

# **Consumer exposure information**

Overview for incorporation on ConsExpo website

RIVM Letter Report 320104013/2011 S.W.P. Wijnhoven | J.D. te Biesebeek | W. ter Burg



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This investigation has been performed by order and for the account of New Food and Consumer Products Safety Authority, within the framework of Consumer exposure

# Rapport in het kort

#### Consumenten blootstellingsinformatie

Overzicht voor plaatsing op de ConsExpo website

Het RIVM heeft een overzicht gemaakt van de blootstellingsinformatie van consumenten aan chemische stoffen die publiekelijk beschikbaar is. Deze informatie is vervolgens via de vernieuwde RIVM-website verspreid, zowel in het Nederlands als in het Engels. Daarnaast is het overzicht in onderliggend rapport weergegeven. Op deze manier wordt de informatie gestructureerd ontsloten; tot voor kort ontbrak een dergelijk overzicht.

Om het risico van een chemische stof in een consumentenproduct goed te kunnen beoordelen is informatie nodig over de mate waarin de consument eraan blootstaat als hij het product gebruikt. Relevant informatie is onder meer: welke chemische stoffen zitten er in een product, komen ze uit het product bij gebruik, maar ook hoe vaak gebruikt een consument een product, wanneer en hoeveel gebruikt hij ervan? Verschillende onderzoeksgroepen wereldwijd werken aan dit onderwerp en stellen hun informatie via de literatuur of via websites beschikbaar.

Onder consumentenblootstelling is op de website aandacht voor de volgende onderwerpen: Belangrijkste opdrachtgevers, Internationale regelgevende kaders, Consumenten blootstellingsmodellen, Blootstellingsscenario's en blootstellingsfactoren, Productgerelateerde informatie, Stof-gerelateerde informatie, Geaggregeerde blootstelling, Blootstelling bij kinderen en Nano.

Binnen de informatie over consumentenblootstelling is er aandacht voor het model ConsExpo dat het RIVM heeft ontwikkeld. Met dit veelgebruikte model kan worden berekend hoe groot de blootstelling aan een stof in een product is. De webpagina over ConsExpo is onderverdeeld in drie subthema's: Spray model, Emissie tool en Factsheets. Alle relevante referenties en weblinks van dit moment worden gegeven.

http://rivm.nl/Onderwerpen/Onderwerpen/C/Consumentenblootstelling\_chemisc he\_stoffen\_

http://rivm.nl/en/Topics/Topics/C/Consumer exposure to chemical substances

http://rivm.nl/Onderwerpen/Onderwerpen/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/ConsExpohttp://rivm.nl/en/Topics/Topics/ConsExpohttp://rivm.nl/en/Topics/Topics/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/Topics/C/ConsExpohttp://rivm.nl/en/Topics/ConsExpohttp://rivm.nl/en/Topic

Trefwoorden: blootstellingsinformatie voor consument, ConsExpo, overzicht, RIVM website

# Abstract

#### **Consumer exposure information**

Overview for incorporation on ConsExpo website

The RIVM has made a publicly available overview of consumer exposure information to chemical substances. This information is subsequently distributed via the renewed RIVM website, both in Dutch and English. In addition, the overview is presented in the current report. In this way, the information is provided in a structured way; there was no such overview until now.

To assess the risk of a chemical ingredient of a consumer product, information is needed on consumer exposure during the use of the product. Relevant information is for instance: Which chemical substances are present in a consumer product; Are the substances released from the product during use; but also How often is a consumer using the product; When and how much is he using it?

Various research groups worldwide generate consumer exposure information and publish this information via literature and websites.

Under Consumer Exposure there is particular attention for the following subthemes: Main commissioning bodies, International legislative frameworks, Consumer exposure models, Exposure scenarios and Exposure factors, Product related information, Substance related information, Aggregate exposure, Children's exposure and Nano.

Within the Consumer Exposure information there is specific attention for the software model ConsExpo, the widespread used consumer exposure estimation model that has been developed by RIVM. The webpage on ConsExpo is subdivided in the sub-themes: Spray model, Emission tool and Factsheets. The current references and related links for these themes are given.

http://rivm.nl/Onderwerpen/Onderwerpen/C/Consumentenblootstelling chemisc he stoffen

http://rivm.nl/en/Topics/Topics/C/Consumer exposure to chemical substances

http://rivm.nl/Onderwerpen/Onderwerpen/C/ConsExpo http://rivm.nl/en/Topics/Topics/C/ConsExpo

Key words: consumer exposure information, ConsExpo, overview, RIVM website

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# Summary

In the current report, an overview is given on publicly available consumer exposure information. The aim of the overview is to make the information available via the RIVM website (English as well as Dutch), the current report is the basis for that information. In this way, people who would like to know more about consumer exposure estimation, the relevant models for this and other related information, can find the available information in one place in a well-organized way.

Main themes for the website are "Consumer Exposure" and "ConsExpo", the consumer exposure estimation model that has been developed by RIVM. The following "Sub-themes" under the Consumer Exposure main page are described: Main commissioning bodies, International legislative frameworks, Consumer exposure models, Exposure scenarios and exposure factors, Product related information, Substance related information, Aggregate exposure, Children's exposure and Nano.

The ConsExpo main page consists of the sub-themes Spray model, Emission tool and Factsheets. The current references and related links for these themes are given.

# Samenvatting

In het huidige rapport wordt een overzicht gegeven van blootstellingsinformatie voor de consument die publiekelijk beschikbaar is in de literatuur en via websites. Het doel van dit overzicht is om als basis te dienen voor de verspreiding van deze informatie via de vernieuwde RIVM website (in Engels en Nederlands). Op deze manier kunnen mensen die meer te weten willen komen over schatting van consumenten blootstelling, de relevante modellen en informatie, deze informatie vinden op eén plek op een gestructureerde manier. Hoofdthema's voor de website zijn "Consumentenblootstelling" en "ConsExpo", het model voor blootstellingschattingen van stoffen uit consumentenproducten dat door het RIVM is ontwikkeld.

De volgende subthema's worden onder Consumentenblootstelling beschreven: Belangrijkste opdrachtgevers, Internationale regelgevende kaders, Consumenten blootstellings modellen, Blootstellingsscenario's en blootstellings factoren, Product-gerelateerde informatie, Stof-gerelateerde informatie, Geaggregeerde blootstelling, Blootstelling bij kinderen en Nano. De ConsExpo hoofdpagina bestaat uit de subthema's: Spray model, Emissie tool en Factsheets. Alle relevante referenties en weblinks van dit moment worden gegeven.

# 1 Introduction

Various research groups and institutes are working on consumer exposure worldwide. A lot of valuable information for the exposure science society is produced; however it is not always easy to have an overview of this information. Also easy access to this valuable information can be difficult. To conduct an exposure assessment for a chemical substance, information is needed on that substance as well as on exposure factors. This information is available, in research papers, reports as well as on various websites. The attempt of this report is to give an overview of relevant information for human exposure assessment of chemical substances in and released from everyday consumer products. In the framework of Consumer Exposure, the Dutch Food and Consumer Products Safety Authority (nVWA) commissioned RIVM to collect information for conducting an exposure assessment of chemicals present in consumer products and publish it on the RIVM website. Therefore, the overview and related information and references described in the current report will be used as basis for the information presented in the future on the website of RIVM (both in English and in Dutch).

The content of the report is structured as is the RIVM website. Every chapter is a main page with general information on a theme. Apart from general information, relevant links to references as well as websites will be given. The different paragraphs are the sub-themes with relevant information and links. In the appendices, a schematic overview is described on how the information of this report will be presented on the RIVM website. In the future, the information on the website will be updated once a year.

# 2 Consumer exposure to chemical substances

Consumers are frequently exposed to chemical substances in or released from everyday consumer products like paint, cosmetics, deodorant, cleaning products etc. Chemical substances in these products should not be a concern for human health.

To assess the risk of a consumer product, it is very important to know the exposure to chemicals in these products. Exposure to chemical substances during use of consumer products is mainly determined by the way the product is used (exposure scenario), the concentration of the ingredient in the product and the release of the substance from the product during use. However, no such measurement data are available.

RIVM is involved in the development of methods to determine the safety of chemical substances. For consumer products, RIVM has developed the ConsExpo model, a model that mathematically predicts human exposure to consumer products (<a href="http://www.ConsExpo.nl">http://www.ConsExpo.nl</a>). With the use of ConsExpo, manufacturers and researchers are able to predict to what amount consumers are exposed to chemical substances in a consumer product.

#### 2.1 Main commissioning bodies

The main commissioning bodies for RIVM with respect to consumer products and consumer exposure are the new Dutch Food and Consumer Products Safety Authority (nVWA), the Ministry of Health, Welfare and Sports (VWS) as well as the European Commission (EC). Collaborations in this field are contracted with Wageningen University (WUR) where product use is evaluated as well as with RIKILT and MESA+ that perform measurements of (nano) substances in consumer products.

nVWA: <a href="http://www.vwa.nl/">http://www.vwa.nl/</a>

VWS: http://www.rijksoverheid.nl/ministeries/vws

EC: <a href="http://ec.europa.eu/index\_en.htm">http://ec.europa.eu/index\_en.htm</a>

WUR: <a href="https://www.rikilt.wur.nl">www.rikilt.wur.nl</a>

MESA+: http://www.utwente.nl/mesaplus/

#### 2.2 International legislative frameworks

With respect to regulation of chemical substances in consumer products, different international legislative frameworks are relevant (link to <a href="http://www.rivm.nl/rvs/wet/">http://www.rivm.nl/rvs/wet/</a>). The use and production of all substances that are processed in consumer products (production volume > 1 tonnage and manmade) is regulated by REACH.

Consumer products are subject to 'vertical' (i.e. sector-specific) and 'horizontal' legislation (i.e. workers legislation, chemical legislation and general environmental legislation). Some specific products are directly regulated by vertical legislation e.g. biocidal products, plant protection products, cosmetics food contact materials, detergents and toys. Consumer products that are not governed by specific legislation have to meet the requirements of the General Product Safety Directive.

#### 2.2.1 REACH

REACH is the European Community Regulation on chemicals and their safe use (EC 1907/2006) dealing with the Registration, Evaluation, Authorisation and Restriction of Chemical Substances that came into force on 1 June 2007.

The REACH Regulation places greater responsibility on industry to manage the risks from chemicals and to provide safety information on the substances they produce. Manufacturers and importers are required to collect information on the properties of their chemical substances, which will enable their safe handling. The guidance on information requirements and chemical safety assessment describes the information requirements under REACH with regard to substance properties, exposure, use and risk management measures, in the context of the chemical safety assessment (CSA). When conducting a CSA, the registrant should address the entire life cycle of the chemical substance, including consumer uses of a substance on its own, in a preparation/ mixture or incorporated in a product.

In the REACH Regulation, specific guidance for estimation of consumer exposure is described in Chapter R.15 "Consumer Exposure Estimation". Multiple models to calculate consumer exposure are described in this section, like ECETOC-TRA and ConsExpo.

#### References

ECHA (2010). Guidance on information requirements and chemical safety assessment. Chapter R.15: Consumer exposure estimation. ECHA-10-G-03-EN European Chemicals Agency

http://guidance.echa.europa.eu/docs/guidance\_document/information\_requirements\_en.h tm?time=1285273635#r15

Van Engelen JG, Heinemeyer G, Rodriguez C: Consumer exposure scenarios: development, challenges and possible solutions. J Expo Sci Environ Epidemiol; 2007 Dec;17 Suppl 1:S26-33.

van Engelen JGM, Hakkinen PJ, Money C, Rikken MGJ and Vermeire TG (2007). Human exposure assessment. In: Leeuwen CJ van, Vermeire TG, eds. Risk assessment of chemicals; an introduction. 2nd ed. Dordrecht: Springer, 2007; 195-226 Art.nr. 2007584.

Bruinen de Bruin Y, Hakkinen PB, Lahaniatis M, Papameletiou D, Del Pozo C, Reina V, Van Engelen J, Heinemeyer G, Viso AC, Rodriguez C, Jantunen M: Risk management measures for chemicals in consumer products: documentation, assessment, and communication across the supply chain. J Expo Sci Environ Epidemiol; 2007 Dec;17 Suppl 1:S55-66

#### 2.2.2 Biocides

The Biocidal Product Directive (98/8/EG) aims to harmonize the European market for biocidal products and their active substances. At the same time it aims to provide a high level of protection for humans, animals and the environment. This Guideline is covering the authorization of biocides in the different Member States, implemented in the Netherlands by "de Wet Gewasbeschermingsmiddelen en Biociden (bestaat deze nog, welk nr?)".

#### **References**

Technical notes for Guidance (TNsG) (2007). Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUROPEAN COMMISSION JOINT RESEARCH CENTRE EUR 20418 EN.

EC: Technical Guidance Document on Risk Assessment in support of Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No. 1488/94 on risk assessment for existing substances (Parts I, II, III and IV) and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocidal products on the market. European 2003.

http://ec.europa.eu/environment/biocides/ http://www.ctgb.nl/ (=related link)

# 2.2.3 General Product Safety Directive (GPSD)

The General Product Safety Directive (2001/95/EC) applies to the supply of all new and second hand products to consumers for personal use, whether they were intended for use by consumers or not. The objectives of the Directive are both to protect consumer health and safety and to ensure the proper functioning of the internal market.

The GPSD is intended to ensure a high level of product safety throughout the EU for consumer products that are not covered by specific sector legislation (e.g. toys, chemicals, cosmetics, machinery). The Directive also complements the provisions of sector legislation which do not cover certain matters, for instance in relation to producers' obligations and the authorities' powers and tasks. The Directive provides a generic definition of a safe product. Products must comply with this definition.

http://ec.europa.eu/consumers/safety/prod\_legis/index\_en.htm

RAPEX is the EU rapid alert system for all dangerous consumer products, with the exception of food, pharmaceutical and medical devices. It allows for the rapid exchange of information between Member States via central contact points and the Commission of measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers. Both measures ordered by national authorities and measures taken voluntarily by producers and distributors are covered by RAPEX.

http://ec.europa.eu/consumers/dyna/rapex/rapex archives en.cfm www.vwa.nl

#### 2.2.4 The Cosmetics Directive

The Cosmetics Directive (76/768/EEC) covers cosmetics and hygiene products. A cosmetic product is any substance or preparation intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, and/or correcting body odours, and/or protecting them or keeping them in good condition. The Directive sets out a list of substances which cannot be included in the composition of cosmetic products (Annex II) and a list of substances which cosmetic products may contain only under the restrictions and conditions laid down (Annex III). The Directive also contains lists of colourings (Annex IV), preservatives (Annex VI) and UV filters (Annex VII) permitted in cosmetic products.

http://ec.europa.eu/consumers/sectors/cosmetics/documents/directive/

In 2009, a new resolution has been accepted in which ..... (zie stukje tekst voor nano en wettelijke kaders)

SCCS is the Scientific Committee on Consumer Safety which provides opinions on health and safety risks (chemical, biological, mechanical and other physical risks) of non-food consumer products (e.g. cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products) and services (e.g. tattooing, artificial sun tanning). A selection of ingredients of cosmetics has to be evaluated by SCCS before introduction on the market.

http://ec.europa.eu/health/scientific committees/consumer safety/index en.htm

#### 2.2.5 The Toys Directive

The Toys Directive (2009/48/EC) regulates the safety of toys ("products designed or intended, whether or not exclusively, for use in play by children under 14 years of age") in Europe. This new Toy Safety Directive substantially amends the old Directive across virtually all safety aspects. It fulfils to the highest level the newest health and safety standards. It improves the existing rules for the marketing of toys that are produced in and imported into the EU in view to reducing toy related accidents and achieving long-term health benefits. The new Directive brings in particular more references on chemicals by limiting the amounts of certain chemicals that may be contained in materials used for toys.

Chemicals that are susceptible to provoke cancer, change genetic information or harm reproduction, so-called CMR (Carcinogenic, Mutagenic or toxic for Reproduction) substances, are no longer allowed in accessible parts of toys. For certain substances like nickel tolerable limit values have been introduced and certain heavy metals which are particularly toxic, like lead, may no longer be intentionally used in those parts of toys that are accessible to children. Allergenic fragrances are either completely forbidden, if they have a strong allergenic potential, or have to be labelled on the toy if they are potentially allergenic for some consumers.

http://ec.europa.eu/enterprise/sectors/toys/documents/directives/index en.htm

# 2.2.6 The Detergents regulation

The Detergents regulation (648/2004) mainly affects how detergent products are labeled and includes provisions for:

- Ultimate biodegradability requirements (both the level and methodologies used) for all surfactants used in detergents.
- The provision of information provided to the consumer via the labelling of ingredients and websites, in order to make it easier for the consumer to choose the right product, to use it safely and to obtain the best possible results.
- Information to be held by manufacturers and to be supplied to Medical Professionals and competent authorities on request.

http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/detergents/

# 2.2.7 Plant protection products

The evaluation, marketing and use of pesticides (herbicides, insecticides, fungicides etc.) in plant protection in the Community are regulated under Council Directive 91/414/EEC. This Directive lays out a comprehensive risk assessment and authorization procedure for active substances and products

containing these substances. Each active substance has to be proven safe in terms of human health, including residues in the food chain, animal health and the environment, in order to be allowed to be marketed. It is the responsibility of industry to provide the data showing that a substance can be used safely with respect to human health and the environment.

http://ec.europa.eu/food/plant/protection/evaluation/dir91-414eec en.htm http://www.ctqb.nl/ (=related link)

#### 2.2.8 Food contact materials

Food contact materials and articles are regulated by Framework regulation C 1935/2004. The following rules are set by this regulation:

- General principles
- Groups of food contact materials and articles
- Procedure for authorisation
- Establishment of an European Reference Laboratory for food contact materials

The general principles of the regulation are that it requires that food contact materials

- Are safe;
- Must not transfer their components into food in quantities that could endanger human health, change food composition in an unacceptable way or deteriorate its taste and odour.
- Are manufactured according to good manufacturing practice
- An article intended for food contact must be labeled or bear the glassand-fork symbol. This labeling is not obligatory if food contact is obvious by the article's nature e.g. knife, fork, wine glass.
- Labeling, advertising and presentation of food contact materials must not mislead consumers.
- Information on the appropriate use of food contact materials or articles must be provided, if necessary
- Are traceable throughout the production chain.

For more details on the regulation see:

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/framework\_en.htm

# 2.3 Consumer exposure models

Consumer exposure arises from a large diversity of products that may contain chemical compounds. Since experimental data on consumer exposure are scarce or absent, various models have been developed to estimate exposure to chemicals in or released from consumer products. Consumer exposure models can be categorized to various tiers (see Table).

Summary of various consumer exposure models

Tier 1 estimation	ECETOC TRA
Tier 1.5	ESIG
	Habits & practices (AISE use description)
Higher tier estimation	HERA EA method (AISE)
	GEXframe
	BAMA
	ConsExpo

# 2.3.1 ConsExpo

To mathematically predict human exposure to consumer products RIVM has developed the software model ConsExpo, a set of coherent, general models that enables the estimation and assessment of the exposure to substances from consumer products and their uptake by humans. It can be used within REACH for higher tier exposure estimation. (Link to ConsExpo).

#### 2.3.2 ECETOC TRA

The ECETOC tiered risk assessment (TRA) tool is, within the REACH guidance, the tiered (step by step) approach for calculating the exposure to and risks from chemicals that might reasonably be expected in defined circumstances of use. The ECETOC TRA Consumer Tool is a first (lower) tier tool that allows calculation of consumer exposures to substances that are present in preparations and articles used by consumers. <a href="http://www.ecetoc.org/tra">http://www.ecetoc.org/tra</a>.

#### 2.3.3 ESIG Consumer Generic Exposure tool

An improvement of the ECETOC TRA consumer exposure tool has recently been published by the European Solvent Industry Group (ESIG). The ESIG Consumer Generic Exposure tool can be seen as a bridge between ECETOC TA (first tier) and ConsExpo (as higher tier). The refinement is produced in the TRA key factors.

http://www.esig.org/en/regulatory-information/reach/ges-library/consumergess

#### 2.3.4 AISE REACT

A.I.S.E., the international Association for Soaps, Detergents and Maintenance Products, is involved in various key activities with respect to REACH. One of the activities is the development of the A.I.S.E. REACT: Reach Exposure Assessment Consumer Tool. <a href="http://www.aise.eu/reach/?page=exposureass\_sub3">http://www.aise.eu/reach/?page=exposureass\_sub3</a> Another activity of A.I.S.E, in cooperation with Cefic, is the HERA project, Human and Environmental Risk Assessment on ingredients of household cleaning products.

# 2.3.5 BAMA tool

The British Aerosol Manufacturers Organisation (BAMA) has published on it's website a tool for calculation of consumer inhalation exposure. An evaluation of this tool when compared to the ConsExpo spray model has been made by RIVM recently.

BAMA: <a href="http://www.bama.co.uk/">http://www.bama.co.uk/</a>

# Reference 1 4 1

Delmaar JE (2010). Comparing the indoor air and ConsExpo inhalation models. RIVM letter report 320104009/2010, National Institute for Public Health and the Environment, Bilthoven

# 2.3.6 Other models

#### Lifeline model

The Lifeline group is a non-profit organization bringing state-of-the-art science to contemporary challenges of assessing exposure, risk and benefits to elements of people's diets and living environment. The Lifeline group has created different software models for

- Detailed exposure and risk/benefit assessment
- Priority setting and screening assessments
- Models of the body's dynamics and metrics

CEPST™ has evolved from the Complex Exposure Tool© (ComET©) that The LifeLine Group™ developed for Health Canada. CEPST™ currently exists as a proof of concept modeling construct. It demonstrates that for large groups of chemicals with little data and possibly multiple exposure scenarios, users can set priorities for chemicals relative to their exposure potential. http://www.thelifelinegroup.org/

#### Reference

Jayjock MA, Chaisson CF, Franklin CA, Arnold S, Price PS: Using publicly available information to create exposure and risk-based ranking of chemicals used in the workplace and consumer products. J Expo Sci Environ Epidemiol; 2009 Jul;19(5):515-24.

<u>Wall Paint Exposure Assessment Model (WPEM)</u> http://www.epa.gov/oppt/exposure/pubs/wpem.htm

#### Sprayexpo

#### Reference

Eickmann U., Eickmann J., Tischer M. (Exposure to sprays –comparison of the available exposure models) Gefahrstoffe 67 (2007) Nr. 7/8 - Juli/August - Reinhaltung der Luft. <a href="http://www.bgw-online.de/internet/generator/Inhalt/OnlineInhalt/Medientypen/">http://www.bgw-online.de/internet/generator/Inhalt/OnlineInhalt/Medientypen/</a>
Fachartikel/Exposition\_\_\_Spray,property=pdfDownload.pdf

ter Burg W, te Biesebeek JD, Wijnhoven SWP and van Engelen JGM (2011). Risico's van spuittoepassingen. Ontwikkeling van een screeningsinstrument. RIVM report 320104012/2011 (In Dutch).

<u>TUA tool for integrated exposure scenarios:</u> Expofacts and Airmex (tier 1.5 model in REACH) <u>www.jrc.ec.europa.eu/tua</u>

<u>Consumer Exposure Model (CEM) and MMCEM:</u> <u>www.epa.gov/oppt/exposure/pubs/efastdl.htm</u> www.epa.gov/oppt/exposure/pubs/mccemdl.htm

# 2.4 Exposure factors

Exposure factors are actions and media that bring us in contact with environmental agents. Important exposure factors are for instance consumption of food and beverages, housing conditions, time use in micro-environments, but also inhalation rates and consumer products use. Also activities of people contribute to the exposure to environmental agents.

Below, two major initiatives are mentioned that describe exposure factors for the European as well as the American population.

#### 2.4.1 ConsExpo Factsheets

The ConsExpo factsheets give important information for the consistent estimation and assessment of the exposure to, and the uptake of, substances from consumer products. Exposure factors are included in these documents. (link naar ConsExpo-factsheets)

# 2.4.2 The European Exposure Factors (ExpoFacts) Sourcebook

The European Exposure Factors (ExpoFacts) Sourcebook is a collection of statistics and references and contains data on exposure factors from 30 European countries: Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Romania, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland and United Kingdom. It is primarily aimed at being a tool for environmental exposure analysis and risk assessment but it can also serve as a data source for administration, NGO's and anyone interested in European statistics. Expofacts (2007). The European Exposure Factors (ExpoFacts) Sourcebook. http://expofacts.jrc.ec.europa.eu/.

# 2.4.3 US-EPA Exposure Factors Handbook

The US-EPA also has made a summary of the available statistical data on various factors used in assessing human exposure. These factors concern the general (US) population as well as various segments of the population who may have characteristics different from the general population. Specific data for children are included in the latest version of the report. (US-EPA, Exposure Factors Handbook (2011) Final Report) <a href="http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252">http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252</a>

# 2.4.4 US-EPA Consolidated Human Activity Database (CHAD)

The American Consolidated Human Activity Database (CHAD) contains data obtained from pre-existing human activity studies that were collected at city, state, and national levels. CHAD is intended to be an input file for exposure/intake dose modelling and/or statistical analysis. CHAD is a master database providing access to other human activity databases using a consistent format

U.S. EPA Consolidated Human Activity Database (CHAD) (2003). <a href="http://www.epa.gov/chadnet1/">http://www.epa.gov/chadnet1/</a>

#### 2.4.5 Additional exposure factors references

- Australian Exposure Assessment Handbook
   <a href="http://www.health.gov.au/internet/main/publishing.nsf/Content/FAC004">http://www.health.gov.au/internet/main/publishing.nsf/Content/FAC004</a>
   <a href="https://doi.org/10.1007/journal.org/">DCE7F63EF1CA25784000206980/\$File/AEFG.pdf</a>
- IPCS Harmonization Project of the WHO: vast collection of information about exposure and risk assessment, with emphasis on exposure to chemicals <a href="http://www.who.int/ipcs/methods/harmonization/en/">http://www.who.int/ipcs/methods/harmonization/en/</a>
- Mekel O, Mosbach-Schulz O, Schümann M, Okken PK, Peters C, Herrmann J, Hehl O, Bubenheim M, Fehr R und Timm J (2005).
   Evaluation von Standards und Modellen zur probabilistischen Expositionsabschätzung (Xprob.) Gefördert durch das Umweltbundesamt http://www.math.uni-bremen.de/riskom/xprob/
- Umwelt bundesambt (2011). Gesundheit und Umwelthygiene Gesundheitsbezogene Expositionsschätzung. <a href="http://www.umweltbundesamt.de/gesundheit/methoden/exposition.htm">http://www.umweltbundesamt.de/gesundheit/methoden/exposition.htm</a>
- Eis-chemrisk toolbox of JRC http://web.jrc.ec.europa.eu/eis-chemrisks/toolbox/

More additional references are found in the following document, available via the Expofacts website <a href="http://expofacts.jrc.ec.europa.eu/docs/reference.pdf">http://expofacts.jrc.ec.europa.eu/docs/reference.pdf</a>

#### References

Nielsen E and Iskov Kopp T (NEGh) (2010). Existing Default Values in Exposure Assessment. A Nordic Exposure Group Project (Final draft report). Division of Toxicology and Risk Assessment National Food Institute, Technical University of Denmark

Schets MF, Schijven JF and de Roda Husman AM 2011. Exposure assessment for swimmers in bathing waters and swimming pools. Water Research 45 (2011) 2392-2400.

Weegels, MF., Van Veen MP. (2001). Variation of consumer contact with household products: a preliminary investigation. Risk Analysis, 21 499-511

#### 2.5 Product related information

Information on product categories can be found in multiple sources. One important source of product information with respect to consumer exposure estimation via ConsExpo are the factsheets (link ConsExpo). There are factsheets available with information on:

Cosmetics
Cleaning products
Disinfectants
Do-it-yourself products
Paint products
Pest control products

#### 2.5.1 Household Products Database

Another important source for consumer product information is the Household Products Database (2001), a database with a list of product ingredients. It links over 11,000 consumer brands to health effects from Material Safety Data Sheets (MSDS) provided by manufacturers. It allows scientists and consumers to research products based on chemical ingredients. The database is designed to help to answer the following typical questions:

- What are the chemical ingredients and their percentage in specific brands?
- Which products contain specific chemical ingredients?
- Who manufactures a specific brand? How do I contact this manufacturer?
- What are the acute and chronic effects of chemical ingredients in a specific brand?
- What other information is available about chemicals in the toxicologyrelated databases of the National Library of Medicine?

Information in the Household Products Database is from a variety of publicly available sources including brand-specific labels and Material Safety Data Sheets when available from manufacturers and manufacturers' web sites. <a href="http://householdproducts.nlm.nih.gov/index.htm">http://householdproducts.nlm.nih.gov/index.htm</a>

Currently there is an initiative in Europe running to investigate whether it is possible to expand the Household Products Database with European products.

Related link is SPIN database of the Danish EPA: www.spin2000.net

# 2.5.2 Cosmetic products

For cosmetic products, a selection of the ingredients has to be evaluated by SCCS before introduction on the market. In the European Exposure to Cosmetic Products project, various European manufacturers within Colipa (the European trade association of the cosmetics, toiletry and perfumery industry) have worked together to update the currently used exposure data for 12 cosmetic products. (Hall et al, 2007; 2011; Mc Namara et al, 2007). Also in the United States exposure data for various cosmetic products have been published in recent years (Loretz L et al, 2005; 2006; 2008).

#### References

Hall B., Tozer S., Safford B., Coroama M., Steiling W., Leneveu-Duchemin MC., Mc Namara C., Gibney M.(2007) European consumer exposure to cosmetic products, a framework for conducting population exposure assessments. Food and Chem. Tox 45,2097-2108.

McNamara C, Rohan D, Golden D, Gibney M, Hall B, Tozer S, Safford B, Coroama M, Leneveu-Duchemin MC and Steiling W: Probabilistic modeling of European consumer exposure to cosmetic products. Food and Chemical Toxicology 45 (2007) 2086–2096.

Hall B., Steiling W., Safford B., Coroama M., Tozer S., Firmani C., McNamara C., Gibney M.(2011). European consumer exposure top cosmetic products, a framework for conducting population exposure assessments Part 2. Food and Chemical Toxicology 49, 408-422.

Loretz LJ., Api AM., Barraj LM., Burdick J., Dressler WE., Gettings SD., Han Hsu H., Pan YH., Re TA., Renskers KJ., Rothenstein A., Scrafford CG., Sewall C. (2005) Exposure data for cosmetic products: lipstick, body lotion, and face cream. Food Chem Toxicol. 43 (2) 279-291.

Loretz LJ., Api AM., Barraj L., Burdick J., Davis de A., Dressler W., Gilberti E., Jarret G., Mann S., Laurie, Pan YH., Re TA., Renskers KJ., Scrafford C., Vater S. (2006) Exposure data for personal care products: hairspray, spray perfume, liquid foundation, shampoo, body wash, and solid antiperspirant. Food Chem Toxicol. 44 (12) 2008-2018.

Loretz LJ., Api AM., Babcock L., Barraj LM., Burdick J., Cater KC., Jarrett G., Mann S. Pan YH., Re TA., Renskers KJ., Scrafford CG.(2008) Exposure data for cosmetic products:facial cleanser, hair conditioner and eye shadow. Food Chem Toxicol. 46 (5) 1516-1524.

#### http://www.colipa.eu/

**Environment Institute SYKE** 

#### 2.5.3 Textile products

Since consumers spend the majority of the day indoors, textiles products are an important group of consumer products to which consumers are exposed. Textiles are frequently present in indoor environment and consumers might have direct dermal contact with these products. At RIVM, an inventory has been made on the chemical substances that are present in or may be released from textile products in indoor environment such as clothes, shoes, mattresses, cushions, bed linen, furniture upholstery and curtains, carpets and mats. Recently, an extensive overview of chemicals used in textile products during their entire life cycle has been published on the website of the Finnish

http://www.ymparisto.fi/download.asp?contentid=128579&lan=en

#### Reference

Wijnhoven SWP, Kooi MW, te Biesebeek JD (2010) Consumer exposure to chemicals in indoor environment A specific focus on chemicals from textile products.

#### 2.5.4 Cleaning products

In America and Canada various institutes and organisations have developed an ingredient communication initiative to provide consumers with information about the ingredients in consumer products in four major categories: air care, automotive care, cleaning, and polishes and floor maintenance products. Lists of ingredients for most of the cleaning products consumers use every day are now available.

http://www.cleaninginstitute.org/ingredientcentral/

#### 2.6 Substance related information

Chemicals in consumer products can be divided in various (groups of) substances for instance plasticizers (phthalates), flame retardants, pesticides, biocides, metals. Information on specific types of chemicals in consumer products are generally obtained from analysis of the substances in or released from consumer products. Examples are Dutch reports on inspection results of the nVWA, the Danish surveys on chemicals in consumer products, reports of Greenpeace or consumer organisation in Europe, like the European consumer organisation BEUC.

http://www.vwa.nl/actueel/inspectieresultaten?onderwerp=0&maand=0&jaar=0 &submit=&page=3

http://www.mst.dk/English/Chemicals/consumers consumer products/danish s urveys consumer products/

Other relevant links BfR: www.bfr.bund.de www.testaankoop.be BEUC: www.BEUC.org

Greenpeace: <a href="www.greenpeace.com">www.greenpeace.com</a> Stiftung Warentest: <a href="www.test.de">www.test.de</a>

# 2.6.1 Allergens

Many consumer products contain substances that can cause an allergic reaction, such as contact dermatitis or contact eczema. A reaction can also occur due to allergen exposure through the airways. Since allergic diseases, like rhinitis, asthma and eczema, are among the biggest causes of health problems worldwide, RIVM is conducting research on allergens in the past five years, especially those that are present in consumer products. A couple of inventories have been carried out and published (Wijnhoven et al, 2008; Ezendam et al, 2009; 2011). The methodology for performing quantitative risk assessment (QRA) on dermal allergens, as developed by RIFM/ IFRA (Research Institute on Fragrance Materials), has been evaluated. http://www.rifm.org/

#### **References**

Wijnhoven SWP, Ezendam J, Schuur AG, van Loveren H. and van Engelen JGM (2008). Allergens in consumer products. RIVM report 340370001/2008

Ezendam J, te Biesebeek JD and Wijnhoven SWP (2009). The presence of fragrance allergens in scented consumer products. RIVM Letter report 340301002/2009

Ter Burg W, Wijnhoven SWP, and Schuur AG (2010). Observations on the methodology for quantitative risk assessment of dermal allergens. RIVM report 320015003/2010

Ezendam J, ter Burg W, Wijnhoven SWP. (2011) Inhalation Exposure to fragrance allergens. Are consumers at risk for respiratory allergies? RIVM report 340301004/2011.

Api A and Vey M. (2008) Dermal Sensitization Quantitative Risk Assessment for Fragrance Regulatory Toxicology and Pharmacology, 52, 1-2. Ingredients. Special Issue on QRA.

Basketter DA., Clapp CJ., Safford BJ., Jowsey IR., McNamee P., Ryan C., Gerberick FG (2008) Preservatives and skin sensitization quantitative risk assessment. Dermatitis 19, 20-27.

#### 2.7 Aggregate exposure

Aggregate exposure is the exposure to one single chemical via all exposure routes (dermal, oral and inhalatory) and from different sources (for example several different consumer products and/ or in combination with food). RIVM has performed different studies with respect to aggregate exposure. It has been studied to what extent available computer models are suitable for evaluating aggregate exposure to consumer products (Delmaar et al, 2006). Several case studies have been described to investigate the feasibilities and limitations of current aggregate risk assessments (Wolterink et al, 2009). Furthermore, the use and application of aggregate exposure assessment in some international legal frameworks has been investigated (Schuur et al, 2009). Currently, a CEFIC study on aggregate exposure ("Estimation of realistic consumer exposure to substances in multiple sources and exploration of possibilities for validation of selected model components") is conducted at RIVM in which a framework for aggregate exposure will be built. Furthermore, a case a study of aggregate exposure of children to parabens from different sources is currently investigated (Gosens et al, 2011).

#### References

Delmaar JE, van Engelen JGM, (2006) Aggregating human exposure to chemicals – An overview of tools and methodologies. RIVM report 630700001/2006.

Schuur AG, van Engelen JGM and Delmaar JE (2009). Geaggregeerde blootstelling. Gebruik in verschillende kaders en mogelijkheden. RIVM briefrapport 320015002/2009.(In Dutch)

Wolterink G, van de Ven, BM, ter Burg W, Verkaik-Kloosterman, J. (2009) Aggregate exposure to chemicals. RIVM report 320108002/2009.

Gosens I, Delmaar JE, ter Burg W, Schuur AG. (2011) Aggregate exposure assessment of chemicals in consumer products. Paraben exposure in children as a case study. RIVM letter report 32001500x/2011, in preparation.

http://www.tags.cperi.certh.gr/

#### 2.8 Children's exposure

During the last few years, considerable attention is given to children as a sensitive subpopulation in chemical risk assessment. Knowledge on the exposure

part of the risk assessment is equally important as the toxicological endpoints, but this knowledge is scarce. A child's exposure pattern to a consumer product can be very different from that of an adult, due to distinct child-specific behaviors and activities such as mouthing and crawling. For this reason, an exposure assessment for a child requires incorporation of these child-specific behaviours and activities when defining exposure scenarios. RIVM has aimed to provide guidance for child-specific exposure assessments for non-food consumer products (Van Engelen et al, 2007). Characteristics of children may influence exposure due to their different behaviour, physiology and activities. Children can be categorized in different age groups based on age-related activities. Default values for children are attached in Appendix 3 of this report. Part of this guidance is based on the Guidelines for Exposure Assessment, US-EPA, 1992 as well as on the US-EPA's Child Specific Exposure Factors Handbook (US-EPA, 2008). These data are integrated in the general update of the Exposure Factor Handbook that is recently published (US-EPA, 2011).

#### <u>References</u>

Van Engelen, J.G.M., Prud'homme de Lodder, L.C.H.. (2007) Non-food products: How to assess children's exposure? RIVM report 320005005/2007.

US-EPA (2008). Child-Specific Exposure Factors Handbook (Final Report). http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=199243.

US-EPA (2011). Exposure Factors Handbook (Final Report). http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252

Guillam MT, Thomas N, Nedellec, V, Derbez M, Kirchner S, Pédrono G and Ségala C (2010). Children's indoor leisure activities in France: Time budget data for indoor air risk assessment. Volume 16, Issue 5, 2010, Pages 977-988.

#### 2.8.1 Hand-to-mouth contact

Hand-to-mouth contact is a child specific behaviour that can lead to a relevant exposure for children. It is defined as all activities in which hands or fingers are touched by the mouth or put into the mouth, except for dietary activities. The extent of oral exposure as a result of hand-to-mouth contact is influenced by the frequency of contacts, insertion of the hand into the mouth and hand surface area which is contacted by the mouth. RIVM has proposed new default values for assessing the degree of exposure of children to chemicals following hand-to-mouth contact in 2007 (Ter Burg, 2007). This behaviour is also described in chapter 4 of the update of the Exposure Factor Handbook (US-EPA, 2011).

#### <u>Reference</u>

Ter Burg W., Bremmer H.J., Van Engelen J.G.M. (2007) Oral exposure of children to chemicals via hand-to-mouth contact. RIVM Report 320005004/2007.

US-EPA (2011). Exposure Factors Handbook (Final Report). http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252

# 2.8.2 Chemical substances in toys

Another important source of exposure for children are chemical substances in toys, for which RIVM has developed a special risk-based methodology at the request of DG-Enterprise of the European Commission (Van Engelen et al, 2008). Default values for estimation of exposure using the ConsExpo model can be found in the Children's toys Factsheet (Bremmer et al, 2002).

#### **Reference**

Van Engelen, J.G.M., Park, M.V.D.Z.,. Janssen, P.J.C.M, Oomen, A.G., Brandon, E.F.A., Bouma, K., Sips A.J.A.M., Van Raaij, M.T.M. (2008) Chemicals in Toys A general methodology for assessment of chemical safety of toys with a focus on elements. RIVM report 320003001/2008.

Bremmer H.J., Van Veen, M.P. (2002). Children's Toys Fact Sheet. RIVM report 612810012/2002

#### 2.9 Nano

Nanotechnologies and nanomaterials are applied in consumer products. Examples of consumer products that are claimed to contain nanoparticles or produced using nanotechnology, are the use of titanium dioxide in sunscreens, cerium oxide nanoparticles in diesel for combustion improvement and antibacterial properties of silver nanoparticles in wound dressings, textiles or large appliances (See subject **nanotechnology**).

# 2.9.1 Inventories on nano in consumer products

Consumers are potentially exposed to nanomaterials during the use of nano-consumer products. Possible health effects of consumers of using nano-products are not known.

To reliably assess the exposure of consumers to nanomaterials in consumer products, it is important to know which consumer products contain nanomaterials. In 2007, RIVM published its first nano-consumer product inventory for consumer products on the Dutch as well as European market (Dekkers et al, 2007). Recently, an update of this EU inventory has been published (Wijnhoven et al, 2010) in which a six fold increase of nano-consumer products on the European market has been reported. The product inventories are mainly based on products with a 'nano claim' provided by the manufacturer of the product. It is unclear if these products actually contain nanomaterial, therefore the products have to be further analysed (see measurements of nanomaterials in consumer products)

For a robust exposure assessment, additional exposure characteristics (Wijnhoven et al, 2009) are essential. Examples are characteristics and concentration of the nanomaterial in the product, but also the application of the product and exposure route.

#### **References**

Dekkers S. Prud'homme De Lodder LCH., de Winter R., Sips AJAM., de Jong, W.H (2007). Inventory of consumer products containing nanomaterials. RIVM letter report 340120001/2007.

Wijnhoven SWP, Dekkers S, Hagens WI and de Jong, WH (2009). Exposure to nanomaterials in consumer products. RIVM report 320025001/2009.

Wijnhoven S, Dekkers S, Kooi M, Jongeneel R and de Jong W (2010). Nanomaterials in consumer products Update of products on the European market in 2010. RIVM report 340370003/2010.

# 2.9.2 Measurements of nanomaterials in consumer products

Together with MESA+, RIVM recently published a report describing orientating research on the detection of nanomaterials in various consumer products

(Oomen et al, 2011). Twenty two consumer products were obtained and analyzed with microscopic techniques. RIKILT has analysed nanomaterials in various cosmetic products by the order of Stichting Natuur en Milieu (SNM). In addition, more studies have been published in which consumer products were analysed on the presence of nanomaterials, especially spray products with nanomaterials receive a lot of attention.

#### References

Oomen AG., Bennink M., Van Engelen JGM., Sips AJAM. (2011) Nanomaterial in consumer products- Detection, characterisation and interpretation. Report 320029001/2011

http://www.rikilt.wur.nl/NR/rdonlyres/BDEEDD31-F58C-47EB-A0AA-23CB9956CE18/143938/Rapport2011009lageresolutie.pdf

Lorenz et al (2010) Nanosized aerosols from consumer sprays: experimental analysis and exposure modeling for four commercial products. J. Nanopart. Res. DOIm10.1007/s1105051-0256-8

Quadros ME., Marr LC. (2011) Silver nanoparticles and total aerosols emitted by nanotechnology-related consumer spray products. Environ Sci Technol. 2011 Nov 9. [Epub ahead of print]

Chen BT., Afshari A., Stone S., Jackson M., Schwegler-Berry D., Fraxer DG., Castranova V., Thomas T. (2010) Nanoparticles-containing spray can aerosol: characterisation, exposure assessment, and generator design. Inhalation Toxicology 22, 1072-1082.

#### 2.9.3 Nano and ConsExpo

Currently, RIVM is investigating whether consumer exposure to nanomaterials can be modelled by the conventional model ConsExpo, especially for exposure to spray products. The project called "Predictive modelling of human exposure" is a national project in which various partners collaborate, like TNO, IVAM, UU-IRAS. For this NanoNext.NL project, which is financed by STW and nVWA, two recent reviews have been published in which the current status of research groups, and publications in this area are described (Wijnhoven, 2011; Brasser and Wijnhoven, 2011).

#### References

Wijnhoven SWP (2011). The current position of exposure research on nanomaterials in air-Report on relevant projects, networks and workshops. RIVM Letter report 340370004/2011.

Brasser P., Wijnhoven SWP (2011). Creation and detection of nanoparticles in air A literature review. RIVM Letter report 34037005/2011.

#### 2.9.4 Nano and REACH

In 2009, RIVM published a report in which the suitability of REACH in ensuring the safety of nanomaterials is investigated by conducting a hypothetical registration under REACH of metallic silver, a substance that exists both in nanoform and in non-nanoform (*i.e.* bulk form) (Pronk et al, 2009). In this report a complete (hypothetical) chemical safety assessment (CSA) is described for silver and nano-silver including consumer exposure.

#### **References**

Pronk M.E.J., Wijnhoven S.W.P., Bleeker E.A.J, Heugens E.H.W., Peijnenburg W.J.G.M., Luttik R., Hakkert B.C. Nanomaterials under REACH, Nanosilver as a case study. RIVM Report 601780003/2009

# Other relevant institutes/ organisations

www.saferproducts.gov

www.nano.gov www.cpsc.gov

BAuA: <a href="http://www.baua.de/de/Startseite.html">http://www.baua.de/de/Startseite.html</a>
BfR: <a href="http://www.bfr.bund.de/de/start.html">http://www.bfr.bund.de/de/start.html</a>

CEFIC: <a href="http://www.cefic.org/">http://www.cefic.org/</a>

Danish Ministry of Environment Eco innovation.

http://www.ecoinnovation.dk/English/ UBA: http://www.umweltbundesamt.de/

# 3 ConsExpo

The software model ConsExpo is a set of coherent, general models that enables the estimation and assessment of exposure to substances from consumer products that are used indoor and their uptake by humans. ConsExpo is used by the European assessment of industrial chemicals (REACH) and biocides. Models for various exposure routes (the inhalatory, dermal or oral route) are included The most appropriate exposure scenario and uptake model is chosen for each route. The parameters needed for the exposure scenario and the uptake models are then filled in. It is possible to choose for a screenings model or a higher tier exposure estimation (www.rivm.nl/consexpo).

This program is designed for the use by expert exposure assessors only. To enhance transparency and standardization, for a number of product categories, default parameter values have been compiled in so-called fact sheets (see below). The default-models and default-parameter values are available in the form of a database. Currently, the most recent version is ConsExpo 4.1. A betaversion of ConsExpo 5.0 is available in which the methods for probabilistic exposure evaluation have been improved.

#### References

Delmaar J.E. Park, M.V.D.Z., Engelen, J.G.M. van. (2004), ConsExpo 4 Consumer exposure and uptake models, RIVM report 320104004/ 2004.

Delmaar, J.E., M.V.D.Z. Park, J.G.M. van Engelen (2005). ConsExpo 4.0, Consumer Exposure and Uptake Models. Program Manual. RIVM Report 320104004/2005.

Park, M.V.D.Z., Delmaar J.E., van Engelen, J.G.M (2006).Comparison of consumer exposure modelling tools. Inventory of possible improvements of ConsExpo. RIVM report 320104006/2006.

# 3.1 Spray model

The specific model for the inhalation route of exposure is the spray model of ConsExpo. This is an important model since the number of consumer spray products on the market is increasing.

Delmaar JE and Bremmer HJ (2009). The ConsExpo spray Model. Modeling and experimental validation of the inhalation exposure of consumers to aerosols from spray cans and trigger sprays. RIVM report 320104005/2009.

Delmaar JE (2010). Comparing the BAMA indoor air and ConsExpo inhalation models. RIVM letter report 320104009/2010.

Delmaar JE and Bremmer HJ (2010). New default values for the spray model. RIVM, March 2010. Available at <a href="https://www.consexpo.nl">www.consexpo.nl</a>

Tuinman, I.L. (2004). Aerosols from Spray Cans and Trigger Sprays. Particle Size Distributions and Spreading in a Closed Environment. TNO report PML 2004-C106.

Tuinman, I.L. (2007). Particle size distributions of aerosols from spray cans and trigger sprays. TNO report august 2007.

#### 3.2 Emission tool

The emission tool is a recently developed model for the estimation of exposure to substances from solid materials (Delmaar et al, 2010). Such a method is lacking in the current version of ConsExpo. This exposure is via indoor air into the lungs. An emission model for dermal exposure from solid materials is currently under development.

At present, the model is implemented in a separate computer program that can be downloaded (link)

#### Reference

Delmaar, JE. 2010. Emission of chemical substances from solid matrices. RIVM Report 320104011/2010.

#### 3.3 Factsheets

The fact sheets are 'living documents' giving information that is important for the consistent estimation and assessment of the exposure to, and the uptake of, substances from consumer products. In the fact sheets, information about exposure to chemical substances is bundled into certain product or exposure categories and default parameters are given. The product categories are chosen so that products with similar exposures can be combined.

On the one hand, the fact sheet gives general background information; while on the other hand, it quantifies exposure parameters which, together with an exposure scenario, or a combination of the various exposure scenarios, produce a quantitative estimate of the exposure.

#### 3.3.1 General factsheet

A general factsheet, "Limiting conditions and reliability, ventilation, room size, body surface area" is provided (Bremmer et al, 2006) that gives general information needed for consumer exposure assessment in addition to the more specific information provided in the fact sheets on the different product groups. http://www.rivm.nl/bibliotheek/rapporten/320104002.pdf

Information of the general fact sheet includes:

- the volume and surface area of rooms in Dutch dwellings,
- the air-change rate in various rooms in dwellings,
- the total body surface and surface of body parts of adults and children.

Also, general information on the fact sheets is given, such as a description of the format of the fact sheets, the connection with the ConsExpo program and the boundary conditions under which the defaults in the factsheet are defined.

#### 3.3.2 Children's Toys Fact Sheet

The Children's Toys Fact Sheet (Bremmer and van Veen, 2002) supplies information on use of children's toys. The use of children's toys is described by classifying the ways in which children can be exposed. Representative examples are chosen for each way in which children can be exposed. Default models are chosen for these examples. The default parameter values are also filled in. Based on these representative example-defaults, it is possible to derive the default values for the exposure of any type of toy. http://www.rivm.nl/bibliotheek/rapporten/612810012.pdf

# 3.3.3 Cleaning Products Fact Sheet

The Cleaning Products Fact Sheet (Prud'homme de Lodder et al, 2006) covers the use of cleaning products by consumers. In the fact sheet 36 product categories are described including laundry detergents, dishwashing products, abrasives and toilet cleaners. For products in these categories, default exposure models and input parameters for these models are suggested. http://www.rivm.nl/bibliotheek/rapporten/320104003.pdf

#### 3.3.4 Cosmetics Fact Sheet

The Cosmetics Fact Sheet (Bremmer et al, 2006) covers the use of cosmetics by consumers. In the fact sheet 35 product categories are described, including shampoo, make-up, lipstick, deodorant and toothpaste. For products in these categories, default exposure models and input parameters for these models are suggested. <a href="http://www.rivm.nl/bibliotheek/rapporten/320104001.pdf">http://www.rivm.nl/bibliotheek/rapporten/320104001.pdf</a>

#### 3.3.5 Disinfectant Products Fact Sheet

The Disinfectant Products Fact Sheet (Prud'homme de Lodder et al, 2006) covers the use of disinfectant products by consumers. In the fact sheet nine product categories are described, including algae/green deposit removers, black mould removers, swimming pool disinfectants, veterinary hygiene biocidal products and disinfectants for drinking water, waterbeds, chemical toilets and for rubbish bins. For products in these categories, default exposure models and input parameters for these models are suggested. http://www.rivm.nl/bibliotheek/rapporten/320005003.pdf

#### 3.3.6 Do-it-Yourself Products Fact Sheet

The Do-it-Yourself Products Fact Sheet (ter Burg et al, 2007) supplies information on the use of Do-it-Yourself products by consumers. The fact sheet covers 6 product types including glues, fillers, sealants, plasters, coatings, and removers showing 26 product categories. For products in these categories, default exposure models and input parameters for these models are suggested. http://www.rivm.nl/bibliotheek/rapporten/320104007.pdf

# 3.3.7 Paints Products Fact Sheet

The Paints Products Fact Sheet (Bremmer and van Engelen, 2007) supplies information on the use of paint products by consumers. Product categories were developed with the use of default models and default values for several methods of paint application, several types of paints and several types of use. Default exposure assessments for the consumer's exposure to paints, including tool and hand cleaning, can be performed using this fact sheet. http://www.rivm.nl/bibliotheek/rapporten/320104008.pdf

#### 3.3.8 Pest Control Products Fact Sheet

The Pest Control Products Fact Sheet (Bremmer et al, 2006) covers the use of pest control products by consumers. In the fact sheet eight product categories are described, including sprays, dusting powders, repellents, electrical evaporators and baits. For products in these categories, default exposure models and input parameters for these models are suggested. <a href="http://www.rivm.nl/bibliotheek/rapporten/320005002.pdf">http://www.rivm.nl/bibliotheek/rapporten/320005002.pdf</a>

#### References

Bremmer HJ and van Veen MP (2002) Children's Toys Fact Sheet. RIVM rapport 612810012/2002.

Bremmer HJ, Prud'homme de Lodder, LCH,van Engelen JGM (2006) General Fact Sheet Limiting conditions and reliability, ventilation, room size, body surface area. Updated version for ConsExpo 4, RIVM report 320104002/2006.

Prud'Homme de Lodder LCH, Bremmer HJ and van Engelen JGM (2006). Cleaning Products Fact Sheet. To assess the risks for the consumer. RIVM report 320104003/2006.

Bremmer HJ, Prud'Homme de Lodder LCH and van Engelen JGM (2006). Cosmetics Fact Sheet. To assess the risks for the consumer. Updated version for ConsExpo 4. RIVM report 320104001/2006.

Prud'Homme de Lodder LCH, Bremmer HJ, Pelgrom SMGJ, Park MVDZ and van Engelen JGM (2006). Disinfectant Products Fact Sheet. To assess the risks for the consumer. RIVM report 320005003/2006.

Bremmer HJ, Blom M, van Hoeven-Arentzen, Prud'Homme de Lodder LCH, van Raaij MTM, Straetmans EHFM, van Veen MP and van Engelen JGM (2006). Pest Control Products Fact Sheet. To assess the risks for the consumer. Updated version for ConsExpo 4. RIVM report 320005002/2006.

ter Burg W, Bremmer HJ and van Engelen JGM (2007). Do-It-Yourself Products Fact Sheet. To assess the risks for the consumer. RIVM report 320104007/2007.

Bremmer HJ and van Engelen JGM (2007). Paint Products Fact Sheet. To assess the risks for the consumer. Updated version for ConsExpo 4. RIVM report 320104008/2007.

# Appendix 1: Consumer exposure home page at RIVM website

nsumer exposure  • Main commissioning bo	dies	Tekst Consumer exposure	Bibliotheek / ger onderwerpen
nVWA	uies		
VWS			
EU			
International legislativ	e frameworks		
REACH	c ii diii cii cii ci		
Biocides			
GPSD and RAPEX			
Cosmetics Directive			
Toys Directive			
Detergents Regulation			
Plant Protection Products			
Food Contact Materials			
<ul> <li>Consumer Exposure Mo</li> </ul>	dels		
ConsExpo			
ECETOC TRA			
ESIG Consumer Generic	Exposure tool		
AISE react			
BAMA tool			
Other models			
<ul> <li>Exposure scenarios and</li> </ul>	l exposure factors		
ConsExpo fact sheets			
The European Exposure fa	actors sourcebook		
US-EPA Exposure factors	handbook		
CHAD database			
Additional exposure factor	rs references		
<ul> <li>Product related information</li> </ul>	ation		
Household products datab	ase		
Cosmetic products			
Textile products			
Cleaning products			
<ul> <li>Substance related information</li> </ul>	mation		
Allergens			
Additional references			
<ul><li>Aggregated exposure</li><li>Children exposure</li></ul>			
Hand-to-mouth contact			
Chemical substances in to			
Chemical substances in (c	children's) cosmetics		
<ul> <li>Nano         Inventories on nano in co     </li> </ul>	nsumer products		
Measurements on nanoma			
products			
Nano and ConsExpo			
Nano and REACH			

# Appendix 2: ConsExpo home page at RIVM website

		Gevonden voor
ConsExpo	Tekst ConsExpo	`onderwerpen G&M'
Spray model		Bibliotheek / ger.
<ul><li>Emission tool</li><li>Fact sheets</li></ul>		onderwerpen
General fact sheet		
Children's toys fact sheet		
Cleaning products fact sheet		
Cosmetics fact sheet Disinfectant fact sheet		
Do-it-yourself products fact		
sheet		
Paint products fact sheet		
Pest control products fact sheet		
sneet		