REACH

Handbook

von

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uphold dual accountability with the manufactures if problems or questions arise regarding the product. They must notify EU Authorities of all major incidents pertaining to products. An E.A.R. must understand all EU regulations from each of the twenty seven EU member states as well as the four EFTA[71] states, and provide notification of changes and amendments to directives that affect individual products. They must keep the product's technical file available at any time for the EU member states authorities and maintain confidentiality with manufacturer's sensitive product information, releasing them only to the appropriate authorities when called upon.

The CE marking is a mandatory conformance mark on many products placed on the single market in the European Economic Area (EEA). The CE marking certifies that a product has met EU consumer safety, health or environmental requirements. However, not all products sold in the EU need to bear CE marking. Only the products that are covered by the scope of one or more of the New Approach Directives shall be affixed with it in order to be placed on the EU market. Products bearing the CE marking are presumed to be in compliance with the applicable directives and hence benefit from free circulation in the European Market. CE-Marking is obligatory for the following product groups: 113

- Active implantable medical devices
- Appliances burning gaseous fuels
- Cableway installations designed to carry persons
- Eco-design of energy related products
- Electromagnetic compatibility
- Equipment and protective systems intended for use potentially explosive atmospheres
- Explosives for civil uses
- Hot-water boilers
- In vitro diagnostic medical devices
- Lifts
- Low voltage Machinery
- Measuring Instruments
- Medical devices
- Noise emission in the environment
- Non-automatic weighing instruments
- Personal protective equipment
- Pressure equipment
- Pyrotechnics
- Radio and telecommunications terminal equipment
- Recreational craft
- Safety of toys
- Simple pressure vessels

[71] http://www.eftafairtrade.org/.

114 A Declaration of Conformity is a common requirement in European Directives. However, the details vary from directive to directive. Several European CE Marking Directives spell out the need to appoint an E.A.R. Representative, e. g.:

- Medical Devices Directive (MDD) - 93/42/EEC as amended by 2007/47/EC[72]
- In-Vitro Diagnostic Devices Directive (IVDD) – 98/79/EC[73]
- Active Implantable Medical Devices Directive (AIMDD) – 90/385/EEC[74]
- Toys Directive (2009/48/EC)[75]

115 The EC declaration of conformity is the procedure by which the manufacturer, or his authorised representative established in the Community declares that the machinery being placed on the market complies with all the essential health and safety requirements applying to it. The European Association of Authorized Representatives (E.A.A.R.)[76] was established in 2002 in order to accurately represent organizations that provide European Authorized Representative services to non-European manufacturers of medical devices and in-vitro diagnostic medical devices. Its purpose is also to maintain a dialogue with the Competent Authorities, Notified Bodies and trade associations about the role of Authorized Representatives in the context of compliance with European regulatory requirements.

116 The E.A.A.R. possesses a shared vision of enhancing the quality of European Authorized Representation and acts as a unified body dedicated to ensuring that the designation of a European Authorized Representative accurately portrays the quality standards of a professional Authorized Representative. As an organization the E.A.A.R. is officially recognized by the European Commission and is also involved in the political issues surrounding CE Marking in Europe. This body of representatives together has a goal to utilize the opportunity to enhance all stakeholders' understanding of European Authorized Representatives' responsibilities.

117 The EU Cosmetics Directive (76/768/EEC)[77] has established a '***Responsible Person***' providing regulatory responsibility for the introduction of cosmetic products within the EU territory. The Cosmetics Directive requires the persons responsible for placing cosmetic products on the market, to have a safety assessment carried out and ensure the results are available for inspection. The major responsibilities of the Responsible Person can be summarized as follows:

- Product classification
- Product Information File (PIF) preparation to be submitted to the EU Authorities per EU Member State
- Organize a Safety Assessment of the cosmetic product by an external Safety Assessor

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[72] Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

[73] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

[74] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.

[75] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

[76] http://www.eaarmed.org/index.html.

[77] Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (76/768/EEC).

- Pre-Market Notification of cosmetic products per EU Member State
- Notification to Poison Centers per EU Member State
- Undesirable and serious undesirable effect communication and complaint handling coordination

On 30 November 2009, the new Cosmetic Products Regulation (EU Regulation 1223/2009)[78] was adopted replacing the Cosmetics Directive. With the new Cosmetics Regulation the EU is having a robust, internationally recognized regime, which reinforces product safety taking into consideration the latest technological developments, including the possible use of nanomaterials. Most of the provisions of this new regulation will be applicable as from 11th July 2013. The new regulation implies greater responsibility for the 'Responsible Person' in terms of product safety. It gives clear requirements for generating, keeping and updating information. Hence, the major responsibility in regard to the safety of a cosmetic product will rely on the 'Responsible Person'. Article 5 of the Regulation lists the obligations: **118**

- Responsible persons shall ensure compliance with Articles 3, 8, 10, 11, 12, 13, 14, 15, 16, 17, 18, Article 19 (1), (2) and (5), as well as Articles 20, 21, 23 and 24.
- Responsible persons who consider or have reason to believe that a cosmetic product which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate.
- Furthermore, where the cosmetic product presents a risk to human health, responsible persons shall immediately inform the competent national authorities of the Member States in which they made the product available and of the Member State in which the product information file is readily accessible, giving details, in particular, of the non-compliance and of the corrective measures taken.
- Responsible persons shall cooperate with these authorities, at the request of the latter, on any action to eliminate the risks posed by cosmetic products which they have made available on the market. In particular, responsible persons shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of specific aspects of the product, in a language which can be easily understood by that authority.

The Responsible Person, indicated on the package with registered office within the European Community must guarantee compliance with all the safety and labelling requirements of the cosmetic product as well as compliance with the notification obligations and – inasmuch as this is necessary in individual cases – the taking of corrective measures (MILDAU & HUBER, 2010)[79]. The Responsible Person will carry out the legal obligations of the cosmetic manufacturer or importer in regard to the new regulation, including but not limited to registration, maintenance of product files, safety assessments, etc. Regarding product safety, the Regulation underlines strict requirements for the content of the Safety Assessment and that of the Product Information File (Annex I of 1223/2009), as well as outlining the responsibilities of the Responsible Person and the Safety Assessor. **119**

[78] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

[79] *Mildau, G./Huber, B.* (2010), The New EC Cosmetics Regulation 1223/2009 – Contents and First Explanations, SOFW-Journal 136, 3–2010.

The process of registration is changed by the notification of sales and compositional information being delivered to the Commission, who will circulate the information to Poison Centers and Member States.

120 Moreover, the new regulation introduces changes in regard to the notification, evaluation and labeling requirements for all cosmetic products that contain nanomaterial. Additional safety assessment provisions related to nanomaterial have also been incorporated in the regulation. In line with REACH, the new Cosmetics Regulation highlights the need to make information available to the public and to consumers.

121 ERPA[80] is the European Cosmetics Responsible Person Association and aims to support the efforts in protecting the safety of the cosmetic products users in Europe by promoting high standards of services and professional conduct among the European Responsible Persons.

[80] http://www.erpacosmetics.org/.

VII. Annexes

SONGWON CHEMSERVICE

To: October 2008

Customers of

Songwon Industrial Co., Ltd., Ulsan, Korea
Songwon International AG, Frauenfeld, Switzerland
Songwon International - Americas Inc., Friendswood, TX, USA

We herewith confirm that

Chemservice S.A., 51, Route de Mondorf, L-5552 Remich, Luxembourg

has been appointed by

Songwon Industrial Co., Ltd. 737-2, Yochon-Dong, Nam-Gu, Ulsan, Korea

as Only Representative (OR) according to Article 8 of the Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

Within this appointment, Chemservice has completed the pre-registration for all substances equal or greater than 1 ton/year included in all Songwon products sold on the EU-market.

Further information can be obtained either from the Songwon REACH Coordinator, Ms. Ah-Reum Seo (arseo@songwonind.com) or Chemservice (info@chemservice-group.com).

We trust this response provides the information requested. If not, please don't hesitate to let us know.

Sincerely,

For Songwon

Jongho Park
Chairman & CEO

For Chemservice

Dr. Dieter Drohmann
Managing Director

123 Annex 2. Example of OR-Appointment by NCM

LETTER OF APPOINTMENT

[*Please insert company name*], a company duly organized and existing under the laws of [*please add country*] with address at [*please add address*] (the 'Company'), manufactures substances, formulates preparations and/or produces articles that are imported into the Community.

This letter is to confirm the appointment of:

Chemservice GmbH

Von-Steuben Strasse 13, D-67549 Worms, Germany

Represented by its Managing Director

Dr. Dieter Drohmann

as its **Only Representative** pursuant to Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

The undersigned is/are officer/s of the Company and duly authorized to act on behalf of the Company.

_____ _____

(Place/Date) (Signature/s)

Annex 3. REACH Article 8 **124**

Only Representative of a non-Community manufacturer

(1)

A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title.

(2)

The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.

(3)

If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.

125 Annex 4. Example of Only Representative Coverage Statement

ONLY REPRESENTATIVE COVERAGE

STATEMENT

As the appointed Only Representative of a non-EU manufacturer, according to Article 8 of the Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), we herewith confirm that

the following product(s) **Multimix 25**
Multimix 37

supplied by Mishmash Chemicals
Uphill Road 1423
Plastics Town, KL 72533
USA

to European Importer
P.O. Box 53778
D-09724 Nordhall
Germany

are included under our volume tracking obligations of REACH Article 8 (2) and are either exempt from the obligation to register according to REACH Article 2, or are covered by our (Pre-)Registration(s) at the European Chemicals Agency (ECHA).

We are prepared to provide enforcement authorities in the EU with the necessary details upon request.

The annual import volumes of each calendar year will be certified retroactively at the beginning of the following calendar year.

This statement is valid for the calendar year of issuance.

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5, an de Laengten L-6776 Grevenmacher
Tel.: +352 270776-1 Fax: +352 270776-75
Email: info@chemservice-group.com

Dr. Dieter Drohmann
Managing Director

May 27, 2011

Chemservice S.A.
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