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DOCUMENT	4
2. GENERAL INTRODUCTION	4
3. LEGISLATION BACKGROUND	5
3.1. The new hazard label	5
3.2. The safety data sheet (SDS)	8
3.3. Special cases	9
4. METHODS OF CLASSIFICATION	11
5. TRANSPORT CLASSIFICATIONS	12
6. ENVIRONMENTAL RISK ASSESSMENT	13



1. PURPOSE OF THE GUIDANCE DOCUMENT

SUMMAR

This guidance is intended to assist environmental safety representatives in the dye user industries to understand the new hazard labelling requirement "dangerous for the environment". This guidance is designed to assist those persons responsible for environmental safety with respect to the use of dyes in the leather, paper, and textile industries. In addition to the existing physical and health hazards the revised Preparations Directive makes the classification and labelling requirement "dangerous for the environment" applicable to dye preparations.

The information provided in this document should enable the plant manager to understand the concept of this new piece of legislation and to take the necessary measures to use dyes in a responsible way, i.e. to ensure that the application process does not present an unjustifiable risk to the environment (see also ETAD Information Notice No.4).

2. GENERAL INTRODUCTION

SUMMAF

Labelling and Safety Data Sheets form the basis of hazard communication leading to the safe handling of chemicals and to exposure control.

This guidance document illustrates how dye preparations are classified in terms of environmental hazards. A fundamental aspect of EU chemical control legislation is the hazard assessment of dangerous substances and preparations. This leads to testing requirements (for the notification of new substances) and classification criteria which should enable harmonised labelling and the issue of adequate Safety Data Sheets.

Labelling and Safety Data Sheets form the basis of Hazard Communication and they provide advice on appropriate exposure controls for the safe handling of chemicals. Hazard and exposure are the integral parts of Risk Assessment. Correct evaluation and the control of risks arising from the use of chemicals can only be

achieved by performing a risk assessment. This guidance document illustrates how preparations of dyestuffs are classified in terms of environmental hazards which form the basis of pollution prevention.

3. LEGISLATION BACKGROUND

UMMARY

The framework of EU chemical contro directives consists of the three pillars Hazard Assessment, Risk Assessmer and Risk Management. Hazard Assessment addresses the evaluation of intrinsic properties in terms of potential adverse effects on huma health, environment and physica aspects (e.g. explosive materials). Risk Assessment describes the probability of an adverse effect to occur depending on the extent of the exposure during the use of dangerous substances or preparations. Exposure is therefore a key parameter to control and limit risk. Risk Management is the process of preventing and controlling exposure by safety measures to protect workers and the environmen from hazardous substances (prepara

Hazard Assessment is a prerequisite for the classification and labelling of substances and preparations. In the case of new substances, a base set of data must be submitted as a notification to the authorities of an EU member state. Hazard classification criteria, labelling and packaging requirements are laid down in the "Dangerous Substances Directive" as last amended by the 7th Amendment (92/32/EEC) and in the "Dangerous Preparations Directive" (99/45/EC). The evaluation and control of risks from existing substances is covered by the European Commission Regulation 1488/94 and those for new substances by Regulation 93/67/EEC. Proper risk management includes advice on safe handling procedures as displayed in the Safety Data Sheet Directive (91/155/EEC). Reduction of environmental releases (e.g. dyes into water effluents) is addressed by the directive on "Integrated Pollution Prevention and Control" (96/61/EC). The most stringent laws on risk management are those which prohibit or severely restrict the use of certain products. In the EU it is the Council Directive (76/769/EEC)

"Restrictions on the marketing and use of certain dangerous Substances and Preparations" which prescribes such risk reduction measures.

3.1 The new hazard label

Manufacturers and suppliers are required by law to classify and labe hazardous substances.

The classification of hazardous substances is based on the available data.

Preparations are mixtures of substances. Dangerous preparations must also be classified and labelled. Hazard classifications for substances are officially determined and listed by the Commission of the European Communities in Annex I of Directive 67/548/EEC. If a substance is not listed the manufacturer of chemical products is obliged to assess substances on the basis of available product data. If a hazard is identified according to the criteria described in the legislative guidelines the substance must be classified accordingly. This classification is regarded by the authorities as provisional prior to any official listing in Annex I. Substances and preparations allocated a hazard classification must carry an appropriate hazard label on being supplied.

This label includes:

- the hazard symbol
- the identification, in the case of a dangerous preparation, of the substance/s i.e. component/s responsible for the hazard classification (with some exceptions)
- officially prescribed texts identifying the hazard (risk-phrases)
- officially prescribed texts indicating the safety measures to be taken (safety-phrases)

The hazard classification "dangerous for the environment" has been in use for some time in the case of substances.

Due to the revision of the EU **Dangerous Preparations Directive the** hazard classification "dangerous for the environment" has now been extended to include preparations.

Dyes are preparations and for the first time they must be labelled for supply if they are "dangerous for the envi-

In order to carry out a hazard assessment, data must be generated.

The absence of hazard labelling cannot be taken to mean that a product is not hazardous. It may mean that the required data are not available.

ETAD member companies in complying with the ETAD Code of Ethics, are committed to provide sufficient data for an initial hazard assessment thus ensuring correct labelling, if necessary.

In the case of preparations (i.e. mixtures of substances) the Preparations Directive allows three alternatives for making an assessment which may or may not lead to a hazard classification:

- based on given concentration limits of hazardous components
- by calculation from known data on the components
- based on test data for the preparation itself

The majority of dyes have been tested as the final standardised products and these data have priority over limits or calculation methods. Thus the actual classification is essentially the same procedure as that used for substances. Classifications such as "irritant", "harmful", "corrosive" are well known for both substances and preparations within the dye user industry. Less well known is the classification "dangerous for the environment". Although already in use for some time in the case of substances this classification has now been newly introduced for preparations. As dyes are preparations this means that the end-users will be encountering this labelling for the first time. The example below shows a typical labelling used for a product classified as "dangerous for the environment".

N; Dangerous for the environment

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Avoid release to the environment. Refer to special instructions/Safety data sheets

Typical labelling used for a product classified as "dangerous

A comprehensive hazard assessment based on ecological and ecotoxicological data includes parameters such as the acute toxicity to aquatic organisms (tested on three species- fish, daphnia and algae), biodegradation, elimination by physical processes (e.g. flocculation or adsorption), bioconcentration, solubility, partition coefficient and chronic or long-term ecotoxicity. Not all these data are available for every product and the hazard assessment is normally based on the data quoted in the safety data sheet. Thus products which are not labelled as "dangerous for the environment" must be viewed within the context of the stated data because the full data package may not be available e.g. tests may not have been carried out on each of the three major species: fish, daphnia and algae. This is also true in the case of the better known toxicological and physical-chemical hazards. It cannot be assumed that a product is not hazardous because it is not labelled as hazardous unless all the test data cited in the legislation are available. A complete data set is not required by law for substances unless these are "notified substances" and even then the data package required is determined according to the sales volume. ETAD members, however, complying with the ETAD Code of Ethics and the Responsible Care® programme, are committed to provide sufficient data for an initial hazard assessment.

A major determining factor involved in the environmental classification is the ready biodegradability. Dyes in general are not readily biodegradable in standard tests which allows the following simplified table of criteria. The table assumes that data are available for the product itself and that the product has not been classified on the basis of component data.

Water-soluble dyes are not readily biodegradable and a simplified scheme as shown below can be used according to the ecotoxicological

The assessment "very toxic to aquatic organisms" is applicable to substances with an LC50 or EC50 of \leq 1 mg/l even if these are readily biodegradable. If a substance is readily biodegradable the classifications "toxic to aquatic organisms" or "harmful to aquatic organisms" (see above) do not apply. Thus water-soluble dyes are classified almost entirely on the basis of their ecotoxicity values.

In all cases when a product is not readily biodegradable the R-Phrase describing the hazard must be accompanied by the R-Phrase 53 -"May cause long-term adverse effects in the aquatic environment". This is because the classifications R51 "Toxic to aquatic organisms" and R52 "Harmful to aquatic organisms" already

confirm a lack of ready biodegradability and thus, at least a short term persistence in the environment. R 50 "Very toxic to aquatic organisms" is used alone if a substance is readily biodegradable and R52 "Harmful to aquatic organisms" can be used alone for readily biodegradable substances in a few exceptional cases.

The classification "Harmful to aquatic organisms" does not require the hazard symbol on the labelling.

Species Fish (LC 50) or Daphnia (EC 50) or Algae (EC 50)	≤1mg/l	≤ 10 mg/l	≤ 100 mg/l
Classification	N. Damara fautha	N. Dangaraus for the	No symbol
	N; Dangerous for the environment	N; Dangerous for the environment	
R-Phrases	R50 "Very toxic to aquatic organisms"	R51 "Toxic to aquatic organisms"	R52 "Harmful to aquatic organisms"
	R53 "May cause long-term adverse effects in the aquatic environment"	R53 "May cause long-term adverse effects in the aquatic environment"	R53 "May cause long-term adverse effects in the aquatic environment"

Note: When, as shown above, two R-phrases are used (e.g. R-phrases 50 and 53 or R-phrases 51 and 53) a combination text is generally given on the actual label e.g. R51/53 "Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment".

A simplified scheme for classifying not readily biodegradable water soluble dyes on the basis of the ecotoxicological data

Safety data sheets containing little or no data should be treated with caution. Insufficient data may be available to classify the product correctly.

The introduction of the EU Safety Data Sheet Directive was used by ETAD member companies to expand the data base for products and to make the data more understandable.

3.2 The safety data sheet (SDS)

In addition to the hazard labelling the supplier of a hazardous product must by law provide a Safety Data Sheet. In 1975 the member companies of "ETAD" (The Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers) introduced, on a voluntary basis, a safety data sheet containing a recommended minimum set of data. It was – and remains – recommended that SDSs should be available for all products even if these are not classified as hazardous. The ETAD SDS preceded the present legislation by many years and was one of the first standardised SDSs. It was adopted by many other branches of the chemical industry.

A relatively new piece of legislation in the European Union is Directive 91/155/EEC; better known as the Safety Data Sheet Directive. The introduction of this Directive has given industry the opportunity to revise and improve the communication of data relevant to safety between the manufacturer and the user. The EU Safety Data Sheet has been used by many chemical manufacturers to ensure that sufficient data are provided to enable a full assessment of chemical products with respect to their environmental and human safety.

The impact of chemical products on the environment can only be assessed fully by considering the actual quantities entering the environment and these figures are dependent on local and regional conditions. It is, therefore, essential that end-users and local authorities have access to all the relevant product data. In order to support personnel involved in such environmental work the manufacturer must make the data available in a readily understandable form. Emphasis is placed here on the communication of data by means of a safety data sheet containing all relevant data.

ETAD member companies have attempted in the change to the EU SDS to supply the user with data in a more understandable form.

An idealized example of such a safety data sheet is given below. The content shown is limited to the ecological data.

The data given can be summarized as follows:

The product is a dye and therefore it can be assumed to be not readily biodegradable. This is reflected in the ratio of the BOD5 and COD which is less than 0.5. The product is only partially eliminated by adsorption onto effluent treatment sludge as shown in a test for inherent biodegradation (OECD 302B). Thus some product can be expected to enter surface waters. It is not harmful or toxic to waste water treatment organisms. As the fish toxicity is greater than 1mg/l but less than 10mg/l and the product is not readily biodegradable it must be classified as "toxic to aquatic organisms" (N, R51/53) and be labelled accordingly. Due to the high water solubility no bioconcentration is expected. Emissions to the aqueous environment are a point source i.e. localized and not diffuse such as those originating from numerous or public sources.

C.I. Acid Red XX

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12.ECOL	OGICAL INFOR	MATION	J					
Bioelimin	ation		40-50%, DOC an	alysis				OECD 302B
Mobility			On application -	point source int	to the aquatic	environment		
Bioconce	ntration		Due to the high	water solubility,	not expected	to bioconcentra	ate	
ECOTOXI	COLOGICAL D	ATA						
Bacterial	toxicity		IC 50	> 300 mg/	Ί			OECD 209
Fish toxic	ity		LC0	3.2				
			LC 50	8 mg/l	96h Rainbo	w trout		OECD 203
Daphnia t	toxicity		EC 50	30 mg/l				OECD 202
Algae tox	icity		EC 50	no data				
Behaviou	r in treatment p	lants	no adverse effec	ts are to be expe	ected			
ADDITIO	NAL ECOLOGY	DATA						
BOD 5	0 mg	O2/g	COD	1200	mg O2/g	TOC	32%	

SUMMAR

3.3 Special cases

In this section two special cases are described:

a) the algal toxicity test with respect to water soluble dyes with intense colour properties

b) dyes that are poorly water-soluble

a) water soluble dyes with intense colour properties

The algae toxicity test requires special consideration as water-soluble dyes can reduce the transmission of light required by algae for optimal growth.

One of the tests required for the environmental classification of dyes is the algae growth toxicity study. Algae, which are unicellular aquatic plants, need light in order to grow (photosynthesis). Under the conditions of the standard OECD test, intensely coloured substances prevent the passage of light to the algae which inhibits the growth and gives the impression that the dye has produced a toxic effect. In reality the observed inhibition of growth is normally not a result of the chemical's inherent toxicity, but a function of its light reducing capacity. Even if the acute toxicity

results in other species show no toxicity, classification would be made on the basis of this erroneous algal toxicity result. Recent developments include an additional test method that compensates to some degree for light absorption.

Poorly water soluble dyes are often classified as hazardous purely on physical-chemical data rather than on any known ecotoxicity.

b) dyes that are poorly water-soluble

Three areas are critical for the assessment of poorly water- soluble dyes.

I) testing for acute toxicity effects

As previously mentioned water-soluble dyes are classified almost entirely on the basis of the acute toxicity results. However, for poorly water-soluble dyes e.g. disperse dyes it is difficult to test them at the concentrations recommended in the OECD guidelines. Under these circumstances the acute tests are carried out up to the limit of solubility in the test media. If a toxic effect is observed then a true result can be quoted. However, if no toxic effect is seen and because testing at high concentrations is not possible then the only conclusion that can be reached is that the dye is not toxic up to the limit of solubility. Alternatively, the test can be carried out, despite the insolubility, at a nominal concentration e.g. 100 mg/l test substance and any toxic effects observed.

II) bioconcentration potential

The partition coefficient is a measure of the tendency of a substance to dissolve preferentially in either water or n-octanol. n-Octanol is considered a surrogate for fat tissue. The Partition Coefficient is usually expressed as its logarithm (log P). If the log P is \geq 3 then the substance prefers to dissolve in octanol and a potential to bioconcentrate is assumed. If the log P is < 3 then bioconcentration is extremely unlikely to be significant. In the former case a bioconcentration test can be carried out to confirm the predicted behaviour. Bioconcentration is the tendency of a substance to be stored in living tissue and thus to enter the food chain. Poorly

water-soluble substances often have a high n-octanol-water partition coefficient. The fact remains, however, that the majority of dyes that have been tested in a fish bioconcentration test did not show any tendency to bioconcentrate.

III) biodegradation

The majority of dyes are not readily biodegradable.

Overall effect:

Considering all three parameters, a poorly water-soluble dye showing the following properties is labelled R53 – "may cause long-term adverse effects in the aquatic environment". No symbol is required.

- ▶ a water solubility of < 1 mg/l
- ▶ no acute toxicity up to the limit of solubility
- ▶ partition coefficient (log Pow) greater or
- ▶ not readily biodegradable

Long term toxicity studies can be used to further investigate and possibly allay the need to classify a product as "dangerous for the environment". However these tests are time consuming, expensive and not routinely required by the majority of the world's regulatory authorities and are thus not generally carried out. The poorly water-soluble dyes thus remain classified and labelled on the basis of their water solubility and partition coefficient rather than on any known toxicity or bioconcentration.

4. METHODS OF CLASSIFICATION

The classification "dangerous for the environment" can be reached in two

- ► Test data on the preparation itself
- ► The proportion of one or severa components in a preparation that are "dangerous for the environ

The evaluation of the health and environmental hazards of a preparation can be assessed either by a calculation method based on the concentration(s) in the preparation of any component(s) that are hazardous or based on tests carried out on the preparation itself. If test results are available for the preparation then the hazard classification based on these results has priority over calculation methods.

5. TRANSPORT CLASSIFICATIONS

The concept of classifying and label ling preparations as environmentally hazardous is not new

The dyes that will now carry the classification "dangerous for the environment" are actually already known to the customer.

The transport codes ADR and RID introduced this classification for preparations before the EU. Those products which will now carry the symbol "N" are also transport hazards although the labelling is not the same as that required by the EU for supply and the criteria are not identical.

The United Nations recommendations on the transport of hazardous goods introduced, several years ago, two new UN Numbers for goods which are environmentally hazardous but possess no other transport classification. The numbers were allocated to class 9-"Miscellaneous Dangerous Substances" and were UN 3082 (Environmentally Hazardous Substance, liquid, not otherwise specified) and UN 3077 for solids. In 1995 ADR – "Accord Dangereux Routiers" (European Agreement for the international carriage of dangerous goods by road) and RID -"Règlement International concernant le transport des marchandises dangereuses par chemin de fer" (International regulations concerning the carriage of dangerous goods by rail) assigned these two UN numbers item numbers 11 and 12.

The criteria for assignment to this classification were also introduced. The criteria for transport classification are not always the same as for EU hazard labelling but it was clear in the case of dyes that the simplified scheme shown previously could also be applied to this new transport classification. A complicating factor was that ADR and RID also included rules for preparations which preceded the introduction of the EU environmental hazard labelling for such products. In addition much confusion about the country specific introduction date of these rules existed. As some countries adopted the rules faster than others many multinational chemical manufacturers were obliged to immediately classify those products affected - including preparations – as environmental hazards. Those dves which will now carry the EU labelling and R-phrases 50 "Very toxic to aquatic organisms" and R51 "toxic to aquatic organisms" for the first time were already classified under ADR/RID rules as transport hazards by many companies as early as 1995/6. In addition substances and preparations with an ecotoxicity to fish, daphnia or algae of $\leq 1 \text{ mg/l}$ are classified for marine transport as "Marine Pollutants".

Thus the concept and labelling of products which are environmental hazards is not new. In many cases the products have already been identified and labelled for transport by major manufacturers and these labels have been seen by end-users.

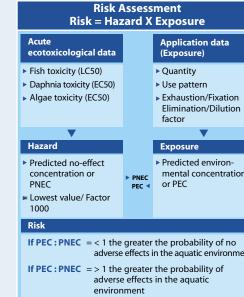
6. ENVIRONMENTAL RISK ASSESSMENT

The classification "dangerous for the environment" is a hazard classifica tion based on product specific data.

The objective of the legislator in the EU is, by means of the enactment of Directives and Guidelines, to achieve a comprehensive control over hazardous chemicals and to harmonise the requirements within the single market. Strategically this objective can only be achieved stepwise. A legislative basis for the process already exists although the implementation and enactment especially with respect to differing product classes e.g. for substances and preparations, are in differing stages of development. In general the legislation controlling substances is developed faster than that for preparations. The classification "dangerous for the environment" was introduced for substances well before being introduced for preparations.

The final step is risk-management achieved by (in order of severity) reporting of import and export quantities, special use conditions, use restrictions, product replacement, and even prohibition. Before risk-management is required it must first be established whether a risk actually exists. The possibility of risk is ascertained by means of a risk-assessment which on its own part follows from a prior knowledge of the potential hazard of a chemical substance. The extent to which a hazard assessment can be carried out depends on the amount of available data. In this process it is crucial to differentiate between hazard and risk. Risk is a function of hazard and exposure. If either of these factors is zero then the risk is also zero.

The classification "dangerous for the environment" is based on hazard assessment. It relates to product specific data and does not necessarily mean that the product involved poses a risk. It must be considered that dyes are intended to be fixed onto the substrate to be coloured and that the amounts entering the aquatic environment will be much smaller than the amount used in the application process. The existence of an actual risk (in this case for the environment) is determined



from the exposure i.e. the concentration of the chemical in a relevant environmental compartment (e.g. water, air, ground) and this may be either calculated or measured. The impact of dyes on the environment is largely limited in the first instance to the aquatic environment. The risk assessment involves a comparison of the "predicted environmental concentration" (PEC) with the ecotoxicological data. Normally the lowest ecotoxicological test value is taken and divided by an assessment factor to give the "Predicted No Effect Concentration" (PNEC). The assessment factor depends on the amount of available data. If only acute data are available an assessment factor of 1000 is used. Generally the assessment factor can only be reduced if long-term (chronic) test data are available. This assessment factor compensates for the fact that not all the data required for a full hazard assessment may be available.

A product classified as "dangerous for the environment" does not necessari present a risk.

The risk is assessed separately and includes the exposure data.

Parameters used for determining environmental concentrations and thus the risk, include the quantity and frequency of use, use patterns, degree of exhaustion and fixation onto the substrate, elimination and/or biodegradation in effluent treatment plants, adsorption-desorption data and the degree of dilution. These parameters vary depending on dye types, application methods, waste water treatment flows and river sizes. The dye manufacturer, in the absence of local data, can normally make only generalised assumptions on the actual risk by using standard models to provide the factors described above.

If the "Predicted Environmental Concentration (PEC)" in the environment is higher than the "Predicted No Effect Concentration (PNEC)" under realistic and typical conditions or using default values the manufacturer is obliged to address the potential risk. For instance additional data could be generated in order to reduce the assessment factor and/or the factors used in the standard model calculation of the predicted environmental concentration can be made more realistic by basing these on actual conditions in practice (e.g. parameters for a major user). In extreme cases field measurements may be necessary. By calculation or measurement the certainty must be assured that the concentration in the environment is below the predicted no effect concentration. If this proves unattainable then risk-management must be introduced.

The parameters for calculating environmental concentrations e.g. quantities, application methods, process and effluent treatment flow volumes, river flow volumes and frequency data differ significantly according to user and region. Thus the manufacturer initially starts with a screening calculation based on "worst case" conditions.

A constant problem is that risk management is introduced by many local authorities based on the hazard assessment and not on a risk assessment. A hazard assessment considers only product specific properties and not the actual risk or total effluent load. Based on these considerations a less hazardous product can pose a higher risk than a more hazardous product.

The following table demonstrates the parameters with an impact on the environmental classification, and hence the labelling of dyes, and the parameters with an impact on the environmental risk assessment.

Parameters with impact on the classification	Parameters with impact on the risk
Aquatic toxicity	Aquatic toxicity
Biodegradation Bioconcentration	Biodegradation – removal (abiotic or adsorption)
	Bioconcentration
	Quantity used per day Exhaustion/fixation rate
	Effluent treatment (flocculation/filtration)
	Waste treatment (printing pastes)
	Dilution factor

Parameters with an impact on the classification, and hence the labelling of dyes, and the parameters with an impact on the environmental risk assessment.

UMMARY

Examples of risk assessment

The first example below shows that a dye classified as "hazardous for the environment" does not pose a high priority risk when assessed by a screening calculation. The second example shows a dye which is not classified as "hazardous for the environment" but which nevertheless presents a risk. These case studies illustrate that the hazard classification may not predetermine the need or otherwise for risk management measures.

Examples of risk assessment Acute ecotoxicity data **Application data** Acute ecotoxicity data Application data ▶Exhaust application ▶ Fish toxicity (LC 50) 200 mg/l ▶Exhaust application ▶Fish toxicity (LC50) 8 mg/l ▶Daphnia toxicity (EC50) 100 mg/l ▶Quantity used = W = 8000 g/d Daphnia toxicity (EC50) 100 mg/l ▶Quantitiy used = W = 150000 g/d ►Algae toxicity (EC50) 80 mg/l ▶Exhaustion = F = 95% ► Algae toxicity (EC 50) 100 mg/l ▶Exhaustion = F = 50% ▶ Water flow = $Q = 40000 \,\text{m}^3/\text{d}$ ► Water flow = $\Omega = 40000 \,\text{m}^3/\text{d}$ ▶Bioelimination = P = 90 % ▶Bioelimination = P = 10% Hazard Hazard ▶ Predicted concentration PNEC Predicted environmental ► Predicted environmental ▶ Predicted concentration no-effect 8/Factor 1000 ▶= 0.008 ppm ►W.((100-F)/100.(100-P)/100))/ ►W.((100-F)/100.(100-P)/100))/ ▶= 0.1ppm 40000 = 0.001 ppm40000 = 0.169 ppmIf PEC: PNEC = < 1 thus a greater probability of no adverse effects in If PEC: PNEC = > 1 thus a greater probability of adverse effects in the the aquatic envir The product is not a priority for further study under these Under these application conditions the product presents application conditions a risk that must be addressed by the manufacturer. **Example 1:** The water soluble dye is classified as "dangerous for the **Example 2:** The water soluble dye is not classified as "dangerous for the nment." Based on the fish toxicity the dye is "toxic to aquatic organisms".

A dye classified as "dangerous for the environment" can still be used safely.