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Publication "Example Safety Assessment of an Impregnation Spray"

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IKW Working Group »Shoe and Leather Care Products, Impregnation Agents«*

Example Safety Assessment of an Impregnation Spray

Introduction

The »Recommendation for the safety assessment of detergents, maintenance and cleaning products« (1) gives a general description of the steps to be observed in the development and marketing of safe products of these types.

The present publication highlights essential points of a safety assessment, by way of example, for the product group of impregnation sprays for leather and textiles. This publication was compiled by the IKW expert committee »Cleaning and Maintenance Products«, which consists of experts from competing companies. The neutrality of the committee is thus ensured.

■ Product Type Impregnation Sprays: General Description and Use

Impregnation sprays are preparations which predominantly contain fluorocarbon resins and/or silicones as active substances. They are offered as aerosols with or without propellant. Solvents used in these preparations are benzines or alcohols or mixtures of both.

Impregnation sprays are used to provide protection against moisture and dirt; they are mainly applied onto shoes and items of clothing. They unfold their effect after suitable drying time.

■ Example Formulation, Classification of Raw Materials and Further Details

Contents	Ingredient and classification according to the Dangerous Substances Directive (2)
1%	Fluorocarbon resins; not classified as dangerous
0,5%	Silicone oils; not classified as dangerous
45%	Aliphatic hydrocarbons; R11, R38, R51/53, R65, R67
15%	Isopropanol; R11, R36, R67
5%	n-Butyl acetate; R10, R66, R67
ad 100%	Propellant propane/butane; R12
Classification of the finished product, calculated according to the Preparations Directive (3): R12, R38, R51/53, R67	

Notes:

It is important to ascertain that the safety data sheets of raw materials do not advise against use in spray products.

If the raw materials are already registered under the REACH Regulation (4) and if a chemical safety report has been elaborated, exposure scenarios need to be attached to the safety data sheets. For each raw material, use in a spray product needs to be covered by an exposure scenario; where necessary, the formulator of the impregnation spray needs to follow the recommended risk reduction measures, in order to adequately control risks.

If use in spray products is not included in the safety data sheets of raw materials, the manufacturer of the impregnation spray needs to become active according to Article 37 (4).

■ Example Safety Assessment

Step	Entry in the dossier; comments
Selection of raw materials	
<p>Not suitable based on general experiences:</p> <p>Reactive components</p> <p>Film formers with high retention to the substrate (> 90% retention on cotton-polyester [30/70] after one single wash (5))</p> <p>Metal alcoholates, methylol compounds</p> <p>Fragrances</p> <p>Substances for which no experience is available in use in pressurized gas packaging</p>	<p>»None of the listed components are present«.</p>
Assessment of input raw materials	
<p>Plausibility check of safety data sheets</p>	<p>»The toxicological and physical-chemical information in the safety data sheets is plausible«.</p>
<p>Information on constituents/components of the 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 let us have all the items of information which are necessary for the formulating of a spray product and its classification«.</p> <p>These extra items of information ensure avoidance of additional risks.</p>	<p>Stating of all constituents / components of the raw materials which are relevant to classification (prescribed, but not always available).</p> <p>Stating of constituents with special structures, e.g. nanoparticles.</p> <p>Check for exclusion criteria.</p>
<p>Further relevant data:</p>	<p>No substances are present which are banned or restricted under the REACH Regulation or under the German Chemicals Ban Ordinance (Chemikalienverbotsverordnung)</p>
Assessment of the preparation	
<p>Description of classification and labelling of the preparation</p>	<ul style="list-style-type: none"> • <i>Flammability:</i> The use of propane/butane as propellant results in classification as »extremely flammable« with R12. • <i>Acute toxicity:</i> According to the calculation method of the Preparations Directive, this preparation is <u>not</u> classified as dangerous to health – based on the classifications of its ingredients (6). • <i>Irritant effect on skin:</i> According to the calculation method of the Preparations Directive, this preparation is classified as irritating to skin with R38 – based on the classifications of its ingredients. • <i>Irritant effect on eyes:</i> According to the calculation method of the Preparations Directive, this preparation is <u>not</u> classified as irritant to eyes – based on the classifications of its ingredients. • <i>Sensitising ingredients:</i> This preparation does <u>not</u> contain any ingredients in a percentage share of >0.1% which are classified as sensitising.

Step	Entry in the dossier; comments
	<ul style="list-style-type: none"> <i>Ecotoxicity:</i> According to the calculation method of the Preparations Directive, this preparation is classified as toxic to the aquatic environment with R51/53 – based on the classifications of its ingredients.
Description of intended use:	<i>Application according to the respective instructions for use and taking into account the specific warning (7).</i>
<p>Assessment of impacts on human health</p> <p>Impacts on human health are assessed stepwise, taking into account the items of information on the following points:</p> <ol style="list-style-type: none"> Results of the calculation method (see above) Further necessary data for ingredients Extra safety of the preparation as regards toxicity by inhalation (8) Accompanying measures to limit the particle size spectrum (9) <ul style="list-style-type: none"> Optimization of internal pressure through the share of propellant Optimization of the primary particle size spectrum through the valve-spray nozzle-combination Selection of solvents of medium vapour pressure, e.g. between 45 and 3 mbar at 20 °C <p><u>Note for foam sprays:</u> In order to avoid high exposure of consumers using foam sprays, the following measures should be taken:</p> <ul style="list-style-type: none"> A so-called foam head needs to be used. The foam head dispenses the content as foam which can be placed directly onto a cloth and distributed. The share of propellants, <i>referred to the total formulation</i>, should not be selected to be too high, e.g. max. 15%. <ol style="list-style-type: none"> Irritant effect on skin 	<ol style="list-style-type: none"> <i>The product is classified and labelled according to the Preparations Directive (see above).</i> <i>The active constituents are not classified as toxic by inhalation.</i> <i>Test conditions chosen for the test – in respect of concentration and exposure duration – constitut extremes, which will <u>not</u> occur in the intended use and when observing the warnings. Therefore slight, reversible impairments – which might be observed in the test – do not need to be expected in practice.</i> <p>Note: If the result of the extra safety test for toxicity by inhalation shows that irreversible impairments or mortalities are observed, the formulation is not eligible for placing on the market.</p> <ol style="list-style-type: none"> <i>Also with the expected aging of the spray mist, the concentration of respirable particles is outside the critical range (10).</i> <ol style="list-style-type: none"> <i>In the intended use, dermal contact is expected to be only short and at low concentration.</i>

Step	Entry in the dossier; comments
6. Oral exposure	6. <i>The input aliphatic hydrocarbons are labelled with risk phrase R65; however, according to Directive 67/548/EEC Annex VI 8.4. this does not apply in the following cases: »Substances classified as harmful on the basis of an aspiration hazard need not be labelled as harmful with R65 when placed on the market in aerosol containers or in containers fitted with a sealed spray attachment«.</i>
Impacts on the environment:	<p><i>Labelling with the symbol »dangerous to the environment« refers to the aliphatic hydrocarbons contained in the product, which constitute a danger to aquatic organisms. However, with the aerosol container the risk of solvents being released into waters is very low. Consequently, in the intended use there is no risk of damage to the aquatic environment.</i></p> <p><i>Solvents evaporate after use of the product. Like the propellant, they are degraded in the atmosphere within a few days.</i></p>
Additional criteria: <ul style="list-style-type: none"> • Storage stability of the preparation (testing at -5 °C, +50 °C) • Packaging 	<p><i>Storage stability of the finished product was substantiated by way of suitable tests at -5 °C and +50 °C.</i></p> <ul style="list-style-type: none"> • <i>The packaging fulfils the requirements of the Aerosol Directive and is labelled accordingly (11).</i> • <i>Child-resistant fastening and tactile warning of danger according to the Preparations Directive are not necessary.</i>
Transport classification	Class 2, item 5F, UN1950, aerosols
Labelling	<p><u>Labelling according to the Preparations Directive</u> <i>Extremely flammable. Irritant to skin. Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Vapours may cause drowsiness and dizziness. Do not breathe vapour/aerosol. Use only in well-ventilated areas. If swallowed, seek medical advice immediately and show this container or label. Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.</i></p> <p><i>Müllermaier GmbH, Müllerstraße 3, 99999 Maierdorf; 09999/99-0, info@muellermaier.de, www.muellermaier.de</i></p> <p><u>Additional labelling according to the German Prepackages Ordinance (Fertigpackungsverordnung)</u> 200 ml 3 e 270</p> <p><u>Additional labelling according to the German Chemicals Ban Ordinance (Chemikalienverbotsverordnung)</u> not necessary</p> <p><u>Additional labelling according to the German Commodities Ordinance (Bedarfsgegenständeverordnung)</u> <i>Vorsicht! Unbedingt beachten! Gesundheitsschäden durch Einatmen möglich! Nur im Freien oder bei guter Belüftung verwenden! Nur wenige Sekunden sprühen! Großflächige Textil- und Ledererzeugnisse nur im Freien besprühen und gut ablüften lassen! Von Kindern fernhalten!</i> <i>(Free translation of labelling items – only for the purpose of this translation: »Caution! It is essential to observe these warnings! Inhalation can cause damage to health! Use only outdoors or in well-ventilated areas! Spray only for a few seconds! For large textile and leather products: spray only outdoors onto these products and allow to evaporate thoroughly! Keep out of reach of children!«)</i></p>

IMPREGNATION SPRAY

Step	Entry in the dossier; comments
	<i>Additional labelling according to the Aerosol Directive Pressurized container. Protect from sunlight and do not expose to temperatures exceeding 50 °C. Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material. Keep away from sources of ignition – no smoking. Keep out of reach of children.</i>
Instructions for use	<i>Use the spray outdoors, if possible. Spray onto surfaces to be treated from a distance of 20 cm; allow to evaporate outdoors.</i>
Conclusion	<i>The examined impregnation spray is safe, on condition that the above-mentioned requirements be met and that the product is used as intended and observing the warnings.</i>

Note:

The results of this safety assessment are included in quality assurance within the production of the finished product (determined ingredients, conditions of filling). Adequate quality assurance measures ensure that the requirements derived from this safety assessment are complied with in production.

References:

- (1) »Empfehlung zur Sicherheitsbeurteilung von Wasch-, Pflege- und Reinigungsmitteln (WPR-Produkten)«, SOFW-Journal 133, 2007, issue 10, p. 53-69; http://www.ikw.org/pdf/broschueren/WPR_Produkte_d.pdf
- (2) Directive on the classification and labelling of dangerous substances (67/548/EEC) of 27.6.1967 (EC OJ 196 of 16.8.1967), last amended by the adaptation (2009/2/EC) of 15.1.2009 (OJ of the EU L 11 of 16.1.2009)
- (3) Directive on the classification, packaging and labelling of dangerous preparations (1999/45/EC), last amended by Regulation (EC) No 1272/2008 of 16.12.2008 (OJ of the EU L 353 of 31.12.2008)
- (4) Regulation (EC) no. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ of the EU L 396 of 30.12.2006, p. 1, amended by the OJ of the EU L 36 of 5.2.2009, p. 84, last amended by Regulation (EC) no. 1272/2008, OJ of the EU L 353 of 31.12.2008, p. 1
- (5) For example, hot wash/coloured laundry programme of a standard household washing machine at 40°C, using a heavy-duty detergent with bleaching agent on oxygen basis, drying in a tumble dryer at max. 65°C for 45 + 5 minutes
- (6) See »Assessment of impacts on human health«
- (7) Labelling according to § 9 in conjunction with annex 7 of the German Commodities Ordinance (Bedarfsgegenständeverordnung) of 23 December 1997 (BGBl. I, 1998, p. 5), last amended by the 17th amending ordinance of 23.9.2009 (BGBl. I p. 3130)
- (8) Swiss Federal Office of Public Health, Dutch Food and Consumer Product Safety Authority, German Federal Institute for Risk Assessment, SOFW-Journal (English Edition) 135, 3-2009, p. 39-43
- (9) For example, SEHSC Guidance for aerosol application of silicon based materials (<http://www.sehsc.com>)
- (10) For example, Guide on Particle Size Measurement from Aerosol Products of the European Aerosol Federation FEA, e.g. at www.rifm.org/doc/20090831%20FEA%20Guide%20on%20Particle%20Size%20Measurement.pdf
- (11) Aerosol Directive 75/324/EEC of 20 May 1975, last amended on 14 April 2003

* Members of the Working Group »Shoe and Leather Care Products, Impregnation Agents« within the German Cosmetic, Toiletry, Perfumery and Detergent Association (Industrieverband Körperpflege- und Waschmittel e. V. / IKW)

Klaus Lange
Salzenbrodt GmbH & Co. KG
Hermsdorfer Straße 70
13437 Berlin, Germany

Mainzer Landstraße 55
60329 Frankfurt am Main, Germany

Horst Kraß
Werner & Mertz GmbH
Ingelheimstraße 1-3
55120 Mainz, Germany

Dr. Uwe Gibbels
Brauns-Heitmann GmbH & Co. KG
Im Lütkefeld 15
34414 Warburg/Westf., Germany

Dr. Wolfgang Herrmann
melvo GmbH
Voithstraße 1
71640 Ludwigsburg, Germany

Dr. Bernhard Pfeil
Poliboy-Werk Emigholz & Brandt GmbH
Tornéestraße 5
28865 Lilienthal, Germany

Dr. Bernd Glassl
Industrieverband Körperpflege- und
Waschmittel e. V. (IKW)

Dr. Ir Ad B. K. Jaspers
Sara Lee Household & Body Care
Research bv
Fruitweg 25
2525 KG Den Haag / Netherlands