

**Classification of Substances and Mixtures into Water Hazard Classes
according to the Administrative Regulation
on the Classification of Substances Hazardous to Waters
(*Verwaltungsvorschrift wassergefährdende Stoffe; VwVwS*) of 17 May, 1999
- Guidelines for self-classification -**

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1. Introduction

An amended version of the Administrative Regulation on Substances Hazardous to Waters (*Verwaltungsvorschrift wassergefährdende Stoffe*; VwVwS) was published on 17 May, 1999, and entered into force as of 1 June, 1999, creating a new basis for the classification of substances into water hazard classes (*Wassergefährdungsklassen*; WGK) in Germany. In the past, substances were classified on the basis of an evaluation scheme published in 1979 and the classifications were published in VwVwS. This evaluation scheme was subsequently revised according to scientific developments and published in 1998 as a report of the Advisory Council on the Storage and Transport of Substances Hazardous to Waters (LTwS-Schrift No. 28); adequate classification of substances into water hazard classes was thus possible from a technical standpoint, but it did not conform to recent developments in the classification and evaluation of substances in the context of European Law on Chemicals.

The VwVwS Amendment is therefore primarily intended to adapt WGK classifications to the Law on Hazardous Substances. At the same time, however, it is designed to facilitate self-classification by the industry, thus increasing its independence and responsibility. The Administrative Regulation foresees a combination of defined WGK classifications (Annexes 1 and 2), and self-classifications (according to the schemes in Annexes 3 and 4).

All WGK classifications of substances are registered and published by the Federal Environmental Agency. It is therefore irrelevant with respect to legal implementation whether a classification is based upon VwVwS Annex 1, 2, or 3. **All of these classifications are equivalent with regard to their implementation.** Classifications of preparations and mixtures based on VwVwS Annex 4 are usually not centrally registered and published. They are the sole responsibility of the classifier.

This guideline aims at providing an overview of the procedures for self-classification into water hazard classes. It cannot provide rules for each and every particular case. **In borderline cases, the authoritative texts are the Administrative Regulation on Substances Hazardous to Waters (VwVwS) and the Ordinance on Hazardous Substances (and not this guideline).**

Detailed and binding rules for classification are also given in a report of the Advisory Council on the Storage and Transport of Substances Hazardous to Waters (LTwS-Schrift No. 10 of 1999), including cases in which the VwVwS classification scheme does not apply. Classifications of this type will continue to be the responsibility of the Commission for the Evaluation of Substances Hazardous to Waters (whose guidelines are documented in LTwS-Schrift No. 10), and they will be published in VwVwS Annexes 1 and 2.

2. General procedures for the determination of water hazard classes

With respect to the classification into water hazard classes (WGK), VwVwS discriminates between substances (*Stoffe*) and mixtures (*Gemische*). Before the WGK can be determined, it is therefore necessary to decide whether the compound represents a substance or a mixture (the latter term being largely equivalent to the term preparation - *Zubereitung* - of the Chemicals Act). In borderline cases, the definitions in the Chemicals Act apply. The following points may serve as a guide:

- A substance may contain impurities resulting from technical processes. These will usually not have to be evaluated separately, as long as the tests on which the evaluation is based were conducted with the same technical product.
- A reaction mixture not subject to further separation or processing may be considered a substance. The same applies to substances having a complex chemical composition resulting from their (partly) natural origin (e.g. petroleum products and fatty acid esters).
- The Chemicals Act and the Ordinance on Hazardous Substances do not apply to all substances requiring classification into a WGK. In these cases, the R-phrases merely represent a practical procedure for the purpose of WGK classification; they are of no consequence in other sectors of the law.
- If a manufacturer deliberately mixes individual constituents (which may themselves consist of several substances), the result is a mixture.

In the classification of a **substance**, VwVwS discriminates between two groups:

- Substances specified in VwVwS Annexes 1 and 2, and
- all other substances (regardless of whether they are existing or new notified substances in the sense of the Chemicals Act).

VwVwS unequivocally prescribes the priority of the classifications in Annexes 1 and 2; the water hazard classes named in these Annexes therefore apply to the corresponding substances or groups of substances (see Section 4.2 on the possibility of reclassification). The classification scheme in Annex 3 only applies if a substance is not named in Annexes 1 and 2, in which case the water hazard class is derived from R-phrases and/or default values. This procedure is explained in Section 3 of this guideline.

The procedure for a **mixture** is analogous. First, it needs to be ascertained whether the mixture is named in Annexes 1 and 2. This will usually not be the case, however, and the manufacturer will bear the responsibility of classifying the mixture according to VwVwS Annex 4. This procedure is explained in Section 5 of this guideline.

The rules of VwVwS Annex 4 will in general not apply to mixtures of undefined composition (e.g. wastes). The Commission for the Evaluation of Substances Hazardous to Waters (KBwS) will classify these mixtures on the basis of preliminary studies of their composition and their effects.

3. Classification on the basis of R-phrases according to VwVwS Annex 3

If a substance is **not** named in Annexes 1 and 2 of VwVwS¹, then it needs to be classified by the industry according to the provisions in VwVwS Annex 3, and the Office of Documentation and Information on Substances Hazardous to Waters at the Federal Environmental Agency must be informed of the classification.²

The following steps are to be taken in order to derive a water hazard class:

- I. Assessment of the basic data set
- II. Assessment of other hazardous features of the substance
- III. Determination of the R-phrases classifications
- IV. Allocation of evaluation points and default values
- V. Derivation of the water hazard class (WGK)
- VI. Documentation of the classification

These steps are explained below.

3.1 The basic data set

VwVwS provides that a WGK should be assigned to a substance on the basis of at least four hazard characteristics (the so-called "basic data set"):

- Acute oral or dermal toxicity to mammals (e.g. LD₅₀ in rats).
- One piece of data on aquatic toxicity - fishes (acute), daphnia (acute) or algae).
- Biodegradability.
- Potential for bioaccumulation.

Additional data are required before a substance may be classified as "non-hazardous to waters" (cf. Section 3.7).

There are two fundamental ways to establish the data of the basic data set:

a) the substance has been classified into a corresponding R-phrases in Annex 1 of Directive 67/548/EEC ("legal classification" according to the Law on Hazardous Substances),

b) corresponding studies have been conducted and are known to the classifier.

Possibility a) only provides evidence that a substance has certain hazardous characteristics (e.g. toxicity to mammals). Because the EU does not publish whether a substance has been evaluated and determined to be non-toxic, possibility b) applies in such cases. The classifier must therefore procure the corresponding report. This obviously results in a duplication of effort, but it remains unavoidable as long as the EU does not publish "negative classifications". Table 1 shows the R-phrases available

¹ All classifications - including those in VwVwS - are registered at the Office of Documentation and Information on Substances Hazardous to Waters at the Federal Environmental Agency. It is therefore possible to inquire whether a substance has already been classified, either in VwVwS, or by a third party (cf. Section 6).

² Section 4.1. describes the procedure in cases where several classifiers have classified the same substance into different water hazard classes.

for establishing the various components of the basic data set according to possibility a).

Table 1: Establishment of basic data by R-phrases classifications in Annex 1 of Directive 67/548/EEC

Characteristic	R-phrases
Acute toxicity to mammals (oral or dermal)	21, 22, 24, 25, 27, 28, 20/21, 20/22, 20/21/22, 21/22, 23/24, 23/25, 23/24/25, 24/25, 26/27, 26/28, 26/27/28, 27/28
Toxicity to an aquatic organism (fishes, algae or daphnia)	50, 52, 53, 50/53, 51/53, 52/53
Biodegradability	50*, 52*, 53, 50/53, 51/53, 52/53
Potential for bioaccumulation	50*, 52*, 53, 50/53, 51/53, 52/53

* R-phrases 50 and 52 do not describe hazards concerning degradability and potential for bioaccumulation. These characteristics have, however, been tested in each case prior to "legal classification", so that an R-phrases classification into R50 or R52 permits the conclusion that no hazard exists with respect to degradability and potential for bioaccumulation.

Example 1: A substance is "legally classified" into R22-40. In this case there is no need to determine its acute toxicity to mammals, because this characteristic has already been evaluated by the EU. The remaining three characteristics of the basic data set need to be investigated.

Example 2: A "legal classification" into R23/25-52/53 means that all basic data have been established. The classifier therefore does not need to conduct any further investigations.

If the basic data set cannot, or can only partly be established by "legal classifications", the missing data needs to be established in a study by the classifier, or by valid data from the literature (possibility b). The recommended test procedures are given in Annex 1. It is also possible, however, to conduct investigations by other comparable standardized test procedures.

3.2 Other characteristics for hazard assessment

The R-phrases listed in VwVwS Annex 3 (cf. Annex 2 of this guideline) also describe some characteristics hazardous to waters that are not part of the basic data set (e.g. R-phrases on carcinogenic and mutagenic effects).

If such R-phrases are listed in Annex 1 of EU Directive 67/548/EEC ("legal classifications") they must be taken into account in deriving the water hazard class. When this is not the case, the manufacturer or distributor is responsible for allocating an R-phrases according to § 4a of the Ordinance on Hazardous Substances if the corresponding hazards are known. After this R-phrases classification according to the Law on Hazardous Substances, evaluation points are allocated according to Annex 2.

It must be pointed out that the Ordinance on Hazardous Substances requires manufacturers and distributors to search for any specific data available on hazardous characteristics of "their" products. As opposed to the case of basic data (Section 3.1), however, there is no need to demonstrate that scientific studies on other hazard

characteristics have been carried out. Default values are not assigned when such studies are lacking.

3.3 Determination of R-phrases classifications

R-phrases are allocated according to the provisions of the Ordinance on Hazardous Substances. In the case of substances to which the provisions of the Chemicals Act and of the Ordinance on Hazardous Substances do not apply (e.g. pharmaceuticals), R-phrases are determined by analogous procedures. These R-phrases, however, merely represent a practical instrument to determine the water hazard class; they are of no consequence in other sectors of the law.

Tables 2 and 3 provide an overview of the characteristics of the basic data set, and of the resulting R-phrases classifications and WGK evaluation points. The Ordinance on Hazardous Substances and VwVwS remain, however, the authoritative texts in borderline cases.

With respect to R-phrases classifications, it must be kept in mind that the classification always depends on the most sensitive data item.

Table 2: Overview of R-phrases and evaluation points for acute toxicity to mammals

Exposure	LD ₅₀ in mg/kg body weight	R-phrase	Evaluation points
oral	LD ₅₀ ≥ 2000	-	0
dermal	LD ₅₀ ≥ 2000	-	0
oral	200 < LD ₅₀ ≤ 2000	R22	1
dermal	400 < LD ₅₀ ≤ 2000	R21	1
oral	25 < LD ₅₀ ≤ 200	R25	3
dermal	50 < LD ₅₀ ≤ 400	R24	3
oral	LD ₅₀ ≤ 25	R28	5
dermal	LD ₅₀ ≤ 50	R27	5

Example: The acute oral toxicity to rats has been determined as LD₅₀ = 1400 mg/kg. This leads to a classification into R22 and to the allocation of one evaluation point.

Table 3: Overview of R-phrases and evaluation points for various combinations of aquatic toxicity (fishes, algae or daphnia), biodegradability and potential for bioaccumulation

Bio-degradability	Potential for bioaccumulation	aquatic toxicity (LC ₅₀ , EC ₅₀ or IC ₅₀) in mg/l (most sensitive organism)			
		> 100	10 - ≤100	1 - ≤10	≤1
Readily degradable (corresponding to OECD 301)	yes	0 points*	0 points*	R51/53 (6 points)	R50/53 (8 points)
	no	0 points*	0 points*	0 points*	R50 (6 points)
inherently (but possibly not readily) degradable**	yes	0 points	0 points	R51/53 (6 points)	R50/53 (8 points)
	no	0 points	0 points	R51/53 (6 points)	R50/53 (8 points)
not readily and/or not inherently degradable	yes	R53 (3 points)	R52/53 (4 points)	R51/53 (6 points)	R50/53 (8 points)
	no	0 points	R52/53 (4 points)	R51/53 (6 points)	R50/53 (8 points)

* 10 d window is not taken into account in the evaluation of the test on ready biodegradability.

** Substances are inherently biodegradable if they are mineralized in a test on inherent degradability to an extent of more than 60/70% (oxygen demand / DOC elimination) within 28 days. In the test according to OECD 302 B, however, the 70% mark must be attained within 7 days.

Example 1: A substance has a toxicity to fishes of LC₅₀ = 7 mg/l; the degradability study shows that it is not readily degradable; there is no potential for bioaccumulation (log Pow < 3.0). This leads to a classification into R51/53, and 6 evaluation points are allocated to the substance.

Example 2: If the substance in Example 1 is readily degradable, an R-phrases classification becomes unnecessary and no evaluation points are allocated.

If other hazard characteristics are known in addition to those mentioned above (e.g. mutagenic effects), then R-phrases classification must follow the provisions of the Ordinance on Hazardous Substances (cf. Section 3.2).

3.4 Allocation of evaluation points and default values

The allocation of **evaluation points** to the R-phrases of a substance follows the procedures in VwVwS Annex 3. An overview of the evaluation points is given in Annex 2 of this guideline.

The consideration of the R-phrases and, thus, the allocation of evaluation points is based on the following principles:

- There is no double tally of R-phrases on acute oral and dermal toxicity to mammals. The more sensitive characteristic is the only relevant one.

Example 1: A substance classified into R21/22 is allocated 1 evaluation point (not 2 points).

Example 2: A substance classified into R22-24 is allocated 3 evaluation points (neither 4 nor 1 point).

- Classifications reflecting long-term or irreversible effects, and repeated exposures are taken into account in addition to the acute toxicity. Example: A substance classified into R22-40/21/22 is allocated $1 + 2 = 3$ evaluation points.³
- There is no double tally of carcinogenic and mutagenic properties. The more sensitive characteristic is the only relevant one.
- There is no double tally of toxic effects on reproduction; here again, the more sensitive characteristic is the only relevant one. Example: A classification into R61-62 results in 4 evaluation points (not: $4 + 2 = 6$).

If an item is missing from the basic data set, then as a precaution a high level of risk is assumed, and default values are allocated for the corresponding area. For juridical reasons, the allocation of default values is described in a rather incomprehensible manner in VwVwS, and a more intelligible procedure is given below:

In the case of gaps in the basic data set, a high level of risk is assumed for precautionary reasons, and the values given in Table 4 are assigned to the characteristic. This permits a "hypothetical" classification into R-phrases, leading to a derivation of evaluation points. The default value is the difference between the evaluation points of the "hypothetical" R-phrases and the R-phrases from the Ordinance on Hazardous Substances.

Table 4: Precautionary values used to fill gaps in the basic data set

Characteristic missing from the basic data set	Precautionary value used for "hypothetical" R-phrases classification
acute toxicity to mammals (oral or dermal)	LD ₅₀ = <25 mg/kg body weight
toxicity to an aquatic organism (fishes, algae or daphnia)	LC ₅₀ /EC ₅₀ /IC ₅₀ = <1 mg/l
biodegradability	poor degradability
potential for bioaccumulation	BCF > 100

Example 1: The acute toxicity to mammals is unknown. Therefore, a precautionary LD₅₀ of <25 mg/kg is assumed according to Table 4, leading to a "hypothetical" classification into R28 and thus to a default value of 5 points.

Example 2: The toxicity to fishes is LC₅₀ = 8 mg/l. The potential for bioaccumulation is low (log Pow = 2,0); the degradability is unknown. According to the Ordinance on Hazardous Substances, there is no need to classify the substance in this case. The "hypothetical" assumption of poor biodegradability, however, results in a classification into R51/53 and thus to a default value of 6 points.

³ When R-phrases 20 to 28 form part of an R-phrase combination that applies to long-term or irreversible effects (e.g. R48/25), this describes the pathway of exposure (in this case: oral), and does not provide an assessment of the acute toxicity. The evaluation points are obtained from Annex 2. This type of classification does not represent evidence for the completeness of the basic data set.

3.5 Derivation of water hazard classes (WGK)

The evaluation points and default values allocated to a substance are added up to obtain the total number of points, and thus the water hazard class:

Total number of points	Water hazard class (WGK)
0 to 4	1
5 to 8	2
9 and more	3

When the total is 0 the substance may be classified as "non-hazardous to waters" if it fulfills certain other prerequisites; see Section 3.7.

3.6 Documentation of the classification

The classifier is required to document the classification and send a copy for registration and publication purposes to the Office of Documentation and Information on Substances Hazardous to Waters (Dokumentations- und Auskunftsstelle wasser-gefährdende Stoffe im Umweltbundesamt, Schichauweg 58, 12307 Berlin; Fax +49 030-8903-4200). The documentation should adhere to the form of Annex 3. It is planned to perform the documentation electronically in the future.

The classifier is required to inform the Office of Documentation and Information without delay of any changes in the data documented.

3.7 Substances non-hazardous to waters

To classify a substance as "non-hazardous to waters", it must first be evaluated according to VwVwS Annex 3 (as described above). A substance is non-hazardous to waters if its total number of points is 0 and it fulfills all of the following prerequisites:

- Low solubility in water (less than 100 mg/l in the case of gases and solids, less than 10 mg/l in the case of liquids),
- No toxicity at saturation levels (tested with at least two organisms - fishes, daphnia or algae),
- Ready biodegradability in the case of organic liquids.

The data on toxicity and biodegradability must be documented by laboratory reports or appropriate literature citations, and they must be sent to the Office of Documentation and Information on Substances Hazardous to Waters along with the documentation form.

4. Special cases

4.1 Discordant classifications of the same substance

If the Office of Documentation receives two different WGK classifications for one and the same substance, it will first examine whether one of them is based on default

values. If this is the case, the classification with the lower number of default points will be valid.

If the difference in classification is based on different R-phrases, the Office will inform both classifiers of the discordance and ask them to compare their data. If this leads to an agreement, the resulting WGK will be published.

If the comparison does not result in an agreement, the substance will be classified by the Commission for the Evaluation of Substances Hazardous to Waters (KBwS). If a prolonged delay in the evaluation by KBwS is to be expected, the higher WGK will be published provisionally. The classification by KBwS will be published in VwVwS Annex 2.

The data of a documented classification will be made available to third parties only if they can show a legitimate interest. This usually applies if they are themselves conducting and documenting a classification of the substance in question, or if they require the data in their capacity as operators in a water licensing procedure.

4.2 Reclassification of substances named in VwVwS Annex 2

The classifications in VwVwS Annex 2 are based on the former scheme for classification of substances hazardous to waters. This procedure is documented in LTwS-Schrift No. 28. Applications to reclassify substances in Annex 2 on the basis of the new evaluation scheme may be submitted to the Commission for the Evaluation of Substances Hazardous to Waters (KBwS).

The application for reclassification must include the data on the identity of the substance along with its present R-phrase classifications.

The KBwS decides whether a substance is to be reclassified according to VwVwS Annex 3, or whether it will continue to be named and classified specifically in Annexes 1 or 2.

4.3 Classification of groups, and classification based on analogies

VwVwS does not provide for a classification of groups by classifiers in the industry. If it is desired to categorize certain groups of substances having the same structural or functional characteristics, or the same mode of action as a substance group in VwVwS Annexes 1 and 2, a corresponding application must be submitted to the Commission for the Evaluation of Substances Hazardous to Waters (KBwS). The WGK of a substance group applies to each individual substance in the group.

In principle, VwVwS does not permit classifications by analogy; rather, the basic data set (cf. Section 3.1) must be created for every substance. Analogies are only permissible in the very restrictive framework applying to the registration of new notified substances according to the Chemicals Act. Classifications by analogy are restricted to special cases in which testing is superfluous according to the present level of scientific knowledge, or impossible for technical reasons.

On the other hand, assessments by analogy may be conducted by KBwS if the data indicate it to be plausible and sensible. This will generally follow the same procedures named above for the classification of groups.

4.4 Classification by procedures other than those in VwVwS Annex 3

In most cases the classification scheme based on R-phrases adequately reflect the water hazard characteristics of a substance. There are a few substances, however, where classification by procedures other than those in VwVwS Annex 3 will be appropriate. This may be the case when a hazardous characteristic is not accounted for by R-phrases (e.g. high mobility in the soil with resulting hazards to the groundwater), or when certain hazardous characteristics leading to R-phrase classifications are not, or hardly applicable to aquatic pathways (e.g. limited bioavailability).

These cases are assessed by the Commission for the Evaluation of Substances Hazardous to Waters (KBwS) and published in VwVwS Annexes 1 and 2. Corresponding applications may be submitted to KBwS. The procedure is described in detail in LTWS-Schrift No. 10 of 1999.

5. Classification of mixtures

VwVwS Annex 4 specifies the methods to derive the water hazard class for a mixture. The first consists of a computation of the WGK on the basis of the components WGK (as in the 1996 VwVwS). Secondly, the WGK may be derived from tests conducted with the mixture itself. Results obtained by the latter method have priority.

5.1 Classification based on the water hazard classes of the components

The computation rule in Annex 4 is basically identical to the former rule in the 1996 VwVwS. It first requires the determination of the WGK of each single component by the methods that apply to substances in general. If the identity of a component is unknown or undefined, then as a precaution WGK 3 is assumed for that component.

The mass fractions of the individual components are added up by their WGK, and the WGK of the mixture is then determined according to Table 5. Components are taken into account if their fraction surpasses the following thresholds:

- 0.1% in the case of carcinogenic substances
- 0.2% in the case of all other substances
- If carcinogenic substances are *actively added* to a mixture and their fraction is less than 0.1%, the mixture is classified at least into WGK 1; the same applies when the fraction of WGK 3 additives is less than 0.2%.

Table 5: Computation rule for the derivation of the WGK of a mixture from the WGK of its components

Ingredients (components)	Result			
	WGK 3	WGK 2	WGK 1	non-hazardous
WGK 3	≥ 3 %	0.2 to 3 %	< 0.2% in case of additives	< 0.2% (no addi- tives permitted)
WGK 2		≥ 5%	0.2 to 5%	< 0.2%
WGK 1			≥ 3%	< 3%
non-hazardous				
R45 (carcinogenic)	≥ 0.1%	≥ 0.1%, but WGK 2	< 0.1% in case of additives	< 0.1% (no addi- tives permitted)

Example 1: If a mixture contains a total of 3% of WGK 2 components and no WGK 3 components, this yields WGK 1 for the mixture as a whole.

Example 2: If a 0.05% fraction of a WGK 3 component is added to a substance non-hazardous to waters, the mixture is classified into WGK 1. If, however, the substance contains this component only as an impurity resulting from the production process, then it is "non-hazardous to waters".

Example 3 (dilution): A mixture containing a total of 20% of WGK 2 components and 80% of WGK 1 components is classified into WGK 2. If the mixture is diluted with water at a ratio of 1:1, yielding a fraction of 10% of WGK 2 components, it is still classified into WGK 2. If, however, it is diluted at a ratio of 1:4, the total fraction of WGK 2 components is only 4%, and the diluted mixture is classified into WGK 1.

5.2 Classification based on test data obtained with the mixture

A novel feature of the present VwVwS, compared to the 1996 VwVwS, is that it permits the classification of mixtures on the basis of test data obtained with the mixture itself. It may become feasible in the future to apply the corresponding provisions of the Law on Hazardous Substances in such cases, but the EU Directive 1999/45/EC on classification, packaging and labelling of dangerous preparations has not yet been adopted into German legislation.

VwVwS Annex 4 Number 4 provides for the following procedure:

- The R-phrases on acute toxicity to mammals are to be determined according to the Law on Hazardous Substances (either from data obtained with the mixture, or from data on the components). There are no specific provisions in VwVwS. If test data are not available, then a default value of 5 points is assumed (as in the case of substances, cf. Section 3).
- The environmental hazard is to be assessed by toxicity tests with at least two aquatic organisms (fishes, daphnia, or algae). The results lead to an allocation of evaluation points according to Table 6.⁴

⁴ Table 6 is based on the assumption that the usual tests on degradability and bioaccumulation will not always yield adequate results in the case of mixtures. Example: A mixture may have 65% de-

- R-phrases on all other hazard characteristics are classified according to the Law on Hazardous Substances (Ordinance on Preparations) and the evaluation points are allocated according to VwVwS.
- The evaluation points are added up and the WGK is derived according to the Table in Section 3.5.

Table 6: Evaluation of test results on the aquatic toxicity of mixtures

LC₅₀/EC₅₀/IC₅₀ in mg/l (most sensitive value of two trophic levels)	Evaluation points
LC/EC/IC > 100	3
10 < LC/EC/IC ≤ 100	4
1 < LC/EC/IC ≤ 10	6
LC/EC/IC ≤ 1	8
tests lacking (or tests with only one species)	8

5.3 Documentation and publication

The classification of mixtures is the responsibility of the manufacturer or distributor. There are no provisions for centralized collection and publication of the classifications. It is recommended, however, that classifiers maintain a documentation (on the safety data sheet, if possible), to enable operators of facilities to prove their adherence to the guidelines in a water licensing procedure.

5.4 Deviation from the classification in VwVwS Annex 4 and Number 2.2.2

The Administrative Regulation provides that classification of a mixture may deviate from the procedures named above. This may be necessary, for instance, if substances behave differently in the mixture than they do in the pure state. Another aspect might be that studies on degradation and bioaccumulation potential of the individual components demonstrate that a mixture exclusively contains components that are readily degradable and do not bioaccumulate.

In such cases, an application may be submitted to the Commission for the Evaluation of Substances Hazardous to Waters (KBwS), which may then classify the mixture differently, if appropriate, and subsequently propose its publication in VwVwS Annex 1 or 2 to the Federal Ministry of the Environment. Deviating classifications may only be conducted by KBwS; VwVwS does not provide for classifications based on expert opinions and the like.

gradability, even though it contains a 10% fraction of a persistent component; based on the precautionary principle, it is therefore assumed that the mixture is not readily degraded and/or that it may bioaccumulate.

6. Office of Documentation and Information on Substances Hazardous to Waters at the Federal Environmental Agency

Documented WGK classifications are registered and published by the Office of Documentation and Information on Substances Hazardous to Waters at the Federal Environmental Agency. Publications by the Office include the substances classified by VwVwS Annexes 1 and 2. Thus, all classifications are available in single list.

Classifications are published by the following methods:

- Internet (Address: www.umweltbundesamt.de/wgk.htm); updated monthly.
- CD-ROM (first publication: end of 1999); updated twice a year.
- In print (first publication: end of 1999); updated once a year.

In addition, WGK classifications can be obtained by calling the phone number +49-030-8903-4168 (Fax: -4200).

Addresses:

Umweltbundesamt
Dokumentations- und Auskunftsstelle wassergefährdende Stoffe
Schichauweg 58
12307 Berlin

Email: wgk@uba.de

Applications for reclassification and for deviating classifications may be submitted to the KBwS Secretariat

Geschäftsstelle der Kommission Bewertung wassergefährdender Stoffe (KBwS)
im Umweltbundesamt
Schichauweg 58
12307 Berlin

Annex 1: Test procedures for the determination of the basic data set

Characteristic	Test protocol					
	EU	OECD	CEN	DIN EN ISO	DIN	DEV
Acute oral or dermal toxicity to mammals	Corresponding to the effective OECD guidelines (401, 402, 420 oder 423) or EU Directives; for reasons of animal protection, results of similar studies are acceptable if the data have been published in the scientific literature.					
Toxicity to aquatic organisms:						
Fishes (acute)	92/69/EEC C.1	203		7346	(38412 L15)**	L15
Algae	92/69/EEC C.3	201	28692	8692		L9
Daphnia (acute)	92/69/EEC C.2	202, Part I		6341	38412 L11	L40
Inherent bio-degradability	88/302/EEC Teil C	302 B 302 C	29888	9888	(38412 L25)**	L25
Readily bio-degradable	92/69/EEC C.4-A	301 A		7827		L29
	92/69/EEC C.4-C	301 B	29439	9439		L23
	92/69/EEC C.4-F	301 C				
	92/69/EEC C.4-E	301 D		10707 (draft) 10708		
	92/69/EEC C.4-B	301 E				
	92/69/EEC C.4-D	301 F	29408	9408 (draft) 14593 (draft)		L22
Bioaccumulation behavior,* log Pow		107 117				
Bioaccumulation in fishes		305				

* It is permissible to assess the bioaccumulation behavior by computing a log octanol/water distribution coefficient (log Pow) (according to Chapter 4 of the Technical Documents in Support of the Commission Directive 93/67/EEC on Risk Assessment of New Notified Substances, and of Commission Regulation 1488/94 on Risk Assessment of Existing Substances, Ispra 1996).

** Older results obtained with tests corresponding to this norm may be used as well.

Annex 2: Allocation of evaluation points for R-phrases, and of default values

Number of points	1	2	3	4	5	6	7	8	9
Ecotoxicity and degradation/bio-accumulation				52/53		51/53		50/53	
undetermined				☼ 3)		☼ 2)		☼ 1)	
Ecotoxicity			52			50			
undetermined						☼ 4)			
Degradation/bio-accumulation			53						
undetermined			☼ 5)						
Acute oral and/or dermal toxicity to mammals	22 65 21 20/22 21/22 20/21/22 20/21		25 24 23/25 24/25 23/24/25 23/24		28 27 26/28 27/28 26/27/28 26/27				
undetermined					☼				
Carcinogenic and/or mutagenic effects		40							45 46
Irreversible effects		40/21 40/22 40/20/21 40/20/22 40/21/22 40/20/21/22		39/24 39/25 39/23/24 39/23/25 39/24/25 39/23/24/25		39/27 39/28 39/26/27 39/26/28 39/27/28 39/26/27/28			
Repeated exposure		33 48/21 48/22 48/20/21 48/20/22 48/21/22 48/20/21/22		48/24 48/25 48/23/24 48/23/25 48/24/25 48/23/24/25					
Toxic effects on reproduction		62 63		60 61					
Harmful reaction with water		29 15/29							

☼ = Number of points in cases where one or several of the characteristics "ecotoxicity", "degradation/bioaccumulation" and "acute toxicity" are not determined, or unknown (see footnotes)

Note: Not all evaluation points are allocated additively (cf. VwVwS Annex 3).

Footnote 1) : This value is allocated when

- Ecotoxicity, and degradation and/or bioaccumulation are unknown, or
- Ecotoxicity is unknown and ready degradation has not been demonstrated, or
- Ecotoxicity is unknown and bioaccumulation potential exists, or
- The substance is classified into R 50, and degradation and/or bioaccumulation are unknown

Footnote 2) : This value is allocated when ecotoxicity is greater than 1 and smaller than or equal to 10 mg/l, and degradation and/or bioaccumulation are unknown.

Footnote 3) : This value is allocated when ecotoxicity is greater than 10 and smaller than or equal to 100 mg/l, and degradation is unknown.

Footnote 4) : This value is allocated when ecotoxicity is unknown, and ready degradation has been demonstrated and no potential for bioaccumulation exists.

Footnote 5) : This value is allocated when

- Degradation and bioaccumulation are unknown, and ecotoxicity is greater than 100 mg/l, or
- Degradation is unknown and bioaccumulation potential exists, and ecotoxicity is greater than 100 mg/l, or
- Bioaccumulation is unknown and ready degradation or inherent degradation have not been demonstrated, and ecotoxicity is greater than 100 mg/l.

Note: Bioaccumulation potential exists when $\log Pow \geq 3.0$, unless $BCF \leq 100$.

Annex 3 Documentation form for WGK classifications

**Documentation of WGK classification according to Annex 3 of the
Administrative Regulation on Substances Hazardous to Waters (VwVwS) of 17
May, 1999**

Applicant data

Firm
Department
Contact Person
Street / P.O. Box
Post Code City
State

Date

--

e-mail-address

--

Telephone/Fax

--

Substance specifications**Unequivocal chemical
name of the substance**

--

**Synonymous name
(optional)**

--

CAS-No(s).⁵

	EG-No(s).	
--	------------------	--

**R-pharse classification
according to § 4a (3) of the
Ordinance on Hazardous
Substances**

--

**R-pharse-evaluation points
according to VwVwS****Default value for toxicity
to mammals**

--

**Default value for
Environmental hazard**

--

Total number of points

--

WGK⁶

--

Comments

--

--

⁵ This information is only required if a CAS-number has been allocated. The commercial name and the EG-number are sufficient in the case of new notified substances according to the Chemicals Act if the characteristics of the substance are confidential.

⁶ For substances non-hazardous to waters please indicate „nwg“.

Additional data only for „substances non-hazardous to waters“:

State (solid, liquid, gas)		at 20° C		Laboratoy report included?
Solubility in water		mg/l at 20°C		
Acute oral/ dermal toxicity for mammals	Species/sex	LD_x/ Application procedure	Value in mg/kg b.w.	
Aquatic toxicity	Species	LC_x/EC_x/IC_x	Value in mg/l	
Species 1				
Species 2				
Biodegradability	Test procedure	Degree of degradation after 28 d in %	10 d window attained?	
(only in case of organic liquids)				

Applicants must inform the Federal Environmental Agency, Office of Documentation and Information on Substances Hazardous to Waters (Dokumentations- und Auskunftsstelle wassergefährdende Stoffe im Umweltbundesamt, Schichauweg 58, 12307 Berlin) of any new information leading to a change in WGK.

Signature of the applicant , stamp

Comments of the applicant

Applicants should inform the Office of Documentation and Information on Substances Hazardous to Waters at the Federal Environmental Agency of any characteristics that may affect the hazard to waters and are not represented by R-phrase classifications known to them (e.g. characteristics related to mobility in the soil).

Annex 4: Examples of evaluations

Example 1 - A substance that is already classified

Situation

The water hazard class of 2-chloroaniline is to be determined.

Procedure

2-chloroaniline is classified in VwVwS Annex 2 (Registration No. 694, WGK 2). This water hazard class is valid and no further action is needed.

Example 2 - A substance that is well-researched and relatively non-hazardous

Situation

The following data are known:

- Acute oral toxicity to mammals, determined in rats: $LD_{50} > 2000$ mg/kg body weight
- Toxicity to fishes: $LC_{50} > 100$ mg/l
- Toxicity to algae: $IC_{50} = 580$ mg/l
- Toxicity to daphnia: $EC_{50} = > 1000$ mg/l
- Degradability: readily biodegradable according to OECD 301 D
- $\log Pow = 2.5$
- State: solid
- Solubility in water = 1150 mg/l

Procedure

According to Hazardous Substances Law, an R-phrase classification of this substance is unnecessary. The basic data set is available. There are no default values to be allocated and the total number of points is 0. Because the substance has a solubility in water greater than 100 mg/l, however, it can not be classified as "non-hazardous to waters" (VwVwS No. 2.2.2). Therefore the water hazard class is WGK 1.

Example 3 - A substance that is well-researched and relatively hazardous

Situation

The following data are known:

- Acute oral toxicity to mammals, determined in rats: $LD_{50} = 150$ mg/kg body weight
- Toxicity to fishes: $LC_{50} = 10$ mg/l
- Toxicity to algae: $IC_{50} = 5$ mg/l
- Toxicity to daphnia: $EC_{50} = 70$ mg/l
- Degradability: not readily biodegradable according to OECD 301 E, but inherently degradable according to OECD 302 B
- $\log Pow = 2.5$

Procedure

Because of its toxicity to mammals, the substance is classified into R25 (range of toxicity: $25 < LD_{50} \leq 200$ mg/kg).

The assessment of environmental hazard depends on the most sensitive organism (in this case: algae). The toxicity to algae is situated in the range between 1 and 10 mg/l, and the substance is not readily biodegradable. Therefore, it is classified into R51/53. Comments: The inherent degradability of the substance does not result in a change in classification; if it were readily biodegradable, an R-phrase classification due to environmental hazard would be unnecessary.

All of the data of the basic data set are available; therefore no default values are allocated.

The total number of points according to VwVwS Annex 3 No. 1 is 3 (due to R25) plus 6 (due to R51/53), equal to 9 points. Therefore the water hazard class is WGK 3.

Example 4 - A substance that is not well-researched (I)

Situation

The following data are known:

- Acute oral toxicity to mammals, determined in rats: $LD_{50} > 2000$ mg/kg body weight
- State: solid
- Solubility in water = 50 mg/l

Procedure

The data do not necessitate a classification into R-phrases; therefore, this does not result in any evaluation points.

The basic data set is incomplete, however, because there are no known experimental data on the environmental hazard. Therefore, VwVwS Annex 3 No. 2 requires the allocation of a default value with the highest possible number of points for environmental hazard (8 points, corresponding to R50/53).

Thus, the total number of points is 8 and the water hazard class is WGK 2.

Example 5 - A substance that is not well-researched (II)

Situation

The following data are known:

- Acute oral toxicity to mammals, determined in rats: $LD_{50} > 500$ mg/kg body weight
- Toxicity to fishes: $LC_{50} = 50$ mg/l

Procedure

Because of its toxicity to mammals, the substance is classified into R22 (range of toxicity: 200 to 2000 mg/kg).

The data on toxicity to fishes do not necessitate an R-phrase classification. The need to allocate default values according to VwVwS Annex 3 No. 2 must be examined, however, because the basic data set is incomplete (lack of data on biodegradability and on bioaccumulation potential). The lack of data implies that the substance might not be readily biodegradable, in which case it would have to be classified into

R52/53. Therefore, the default value is 4 (corresponding to R52/53). On the other hand, the bioaccumulation potential is irrelevant with respect to an allocation of default values, because it would not require R-phrases classification in any case. Thus the total number of points is 1 (due to R22) plus 4 (default value), equal to 5, and the water hazard class is WGK 2.

Example 6 - Classification of a mixture based on data on its components

Situation

All components of a mixture, as well as their water hazard classes, are known. The total sums of the fractions by water hazard class are as follows:

- Substances non-hazardous to waters: 9.9%
- WGK 1: 89%
- WGK 2: 1%
- WGK 3: 0.1 %
- Carcinogenic substances: none

Procedure

The hazard is determined in this case by the fractions of WGK 1, as well as WGK 2 substances. According to VwVwS Annex 4 No. 3.2, mixtures consisting of 0.2 to <5% WGK 2 substances, and mixtures with 3% or more WGK 1 substances are classified into WGK 1. At the same time, the fraction of WGK 3 substance is lower than the threshold required for consideration according to VwVwS Annex 4 No. 1.

The water hazard class of the mixture is WGK 1.

Example 7- Classification based on test data obtained with the mixture

Situation

The components of a mixture are only partially known, but tests with the mixture itself have given the following results:

- Acute oral toxicity to mammals, determined in rats: LD₅₀ >2000 mg/kg body weight
- Toxicity to fishes: LC₅₀ = 15 mg/l
- Toxicity to daphnia: EC₅₀ = 7 mg/l

Procedure

The acute toxicity to mammals does not necessitate a classification into R-phrases; therefore, it does not result in any evaluation points.

According to VwVwS Annex 4 No. 4.3, the allocation of evaluation points for environmental hazard depends on the most sensitive organism (in this case: daphnia). As the toxicity to daphnia is in the range between 1 and 10 mg/l, 6 points are allocated according to VwVwS Annex 4 No. 4.3.

The total number of points is 6 and the resulting water hazard class of the mixture is WGK 2.