCEQ, 2018. Diethanolamine (CAS Registry Number 111-42-2) and Triethanolamine (CAS Registry Number 102-71-6), Development Support Document. Texas, USA: Texas Commission on Environmental Quality.

USEPA, 2012. Provisional Peer-Reviewed Toxicity Values for Diethanolamine (CASRN 111-42-2). Cincinnati, USA: United States Environmental Protection Agency.

XUE B., YU Y., CHEN J., LUO X., WANG M., 2017. A comparative study of MEA and DEA for post-combustion CO2 capture with different process configurations. INTERNATIONAL JOURNAL OF COAL SCIENCE AND TECHNOLOGY, 4(1), 15–24.

# 3. Diethylamine (CAS Number 109-89-7)

Diethylamine or N-ethylethanamine (DiEA) is a linear aliphatic amine with a secondary amine group. It is a colourless liquid at room temperature with an ammonia-like odour and is miscible in water. It has a predicted half-life of <1 day in the atmosphere (OECD 2013). DiEA is mainly used in the production of the corrosion inhibitor N,N-diethylethanolamine, pesticides, insect repellents, and rubber products (NTP 2011). New uses include as a solvent in post-combustion carbon capture systems (Lathouri et al. 2022).

DiEA vapours are strong irritants to the eyes, nose, and throat (NTP 2011). In animals, it causes an increase in incidences of lesions of the nose in mice and rats and decreased sperm motility in male rats and mice following long-term inhalation exposure. DiEA is not considered carcinogenic or genotoxic.

### Recommended Environmental Assessment Level in Air

|  |  |
| --- | --- |
| Long-term EAL | 0.033 mg/m3 as a 24-hour mean |
| Short-term EAL | 0.33 mg/m3 as a 1-hour mean |

### Supporting Information

A short-term EAL of 0.33 mg/m3 as a 1-hour mean was based on the acute 1-hour AMCV (TCEQ 2015), which used a LOAEC of 29.9 mg/m3 from an acute human clinical study (Lundqvist et al. 1992 cited in TCEQ 2015) for nasal and eye sensory irritation, following exposure to increasing concentrations of DiEA for 60 minutes. The LOAEC was divided by a total UF of 90 (a factor of 10 for intraspecies variability, a factor of 3 for the use of a LOAEC, and a factor of 3 for an incomplete database because the study used only 5 subjects, and the study design was not blind).

A long-term EAL of 0.033 mg/m3 as a 24-hour mean was based on the chronic AMCV (TCEQ 2015) derived from a 2-year inhalation study in mice (NTP 2011) in which a significant increase in hyperostosis in the turbinates was seen. TCEQ calculated a BMCL10 of 3.04 mg/m3, after adjusting for continuous exposure (6/24 \* 5/7), from the study data. The adjusted BMCL10 was divided by a total UF of 90 (a factor of 3 for interspecies variability, a factor of 10 for intraspecies variation, a factor of 1 for use of a benchmark concentration modelling and ‘that the resulting POD was considered a NOAEC’, and a factor of 3 for an incomplete database).

### References

LATHOURI, M., KORRE, A., DUSINSKA, M., AND DURUCAN, S., 2022. Sustainable operation of post-combustion capture plants (SCOPE). Human Health hazard assessment strategy for amine emissions around PCC facilities. Deliverable D3.3.

NTP, 2011. Toxicology and Carcinogenesis Studies of Diethylamine (CAS No. 109-89-7) In R344/N Rats and B6C3F1 Mice (Inhalation Studies).

OECD, 2013. SIDS Initial Assessment Profile, CoCAM 16-18 April 2013.

TCEQ, 2015. Development Support Document, Diethylamine. CAS Registry Number: 109-89-7.

# 4. Diethylaminoethanol (CAS Number 100-37-8)

Diethylaminoethanol or 2-(diethylamino)ethanol (DEELA / DEEA) is a linear aliphatic alkanolamine with one tertiary amine group. It is a colourless/light yellow organic flammable liquid with an amine-like odour. Its industrial uses include the synthesis of pharmaceuticals, as a catalyst for the synthesis of polymers, and as a pH stabiliser to inhibit corrosion in heating systems and steam humidifiers (OECD 2002). New uses include as a solvent in post-combustion carbon capture systems (Zhao et al. 2023). DEELA is registered for use under EU REACH for ≥ 1 000 to < 10 000 tonnes per annum.

Localised effects on the upper respiratory tract and eyes have been observed following short- and long-term inhalation exposure to DEELA, along with reduction in bodyweight, and changes in kidney and liver weights (Hinz et al. 1992).

### Recommended Environmental Assessment Level in Air

|  |  |
| --- | --- |
| Long-term EAL | 0.11 mg/m3 as a 24-hour mean |
| Short-term EAL | None (practical compliance) |

### Supporting Information

A long-term EAL of 0.11 mg/m3 as a 24-hour mean was derived from the indications of systemic toxicity (reductions in bodyweight, and changes in kidney and liver weights) observed in a 14-week inhalation study in rats (Hinz et al. 1992). A NOAEC of 120 mg/m3 was adjusted for continuous exposure (6/24 hours and 5/7 days) to give a POD of 21.4 mg/m3. A total UF of 200 was applied (a factor of 10 for interspecies variability, a factor of 10 for intraspecies variability and a factor of 2 for study duration). While there is debate over the reliability of the evidence for systemic effects from this study, maternal toxicity (reductions in bodyweight gain) was observed in the developmental study reported. This EAL is considered protective of all potential health effects including respiratory effects.

A short-term EAL was not recommended due to constraints for practical compliance.

### References

HINZ J.P., THOMAS J.A., BEN-DYKE R., 1992. Evaluation of the Inhalation Toxicity of Diethylethanolamine (DEEA) in Rats. FUNDAMENTAL AND APPLIED TOXICOLOGY 18, 418-424.

OECD, 2002. 2-Diethylaminoethanol SIDS ASSESSMENT REPORT. United Kingdom: Organisation for Economic Co-operation and Development.

ZHAO Y., ZHANG Y., LIU Q., GUO X., CAO Y., XU N., QI T., CHEN Y., CHEN S., 2023. Energy-efficient carbon dioxide capture using piperazine (PZ) activated EMEA+DEEA water lean solvent: Performance and mechanism. SEPARATION AND PURIFICATION TECHNOLOGY, 316, art. 123761.

# 5. Morpholine (CAS Number 110-91-8)

Morpholine (MOR) is a cyclic aliphatic amine with one secondary amine group and one ether group. It is a colourless, oily, hygroscopic, volatile liquid with a characteristic amine odour that is denser than air (IPCS 1995). Its uses have been reported in the production of rubber chemicals and optical brighteners, as a corrosion inhibitor in steam condensate systems, as an ingredient in waxes and polishes, and as a component of protective coatings on fresh fruits and vegetables. New uses for MOR include as a solvent in post-combustion carbon capture systems (Borhani and Wang 2019). It is registered for use under EU REACH for ≥ 10 000 to < 100 000 tonnes per annum.

### Adverse health effects from inhalation exposure to MOR include severe eye and respiratory irritation, respiratory distress, and lung damage (OECD 2013a and 2013b).

### Recommended Environmental Assessment Level in Air

|  |  |
| --- | --- |
| Long-term EAL | None (practical compliance) |
| Short-term EAL | 0.04 mg/m3 as a 24-hour mean |

### Supporting Information

A short-term EAL of 0.04 mg/m3 as a 24-hour mean was derived from an 8-day inhalation study in rats (Grodeckaja and Karamzina 1973 cited in OECD 2013b), from which a LOAEC of 80 mg/m3 was derived based on thyroid gland hypersecretion and iodine uptake. The LOAEC was adjusted to account for continuous exposure (i.e., \* 4 hours/24 hours) to give a POD of 13.3 mg/m3. The POD was divided by a total UF of 300 (a factor of 10 for interspecies differences, a factor of 10 for intraspecies differences, and a factor of 3 to extrapolate from a LOAEC to a NOAEC). This EAL is considered protective of local and systemic effects from short-term exposure.

There are some caveats to this recommendation with respect to the availability of information from the underlying study that could result in an overestimation of risk to public health. However, the possibility of potential endocrine effects in humans cannot be excluded.

The short-term EAL was numerically equal to the recommended long-term EAL and therefore it is also considered protective of long-term exposure.

### References

BORHANI T.N., WANG M., 2019. Role of solvents in CO2 capture processes: The review of selection and design methods. RENEWABLE AND SUSTAINABLE ENERGY REVIEWS, 114, art no. 109299.

IPCS 1995. Morpholine. Geneva: IPCS INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY.

OECD, 2013a. Morpholine SIDS PROFILE. United States: Organisation for Economic Co-operation and Development.

OECD, 2013b. SIDS Initial Assessment Report for Morpholine. CoCAM 5. Paris (FR): Organisation for Economic Cooperation and Development. pp 1-47.

# 6. N-nitrosomorpholine (CAS Number 59-89-2)

N-nitrosomorpholine or 4-nitrosomorpholine (NMOR) is a nitrosamine with a yellow crystalline structure. It is soluble in organic solvents and presents as a golden crystalline liquid. No registered manufacturer or uses are recorded (BAuA 2020). NMOR is not registered for use under EU REACH.

There are few inhalation studies that have reported on the adverse health effects of NMOR. Longer-term oral studies in rodents have shown effects on body weight, the liver (hypertrophy of hepatocytes, necrosis, reduced weight, hepatocellular adenomas and carcinomas, cirrhosis, scarring, biliary hyperplasia and telangiectasis) and adrenal cortex. NMOR has produced mixed results for genotoxicity in *in vitro* and *in vivo* tests, but overall appears to be genotoxic with metabolic activation (BAuA 2020) and is considered carcinogenic (Group 1B).

### Recommended Environmental Assessment Level in Air

|  |  |
| --- | --- |
| Long-term EAL | 0.000005 mg/m3 (5 ng/m3) as an annual mean |
| Short-term EAL | 0.000037 mg/m3 (37 ng/m3) as a 24-hour mean |

### Supporting Information

A short-term EAL of 0.000037 mg/m3 as a 24-hour mean was derived from a sub-acute inhalation study in rats (Klein et al. 1990 cited in BAuA 2020), from which a LOAEC of 7.7 mg/m3 was identified for neoplastic nodules in the liver. Although BAuA (2020) considered the study to be reliable, significant reservations have been noted about the study design including the use of only a single sex and dose. However, the study reported a clear carcinogenic response from exposure to NMOR even after a short period of time. Modifying the LOAEC for continuous exposure (i.e. \* 4 hours/24 hours \* 4 days/7 days), resulted in a POD of 0.73 mg/m3. This POD was divided by a margin of exposure of 20,000, considering the high level of tumour incidence (nominally 20%) observed at the LOAEC, as NMOR is a genotoxic carcinogen.

### A long-term EAL of 0.000005 mg/m3 (5 ng/m3) as an annual mean was derived using route-to-route extrapolation from a repeat-dose oral study in female F344 rats (Lijinsky et al. 1988 cited in EFSA 2023 and SCCS 2012), from EFSA’s BMDL10 of 0.014 mg/kg bodyweight/day, based on benign and malignant liver tumours. The BMDL10 derived by EFSA (2023) was chosen instead of the one derived by SCCS (2012) as it was based on a more sensitive endpoint and was reported in sufficient detail to evaluate the modelling approach. This POD was divided by a UF of 10,000 and converted to an equivalent air concentration by assuming a 70 kg person breathes 20 m3 of air per day. The application of a large UF to the BMDL10 ensures that the margin of exposure, the ratio of carcinogenic dose in the laboratory animal to the permitted human exposure, is sufficiently large that any cancer risk associated with the long-term EAL will be, in the opinion of expert groups, of “low concern from a public health point of view” and “unlikely to be a concern”.

### References

BAuA, 2020. CLH report: Proposal for Harmonised Classification and Labelling for 4-nitrosomorpholine. Helsinki: European Chemicals Agency.

EFSA, 2023. Risk assessment of N-nitrosamines in food. Italy: European Food Safety Authority.

SCCS, 2012. Opinion on NDELA in Cosmetic Products and Nitrosamines in Balloons. Brussels: Scientific Committee on Consumer Safety.

# 7. Piperazine (CAS Number 110-85-0)

Piperazine (PZ) is a cyclic compound with two secondary amine groups. It is solid at room temperature, the anhydrous compound forming white or translucent, rhomboid, or flake like crystals that are highly hygroscopic (ECB 2005). PZ is used as a hardener, as a gas scrubber, as a corrosion inhibitor, as an intermediate and a process regulator in the production of industrial chemicals and in the manufacture of food contact materials, as an insecticide, and, previously, as an active ingredient in oral anthelmintic drugs. New uses include as a solvent in post-combustion carbon capture systems (Rochelle et al. 2011). PZ is registered under EU REACH in the tonnage band ≥ 1 000 to < 10 000 tonnes.

Studies on the adverse effects following inhalation exposure are very limited. It is a respiratory sensitiser, based on observations in humans, a skin sensitiser based on *in vivo* animal studies, and a corrosive agent (AICIS 2020). Repeated exposure to PZ by inhalation in human studies may induce chronic bronchitis (Rutter and Voelker 1975 cited in ECB 2005). PZ salts were used extensively in oral anthelmintic drugs from the 1950s in adults and children for treatment durations up to a week (ECB 2005). Reversible neurotoxic effects were observed including abnormal EEG changes, which resulted in a decline in its therapeutic use. In oral reproduction and developmental studies *in vivo*, PZ has demonstrated adverse effects on fertility, but no symptoms of developmental toxicity (ECB 2005).

### Recommended Environmental Assessment Level in Air

|  |  |
| --- | --- |
| Long-term EAL | 0.015 mg/m3 as a 24-hour mean |
| Short-term EAL | None (practical compliance) |

### Supporting Information

A long-term EAL of 0.015 mg/m3 as a 24-hour mean was derived from a clinical case study (Belloni and Rizzoni 1967 cited by ECB 2005), where abnormal EEG changes were observed in children prescribed PZ hexahydrate at a dose of 35 mg/kg body weight/day PZ base for five days. ECB (2005) regarded the approximate 30 mg/kg body weight/day as an effect level as it was based on the therapeutic dose. This has been converted to a LOAEC of 45 mg/m3 by assuming a young child inhales 10 m3 per day and weighs 15 kg. A total UF of 3,000 was applied (a factor of 10 for intraspecies variation, a factor of 10 for extrapolation from LOAEC to NOAEC, a factor of 10 to extrapolate to chronic exposures, and a factor of 3 for the quality of the database). ECB (2005) identified the importance of neurotoxicity in clinical case studies in humans, which were not observed in rodent laboratory studies. There is a lack of dose-response information. This EAL is considered protective of other toxic effects and potential carcinogenicity resulting from *in vivo* conversion of PZ to the corresponding nitrosamine.

A short-term EAL was not recommended due to constraints for practical compliance.

### References

AICIS, 2019. Piperazine: Human health tier II assessment. CAS Number 110-85-0.

ECB, 2005. European Union Risk Assessment Report. Piperazine. CAS No. 110-85-0.

ROCHELLE G., CHEN E., FREEMAN S., VAN WAGENER D., XU Q., VOICE A., 2011. Aqueous piperazine as the new standard for CO2 capture technology. CHEMICAL ENGINEERING JOURNAL, 171, 725 - 733.

# List of Abbreviations and Definitions

|  |  |
| --- | --- |
| AICIS | Australian Industrial Chemicals Introduction Scheme |
| AMCV | Air Monitoring Comparison Values |
| BAuA | German Federal Institute of Occupational Safety and Health |
| BMCL | Lower 95 Percentile Confidence Level of the Benchmark Concentration |
| BMDL | Lower 95 Percentile Confidence Level of the Benchmark Dose |
| ECB | European Chemicals Bureau (now disbanded) |
| ECHA | European Chemicals Agency |
| EEG | Electroencephalogram |
| EFSA | European Food Safety Authority |
| IPCS | International Programme on Chemical Safety (World Health Organization) |
| LOAEC | Lowest Observable Adverse Effect Concentration |
| NOAEC | No Observed Adverse Effect Concentration |
| NTP | National Toxicology Program |
| OECD | Organisation for Economic Co-operation and Development |
| POD | Point of Departure |
| SCCS | Scientific Committee on Consumer Safety |
| TCEQ | Texas Commission on Environmental Quality |
| USEPA | United States Environmental Protection Agency |
| UF | Uncertainty Factor |

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