UEIL – Position Paper

Boric acid

Chemical legislation, risk assessment and protective measures

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Contents

1. Introduction

The subject of hazard assessment places high demands on the expertise of the persons in charge. The case of boric acid (and some compounds, see Table 1) is particularly complex. This guide is based on DGUV[1] information FB HM-030 "MWFs containing boric acid/boron" (Edition 02/2014 FB HM-030 [0]). Due to the change in classification of boric acid, the DGUV Information has been updated. This VSI guidance document has been published in order to provide manufacturers and users of cooling lubricants (MWF) with information on this change in classification and labelling as well as on the safe handling and use of MWF.

[1] Deutsche gesetzliche Unfallversicherung, German Social Accident Insurance

2. Classification and labelling of boric acid in the 17th ATP to CLP

On 28.05.2021, the 17th ATP [2] to the CLP Regulation [1] was published.

Within the 17th ATP, the specific concentration limit for boric acid of 5.5 % is no longer applicable. In future, the generic concentration limit for substances toxic to reproduction of category 1B of 0.3 % will apply for the classification of MWFs containing free boric acid (concentrate or emulsion). The regulation will come into force after the expiry of the transitional period on 17th December 2022, i.e. from this date at the latest, mixtures containing 0.3% or more free boric acid must be labelled accordingly as "Toxic to reproduction category 1B".

"Toxic for reproduction category 1B" means: "Substance that is probably toxic for reproduction in humans. This presumption is generally based on the following: appropriate long-term animal studies, other relevant information; it may affect fertility or harm the unborn child."

Classification and labelling will have an enormous impact on the manufacture and use of boric acid-based MWFs. For this reason, it should be known in good time before the new CLP regulation comes into force what classification and labelling is applicable and which protective measures (activity-specific!) have to be implemented.

Index No.	Chemical name	EC no.	CAS no.	Classification		Labelling		Specific Conc. Limits – M;
				Dangers-class and category code (s)	Dangers - hint	Pictogram, signal word	Danger notice	
'005-007-00-2	Boric acid [1] Boric acid [2]	233-139-2 [1] 234-343-4 [2]	10043-35-3 [1] 11113-50-1 [2]	Repr. 1B	H360FD	GHS08 Danger	H360FD"	
'005-008-00-8	Dibor trioxide	215-125-8	1303-86-2	Repr. 1B	H360FD	GHS08 Danger	H360FD"	
'005-011-00-4	Tetraborddinatrium-heptaoxide, Hydrate; [1] Disodium tetraborate, anhydrous; [2] Orthoboric acid, sodium salt [3]	235-541-3 [1] 215-540-4 [2] 237-560-2 [3]	12267-73-1 [1] 1330-43-4 [2] 13840-56-7 [3]	Repr. 1B	H360FD	GHS08 Danger	H360FD"	
'005-011-01-1	Disodium tetraborate decahydrate	215-540-4	1303-96-4	Repr. 1B	H360FD	GHS08 Danger	H360FD"	
'005-011-02-9	Disodium tetraborate-pentahydrate	215-540-4	12179-04-3	Repr. 1B	H360FD	GHS08 Danger	H360FD"	
Repr. 1B Substance likely to be toxic for reproduction in humans. This assumption is generally based on the following: appropriate long-term animal studies, other relevant information.. H360FD May impair fertility or harm the unborn child, signal word „Danger".								

Table 1: Extract from the 1st ATP/CLP Annex II

Depending on the progress of the implementation of the CLP Regulation, the following classifications and labels will be applied:

2.1 Classification and labelling of boric acid as pure substance:

 **Signal word: Danger**	Classification and Labelling: Toxic to reproduction Category 1B: H 360FD: May impair fertility, may cause harm to the unborn child.

2.2 Classification not later than 17.12.2022 for mixtures containing ≥ 0.3 % free boric acid:

 **Signal word: Danger**	Classification and Labelling: Toxic to reproduction category 1B: H 360FD: May impair fertility, may cause harm to the unborn child.

2.3 Declaration of boric acid: Occupational exposure limit value (OEL) for boric acid and its monitoring.

Boric acid has an AGW[2] (0.5 mg/m3 E, Note Y) in TRGS[3] 900 [4]. Manufacturers and users of cutting fluids are required to demonstrate compliance with this limit as part of a risk assessment.

Currently (January 2022), boric acid has the remark "Y" in TRGS 900, which means: "A risk of embryo and foetal damage need not be feared if the occupational exposure limit value and the biological limit value (BGW) are complied with"[4].

If free boric acid is contained or released above the general declaration limit for AGW substances (0.1 %), the AGW must be stated in section 8 of the safety data sheet ("Limitation and monitoring of exposure/personal protective equipment").

Information on the concentration of classified components of a mixture, e.g. boric acid, can be found in the safety data sheet, chapter 3.

The classification and labelling of the mixture placed on the market (e.g. the MWF concentrate) depends on the content of free boric acid. It is important to distinguish between boron compounds and free boric acid in the assessment [6].

[2] Arbeitsplatzgrenzwert, occupational exposure limits according to German law
[3] Technische Regeln Gefahrstoffe, technical guidance on hazardous substances (legal framework in Germany)
[4] Biological limit value (BGW): TRGS 903, edition 2013, updated 4.5.021, boric acid is currently not listed there.

2.4 For mixtures formulated without boron compounds

For these mixtures, the usual protective measures for activities with MWF according to DGUV 109-003 [3] must be observed.

2.5 For mixtures containing < 0.3 % free boric acid

A special case is represented by boron-containing MWF concentrates (or special additives) that contain free boric acid in a concentration < 0.3 % and are thus free of the labelling and classification requirements related to boric acid, but nevertheless contain boron-containing compounds. When using these products, boric acid could be released in the application. This must also be taken into account in the risk assessment. Here, confirmation can be obtained from the supplier that boric acid cannot be released above the labelling limit during use.

If the concentration of free boric acid in the application is < 0.3%, the usual protective measures for handling metalworking fluid emulsions according to DGUV 109-003 [3] must be observed.

3. Air limit value and risk assessment

3.1 Air limit value

Since September 2015, a health-based AGW of 0.5 mg boric acid/m³ (corresponds to 0.2 mg boron/m³ = measuring component) has been in force in Germany; this is included in TRGS 900. The remark "Y" in TRGS 900 also means that there is no need to fear a risk of fruit damage if the AGW is observed.

The definition of an AGW also implies that acute or chronic harmful effects on health are not to be expected as a rule if compliance is maintained.

An evaluation by the Institute for Occupational Safety and Health (IFA) [5] to create an exposure scenario for boron and its compounds (in the case of water-mixed MWF: boric acid is shown) results in an exposure level of 0.024 mg/m³ for the 95 % percentile (i.e. statistically for 95 % of all measurements carried out) in mechanical production, which corresponds to 4.8 % of the AGW (corresponds to an assessment index of 0.048 according to TRGS 402).

Boron and its compounds, Sampling duration ≥ 1 h and exposure duration ≥ 6 h					
Workspace	Number of measurem ent data	Number of farms	Concentrations in in mg/m³		
			50-%-value	90-%-value	95-%-value
Turning, grinding, milling	36	22	0,002	0,007	0,024

Table 2: Extract from the IFA evaluation

3.2 Risk assessment:

To carry out a risk assessment, the user must know whether boric acid can be released in the application.

This must be enquired about for products according to section 2.3.

Before use, a substitution test must be carried out as part of the risk assessment, in accordance with the S.T.O.P. Rule.[5]

4. Changes concerning water miscible metalworking fluids (MWF concentrate)

If the MWF concentrate contains more than 0.3 % free boric acid, the special protective measures for activities with reproduction-toxic substances of category 1B must be applied in accordance with the GefStoffV.[6] If no aerosol formation takes place, compliance with the AGW can be safely assumed.

In all other cases, the general protective measures must be applied; these can be taken from DGUV 109-003 [3], depending on the activity.

4.1 Products formulated without boron compounds

These products are not affected by the regulations concerning boric acid.[7]

4.2 Free boric acid < 0.1 % (according to individual manufacturer's certificate)

These products are not subject to the declaration obligation in the sense of the SVHC/candidate list or chapter 8 safety data sheet.

4.3 Free boric acid < 0.3 % (according to formulation, mass percentage)

These products are in scope, but no labelling obligation follows under any conditions. Due to the classification of boric acid as SVHC substance and the AGW, free boric acid from 0.1 % has to be declared in the SDS (chapter 3 and 8).

4.4 Free boric acid ≥ 0.3 % (formulation, mass percentages)

For individual cases in which 0.3 % or more free boric acid is present, the labelling obligation applies as above and the measures to be derived from this must be taken.

Before using these products, a substitution test must be carried out. Appropriate protective measures must be taken in accordance with the risk assessment carried out.

[5] The abbreviation STOP stands for Substitution, Technical Measures, Organisational Measures and Personal Protective Equipment. For more details see TRGS 500 'Protective measures' (https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/TRGS-500.pdf).

[6] Gefahrstoffverordnung, Hazardous Substances Ordinance

7 Traces of boron compounds may be present as unintentional impurities for technical production reasons.

5. Changes concerning water miscible metalworking fluids (Cooling lubricant emulsion or solution)

If the concentrate contains free boric acid ≥ 0.3 %, it must be ensured that the emulsion is present in a concentration that does not exceed the labelling limit in order to ensure that the emulsion is not labelled as "Toxic to reproduction 1B". A conceivable release of boric acid from boric acid compounds must be taken into account.

Example: Due to the dilution, a 10% emulsion does not have to be labelled as "Toxic to reproduction, category 1B" if the concentrate contains less than 3% free boric acid.

The required protective measures according to the Ordinance on Hazardous Substances are described in DGUV 109-003, depending on the activity. Effectiveness can be demonstrated, for example, by compliance with the AGW (see No. 3).

If the "ingestion" route is considered, special care must be taken in the risk assessment to ensure that ingestion is prevented by suitable measures.

According to all information available so far, skin contact is irrelevant, as no absorption takes place (no skin absorption in the case of non-pre-damaged skin).

7. Summary and application limits

This VSI Guidance Document has been prepared in cooperation with MWF manufacturers.

In particular, it is intended to help implement the requirements of European chemicals legislation and the Hazardous Substances Regulation.

According to the CLP Regulation, boric acid and certain sodium borates have been classified as category 2 substances toxic to reproduction (H360FD) since 28.05.2021, with a generic concentration limit of 0.3%. If this value is reached or exceeded, mixtures must be classified and labelled accordingly from 17th December 2022 (after expiry of the transitional period) and appropriate measures must be taken in accordance with the Ordinance on Hazardous Substances.

The following applies to air pollution: If the AGW of 0.5 mg boric acid/m^3 is complied with, activities with boric acid and mixtures containing boric acid are possible without increased health risk. Applying the results of the last available IFA exposure scenario for the work area "mechanical manufacturing" (e.g. turning, grinding, milling), the finding "protective measures sufficient, according to GefStoffV" can be made.

Literature:

[0] DGUV Information Edition 02/2014 FB HM-030, will probably be withdrawn in December 2022,

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ("CLP Regulation" - Regulation on Classification, Labelling and Packaging of Substances and Mixtures); https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=celex%3A32008R1272

[2] Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures for the purpose of adapting it to technical and scientific progress, the "17th ATP to the CLP Regulation"; https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32021R0849

[3] DGUV 109-003: Activities involving cooling lubricants, as of March 2011; https://publikationen.dguv.de/regelwerk/dguv-regeln/1006/taetigkeiten-mit-kuehlschmierstoffen

[4] TRGS 900: Occupational exposure limit values, edition: January 2006. Last amended and supplemented: GMBl 2021, pp. 893-894 [No. 39-40] (of 02.07.2021), https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/TRGS-900.html

[5] MEGA evaluations for the preparation of REACH exposure scenarios for boron and its compounds (02/2012)

http://www.dguv.de/medien/ifa/de/fac/reach/mega_auswertungen/bor_d.pdf

[6] Determination of free boric acid by ^{11}B NMR spectroscopy: The quantitative determination of free boric acid in alkaline buffered MWF concentrate (water-miscible MWF) is difficult because chemical reactions can disturb the equilibrium and lead to incorrect results. Boric acid and its compounds can be determined by 11Boron NMR spectroscopy.

In 2011, a study was made on free boric acid by NMR spectroscopy in MWFs commonly used at that time, and the results can be obtained from the German association VSI.

About UEIL:

UEIL (the Union of the European Lubricants Industry) represents the interests of the lubricants industry in Europe, with a special focus on SMEs and independent companies that produce lubricants and metal processing fluids essential for the automotive and industrial sectors.
Through its thirty-five members, UEIL covers the whole lubricants' value chain, from manufacturing and distribution to recycling, and represents over 450 companies and 100,000 employees.

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