

Technical Rules for Hazardous Substances	National aspects when compiling safety data sheets	TRGS 220
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The Technical Rules for Hazardous Substances (TRGS) reflect the state of the art, the state of occupational health and occupational hygiene as well as other sound work-scientific knowledge relating to activities involving hazardous substances including their classification and labelling. The

Committee on Hazardous Substances (AGS)

compiles or adapts the rules, and they are announced by the Federal Ministry of Labour and Social Affairs (BMAS) in the *Gemeinsames Ministerialblatt* [Joint Ministerial Gazette (GMBI)].

This TRGS specifies, within its scope of application, the requirements of the *Gefahrstoffverordnung* [German Hazardous Substances Ordinance, GefStoffV]. By complying with the Technical Rules, the employer may therefore assume that the corresponding requirements of the Ordinance have been fulfilled. Should the employer choose a different solution, he must then achieve at least the same level of safety and the same health protection for his employees.

Contents

- 1 Scope
- 2 Definition of terms
- 3 General points
- 4 National aspects in the compiling of safety data sheets
- 5 Qualifications for the authors of safety data sheets
- 6 Frequently asked questions on safety data sheets

1 Scope

(1) The basis for this TRGS and for the compiling and supplying of safety data sheets (SDS) is Article 31 and Annex II of Regulation (EC) no. 1907/2006 (REACH)¹ in conjunction with section 5 of the *Gefahrstoffverordnung* (GefStoffV) and the "Guidance on the compilation of safety data sheets" issued by the European Chemicals Agency².

¹ As last amended by Regulation (EU) no. 2015/830.

² https://echa.europa.eu/documents/10162/23036412/sds_en.pdf.

(2) This TRGS supplements the "Guidance on the compilation of safety data sheets" issued by the European Chemicals Agency, incorporating national requirements that apply when substances or mixtures are placed on the market in Germany.

2 Definition of terms

The terms used in the German original of this TRGS are as defined in the *Begriffsglossar zu den Regelwerken der Betriebssicherheitsverordnung (BetrSichV), Biostoffverordnung (BioStoffV) und der Gefahrstoffverordnung (GefStoffV)* glossary issued by the Committee for Industrial Safety (ABS), the Committee for Biological Agents (ABAS) and the Committee on Hazardous Substances (AGS).³

3 General points

3.1 Guidance on the compilation of SDS

The compilation of SDS on the basis of REACH is detailed described in the "Guidance on the compilation of safety data sheets" issued by the European Chemicals Agency. The ECHA Guidance does not, however, cover all national provisions. This TRGS thus provides guidance to help the authors and users of SDS take account of the applicable national requirements.

3.2 Substances and mixtures pursuant to TRGS 905 and TRGS 907

SDS for substances listed in TRGS 905 "List of substances that are carcinogenic, mutagenic or toxic for reproduction" or TRGS 907 "List of sensitising substances and activities involving sensitising substances" and mixtures that contain such substances must indicate the effects of said substances and mixtures. This information should be provided in sections 2, 11 and 15. Where required, the necessary information on safe use should also be included in sections 7 and 8.

3.3 Activities or procedures pursuant to TRGS 906

SDS for substances and mixtures must also indicate activities and procedures that are listed in TRGS 906 "List of carcinogenic activities or processes according to article 3 paragraph 2 no. 3 of the Hazardous Substances Ordinance". The information should be provided in section 15; information on safe use should if applicable also be provided in sections 7 and 8.

3.4 Additional duty of disclosure

If the information on impurities or additives provided on the label or in the SDS of a substance or the information provided on the label or in the SDS of a mixture is not sufficient to allow the correct classification of new mixtures produced from these substances or mixtures, the supplier of the substance or mixture has a duty to provide, on request and without delay, all information required for correct classification of said new mixtures.

³ <http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Glossar/Glossar.html>

3.5 Language of the SDS

Safety data sheets for substances and mixtures that are placed on the market in Germany must be written in German.

4 National aspects when compiling safety data sheets

4.1 Section 1: Identification of the substance/mixture and of the company / undertaking

4.1.1 SDS subsection 1.4: Emergency telephone number

(1) Germany does not currently have an official advisory body to provide an emergency information service. A company emergency telephone number can therefore be specified in section 1.4 of the SDS⁴.

Example:

1.4 Emergency telephone number	Plant fire brigade XXXXXX ...
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If the emergency telephone number is not available around the clock, this must be indicated in the SDS.⁵

Example:

1.4 Emergency telephone number	XXXXXX ... only available Mon. to Fri. between 8:00 and 17:00
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(2) The emergency information service can also be provided by a competent service provider⁶. In Germany, the service is usually provided by *Giftinformationszentren* (GIZ) on the basis of a contractual fee agreement. If this is this case, the telephone number of the GIZ should be specified in the SDS. The use of services is governed by the terms of the agreement.⁷

Example:

1.4 Emergency telephone number	Poison emergency number City XXXXXX ... (24 h, Mon. – Sun.)
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4.2 SDS section 2: Hazards identification

(1) Section 2 should set out the classification of the substance or mixture in accordance with Regulation (EC) no. 1272/2008 (CLP).

(2) Pursuant to section 4 par 3 *Gefahrstoffverordnung*, classification must also comply with the rules and findings published in section 20 par. 4 *Gefahrstoffverordnung*. These include the rules and findings from the AGS that are published as TRGS 905

⁴ A company emergency telephone number must ensure immediate, competent emergency medical advice in German.

⁵ This option should only be used in exceptional cases as accidents with chemical substances and mixtures can occur outside working hours.

⁶ See "Guidance on the compilation of safety data sheets", version 3.1 – November 2015, 3.1, no. 1.4; http://echa.europa.eu/documents/10162/13643/sds_de.pdf

⁷ List of *Giftnotrufzentrale* emergency telephone numbers: <http://www.bfr.bund.de/cm/343/verzeichnis-der-giftinformationszentren.pdf> and <https://www.giz-nord.de/cms/index.php/giftnotrufliste-lang.html>

and TRGS 907 in the *Gemeinsames Ministerialblatt* ministerial gazette and are available on the website⁸ of the Federal Institute for Occupational Safety and Health (BAuA).

(3) Appendix 1 TRGS 907 contains a list of substances and groups of substances that have, on the basis of reliable scientific, evidence been found to have respiratory or skin sensitising effects but which have not to date been classified as sensitisers in Annex VI CLP. When identifying and examining available information on substances pursuant to Article 5 CLP, the manufacturer, importer or downstream user must, however, pursuant to section 4 par 2 GefStoffV, examine the underlying data for classification as a respiratory sensitiser (Sa) or skin sensitiser (Sh) pursuant to Appendix 1 TRGS 907 (see grounds for classification of the substance as a sensitiser) and if applicable include relevant information in the SDS.

(4) The same applies accordingly for the carcinogenicity, germ cell mutagenicity and reproductive toxicity of a substance pursuant to TRGS 905.

(5) The publications of the *Deutsche Forschungsgemeinschaft e. V.* (DFG), in particular the list of MAK and BAT values⁹, contain information on classification that is to be considered as reliable scientific evidence in the establishment and assessment of relevant available information. TRGS 900 "Occupational exposure limits" and the list of MAK and BAT values contain information on substances that can be absorbed into the skin (H), respiratory sensitisers (Sa), skin sensitisers (Sh) and respiratory and skin sensitisers (Sah).

(6) To ensure clear and transparent classification, the procedure used for a given classification endpoint should be stated together with the classification in section 2. Alternatively, the classification procedure can also be specified in section 16. The specific concentration limit (SCL) for a substance should also be indicated in the same way as recommended for M-factors (pursuant to ECHA Guidance on the compilation of safety data sheets).

⁸ See <http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/TRGS/TRGS.html>

⁹ http://www.dfg.de/dfg_profil/gremien/senat/gesundheitschaedliche_arbeitsstoffe/

(7) Example of substance classification information:

Classification Pursuant to CLP	Classification procedure ¹⁰	SCL or M-factor
Flam. Liq. 2; H225	On the basis of test data	
Acute Tox. 4; H332	On the basis of test data	
Acute Tox. 4; H312	Experience from practice/in people	
Acute Tox. 4; H302	List classification pursuant to Annex VI CLP checked	
Skin Corr. 1B; H314	On the basis of test data	Skin Corr. 1B; H314: $C \geq 0.6 \%$ Skin Irrit. 2; H315: $0.06 \% \leq C < 0.6 \%$ Eye Irrit. 2; H319: $0.06 \% \leq C < 0.6 \%$
Skin Sens. 1; H317	TRGS 907, reliable scientific evidence	
Aquatic Acute 1; H400	On the basis of test data	M=10
Aquatic Chronic 2; H411	On the basis of test data	

(8) Example of mixture classification information:

Classification pursuant to CLP	Classification procedure ¹⁰	SCL or M-factor
Flam. Liq. 2; H225	On the basis of test data	
Acute Tox. 4; H332	Calculation method	
Acute Tox. 4; H312	Calculation method	
Acute Tox. 4; H302	Calculation method	
Skin Corr. 1B; H314	Bridging principle: "Substantially similar mixtures"	Skin Corr. 1B; H314: $C \geq 7.0 \%$ Skin Irrit. 2; H315: $5.0 \% \leq C < 7.0 \%$ Eye Irrit. 2; H319: $5.0 \% \leq C < 7.0 \%$
Aquatic Chronic 3; H412	Bridging principle: "Interpolation within one toxicity category"	Aquatic Chronic 3, H412: $C \geq 63 \%$

4.3 SDS section 7: Handling and storage

4.3.1 SDS subsection 7.2 Conditions for safe storage, including any incompatibilities

This section of the SDS should include supplementary information on the substance or mixture in the national storage class system. The storage class [*Lagerklasse*] is to be defined on the basis of TRGS 510 "Storage of hazardous substances in non-stationary containers". The storage class provides information on the bans or restrictions on storing substances together, for example.¹¹

¹⁰ Can also be provided in section 16; otherwise, add "Note: Please see Section 2.1 (Classification)."

¹¹ The storage class pursuant to TRGS 510 can also be specified with the national regulations in section 15.

Examples of information in the SDS:

Information on combined storage	
Storage class (TRGS 510):	Storage class 8B (non-combustible corrosive substance)

4.3.2 SDS subsection 7.3 Specific end use(s)

There is a wide range of information at a national level including advice, recommendations and measures to ensure the safe use of end products i.e. substances and mixtures designed for specific end uses. This information can be referenced in subsection 7.3 of the safety data sheet.

4.3.2.1 Technical Rules for Hazardous Substances (TRGS)

(1) TRGS 420 set out procedural and substance-specific criteria (VSK). For defined activities with hazardous substances, procedural and substance-specific criteria set out practical requirements for the employer for risk assessments and detail suitable protective measures and rules for monitoring their effectiveness.

(2) Further job-specific and substance-specific requirements are set out in the "500" set of Technical Rules, for example TRGS 512 "Fumigations", TRGS 513 "Working with sterilisers using ethylene oxide and formaldehyde" [*Tätigkeiten an Sterilisatoren mit Ethylenoxid und Formaldehyd*] and TRGS 523 "Pest control using highly toxic, toxic and health hazardous substances and preparations".

(3) Certain other TRGS also contain specific requirements such as wording for the SDS. These include TRGS 611 "Restrictions on the use of water-miscible or water-mixed cooling lubricants whose use can result in the formation of N-nitrosamines" and TRGS 430 "Isocyanates – Risk assessment and protective measures".

1. Pursuant to number 5.5. par 12 of TRGS 611 "Restrictions on the use of water-miscible or water-mixed cooling lubricants whose use can result in the formation of N-nitrosamines", the manufacturer must include the following warning in the safety data sheet of the cooling lubricant:

"This cooling lubricant must only be used under the conditions laid down in Numbers 4.4 and 5.5 of Technical Rule 611. Contact the manufacturer to inquire about available knowledge."¹²

2. Number 2 par 2 TRGS 430 "Isocyanates – Risk assessment and protective measures" requires a special product-specific exposure assessment value (EBW) important for activities with polymeric isocyanates to be included in the SDS¹³. Alongside the exposure assessment value, the manufacturer has also to provide information on the NCO content and polymer content in the SDS (Appendix 2 Number 2.1 par 4 TRGS 430). The exposure assessment value should be specified in section 8.1 of the SDS (Annex II REACH no. 8.1.1.3 "any other national occupational exposure limit values").

¹² i.e. requirement for regular N-nitrosamine measurement in used water-mixed cooling lubricant containing secondary amines.

¹³ Explanation: The exposure assessment value is particularly important for spray applications (paint, varnish and glue). It is to be calculated in the light of the lower toxic potential of polymeric isocyanates as compared to monomeric diisocyanates in accordance with Appendix 2 no. 2.3 TRGS 430. The exposure assessment value is always product-based.

4.3.2.2 Sector-specific and activity-specific guidance

(1) Examples of sector-specific and activity-specific guidance:

1. Practical instructions for good working practice¹⁴
2. *Empfehlungen Gefährdungsermittlung der Unfallversicherungsträger (EGU)*¹⁵ and
3. Codes of practice and information from the accident insurer on hazardous substances and for specific industries, for example
 - a) "Working Safely during the production of coatings" (DGUV Information 213-094) or
 - b) "Working Safely in Laboratories - Basic Principles and Guidelines" (DGUV Information 213-851)¹⁶ or
4. Control Guidance Sheets for frequent activities with hazardous substances in the chemical industry¹⁷,
5. Exposure descriptions for the individual areas of the construction industry are, for example, available from GISBAU (information system on hazardous substances operated by the trade association for the building and construction sector). These descriptions provide information on compliance with and violations of limits on the basis of a wide range of workplace measurements.
6. Practical guidelines such as the "*Praxisleitfaden für den Umgang mit Epoxidharzen*" issued by the *Berufsgenossenschaft der Bauwirtschaft* building and construction industry trade association.¹⁸

(2) Examples of industry-specific hazardous substance and product assessments:

1. GISBAU, *Gefahrstoffinformationssystem der Berufsgenossenschaft der Bauwirtschaft* [Information system on hazardous substances operated by the trade association for the building and construction sector].¹⁹ The GISCODE or GISBAU product code is based on product categories that group together mixtures that have similar compositions, similar applications and similar health risks and that therefore require the same protective measures and procedures for handling and processing.
2. GisChem, *Gefahrstoffinformationssystem Chemikalien der Berufsgenossenschaft Rohstoffe und chemische Industrie (BG RCI) und der Berufsgenossenschaft Holz und Metall (BGHM)* [Hazardous substances information system of the trade associations for the raw materials and chemical industry and the timber and metal industry]²⁰. This database provides information on hazardous substances and mixtures from the construction materials, chemical, timber, laboratory, leather, metal and paper industries.

¹⁴ <http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Arbeiten-mit-Gefahrstoffen/Arbeiten-mit-Gefahrstoffen.html>.

¹⁵ [http://www.dguv.de/ifa/praxishilfen/praxishilfen-gefahrstoffe/empfehlungen-gefaehrdungsermittlung-der-unfallversicherungstraeger-\(egu\)/index.jsp](http://www.dguv.de/ifa/praxishilfen/praxishilfen-gefahrstoffe/empfehlungen-gefaehrdungsermittlung-der-unfallversicherungstraeger-(egu)/index.jsp)

¹⁶ <https://www.bgrci.de/fachwissen-portal/themenspektrum/laboratorien/arbeitshilfen/working-safely-in-laboratories/>

¹⁷ <http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/EMKG/Schutzleitfaeden.html>

¹⁸ <http://www.bgbau.de/gisbau/fachthemen/epoxi>

¹⁹ <http://www.bgbau.de/gisbau>

²⁰ <http://www.gischem.de/index.htm>

Examples of information in the SDS:

7.3 Specific end use(s) Recommendations: Specific solutions for the industrial sector:	This product has the GISCODE ZP 1 (products containing cement, low in chromate) (see SDS section 15). GISCODE ZP 1 provides further information on safe use, protective measures and procedures. The code can be found in the GISBAU hazardous materials database. ¹⁹
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4.4 SDS section 8: Exposure controls/personal protection (Subsection 8.1: Control parameters)

4.4.1 National occupational exposure limits

(1) In Germany, the national occupational exposure limits (AGW) are defined in TRGS 900 "Occupational exposure limits"²¹. These are health-related exposure limits for air and are specified in mg/m³ and for gases and vapours also in ml/m³ (ppm). The occupational exposure limits pursuant to TRGS 900 are shift averages, generally for a daily exposure of eight hours a day, five days a week over the course of a person's working life. Exposure peaks during a shift are assessed on the basis of short-term exposure values. The substances are listed with their CAS Registry Number and EC number and it is therefore easy to find the required information.

(2) For additive-free solvent mixtures, the occupational exposure limit for hydrocarbon mixtures ($AGW_{mixture}$) pursuant to TRGS 900 no. 2.9 applies. This occupational exposure limit is to be calculated using RCP. RCP stands for "Reciprocal Calculation Procedure", a method of calculation that uses the proportions by mass of the RCP groups and individual hydrocarbons in the liquid mixture. If insufficient information on the characterisation of the hydrocarbon mixture means that $AGW_{mixture}$ cannot be calculated, the AGW for the relevant lowest RCP group should be used to assess exposure (e.g. 200 mg/m³ for the RCP group of C7-C8 aromatic hydrocarbons).

(3) Detailed information on the use of $AGW_{mixture}$ can be found in the "Arbeitsplatzgrenzwerte für Kohlenwasserstoffgemische (RCP-Methode)" occupational exposure limit information²². An "RCP calculator" for calculating $AGW_{mixture}$ is available on the website of the German Social Accident Insurance (DGUV)²³.

(4) Full occupational exposure limit information in the SDS should also include information on the short-term exposure (peak value) - if available -, on the source of the limit and on the month and year of the last change. TRGS 900 also contain substance-specific information on properties such as

²¹ <http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/TRGS/TRGS-900.html>

²² <http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/TRGS/Arbeitsplatzgrenzwerte.html>

²³ <http://www.dguv.de/ifa/praxishilfen/praxishilfen-gefahrstoffe/software-arbeitsplatzgrenzwerte-fuer-kohlenwasserstoffgemische/index.jsp>

- skin absorption (H),
- respiratory sensitisation (Sa),
- skin sensitisation (Sh) and
- teratogenicity

(Y: no risk in the event of compliance with AGW and BGW;
Z: cannot be ruled out even if the AGW and BGW are complied with),

which are to be stated in the SDS to help the employer with the risk assessment. Examples of how to provide this information in the SDS are provided in number 4.4.6.

4.4.2 National biological exposure limits

(1) The "*Biologische Grenzwerte*" [biological exposure limits, BGW] are set out in TRGS 903 "*Biological limit values*". BGW are defined on the basis of reliable toxicological criteria for occupational health. As with the AGW, the underlying assumption is generally of a maximum exposure of eight hours daily and 40 hours a week. Complete BGW disclosure in the SDS also includes:

1. the parameter to be investigated,
2. the material tested (e.g. blood or urine),
3. the time of sampling and
4. the source of the BGW

A "*Biomonitoring Auskunftssystem*" biomonitoring database with a list of BGW and equivalents is available on the website of the Federal Institute for Occupational Safety and Health (BAuA)²⁴. Examples of information in the SDS are provided in number 4.4.6.

4.4.3 MAK and BAT values

Other criteria for assessing occupational exposure and biological exposure limits are set out in the MAK and BAT value list issued by the DFG. If neither TRGS 900 nor TRGS 903 contain limits for a given substance, the MAK value (maximum workplace concentration, *Maximale Arbeitsplatzkonzentration*) and BAT value (biological agent tolerance value, *Biologischer Arbeitsstoff-Toleranzwert*) should if available be specified in the SDS.

4.4.4 Other assessment criteria

(1) For certain carcinogenic substances, TRGS 910 "*Risk-related concept of measures for activities involving carcinogenic hazardous substances*" contain substance-specific acceptance- and tolerance concentrations and substance-specific equivalents for the biological material. An example of how to provide this information in the SDS is given in 4.4.6.

(2) For certain hazardous substances, assessment criteria in accordance with the notices [*Bekanntmachungen*] issued by the Federal Ministry of Labour and Social Affairs (BMAS) are to be specified.

(3) Pursuant to TRGS 402 "Identification and Assessment of the Risks from Activities involving Hazardous Substances: Inhalation Exposure", number 5.3.2 par. 3, inhala-

²⁴ http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Biomonitoring/Auskunftssystem_content.html

tion DNEL can be used to help assess whether the protective measures in place are sufficient if no AGW is available. Number 3 BekGS 409 contains further information on the relationship between DNEL and the assessment criteria in GefStoffV.

(4) Irrespective of national limits, section 8 of the SDS should specify any DNEL²⁵ and PNEC²⁶ pursuant to the provisions of Annex II REACH.

4.4.5 Currently recommended monitoring procedures

(1) At a national level, monitoring of inhalation exposure in the workplace is governed by TRGS 402 "Identification and Assessment of the Risks from Activities involving Hazardous Substances: Inhalation Exposure".

(2) Please make sure that the right measuring procedure (sampling and analytical process) is used in each case for checking compliance with limits. Suitable analytical procedures can for example be found in the "Recommended measuring procedures for workplace measurements" published by the Federal Institute for Occupational Safety and Health (BAuA) and in the "Measurement of hazardous substances" ["*Messung von Gefahrstoffen*"] of the Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) The online database "GESTIS – Analytical methods" operated by the Institute for Occupational Safety and Health (IFA) also contains recognised measuring processes for a large number of substances²⁷.

²⁵ DNEL: "Derived No Effect Level", derived level of exposure at which there is no damage to health (see also GESTIS DNEL list: <http://www.dguv.de/ifa/gestis/gestis-dnel-datenbank/index.jsp>).

²⁶ PNEC: "Predicted No Effect Concentration" i.e. substance concentration below which no damaging effects are predicted in the environment in question.

²⁷ <http://www.dguv.de/ifa/gestis/gestis-analysenverfahren-fuer-chemische-stoffe/index-2.jsp>

4.4.6 Examples of how to provide this information in the SDS are provided in number 4.4.6.

(1) Example of occupational exposure limits for a powdered mixture

CAS no.	Type of limit	Limit		Peak limit	Source
		in ppm	in mg/m ³	Exceedance factor	
General dust limit (ASGW)					
---	Occupational exposure limit	---	1.25 respirable fraction	8	TRGS 900
			10 inhalable fraction	2 (II)	
Monitoring procedure: TRGS 402					

(2) Example of occupational exposure limits for a solvent-based mixture

CAS no.	Type of limit	Limit		Peak limit	Note	Source
		in ppm	in mg/m ³	Exceedance factor		
Hydrocarbon mixtures, used as solvent (solvent hydrocarbons), free from additives						
—	Occupational exposure limit (calculated on the basis of RCP)	—	150	2 (II)		TRGS 900
Butan-1-ol						
71-36-3	Occupational exposure limit	100	310	1 (I)	Y	TRGS 900
1-Methoxy-2-propanol						
107-98-2	Occupational exposure limit	100	370	2 (I)	Y	TRGS 900
4-Methylpentan-2-on						
108-10-1	Occupational exposure limit	20	83	2 (I)	H, Y	TRGS 900
Monitoring procedure: TRGS 402						

(3) Example of biological limit values for a mixture:

CAS no.	Type of limit	Parameter	Limit	Material tested	Sampling time	Source
Acetone						
67-64-1	Biological limit value	Acetone	80 mg/l	Urine	End of exposure/shift	TRGS 903
2-Butoxyethanol						
111-76-2	Biological limit value	Butoxy acetic acid	100 mg/l	Urine	For long-term exposure: after multiple shifts	TRGS 903
		Butoxy acetic acid (after hydrolysis)	200 mg/l			
Monitoring procedure: AMR 6.2 ²⁸ .						

(4) Example of a substance with substance-specific acceptance and tolerance concentrations:

CAS no.	Criterion	Concentration		Note	Source
		in ppm	in mg/m ³		
Benzene					
71-43-2	Acceptance concentration	0.06	0.2	Acceptance concentration associated with risk 4:10.000	TRGS 910
	Tolerance concentration	0.6	1.9	Exceedance factor: 8	
Monitoring procedure: TRGS 402					

²⁸ Occupational Medicine Regulation (AMR) no. 6.2 "Biomonitoring"

(5) Example of a substance with substance-specific equivalents in biological material:

CAS no.	Criterion	Parameter	Equivalent	Material tested	Sampling time	Source
1,3-Butadiene						
106-99-0	Equivalent value for tolerance concentration	3,4-dihydroxybutyl mercapturic acid (DHBMA)	2900 µg/g creatinine	Urine	End of exposure/shift, in the case of long-term exposure after multiple shifts	TRGS 910
		2-hydroxy-3-butenylmercapturic acid (MHBMA)	80 µg/g creatinine	Urine		
	Equivalent value for acceptance concentration	3,4-dihydroxybutyl mercapturic acid (DHBMA)	600 µg/g creatinine	Urine	End of exposure/shift, in the case of long-term exposure after multiple shifts	
		2-hydroxy-3-butenylmercapturic acid (MHBMA)	10 µg/g creatinine	Urine		
Monitoring procedure: AMR 6.2						

4.5 National measures in SDS section 15: Regulatory information²⁹

(1) Requirements under national regulations differ between products and applications, and no generally applicable rules can therefore be given for section 15.

(2) Information in accordance with the following national regulations should always be provided:

1. *Gesetz zum Schutz der arbeitenden Jugend (Jugendarbeitsschutzgesetz – JArbSchG)* [Act on the protection of young people in employment]

Information on restrictions/bans on employment, for example: comply with employment restrictions pursuant to section 22 JArbSchG for young people.

2. *Gesetz zum Schutz von Müttern bei der Arbeit, in der Ausbildung und im Studium (Mutterschutzgesetz - MuSchG)* [Act on the protection of working mothers]

Indicate whether or not applicable.

3. *Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (state VAwS or AwSV)* [Regulations governing systems for handling substances hazardous to waters]

Specify the water hazard class³⁰ (WGK) including the name of the water hazard

²⁹ At the time these TRGS were published, many national regulations had yet to implement classification and labelling in accordance with CLP. When the amended regulations enter into effect, this may bring changes which will have to be followed by the authors of SDS.

class, and if applicable provide information on whether the substance or components of the mixture have dispersive or emulsifying properties.

In the case of mixtures, it is useful to state the percentage of constituent substances that are classified as WGK 1, 2 or 3, in particular for mixtures that are used to produce new mixtures.

4. *Zwölfte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (12. BImSchV – Störfall-Verordnung)* [Twelfth ordinance for the implementation of the Federal Immission Control Act]

Indicate whether or not applicable. If applicable, provide the product hazard classification pursuant to the *Störfall-Verordnung* and – if applicable – the hazard category or substance number and designation. This information can also be provided in the "EU rules" section ("Seveso Directive").

(3) Alongside compliance the specific legal provisions detailed in the ECHA Guidance, for example plant protection and biocide regulations, compliance with the following national regulations should also be indicated:

1. *Verordnung über Verbote und Beschränkungen des Inverkehrbringens gefährlicher Stoffe, Zubereitungen und Erzeugnisse nach dem Chemikaliengesetz (Chemikalien-Verbotsverordnung – ChemVerbotsV)* [Regulation on bans and restrictions on the marketing of hazardous substances, preparations and products pursuant to the Chemicals Act]
2. *Chemikalienrechtliche Verordnung zur Begrenzung der Emissionen flüchtiger organischer Verbindungen (VOC) durch Beschränkung des Inverkehrbringens lösemittelhaltiger Farben und Lacke (ChemVOCFarbV – Lösemittelhaltige Farben- und Lack-Verordnung)* [Chemical VOC paint regulations]

Relevant for solvent-based paints and varnishes. The following should be specified: product category, type and limit value for the VOC content of the finished product pursuant to Appendix II ChemVOCFarbV. The content of the Ordinance is identical to that of Directive 2004/42/EC ("Decopaint Directive"). All that is needed is a reference to this effect, for example: "See information on Directive 2004/42/EC".

3. *Verordnung über Sicherheit und Gesundheitsschutz bei der Bereitstellung von Arbeitsmitteln und deren Benutzung bei der Arbeit, über Sicherheit beim Betrieb überwachungsbedürftiger Anlagen und über die Organisation des betrieblichen Arbeitsschutzes (Betriebssicherheitsverordnung – BetrSichV)* [Industrial safety ordinance].

Relevant for example for gases under pressure and for explosion prevention requirements for substances and mixtures.

4. *Ausführungsverordnung zum Chemiewaffenübereinkommen (CWÜV)* [Ordinance implementing the Chemical Weapons Convention]

Relevant for substances pursuant to the appendices to CWÜV relating to the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction. For substances pursuant to Appendix 1 CWÜV, the list number and type (toxic chemical or base substance) should be specified, and for substances pursuant to Appendix 2 (explosive sub-

³⁰ or state: "not hazardous to waters"

stances), the substance name and empirical formula pursuant to Appendix 2.

5. *Gesetz über die Kontrolle von Kriegswaffen* (Kriegswaffen-KontrollG) [Weapons of war act]

Relevant for substances in chemical weapons of war pursuant to Appendix Part A III KWKG which Germany has undertaken not to produce.

6. *Gesetz zur Überwachung des Verkehrs mit Grundstoffen, die für die unerlaubte Herstellung von Betäubungsmitteln missbraucht werden können* (Grundstoffüberwachungsgesetz – GÜG) [Precursors monitoring act]

Relevant to substances pursuant to the Annex to Regulation (EC) No. 111/2005 relating to drug precursors. The category of substance, substance name (CN designation³¹, if different), CN code and CAS No. should be provided.

7. Technical instructions on air quality control (TA Luft)

Number and category pursuant to TA Luft (if applicable) for relevant substances and relevant substances in mixtures.

8. *Zweite Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes* (2. BImSchV – *Verordnung zur Emissionsbegrenzung von leichtflüchtigen halogenierten organischen Verbindungen*) [Second Ordinance on the Implementation of the Federal Immission Control Act]

Relevant in the case of solvents containing halogenated hydrocarbons or other volatile halogenated organic compounds with a boiling point of up to 150 °C.³²

9. *Einunddreißigste Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes* (31. BImSchV – *Verordnung zur Begrenzung der Emissionen flüchtiger organischer Verbindungen bei der Verwendung organischer Lösemittel in bestimmten Anlagen – VOC-Verordnung*) [Thirty-first Ordinance on the Implementation of the Federal Immission Control Act]

Relevant: the disclosure of the organic solvent content³³. The specification of the content of other volatile organic compounds (VOC) is relevant for substances that are classified as carcinogenic, germ cell mutagenic or reproductive toxic pursuant to Regulation (EC) No. 1272/2008 and are to be labelled with H statements H340, H350i, H350, H360D or H360F.

The ordinance is largely identical to Part VI of the Annex to Directive 2010/75/EU. A reference such as "See information pursuant to Directive 2010/75/EU" is therefore sufficient.

The example below is of information in the SDS pursuant to EU Directive 2010/75/EU for a synthetic varnish that can be thinned with water and that contains

³¹ CN (Combined Nomenclature) is a standard EC eight-digit nomenclature for goods for foreign trade/customs purposes.

³² Please note: Special emissions reductions requirements apply when this solvent is used in surface treatment or extraction systems that do not require authorisation.

³³ The 31st BImSchV defines an organic solvent as a volatile organic compound which is used alone or in combination with other agents, and without undergoing a chemical change, to dissolve raw materials, products or waste materials, or as a cleaning agent, a dispersion medium, a preservative or a plasticiser, or as a viscosity adjuster or surface tension adjuster.

2 % N-Methylpyrrolidone (CAS 872-50-4); classification Repr. 1B; H360D and 15–40% organic solvent, soluble in water; vapour pressure (20 °C) < 0.01 kPa

Solvent VOC:³⁴

VOC content	Temperature	Method	Comment
21 %	20 °C	Calculation	

CMR or halogenated VOC constituents in the mixture:

VOC content	Components	CAS no.	EG no.
2 %	N-Methylpyrrolidone	872-50-4	212-828-1

Other relevant constituents:

Content	Components	Method
12 %	Non-volatile constituents	Calculation

10. *Verordnung über Stoffe, die die Ozonschicht schädigen, Chemikalien-Ozonschichtverordnung – ChemOzonSchichtV* [Ordinance on substances harmful to the ozone layer]. The substance name and fraction of the substance in the product should be specified.

Relevant to substances that lead to the depletion of the ozone layer, including but not limited to chlorofluorocarbons CFC (for example CFC-112, tetrachlorodifluoroethane).

11. *Verordnung zum Schutz des Klimas vor Veränderungen durch den Eintrag bestimmter fluoriertes Treibhausgase (Chemikalien-Klimaschutzverordnung – ChemKlimaschutzV)* [Ordinance on the protection of the climate from changes caused by the input of certain fluorinated greenhouse gases]

Relevant for certain fluorinated greenhouse gases (F gases) pursuant to Regulation (EC) no. 842/2006. If applicable, the ChemKlimaschutzV should also be referenced.

12. *Gesetz über explosionsgefährliche Stoffe (Sprengstoffgesetz – SprengG)* [Explosive substances act]

Relevant for solid and liquid substances and mixtures that present a danger of explosion with common thermal, mechanical or other stimuli (explosive substances as defined in EU method A.14 in Regulation (EC) No. 440/2008).

³⁴ The VOC content at 20 °C should always be specified.

The information required under legal regulations governing the handling of explosive substances as defined in SprengG in accordance with the national regulations on explosives, in particular *BAM-Bescheid-Nr.* [BAM notice no.], storage class pursuant to 2. *SprengV* [Second ordinance on SprengG] including the packaging, tolerance and substance category should be provided.³⁵

13. *Gesetz über die Umweltverträglichkeit von Wasch- und Reinigungsmitteln (Wasch- und Reinigungsmittelgesetz - WRMG)* [Detergent and cleaning agent act]

If the substance is a detergent or cleaning agent or surfactant for the production of detergents, this must be indicated.

14. Technical Rules for Hazardous Substances (TRGS) and Announcements on Hazardous Substances (BekGS)

A reference is useful if there are substance-specific or substance category-specific TRGS, for example:

- a) TRGS 430 "Isocyanates – Risk assessment and protective measures",
- b) TRGS 505 "Lead",
- c) TRGS 511 "Ammonium nitrate",
- d) TRGS 401 "Risks resulting from skin contact - identification, assessment, measures" and TRBA/TRGS 406 "Sensitising substances for the respiratory system",
- e) TRGS 905 "List of substances that are carcinogenic, mutagenic or toxic for reproduction" and
- f) TRGS 910 "Risk-related concept of measures for activities involving carcinogenic hazardous substances".

15. BGI trade association information/codes of practice

References are useful if there are substance-specific codes of practice, for example DGUV Information 213-071 (M 005) "Hydrogen fluoride, hydrofluoric acid and inorganic fluorides", M 009 "Hydrogen peroxide" and Leaflet M 021 "Fluorine-containing halogenated hydrocarbons".

(4) This list is not exhaustive. More information on referencing environmental regulations can be found on the website of the BAuA.³⁶

5 Qualifications for the authors of safety data sheets

(1) The ECHA Guidance on the compilation of safety data sheets defines the competent person pursuant to Annex II REACH and provides information on his or her training and continued education.

(2) The *Gefahrstoffverordnung* uses a different term to that employed in the German ECHA and EU texts: "*fachkundige Person*" ("person with expert knowledge") instead of "competent person". Pursuant to section 2 par. 16 *Gefahrstoffverordnung*, a person with expert knowledge has the necessary specialist expertise to carry out work

³⁵ http://www.bam.de/de/service/amt_l_mitteilungen/index.htm

³⁶ <http://www.baua.de/dok/3998892>

specified in the Ordinance. The definition of (requirements for) a person with expert knowledge depend on the type of work. Requirements include relevant vocational training, professional experience and recent relevant professional activity, and attendance at specific training professional development courses.

(3) The use of software to generate SDS does not alter the requirement for the authors to be competent and for SDS to comply with Annex II REACH.

(4) The person with expert knowledge for compiling the SDS should, in addition to the regulations stated in ECHA Guidance, also be familiar with national regulations, announcements and sources of information listed in Number 4.5 if and to the extent that these could be relevant for the marketing or use of the substances or mixtures in question. Knowledge of the following regulations is always required:

1. *Chemikaliengesetz* (ChemG) [Chemicals act],
2. *Gefahrstoffverordnung* (GefStoffV) [Hazardous substances ordinance],
3. *Chemikalienverbotsverordnung* (ChemVerbotsV) [Banned chemicals ordinance],
4. Technical Rules for Hazardous Substances, in particular the "900" series, such as
 - a) TRGS 900 "Occupational exposure limits",
 - b) TRGS 903 "Biological limit values",
 - c) TRGS 905 "List of substances that are carcinogenic, mutagenic or toxic for reproduction",
 - d) TRGS 906 "List of carcinogenic activities or processes according to article 3 paragraph 2 no. 3 of the Hazardous Substances Ordinance",
 - e) TRGS 907 "List of sensitising substances and activities involving sensitising substances",
 - f) TRGS 910 "Risk-related concept of measures for activities involving carcinogenic hazardous substances",
5. applicable BMAS announcements and
6. regulations and information from the accident insurer, for example on personal protective equipment.

6 Frequently asked questions on safety data sheets

The REACH-CLP-Biozid Helpdesk advises companies on questions relating to REACH implementation. It provides information and guidance on implementation. Frequently asked questions about safety data sheets can be found on the BAuA/BfC website³⁷.

³⁷ <http://www.reach-clp-biozid-helpdesk.de/de/FAQ/S-T/Sicherheitsdatenblatt/Sicherheitsdatenblatt.html>