The Column Model

An aid to substitute assessment
<table>
<thead>
<tr>
<th>1 Risks</th>
<th>2a Acute health hazards (single affection, e.g. accident with chemicals)</th>
<th>2b Chronic health hazards (repeated affection)</th>
</tr>
</thead>
</table>
| very high | - Highly toxic substances/preparations (R26, R27, R28)  
- Substances/preparations which may produce highly toxic gases when in contact with acids (R32) | - Carcinogenic substances of categories 1 or 2 (Carc.Cat.1, K1, Carc.Cat.2, K2, R45, R49)  
- Mutagenic substances of categories 1 or 2 (Mut.Cat.1, M1, Mut.Cat.2, M2, R46)  
- Preparations containing carcinogenic or mutagenic substances of categories 1 or 2 in concentrations ≥ 0,1 % |
| high | - Toxic substances/preparations (R23, R24, R25)  
- Highly corrosive substances/preparations (R35)  
- Substances/preparations which may produce toxic gases when in contact with water or acids (R29, R31)  
- Skin sensitising substances (R43, Sh)  
- Substances sensitising respiratory tract (R42, Sa)  
- Preparations containing skin or respiratory tracts sensitising substances in a concentration ≥ 1 % (in case of gases ≥ 0,2 %) | - Substances toxic to reproduction of categories 1 or 2 (Repr.Cat.1, R1, R1, Repr.Cat.2, R2, R2, R60, R61)  
- Preparations containing substances toxic to reproduction of categories 1 or 2 in concentrations ≥ 0,5 % (in case of gases ≥ 0,2 %)  
- Carcinogenic substances of category 3 (Carc.Cat.3, K3, R40)  
- Mutagenic substances of category 3 (Mut.Cat.3, M3, R68)  
- Preparations containing carcinogenic or mutagenic substances of category 3 in concentrations ≥ 1 %  
- Substances which can accumulate in the human body (R33) |
| medium | - Substances/preparations harmful to health (R20, R21, R22)  
- Substances which may accumulate in breast milk (R64)  
- Corrosive substances/preparations (R34, pH ≥ 11.5, pH ≤ 2)  
- Substances harmful to eyesight (R41)  
- Non toxic gases; may cause suffocation by air displacement (e.g. nitrogen) | - Substances toxic to reproduction of category 3 (Repr.Cat.3, R3, R3, R62, R63)  
- Preparations containing substances toxic to reproduction of category 3 in concentrations ≥ 5 % (in case of gases ≥ 1 %) |
| low | - Irritant substances/preparations (R36, R37, R38)  
- Skin affections when working in damp environment  
- Substances/preparations which may cause lung defects when swallowed (R65)  
- Skin affecting substances/preparations (R66)  
- Steam causing drowsiness and stupor (R67) | - Otherwise chronically affecting substances (no R-phrase, but nonetheless a hazardous substance!) |
| negligible | - Harmless substances by experience (e.g. water, sugar, paraffin and similar) | |
### Environmental hazards ¹)

- Substances/preparations with the warning symbol **N** and hazards indications **R50, R51, R53, R54, R55, R56, R57, R58, R59**
- Substances/preparations of the German water pollution class **WGK 3**

### Fire and explosion hazards ²)

- Explosive substances/preparations (R2, R3)
- Extremely flammable gases and liquids (R12)
- Spontaneously flammable substances/preparations (R17)

### Exposure potential

- Gases
- Liquids with vapour pressure > 250 hPa (mbar) (e.g. dichloromethane)
- Dust producing solids
- Aerosols

### Hazards caused by procedures

- Open processing
- Possibility of direct skin contact
- Application on large area

<table>
<thead>
<tr>
<th>3 Environmental hazards ¹)</th>
<th>4 Fire and explosion hazards ²)</th>
<th>5 Exposure potential</th>
<th>6 Hazards caused by procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Substances/preparations without warning symbol <strong>N</strong>, but with hazards indications <strong>R52, R53</strong></td>
<td>☐ Flammable substances/preparations (R10)</td>
<td>☐ Liquids with vapour pressure 10 ... 50 hPa (mbar), except water (e.g. toluene)</td>
<td>☐ Closed processing but exposure possibilities e.g. when filling, sampling or cleaning</td>
</tr>
<tr>
<td>☐ Substances/preparations of the German water pollution class <strong>WGK 2</strong></td>
<td>☐ Hardly flammable substances/preparations (flashpoint 55 ... 100 °C)</td>
<td>☐ Liquids with vapour pressure 2...10 hPa (mbar) (e.g. xylene)</td>
<td></td>
</tr>
<tr>
<td>☐ Not water polluting substances/preparations (NWG, before: <strong>WGK 0</strong></td>
<td>☐ Inflammable or very hardly flammable substances/preparations (liquids: flashpoint &gt; 100 °C)</td>
<td>☐ Liquids with vapour pressure &lt; 2 hPa (mbar) (e.g. glycol)</td>
<td>☐ Tightly closed equipment</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐ Non dusting solids</td>
<td>☐ Closed equipment with exhaust facilities at points of emission</td>
</tr>
</tbody>
</table>

²) Explosive dusts have to be analysed carefully in each single case because of their specific problems, thus they are not attached to a concrete risk level.
Notes on Evaluating Substitute Substances with the Column Model

Are recommendations already available on substitute substances?

Answering the question of which product has the lower health risk is often difficult. Recommendations for a whole series of questions regarding substitute substances can be applied directly, such as:

- Technical rules for hazardous substances in the 600 series
- BG/BGIA recommendations, LASI guidebooks
- Productcodes, GISCODES
- Other industry guidelines

The BIA report 2/2002 „Gefahrstoffe ermitteln und ersetzen“, [“Identifying and substituting hazardous substances”], which contains an overview can be downloaded from www.hvbg.de/bgia, webcode 499860.

Procedures

If there are no recommendations available to help you solve your substitute substance problem, the column model can help you make a quick comparison of substances and preparations. To do so, you only need the brief information found in the Material Safety Data Sheet or on the package labelling. Proceed as follows:

1. Copy the column model table once for each product and put each product's name on a different copy.
2. Refer to the Material Safety Data Sheet for the requisite information. There you will find the hazard levels, R-phrases, and the German water pollution classes in chapter 15 of the Material Safety Data Sheet and information on the exposure potential in chapter 9.
3. Note the information you find on the copy for the respective product. Note the procedure used in the last column.
4. Now compare the columns below separately for each product to be evaluated.

- Acute and chronic health hazards
- Environmental hazards
- Fire and explosion hazards
- Hazards due to potential emission
- Hazards caused by procedures

You can also find additional information in chapters 3, 5, 11, and 12.

Please bear in mind:

- Comparisons are only to be made within a column, and never within a line. The columns for “acute health hazards” and “chronic health hazards” count as one single column.
- The column “acute health hazards” has a peculiarity in the R-phrases 20, 21, 22, 23, 24, and 25: if these R-phrases occur in combination with R-phrase 48, then the substance or preparation in question should be categorised in the next higher risk level. These are then chronic health hazards.
- The acute and chronic health hazards of products (preparations) are assessed on the basis of their preparation labelling only.

Interpretation of the results

- If the potential substitute product rates better in all five columns than the product in use, the substitution problem is solved.
- It will mostly be the case that the potential substitute product rates better in some columns, and worse in others. This obliges you to assess which potential hazards – in other words, which columns – play a larger role in your particular situation. If, for example, sources of combustion cannot be avoided in your production processes, then the fire and explosion hazards together with the potential emission will have the greater weight in your comparison. If your production methods result in large quantities of waste by-products, then the environmental hazards will be emphasised.
- Document your decisions in an appropriate manner (e.g. by attaching the copies described above).
Legal Basis for the Obligation of Substitution

The new German Ordinance on Hazardous Substances of 23.12.2004 says that the employer do (among other things):

<table>
<thead>
<tr>
<th>§ 9 (1) Hazardous Substance Ordinance:</th>
<th>§ 7 (9) Hazardous Substance Ordinance:</th>
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<tr>
<td>The employer shall ensure that any worker health or safety risk arising from any work activity involving hazardous substances is eliminated or minimized through implementation of the measures specified in the risk assessment. In complying with this requirement, the employer shall prioritize use of a substitute substance or preparation. In particular, the employer shall avoid activities involving hazardous substances or shall replace hazardous substances with substances, preparations, products or processes that are not deleterious, or less deleterious, to worker health and safety under the relevant application conditions. The employer shall indicate in the risk assessment documentation his reasons for foregoing implementation of any available substitution.</td>
<td></td>
</tr>
<tr>
<td>If the risk assessment shows that worker risk is negligible owing to (a) the nature of the company work environment (b) the use of only small amounts of hazardous substances and (c) the fact that the cumulative duration and amount of exposure to hazardous substances is relatively low, and (d) if the health and safety measures realized for workers pursuant to Article 8 (1) through 8 (8) are sufficient, no further safeguards pursuant to Articles 9 through 17 shall be required (protection class 1). The first sentence shall not apply to activities involving hazardous substances which 1. are classified or labelled as toxic, highly toxic, carcinogenic, mutagenic, or toxic to reproduction pursuant to EC category 1 or 2; or 2. have been classified by a Federal Ministry of Economics and Labor advisory as class 1 or 2 substances that are carcinogenic, mutagenic, or toxic to reproduction.</td>
<td></td>
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</tbody>
</table>

Comment: This does not apply if the risk assessment shows that worker risk is negligible.
Conditions for Using the Column Model according to TRGS 440

What is the problem?
A supposedly harmless product can be more dangerous in reality; yet the concrete hazardous characteristics may not have been tested. TRGS 440 thus demands: “In order to evaluate the substances used and released in processing, these ingredients/preparations should be assessed and labelled on the basis of available data on toxicity, skin irritation, mucous irritation, skin sensitisation and potential to mutagenic characteristics.

The employer must determine whether such studies have already been conducted. Until this information as to their characteristics are available, these characteristics are to be presumed present when deciding on substitutes and protective measures …”

What effects does this have on the column model?
If the information on required tests is unavailable, whereas the instructions in the Material Safety Data Sheet are conform to the TRGS 440, “It is the experience of the manufacturer that no hazards are to be expected beyond those on the label,” then the column model can be applied without exception.

If the Material Safety Data Sheet gives details on none or only a few required tests and if an inquiry with the manufacturer has not yielded any information, then it must be assumed when using the column model that the respective characteristics are present.

What does this mean specifically?

1. If no information is available on tests for irritant effects to the skin/mucous membrane, then the substance or preparation should be categorised at least as a “low risk” in the column “acute health hazards” (in terms of an “irritant” R36/37/38).
2. If no information is available on tests for toxicity, then the substance or preparation should be categorised at least as a “high risk” in the column “acute health hazards” (in terms of a “toxic substance/preparation” R23/24/25).
3. If no information is available on tests for mutagenic properties, then the substance or preparation should be categorised at least as a “high risk” in the column “chronic health hazards” (in terms of a “mutagenic substance of category 3” R68).
4. If no information is available on tests for skin sensitisation, then the substance or preparation should be categorised at least as a “high risk” in the column “acute health hazards” (in terms of a “skin sensitisising substance/preparation” R43).

The most consistent procedure is the one in which those products lacking information with regards to the five basic tests described here are not even considered as potential substitutes, or in which products lacking such information are replaced by others that are backed by studies and tests to support their use.