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Publication "Example Safety Assessment of an All-Purpose Cleaner"

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IKW ad hoc working group »Safety Assessment of Detergents, Cleaning and Maintenance Products«*

Example Safety Assessment of an All-Purpose Cleaner

Introduction

The »Recommendation for the Safety Assessment of Detergents, Cleaning and Maintenance Products« (1) gives a general description of steps to be observed in the development and marketing of safe products of this kind. The present publication highlights essential points of a safety assessment, on the example of the product group of »all-purpose cleaners«. This publication was compiled by the IKW expert committee »Cleaning and Maintenance Products«, which consists of experts from competing companies. This ensures the neutrality of the committee.

■ Product Type »All-Purpose Cleaners«: General Description and Use

All-purpose cleaners are the most frequently used cleaning products in private households, besides hand dish-washing products and sanitary cleaners. All-purpose cleaners in diluted form are commonly applied across large areas, in the cleaning of floors and surfaces. All-purpose cleaners are also applied in concentrated form, in order to selectively remove persistent dirt and smudges.

All-purpose cleaners are preparations of various surfactant mixtures, water-soluble solvents and complexing agents. Furthermore, they contain additives such as fragrances, colorants and preservative agents. Formulations are offered as standard products and concentrates; there are neutral to alkaline formulations as well as acid cleaners (2).

■ Examined Example Formulations, Classification of Raw Materials and Further Items of Information

Content	Ingredient and classification according to the Dangerous Substances
4%	non-ionic surfactant; R36/38
4%	Anionic surfactant; R41
1%	Soap; not classified as dangerous
2,5%	Solubiliser; not classified as dangerous
0,001%	Colorant; not classified as dangerous
0,0013%	Preservative, R23/24/25, R34, R43, R50/53 Note: This preservative is notified for product type 6 (in-can preservation), according to the Biocidal Products Directive
0,2%	Fragrance mixture R10, R43, R50/53, R65
ad 100%	Water

Further items of information for the preparation:

pH value:	9.3 – 9.7
Acid/alkaline reserve	not relevant
Physical-chemical hazard:	not classified
Classification of the finished product, calculated according to the Preparations Directive (4):	not classified

ALL-PURPOSE CLEANERS



■ Example Safety Assessment

Step	Entry in the dossier
Assessment of input raw materials	
<p>Plausibility check of safety data sheets</p>	<p>»The (eco-)toxicological and physical-chemical information in the safety data sheets is plausible«.</p>
<p>Information on constituents / components of raw materials which are not stated in the safety data sheets of the raw materials.</p> <p>These items of information are obtained e.g. by way of the following enquiries:</p> <p>»Please state the full composition of the raw materials, enabling the correct elaboration of an ingredient datasheet for medical personnel according to Annex VII C of the Detergents Regulation (EC) No 648/2005. In particular</p> <ul style="list-style-type: none"> • Statement of all preservatives contained in the raw materials or specific assurance that the raw materials do not contain any preservatives • Statement of all allergenic fragrances according to the Detergents Regulation or specific assurance that the raw materials do not contain any such allergenic fragrances«. <p>These extra items of information ensure that no ingredients are present which are not admissible in detergents and cleaning products, according to the German Chemicals Ban Ordinance (Chemikalienverbotsverordnung/ChemVerbotsV)</p>	<p>Stating of all constituents / components of the raw materials »Non-ionic surfactant 80 percent in water. The non-ionic surfactant underwent preliminary preservation with 0.1% of a 10 percent preservation concentrate (1,2 Benzisothiazolin-3(2H)one). With the input volume of 5%, the final product thus contains 0.1 x 0.1 x 0.05% of preservative«.</p> <p>This should be carried out accordingly for all other ingredients.</p>
<p>Further relevant data:</p>	<ul style="list-style-type: none"> • In-vitro mutagenicity tests according to Ames are negative for all ingredients. • An IFRA Compliance Statement is available for the perfume oil; this means that the fragrances contained in the perfume oil meet the standards of the International Fragrance Association IFRA. • Surfactants are ultimately biodegradable according to the Detergents Regulation (5). • The raw materials do not contain any substances that are banned or restricted under the German Chemicals Ban Ordinance (ChemVerbotsV).
Assessment of the preparation	
<p>Description of the calculation for the classification and labelling of the preparation</p>	<ul style="list-style-type: none"> • <u>Acute toxicity</u>: According to the calculation method of the Preparations Directive, this preparation is classified as not dangerous to health – based on the classifications of its ingredients. • <u>Irritant effect on skin</u>: According to the calculation method of the Preparations Directive, this preparation is not classified as irritant to skin – based on the classifications of its ingredients.

Step	Entry in the dossier
	<ul style="list-style-type: none"> • <i><u>Irritant effect on eyes</u></i>: According to the calculation method of the Preparations Directive, this preparation is not classified as irritant to eyes – based on the classifications of its ingredients. • <i><u>Sensitising ingredients</u></i>: The preparation does not contain any ingredients in a percentage share of > 0.1% which are classified as sensitising. None of the constituents classified with R43 in the fragrance mixture exceeds the percentage share of 0.1% in the final product. - <i><u>Ecotoxicity</u></i>: According to the calculation method of the Preparations Directive, this preparation is not classified as dangerous to the environment – based on the classifications of its ingredients..
Description of intended use	<p><i>In diluted form (30 millilitres of 5 litres of water) in water of wiping surfaces: in concentrated form for removing persistent dirt.</i></p>
<p>Assessment of impacts on human health Impacts on human health are assessed stepwise, taking into account the information on the following points:</p> <ol style="list-style-type: none"> 1. Results of the calculation method (see above) 2. Further necessary data for ingredients 3. Expertise / Experience in the market <ol style="list-style-type: none"> a. Comparison with sufficiently similar formulations for which market experiences are already available <ol style="list-style-type: none"> i. Data from company-internal complaint statistics ii. Data from poison information centres/from the German Federal Institute for Risk Assessment (BfR) b. Description of reasonably foreseeable use 4. Additional tests: 	<ol style="list-style-type: none"> 1. <i>According to the Preparations Directive, the product is not classified as dangerous and does not require labelling</i> 2. <i>The ingredients have no mutagenic properties; in-vitro mutagenicity tests according to Ames (6) showed negative results.</i> 3. <i>Expertise / Experience in the market</i> <ol style="list-style-type: none"> a. <i>Comparison with sufficiently similar formulations</i> <ol style="list-style-type: none"> i. <i>No customer complaints have been received about the all-purpose cleaner X, which is of similar composition and has been marketed for Y years</i> ii. <i>The all-purpose cleaner X, which is of similar composition, has <u>not</u> attracted the attention of German poison information centres.</i> <p><i>Description of reasonably foreseeable use</i></p> <ol style="list-style-type: none"> i. <i>Intended use according to label: diluted according to the manufacturer's instructions or in concentrated form</i> ii. <i>Foreseeable use: Mixture with other cleaning products</i> <p>Skin tolerance was tested in voluntary subjects, because the product claim »dermatologically tested« is planned. Dermal contact was tested with the product in concentrated form. For the purpose of substantiation, a dermatological institute performed a tolerance test in voluntary subjects. The results of the test prove good skin tolerance, also when using the product in concentrated form.</p>

Step	Entry in the dossier
Impacts on the environment:	<ol style="list-style-type: none"> 1. <i>The surfactants used are ultimately biodegradable, according to the Detergents Regulation. This is confirmed in the safety data sheet, according to the recommendation of CESIO (the European federation of surfactant producers). Therefore, no harm to the aquatic environment is expected.</i> 2. <i>No classification according to the Preparations Directive - because those ingredients which require labelling with R phrases 50-53 are not contained in the product in volumes relevant to labelling. Therefore, no harm to the aquatic environment is expected.</i>
Additional criteria: <ul style="list-style-type: none"> • Storage stability of the preparation (Testing at 5 °C, 50 °C) • Packaging • Microbiology 	<p><i>The storage stability of the final product is ensured by means of suitable tests at 5 °C and 50 °C.</i></p> <ul style="list-style-type: none"> o <i>The mechanical stability of the final product was determined after storage, in a drop test from 80 cm.</i> o <i>Child-resistant fastening and a tactile warning of danger are not necessary according to the Preparations Directive</i> <p><i>Microbiological storage stability of the final product was ensured by means of a germ test.</i></p>
Transport classification	<i>No dangerous good</i>
Labelling	<p><u><i>Labelling according to the Detergents Regulation</i></u> <i>< 5% non-ionic surfactants, anionic surfactants, soap, perfume, BENZISOTHIAZOLINONE</i></p> <p><i>Millersmith plc, Miller Street 3, Smith Village 99999; Phone: 09999/99-0, info@millersmith.somewhere, www.millersmith.somewhere</i></p> <p><u><i>Additional labelling according to the Germany Prepackages Ordinance (Fertigpackungsverordnung) 500 ml 500 ml</i></u></p> <p><u><i>Additional labelling according to the German Dangerous Substances Ordinance (Gefahrstoffverordnung)</i></u> <i>not necessary</i></p> <p><u><i>Additional labelling according to the German Chemicals Ban Ordinance (Chemikalienverbotsverordnung)</i></u> <i>not necessary</i></p> <p><u><i>Additional labelling according to the German Commodities Ordinance (Bedarfsgegenständeverordnung)</i></u> <i>not necessary</i></p>

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Step	Entry in the dossier
Publication of list of ingredients on an internet website, according to Annex VII D to the Detergents Regulation	<i>Is made available on the date of first marketing.</i>
Voluntary safe behaviour tips and pictograms on packaging, according to A.I.S.E. (the International Association for Soaps, Detergents and Maintenance Products)	 <p>»Keep away from children«.</p>  <p>»Do not ingest. If product is ingested then seek medical advice«.</p>
Instructions for use	<i>»One dosing cap (30 millilitres) to 5 litres of water for wiping surfaces; in concentrated form to remove persistent dirt«.</i>
Conclusion	<i>»The examined all-purpose cleaner is safe, on condition that the above-mentioned requirements be met.«</i>



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Note

The results of the safety assessment are included in the quality assurance scheme for the production of the final product (minor constituents/components, chemical specification of ingredients, microbiology). By means of suitable quality assurance measures, it is ensured that requirements – as derived from the safety assessment – are met in production.

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References

(1) »Empfehlung zur Sicherheitsbeurteilung von Wasch-, Pflege- und Reinigungsmitteln (WPR-Produkten«, SÖFW-Journal 133, 10-2007, p. 53-69 (»Recommendation for the Safety Assessment of Detergents, Cleaning and Maintenance Products«; publication by IKW forthcoming)

(2) A. Fitzner, U. Abmus, »Empfehlung zur Qualitätsbewertung der Produktleistung von Allzweckreinigern«, SÖFW-Journal 130, 10-2004, p. 83-93 (»Recommendation for the Quality Assessment of the Product Performance of All-Purpose Cleaners«, SÖFW-Journal, English Ed., 130, 9-2005. p. 54-66)

(3) Directive on the classification and labelling of dangerous substances (67/548/EEC) (Dangerous Substances Directive)

(4) Directive on the classification and labelling of dangerous preparations (1999/45/EC) (Dangerous Preparations Directive)

(5) Regulation (EC) No 648/2004 on detergents, published in the Official Journal of the European Union No L 104 of 8.4.2004

(6) 28th adaptation of Directive 67/548/EEC, Annex 5A, test method B. 13/14; Official Journal of the European Union L 225 of 21.8.2001; cp. Ames, B.N., McCann, J. and Yamasaki, E.; Methods for Detecting Carcinogens and Mutagens with the Salmonella/Mammalian-Microsome Mutagenicity Test. Mutation Res., 31 (1975) 347- 364

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