EAC – European Aminocarboxylates Committee

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EUROPEAN RISK ASSESSMENT ON EDTA

Summary
In 2001 the EU Risk Assessment Reports on EDTA and Na_4-EDTA were approved in the Technical Meetings of EU member state representatives.

The reports drafted by the German Authorities offer a comprehensive source of carefully evaluated data and conclusions. EDTA can be considered as a substance of low risk to human health and the environment. It has low aquatic toxicity, it is not persistent, it does not bioaccumulate and there is no need for a specific environmental product labeling.

A risk from EDTA for the local aqueous environment can only be expected to occur in some 'extreme cases' at sites where a large concentrated emission source -lacking adequate treatment- is connected to a small surface water recipient. In such a situation the concentration of EDTA near the effluent could be higher than its no-effect concentration.

The environmental report indicates a need for limiting the risks in four application areas where the potential presence of such 'extreme cases' can not be excluded. We advise users of large volumes of EDTA to evaluate the environmental risk on the basis of their site-specific emissions to the aqueous environment.

EU Risk Assessment Procedure in General

Substances on the various EU Priority Lists must undergo an in-depth risk assessment covering the risks posed by the priority chemical to man and the environment. This risk assessment follows the framework set out in Commission Regulation (EC) 1488/94 and implemented in the detailed Technical Guidance Documents (TGD) on risk assessment for 'New' and 'Existing' Substances.
A Member State Rapporteur evaluates the data and prepares a Risk Assessment Report (RAR). The RAR is discussed at Technical Meetings (TM) for the implementation of the scientific and technical aspects of the Existing Substances Regulation. The risk assessment may result in the following conclusions:

- Conclusion (i):
  There is need for further information and/or testing.

- Conclusion (ii):
  There is at present no need for further information and/or testing and no need for risk reduction measures beyond those, which are being applied already.

- Conclusion (iii):
  There is a need for limiting the risks; risk reduction measures, which are already being applied, shall be taken into account.

The Member States endorse the conclusions of the Technical Meeting in a meeting of Competent Authorities. When there is a need for limiting the risks the Rapporteur proposes a

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risk reduction strategy. The elaboration of such a strategy is done utilizing the Technical Guidance Document on Risk Reduction. The risk reduction strategy is discussed and agreed by the Risk Reduction Strategy Meeting chaired by the Directorate - General Environment and endorsed by the Competent Authorities. In these discussions also costs and impact of alternative products or technologies on human health and environment will be taken into consideration. The Commission proceeds by preparing a proposal regarding the risk assessment and risk reduction measures for adoption by a Member State Committee.

Separately the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) will provide the Commission with independent scientific advice on the quality and outcome of the Risk Assessment Report produced by the Rapporteur prior to developing the commission proposal.

A summary of the conclusions of the risk assessment and the proposed risk reduction measures are published in the Official Journal of the European Communities.

Favorable conclusions on EDTA
In 1994 EDTA (Edetic acid with CAS # 60-00-4) and Na_4-EDTA (Tetrasodium ethylenediaminetetraacetate with CAS # 64-02-8) were put on the priority list of substances for EU Risk Assessment. The German authorities -acting as Rapporteur- drafted the 'environmental' and 'human health' sections of the Risk Assessment Reports. The EU discussions on both sections of the report took place at various Technical Meetings. The technical experts of the EU member states endorsed the conclusions in 2001 (the conclusion on the oil well cleaning scenario was endorsed in 2003).

<u>Conclusions on Environment</u>

- Low aquatic toxicity
  - No risk of EDTA for the aqueous environment below the Predicted No-Effect Concentration (PNEC) of 2.2 mg/l
  - No risk to the aqueous environment due to the influence of EDTA on the mobility of heavy metals, eutrophication and nutrient deficiency
- No need for EDTA to be classified and labeled with a specific environmental symbol and/or risk phrase
- Not persistent in the aqueous environment
  - Biodegradability of EDTA depends on its concentration, pH and the species of complexed ions.
  - Photochemical degradation of Fe(III), Co(III) and Mn(II) EDTA complexes
  - Presence of biodegradable metabolites that are non-toxic to the aquatic environment
  - For risk characterization the Risk Assessment Report uses a worst-case assumption of 'no biodegradation'
- No bioaccumulation in living organisms through the food chain

- There is need for limiting the risks / Conclusion (iii):
  This was concluded because of potential high EDTA concentrations in effluents from:
  - Industrial detergents
  - Paper mills
  - Circuit board production
  - Recovery of EDTA containing waste (photographic waste recycling, etc.)

  This conclusion should be considered in relation to the detailed exposure sections of the Risk Assessment Report. Those sections clearly describe that only a fraction of all EDTA used in the indicated application areas is at risk. The indicated environmental risk of EDTA is limited to those sites that use large volumes of EDTA in the absence of effective biodegradation or high effluent dilution.

Conclusions on Human Health
(With proviso of confirmation of the product classification proposals by the Commission Working Group CMR on the Classification and Labeling of Dangerous Substances)

- Substance of no concern
  - No concern for consumers in any application
  - No concern for workers
  - No concern for the public exposed indirectly via the environment
- Classification proposals
  - EDTA: Xi; R36
  - Na_4-EDTA: Xn; R22-41
    With concentration limits;
    $C \geq 41\%$ → Xn; R22-41
    $25\% \leq C < 41\%$ → Xn; R22-36
    $5\% \leq C < 41\%$ → Xi; R36

Determination of Potential Environmental Risks of EDTA
Under the EU risk assessment framework the potential risk for the environment is determined by comparison of the PEC (Predicted Environmental Concentration) with the PNEC (Predicted No Effect Concentration).

- The PNEC for the aqueous environment is derived from valid eco-toxicity test results on EDTA (Fish, Daphnia and Algae). In the Risk Assessment Report the PNEC for EDTA is 2.2 mg/l.
- In general the PEC_{local} near emission sources is estimated from the daily consumption of EDTA in its various applications. The concentration in the effluent (C_{eff}) is calculated from the estimated emission to a wastewater treatment plant with a hypothetical effluent flow of 2000 m^3/hr. Subsequently the PEC_{local} is estimated from the C_{eff} assuming a hypothetical dilution of 1 to 10 upon release to the local surface waters and taken into account the estimated regional background concentration of EDTA.
- A more site-specific PEC_{local} can replace the generic estimation of PEC_{local} by using the actual site-specific data on the C_{eff}, wastewater treatment effluent flow and the dilution factor upon release into the local surface water. If available adequately measured, representative exposure data are taken into account in exposure assessments.
- A potential risk for the environment is indicated when PEC/PNEC ratio is > 1. For EDTA potential risk for the aqueous environment is expected when PEC > 2.2 mg/l (see table below).

Applications of EDTA	**PEC_{local}** (mg/l)	**Potential Risk** (PEC > PNEC of 2.2 mg/l)
Diffuse emissions from household products		
Releases into household sewage - Household detergents - Cosmetics - Pharmaceuticals - Food additives	0.195	No risk

Applications of EDTA	PEC_{local} (mg/l)	Potential Risk (PEC > PNEC of 2.2 mg/l)
Point emissions from industrial applications		
Industrial detergents		
- emission into municipal wastewater	0.64	No risk
- large (10 t/y) dairy and beverage site and no effective water treatment	**2.6**	Potential risk
- large (10 t/y) dairy and beverage site and effective water treatment	0.35	No risk
Photo chemicals	0.57	No risk See also waste recovery
Textile industry	2.0	No risk
Pulp and Paper		
- Effective water treatment	0.5	No risk
- No effective water treatment	**2.6**	Potential risk
Metal plating (circuit board production)	**12**	Potential risk
Water treatment No high local exposures are anticipated	< 2.2	No risk
Oil production	0.63	No risk
Fuel gas cleaning No exposures in EU	0	No risk
Polymer and rubber production	1.7	No risk
Waste recovery companies	**2.4**	Potential risk
Production of EDTA	< 1.0	No risk

How to use the information of the Risk Assessment Reports on EDTA

The sections of the Risk Assessment Reports are the result of a thorough investigation by the German Rapporteur and present a comprehensive overview of all environmental and human health issues related to the use of EDTA. The reports offer a great source of carefully evaluated data and conclusions that can be very useful in internal and external discussions on the use of EDTA.

We advise users of large volumes of EDTA to evaluate the environmental risk on the basis of their site-specific emissions to the aqueous environment. The PEC_{local} should be determined preferably by using site-specific information on EDTA concentration, removal rates and dilution factors. In case the site-specific PEC_{local} exceeds the PNEC of 2.2 mg/l appropriate measures should be considered to reduce the effluent concentrations. You can ask your supplier for support on this matter.

How to determine your site-specific PEC_{local}?
The calculation of PEC_{local} for the aquatic compartment is described in the Technical Guidance Document that is available on the web site of the European Chemicals Bureau http://ecb.jrc.it/existing-chemicals/. The general procedure is described in Chapter 2.3.8.3.

Below you will find our explanation of that procedure.

Step 1
Estimate the $C_{effluent}$ (concentration of EDTA in the effluent of the site).
This concentration can be measured or estimated from the volume of EDTA discharged and the effluent flow.
If connected to an industrial wastewater treatment plant you can use the effluent flow of that facility. Take also into consideration the removal rate of EDTA at your facility (It will depend on pH, counter ions and concentration).
If connected to a municipal wastewater treatment plant you can use the effluent flow of that specific facility. If that information is unknown you have to use the standard flow of 2000 m^3/24 hr. The removal of EDTA in a municipal wastewater treatment plant is estimated to be negligible.

Step 2
Estimate the C_{local} (concentration of EDTA after discharge in the surface water)
This concentration can be estimated from the $C_{effluent}$ by taking into account the dilution factor upon release of the effluent into the surface water.
Dilution = (flow of river + flow of effluent) / flow of effluent
$C_{local} = C_{effluent}$ / dilution

The C_{local} calculation should be based on the daily emission. If monitoring data are available the 90%ile figure of the $C_{effluent}$ should be used.

EDTA discharge into a river
If no specific data are available you should use the standard dilution of 1 to 10
If detailed data on the river flow are available the 10%ile value should be used.
If the 10%ile of the river flow is not available you can replace it by using 1/3 of the average flow.

EDTA discharges into estuaries or lakes
You should use the standard dilution of 1 to 10

Step 3
Estimate the PEC_{local} (predicted environmental concentration of EDTA)
$PEC_{local} = C_{local} + PEC_{regional}$
In the EU Risk Assessment Report the $PEC_{regional}$ (regional or background concentration in surface water) for EDTA is established at 95 µg/l.

Monitoring data on EDTA concentrations
Measured values shall overwrite the calculated PEC if they pass critical statistical and geographical evaluation.