5 CLASSIFICATION AND LABELING

5.1 Aquatic toxicity

Study reports concerning the acute toxicity of an 80 mole % cationic ester-type polyacrylamide are available for fish, *Daphnia* and algae, all performed in accordance with the appropriate OECD guidelines, and under relevant aquatic conditions. The results are summarized in Table 4.

Table 4: Aquatic toxicity of a 80 mole % cationic ester-type polyacrylamide

taxon	Effect concentrations	
	LC_{50}	*NOEC*
fish (*Danio rerio*)	5.2 mg/L	
Daphnia magna	13.5 mg/L	

As discussed previously, the values reported for the ester-type polyacrylamides represent realistic worst case values since

- products with a lower cationic charge density will less toxic to aquatic organisms;
- average dissolved organic carbon loads in receiving waters are in the range of those employed in the presented studies, and
- toxicity rapidly disappears in the aqueous environment due to rapid hydrolysis of the ester-type cationic functional groups, resulting in non-toxic degradation products.

5.2 Degradability

According to Directive 2001/59/EC, a substance is readily degradable if it is shown to be 'readily biodegradable' in an official test for Ready Biodegradability (the OECD 301 suite), or alternatively:

> *5.2.1.3. (c) if other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level of > 70 % within a 28-day period.*

The results for the abiotic degradation test (hydrolysis) with 80 mole % ester-type cationic polyacrylamide show that at all pHs tested (6–8) disappearance of the parent compound exceeds 70% within 28 days. Moreover, the toxicity study with 28-day aged solutions of 80 mole % ester-type cationic polyacrylamide show that the resulting degradation products are not toxic to fish, with an *NOEC* to fish of greater than 100 mg/L expressed as parent compound. Taken together, these results show that ester-type cationic polyacrylamide rapidly degrades in surface water and does not constitute a potential long-term and/or delayed danger to the aquatic environment.

5.3 Bioaccumulation

No octanol/water partition coefficient is available for ester-type cationic polyacrylamide. The standard methods for the determination of octanol/water partition coefficients do not provide for the determination of the partition coefficient of high molecular weight polymers, especially not for water-soluble polymers. The hydrophilic character of ester-type cationic polyacrylamide suggests that it will possess limited to no hydrophobic character. Regardless, the sheer size and polar nature of these macromolecu-

lar compounds dictates that no accumulation in biota will take place. This can also be concluded from the results of the repeated exposure acute fish toxicity study[1], where repeated exposure to concentrations slightly below the acute LC_{50} showed no effects (other than completely reversible acute effects from individual exposures). Consequently, it can be concluded that cationic polyacrylamides do *not* bioconcentrate.

5.4

Classification according to environmental effects

According to Annex 6 to Directive 2001/59/EC, replacing Annex VI to Directive 67/548/EEC ester-type cationic polyacrylamide does not have to be classified for environmental effects, based on the fact that

- the median concentrations for acute toxic effects on aquatic organisms (LC_{50} for fish, EC_{50} for Daphnia and IC_{50} for algae) are greater than 1 mg/L;
- the substance degrades abiotically more than 70% within 28 days, and
- the NOEC values of the degradation product(s) are greater than 100mg/L.