National Institute for Public Health
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Ministry of Health, Welfare and Sport

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M. Woutersen et al.

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Colophon

Marjolijn Woutersen (author), R.I.V.M.
Korienke Smit (author), R.I.V.M.
Wouter ter Burg (author), R.I.V.M.
Bas Bokkers (author), R.I.V.M.
Gerlienke Schuur (author), R.I.V.M.

Contact:
Gerlienke Schuur
VSP
gerlienke.schuur@rivm.nl

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Prioritisation tool for chemical substances in consumer products

Consumentenproducten bevatten een breed scala aan chemische stoffen. In principe zijn deze producten veilig in het gebruik. Om dit te bewaken ziet de inspectie van de Nederlandse Voedsel- en Waren Autoriteit (NVWA) erop toe dat de hoeveelheden van deze stoffen onder de wettelijke grenzen blijven. Het RIVM heeft een tool ontwikkeld op basis waarvan toezichthouders kunnen bepalen welke stoffen of productgroepen mogelijk de meeste aandacht behoeven.

Welke stoffen in cosmetica hebben bijvoorbeeld de hoogste prioriteit? Waar zitten meer potentieel gevaarlijke stoffen in: schoonmaakmiddelen of doe-het-zelf-producten? Om dit te bepalen is gebruikgemaakt van gegevens uit de Europese database waarin alle stoffen staan die onder de wetgeving voor stoffen REACH vallen. De tool richt zich op stoffen die gebruikt worden in consumentenproducten en één of meer van de volgende schadelijke effecten kunnen hebben: kankerverwekkend, DNA beschadigend, schadelijk voor de voortplanting, of potentieel allergeen bij contact met de huid of inademing.

Voor de prioritering zijn de gevaarseigenschappen van de stoffen in kaart gebracht en gecombineerd met de mate waarin consumenten aan de stoffen blootstaan. Samen vormen zij het risico. Bij de blootstelling worden punten toegekend aan onder andere het aantal producten waarin een stof zit en de mate waarin de stof eruit kan vrijkomen. Voor de gevaarseigenschappen wordt gekeken naar de ernst van de schadelijke effecten van een stof en de hoeveelheid van een stof die het schadelijke effect veroorzaakt.

De tool maakt het mogelijk om uit de zeer grote, nog toenemende hoeveelheid informatie over chemische stoffen, stoffen en productgroepen te selecteren die mogelijk een risico voor de consument vormen.

Kernwoorden: Prioritering, consumentenproducten, CMR, REACH, schadelijkheid, blootstelling, risico, IUCLID

Synopsis

RIVM develops prioritization tool for chemical substances in consumer products

Consumer products contain a wide range of chemical substances. In principle, such products are safe to use. The inspectors of the Netherlands Food and Consumer Product Safety Authority (NVWA) conduct monitoring to ensure that the levels of chemical substances in consumer products do not exceed the applicable statutory limits. The Dutch National Institute for Public Health and the Environment (RIVM) has developed a tool that regulatory authorities can use to determine which substances or product groups require the most attention.

Which substances found in cosmetics should be prioritized? Which product group contains more potentially harmful substances: detergents or DIY products? The tool answers such questions using information obtained from the European database containing all substances that fall within the scope of the so-called REACH Regulation (Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals). The tool focuses on substances that are used in consumer products and that have one or more of the following hazardous properties: carcinogenicity, mutagenicity, reproduction toxicity, skin sensitizer or respiratory sensitizer.

The priority assigned to each substance is determined based on its hazard as well as the extent to which consumers are exposed to the substance. The risk assessment is based on these two factors. Exposure scores are determined by assigning weighting factors to the number of products containing a particular substance and the extent to which that substance can be released by the product concerned. The hazard score is determined by the severity of the substance's harmful effects and the potency of the substance.

Using the prioritization tool, chemical substances and product groups that may pose risks to consumers can be selected from the vast and ever-increasing amount of information about chemical substances.

Keywords: Prioritisation, consumer products, CMR, REACH, hazard, exposure, risk, IUCLID

Contents

The results are presented in the excel files in Annex A:
www.rivm.nl/bibliotheek/rapporten/2015-0194.xlsx

Summary

The Dutch Food and Consumer Product Safety Authority (NVWA) asked the RIVM to develop a methodology that can be used to prioritise consumer products on the risk of exposure to hazardous substances. The tool can be used to make choices for the NVWA's enforcement activities, which are limited by capacity and financial resources.

In the first stage of methodology development, the ECHA registered substance database was chosen as data source. This database contains information on all substances registered under the REACH regulation, which will be compulsory for all substances produced or imported in Europe in volumes of more than one tonne/year in 2018. Currently it includes all substances with a volume ≥100 tonne/year, and CMR classified substances ≥1 tonne/year.
A selection was made from the ECHA database of substances classified as carcinogenic, mutagenic, reproduction toxic, respiratory- and skin sensitisers ($CMRS_{resp}S_{derm}$) and used in consumer products and/or articles. These consumer products/articles are divided in product/article categories (PC/ACs), for example 'Cosmetics' or 'Plastic articles'. Additionally, the Derived No Effect Levels and Derived Minimal Effect Levels (DN/MELs) were collected for these substances.

Two lists were created based on the information from the ECHA database. One list contains substances scored on their hazard and exposure, which may be used to determine which substances pose the highest risk to consumers. The second list contains the PC/ACs, and can be used to compare categories of products/articles on their contribution to consumer exposure to harmful substances.

Substances

The selected substances were scored on two hazard and two exposure parameters. The hazard score consists of a score for the severity of the endpoint (based on classification) and a score for the potency (based on DN/MEL). Both factors were scored on a scale of 1 to 10. The exposure score consists of the total number of PC/ACs in which a substance is used, and a score for the exposure from using these products. This product exposure score is scaled from 1 to 27. The scores are combined as follows:

- Hazard score = endpoint score + potency score
- Exposure score = number of PC/ACs + product exposure score
- Total substance score = hazard score * 3,5 + exposure score

PC/ACs

PC/ACs are ranked on the number of $CMRS_{resp}S_{derm}$ substances they contain, the endpoint scores of these substances, and the product exposure score. These scores are determined as follows:

- Hazard score = sum endpoint scores
- Exposure score = product exposure score * number of substances
- Total PC/AC score = hazard score * 2 + exposure score

A schematic overview of the methodology can be found in Section 3.2. The resulting lists with the ranked substances and ranked PC/ACs are provided in the Excel tables Annex A and confidential Annex B.

Results from the first execution of the tool showed a total of 53 consumer PC/ACs containing a total of 773 $CMRS_{resp}S_{derm}$ substances. Washing/cleaning agents had the highest total score of the PC/ACs, followed by coatings/paints and fuels.
The substance with the highest score was Aluminium oxide, which was classified as carcinogen, probably based on the presence of an impurity. Noteworthy is that three large groups of petroleum derivates were at the upper end of the ranking with similar scores. These compounds are complex cases because their dossiers in the ECHA database include multiple variants; some have CMR classifications and others are used in consumer products.
A group of methacrylates had the highest exposure scores. These compounds are classified for skin sensitisation, and are used in a wide range of products. Only four compounds, all cobalt salts, had a maximal hazard endpoint score of 10, meaning they are classified as C and/or M, R, S_{resp}, and S_{derm}.

The ranking results of the PC/ACs were compared to the prioritisation performed for the ILT (Inspectorate Environment and Transport), and the ranking results of the substances were compared with the SIN list (Substitute it Now). In both cases, the methods agreed well on the high ranking substances and PC/ACs. Most of the differences can be explained by a difference in scope, as these other methods also include workers and the environment. For that reason, the choice of exposure parameters differed between the methods.

As a recommendation for the future: it will be very interesting to perform a more detailed examination of the dossiers and/or other background information for a selection of substances from the ranking. This may be a random selection, or substances belonging to a product/endpoint group of specific interest. This folllowup study can be used to validate the tool as well as for enforcement purposes.
In future iterations of the methodology, other hazard endpoints may also be included, such as repeated dose toxicity. It is also recommended to repeat the retrieval of the substance data from the ECHA database after 1 June 2018, as this is the deadline for the registration of substances with lower tonnages.

To conclude, the tool enables the selection and prioritisation of substances and product/article categories from an extensive and growing amount of information on the risk to consumers of industrial chemicals in Europe.
The methodology allows the addition of other endpoints in the selection if required by the enforcement authorities. As such, it facilitates the use of information in the ECHA registered substance database for a risk-based prioritisation of enforcement activities.

Samenvatting

De Nederlandse Voedsel en Waren Autoriteit (NVWA) heeft aan het RIVM gevraagd om een methodiek te ontwikkelen om consumentenproducten te prioriteren op het risico van blootstelling aan stoffen. Deze methodiek kan worden gebruikt om keuzes te maken in de handhavingsactiviteiten van de NVWA, waarvoor de beschikbare capaciteit en middelen beperkt zijn.

In de eerste fase van de ontwikkeling van de methodologie is de ECHA geregistreerde stoffen-database gekozen als informatiebron. Deze database bevat informatie over alle stoffen die geregistreerd zijn onder REACH, wat vanaf 2018 verplicht wordt voor alle stoffen waarvan meer dan een ton per jaar in Europa geproduceerd of geïmporteerd wordt. Op het moment bevat de database in ieder geval alle stoffen met een volume van ≥100 ton/jaar en CMR geclassificeerde stoffen met een volume van ≥1 ton/jaar.
In de ECHA database is een selectie gemaakt van stoffen met een classificatie als carcinogeen, mutageen, reproductie-toxisch, inhalatie- en/of huid-sensibiliserend ($CMRS_{resp}S_{derm}$) die gebruikt worden in consumentenproducten en/of -artikelen. Deze consumentenproducten/-artikelen worden ingedeeld in product/artikel categorieën (PC/AC's), zoals ‘Cosmetica’ of ‘Plastic artikelen’. Daarnaast zijn de Derived No Effect Levels en Derived Minimal Effect Levels (DN/MEL's) van deze stoffen verzameld.

Op basis van de informatie uit de ECHA-database zijn er twee lijsten opgesteld. De eerste bevat stoffen gescoord op gevaarseigenschappen en blootstelling en kan gebruikt worden om te bepalen welke stoffen het hoogste risico voor consumenten geven. De andere lijst bevat PC/AC's en kan gebruikt worden om product-/artikelcategorieën te vergelijken op de mate waarin ze leiden tot consumentenblootstelling aan schadelijke stoffen.

Stoffen

Er zijn scores toegekend aan de geselecteerde stoffen op basis van vier parameters, twee voor de gevaarseigenschappen (hazard) en twee voor de blootstelling (exposure). De gevaarseigenschappen worden bepaald door de ernst van het effect (gebaseerd op de classificatie) en de potentie van de stof (gebaseerd op de DN/MEL). Beide factoren zijn gescoord op een schaal van 1 tot 10. De blootstellingsscore bestaat uit het totaal aantal PC/AC's waarin een stof wordt gebruikt en een productblootstellingsscore voor de blootstelling als gevolg van het gebruik van deze producten. Deze laatste heeft een schaal van 1 tot 27.

De scores zijn op de volgende manier gecombineerd:
- gevaarsscore = effect score + potentiescore;
- blootstellingsscore = aantal PC/ACs + product blootstellingsscore;
- totale stof score = gevaarsscore * 3,5 + blootstellingsscore.

PC/ACs

PC/ACs zijn gerangschikt op het aantal $CMRS_{resp}S_{derm}$ stoffen dat ze bevatten, de effect scores van deze stoffen en de product blootstellingsscore. De totaalscore is als volgt afgeleid:

- gevaarsscore = som effect scores;
- blootstellingsscore = product blootstellingsscore * aantal stoffen;
- totale PC/AC score = gevaarsscore * 2 + blootstellingsscore.

In Sectie 3.2 staat de methodologie schematisch weergegeven.

De lijsten met de gerangschikte stoffen en PC/AC's staan in de Exceltabellen in Annex A en de confidentiële Annex B.

In de eerste resultaten van de methodologie staan in totaal 53 consumenten PC/AC's die samen 773 $CMRS_{resp}S_{derm}$ geclassificeerde stoffen bevatten. Van de PC/AC's hebben de was-/schoonmaak-producten de hoogste totaal score, gevolgd door coatings/verven en brandstoffen.
De stof met de hoogste score is aluminiumoxide, die geclassificeerd is als carcinogeen, waarschijnlijk op basis van een verontreiniging. Opvallend zijn drie grote groepen met petroleumderivaten in het bovenste deel van de ranglijst die allemaal dezelfde score hebben. Het risico van deze stoffen is moeilijk te beoordelen, omdat er meerdere varianten in hetzelfde dossier staan, waarvan sommige een CMR-classificatie hebben vanwege onzuiverheden en anderen gebruikt worden in consumentenproducten.
De methacrylaten hebben de hoogste blootstellingsscores. Deze stoffen zijn geclassificeerd als huid-sensibiliserend en worden in veel verschillende producten gebruikt. Slechts vier stoffen, alle vier kobaltzouten, hebben een maximale effect score van 10, wat betekent dat ze geclassificeerd zijn als C en/of M, R, S_{resp} en S_{derm}.

De ranglijst van de PC/AC's is vergeleken met de prioritering die is uitgevoerd voor de ILT (Inspectie Leefomgeving en Transport) en de ranglijst met stoffen met de stoffen op de SIN-lijst (Substitute it Now). In beide gevallen is er een behoorlijke mate van overeenstemming over de hoogscorende stoffen en PC/AC's. De verschillen kunnen grotendeels verklaard worden door een verschil in doelstelling, waarbij de andere methoden ook naar werknemers en het milieu gekeken hebben. Hierdoor verschillen de methoden in de keuzes die gemaakt zijn, vooral voor de blootstellingsparameters.

Vooruitkijkend naar de toekomst zou het heel nuttig en interessant zijn om voor een aantal stoffen op de lijst meer in detail naar de dossiers en/of andere achtergrondinformatie te kijken. Dit zou kunnen op basis van een willekeurige selectie of door stoffen te nemen die in een bepaalde productgroep worden gebruikt of een bepaald effect hebben. Een dergelijke studie is zowel nuttig om deze methodiek te valideren als voor de handhaving.
In toekomstige versies van de methodologie kunnen mogelijk ook andere gevaarseigenschappen meegenomen worden, zoals toxiciteit bij herhaalde blootstelling. Het is ook aan te raden om na 1 juni 2018 de gegevens van de stoffen opnieuw uit de ECHA database te halen, omdat dit de registratie deadline is voor alle stoffen met lagere tonnages.

Concluderend wordt in dit rapport een tool gepresenteerd die het mogelijk maakt om stoffen en producten/artikelen te selecteren uit de grote hoeveelheid informatie over industriële chemicaliën in Europa en deze te prioriteren op hun risico voor consumenten.
Binnen de methodologie is ruimte om andere eindpunten toe te voegen aan de selectie als daar vraag naar is vanuit de handhavende autoriteiten. Als zodanig faciliteert de tool het gebruik van de informatie in de ECHA-stoffendatabase voor een risico gebaseerde prioritering van handhavingsactiviteiten.

1 Introduction

1.1 Background

As a requirement of the REACH legislation (Registration, Evaluation, and Authorisation of Chemicals), information is collected on all industrial chemicals produced or imported in Europe. This includes toxicological information and information on the use of substances in product and/or article categories, such as textiles, cosmetics, plastic articles and others. ECHA (European Chemicals Agency) drafts lists of high-priority substances that should be considered for authorisation and/or restriction (substances of very high concern, SVHC). NGOs also have substance lists such as the Substitute it Now (SIN) list with more than 800 substances.
The Dutch Food and Consumer Product Safety Authority (NVWA) does not prioritise substances for their monitoring programmes, but does prioritise consumer products that contain hazardous substances.
The NVWA monitoring focusses on industries, where product samples serve mainly to check the accuracy of the product dossiers. To perform these enforcement checks efficiently, there have to be insights into which consumer products give the highest risk of exposure to potentially hazardous substances. To gain this knowledge, a translation has to be made from priority substances to consumer products, and from products to producers.
The RIVM were asked by the NVWA to develop a prioritisation methodology that shows which categories of consumer products give the highest exposure to substances of concern.

1.2 Objective

One of the important tasks of the NVWA is to determine which consumer products are associated with the highest risks from hazardous substances. To do this, it is necessary to prioritise hazardous substances and determine those consumer products that potentially give the highest exposure to these substances. This information enables the NVWA to focus its enforcement activities on substances and consumer products which have the highest potential for causing adverse health effects.
The aim of this project is to develop a tool that will help the NVWA prioritise surveillance activities regarding consumer products. The tool is based on hazard properties of substances, combined with estimated exposure from consumer products.

The NVWA requested that the RIVM:

- choose the data source(s) most suitable for retrieving the required information on reliability, completeness and usability;
- develop a method to prioritise substances in consumer products based on their risk;
- identify which products are most likely to result in the highest consumer exposure to these substances.

1.3 Approach

First, an evaluation was made of available substance lists and databases, which could be used as data source (see Annexes I and II). Existing prioritisation tools were then evaluated to learn from different methods and to determine the most important criteria for tools that rank substances on risk (see Annex III). The ECHA registered substance database was selected for use in this project as it is an extensive and valuable data source. The rationale behind this choice is given in Chapter 2. The selection was limited to substances having one or more of the following classifications: carcinogenic, mutagenic, reproduction toxic, and respiratory or skin sensitiser.

Exposure scores and hazard scores were determined in the next phase of the project. The scoring methodology is described in Chapter 3, first for hazard and exposure separately (Section 3.1) and then for the combination of both endpoints. An overview of the methodology is given in *Figure 2* and *Figure 3* in Section 3.2.

Substances, including the information used in the methodology, were retrieved from the ECHA database, and scores were assigned. The results are presented in Chapter 4, and the complete lists of the substances and product categories are given in the Excel files in Annex A and confidential Annex B.

The results using this methodology were then compared with two other prioritisation methods, namely the prioritisation tool developed by the Inspectorate Environment and Transport (ILT), and the Substitute it Now (SIN) list of ChemSec, to determine the similarities and differences with the rankings of other groups (Section 4.3 and 4.4).

Chapter 5 contains a disclaimer which includes important considerations for the use of the methodology and interpretation of the results. The methodology is discussed in Chapter 6, and finally, the conclusions and recommendations are presented in Chapter 7.

2 Choice of the data source and retrieval of substance information

In this chapter, an evaluation is made of available substance databases and one is selected as data source for the methodology. In section 2.2, the collection criteria and methods used to retrieve the substances from the database are described.

2.1 Selection of the data source

The starting point for the development of the methodology was to find a suitable data source with substances used in consumer products.
Existing data sources can be divided into lists of (hazardous) substances and databases.
Lists are usually compilations of substances of concern which have been selected due to their hazard properties. Some lists have been developed within legal frameworks, others by Non-Governmental Organisations (NGOs) inside and outside Europe (see Annex I). Some of these lists were compiled using prioritisation tools, others through contributions from experts.
Databases are generally collections of substances used in specific products, locations and/or quantities. Some have to be completed by manufacturers or importers when they bring substances on the market. Others have been compiled by researchers or governmental institutes (see Annex II).

Databases are generally preferable as data source, because they contain a wider array of substances, more information on the usage of the substance, and often have more search options.
To select a suitable database which can be used as input for the tool, existing databases were evaluated on the following aspects:

- Who is the initiator?
- What is the purpose of the database?
- Which criteria are used for the inclusion of substances?
- How many substances are included?
- Is the database up-to-date?
- Is the database information reliable?
- Is there an option to search or sort substances on specific criteria?
- Is the database publicly accessible?

An overview of advantages and disadvantages of available databases was made based on these criteria, see Table 1.
Based on this overview, it was decided to use the substance database of the European Chemical Authority (ECHA) as the source for the new methodology. Under the REACH (Registration, Evaluation, and Authorisation of Chemicals) legislation, all industrial chemicals produced or imported in Europe in quantities of ≥1 ton/year have to be registered in the ECHA database. In addition, information has to be provided on toxicological properties, manufacture, and use, although the information requirements are dependent on the production/import volume of the substance.

The ECHA registered substance database is available in IUCLID (International Uniform Chemical Information Database), which has a query tool that enables searches for substances on specific properties. The non-confidential substance information is also available via the ECHA website [1].

The most important disadvantage is that the complete database can only be accessed by the ECHA and competent authorities of the member states. It should also be mentioned that substances with volumes below 100 ton/year do not have to be registered until 31 May 2018.

Table 1: (Dis)advantages of databases

Database	Advantages	Disadvantages
ECHA substance database (ECHA, 2015)	• It contains all data of industrial substances registered under the REACH regulation • Information about toxicity, manufacturing and use is included • It contains a query tool that enables searches on (toxicological) properties and use	• Access to the database is limited to ECHA and the competent authorities of member states • Information is in many cases generic, on a high level (broad product categories) • No information on substance concentrations in products • Data is provided by manufactures and importers and can be incorrect
SPIN-list (Norden, 2014)	• Contains data on industrial substances produced and imported in the Nordic countries (Norway, Sweden, Denmark and Finland) based on product registries	• Not easily searchable, only per substance • Information is in many cases generic, on a high level (broad product categories or branch information) • No references can be made to specific concentrations of any given substance
US Household Product Database (DHHS, 2014)	• Information included on household product types, brand names and chemical constituents • Information is publicly available	• Data from household products in the US; limited information • Search has to be performed manually per substance/CAS number

National Poison Information Centre (NVIC, 2015)	• Contains detailed information about composition of products per product/brand and information about hazardous properties of substance	• Compliance is not 100% • Information is confidential and not publicly accessible, only usable for statistic investigations
Dangerous Substances Database (Zweers P.G.P.C., de Groot G.M., & Bakker J., 2014)	• Substances can be linked with User Categories (UC)	• Hazardous properties of substances are not included • The database is not very user-friendly
Consumer Product Chemical Profile study (Goldsmith database) (Goldsmith M. R. et al., 2014)	• Particular substances in products (categories) can be identified • Contains minimal and maximal concentrations of individual substances in products • It can be determined in how many products of a product category the substance is used	• Database is not automated, which makes it difficult to keep the database up-to-date • Data comes from MSDSs, which are provided by manufacturers and can therefore be incorrect. • No hazard information • Only data of products from Walmart (US)

2.2 Selection and retrieval of substances from the ECHA database

For this project, the selection of substances is based on the ECHA registered substance database which is accessed in IUCLID, as this database enables searches ('queries') for substances with specific properties or uses. To be able to rank the substances, information on both hazard and exposure was retrieved from the database. These parameters were also used to select substances of interest.

Hazard

The substance selection used in this study was limited to substances classified as $CMRS_{resp}S_{derm}$ (carcinogenic, mutagenic, reproduction toxic, and sensitising (skin/respiratory)). All CMR categories (1A, 1B, or 2) were included in the search. The registrant determines the classification in the database; this can be the harmonised classification or a self-classification. It is not possible to differentiate between harmonised and self-classifications in IUCLID, however, this can be done outside IUCLID by comparing the classification in IUCLID with the registry of harmonised classifications (CLP, Annex IV). There is also a possibility that substances are missing, due to incomplete or incorrect IUCLID entries, and because substances produced in volumes <100 tonnes do not have to be registered in the ECHA database until June 2018. For an overview of the limitations of IUCLID, see section 5.1.

In addition, the Derived No-Effect Levels and Derived Minimal-Effect Levels (DN/MELs) are collected from the ECHA database. They are only used to rank the substances, not as a selection criterion. DN/MELs give an indication of the hazard potency of the substances. Only DN/MELs for general population/chronic/systemic effects were selected, as these are the most relevant for consumers, see also 3.2.1.2.

Use in products/article categories

Substances selected based on hazard classification can be divided in specific Product or Article Categories (PC/ACs) in which they are used, by selecting these PC/ACs in IUCLID (see Table 6 and Table 7). Only consumer PC/ACs were selected, worker PC/ACs were excluded. As with the selection on hazard properties, this has the disadvantage that relevant substances may be missed due to incomplete IUCLID entries, but has the advantage of deselection of a large number of substances that may be very hazardous, but never result in consumer exposure.

Summary substance selection

Included

- **Classification as CMR$S_{resp}S_{derm}$**
- **DN/MELs (for general population/chronic/systemic)**
- **Consumer PC/ACs**

Not included

- **All other classifications (Acute tox, STOT RE e.g.)**
- **Hazards without classification (endocrine disruption)**
- **Occupational/environmental effects (Worker DNELs, OEL's, PBT/vPvB properties)**
- **Worker/environmental exposure (Worker PCs, PROCs, ERCs)**

3 Methodology for the prioritisation of chemical substances in consumer products

In this chapter, the methodology for prioritisation is explained in a step-by-step approach. The substances were selected from the ECHA database based on $CMRS_{resp}S_{derm}$ properties and presence in consumer product/article categories (PC/AC), see section 2.2. Section 3.1 describes the scoring methodology, divided in hazard (3.1.1) and exposure (3.1.2). In section 3.2, the hazard and exposure scores are combined to gain the total scores for both substances and PC/ACs. At the end of the chapter, the methodology is summarised in Figure 2 and Figure 3.

3.1 Assigning scores to the input parameters

The prioritisation of substances is based on hazard and exposure, which are both determined by two parameters. The hazard consists of the hazard endpoint and the potency, exposure of the use in products/articles, and exposure from these products/articles.

3.1.1 Hazard score

To enable ranking of the substances based on their hazardous properties, a hazard score was determined. Two hazard indicators are generally available in the ECHA database: the hazard classification(s) and the derived no effect levels or derived minimal effect levels (DN/MELs). Thus, ranking of the hazard was based on 1) the hazard endpoint, which gives the type of effect the substance may provoke as indicated by its classification (CLP, EC1272/2008), and 2) the potency of a substance, indicated by the DN/MEL. Based on these two hazard indicators, scores were derived for each substance.

3.1.1.1 Hazard endpoint score

The following five hazardous properties were prioritised and used as selection criteria:

- carcinogenic (C)
- mutagenic (M)
- toxic to reproduction (R)
- respiratory sensitising (Sresp)
- dermal sensitising (Sderm)

NOTE: By selecting on the basis of $CMRS_{resp}S_{derm}$ characteristics, substances with other effects, such as specific target organ toxicity after repeated exposure (STOT-RE, which includes neurotoxicity, immunotoxicity e.g.) or endocrine disruption (when not already expressed as reprotoxic effect) were not included.

In the hazard endpoint score, the severity of the classified effect is taken into account by assigning a higher score to more severe hazard outcomes. The scores assigned to various classifications are listed in Table 2. Note that classification categories (e.g. carcinogenic 1A, 1B and 2) are not listed. This is because in most classifications, the division in

categories is based on the available evidence, rather than on the potency of the substance to cause the specific effect (except for sensitisers). When taking carcinogenicity as an example, in the ECHA database, substances are assigned to the three different carcinogenicity categories (1A, 1B, 2) based on the available underlying evidence that a substance causes cancer (in humans). If insufficient information is available, a substance can only be put in one of two possible categories: carcinogenic or not carcinogenic. Therefore, until additional information shows with reasonable certainty that a category 1B or 2 carcinogen is actually not carcinogenic, this substance should be considered as being able to cause tumours in humans just like a category 1A carcinogen. Consequently, all categories should have the same effect score. This also applies to the mutagenic and reprotoxic categories.
It should be kept in mind that, while the division in categories is not directly linked to the potency, there is a large difference in the regulation of CMR 1 and 2 substances. As this methodology focusses on hazard, this is not taken into account.

The explanation in the previous paragraph does not apply to subcategories of sensitisers, as these are based on potency. This subdivision was recently introduced, so in practice most substances are still classified in category 1. To avoid double counting potency (i.e. in the endpoint and potency score) the subcategories of sensitisers are also equally weighted.

Table 2: Scores hazard endpoint, indicated by hazard classification

Classified as*	Score used by Schuur and Traas (2011, incl. potency)	Score in this methodology	Disability weights (Salomon J. A. et al., 2012)
Carcinogenic	4-6	4	0.294-0.519
Mutagenic	6	4	
C & M		4	
Reprotoxic	3-5	3	0.004-0.606
Respiratory sensitising	2 or 4	2	0.009-0.132
Dermal sensitising		1	0.005-0.096

The weight of the hazard endpoint scores is adapted from (Schuur A.G. & Traas T.P., 2011). For some classifications they report a range because the potency (i.e. value of the DN/MEL) is included in the score (Table 2, 2nd column). In the present methodology we propose scores based on classification only (Table 2, 3rd column). Where ranges are reported by Schuur & Traas, the lowest value is taken to avoid double counting the potency. Substances classified as C and/or M are given the same score because they might all result in the same clinical effect, namely cancer.
The effects caused by C and M, R, S_{resp} and S_{derm} classified substances are assumed to decrease in severity respectively. This is reflected by the corresponding scores. S_{derm} was not included in Schuur & Traas (2011), but as this effect is less severe than S_{resp}, S_{derm} received a score of 1.

The chosen order for the severity of the classifications is supported by disability weights (Dws) used to weigh the severity of different health effects against each other in the WHO global burden of disease analysis (Salomon J. A. et al., 2012). In the WHO analysis, cancer has a mean Dw ranging from 0.294 to 0.159. Disabilities considered as reproductive effects have Dws between 0.004 and 0.606. These include infertility, foetal alcohol syndrome, intellectual disability, hearing and vision loss, musculoskeletal problems, disfigurement, and motor and/or cognitive impairments. Allergic reactions are not listed by the WHO. However, asthma (Dw: 0.009-0.132) is considered as an equivalent effect of respiratory sensitisers and burns (<20%) and open wounds (Dw: 0.005-0.096) for effects of dermal sensitisers. The order of severity indicated by the Dws (Table 2, last column) confirms the order of the endpoint scores applied in the current report.
Substances causing only one type of effect, and thus having 'only' one classification, e.g. reprotoxic, are considered less hazardous when compared to substances with more types of effect, or classifications, e.g. reprotoxic and skin sensitising. Therefore, the scores of all classifications of a substance are summed. The theoretical range of the hazard endpoint score for a selected substance has a minimum of 1 (S_{derm} only) and a maximum of 10 ($CMRS_{resp}S_{derm}$: 4+3+2+1).

3.1.1.2 Hazard potency score

The DN/MEL of a substance can be regarded as an indicator of its potency to cause an adverse effect. The ECHA database may contain information on DN/MELs at various levels:

- Acute and chronic
- Dermal, inhalation, and oral routes of exposure
- General population and workers
- Systemic and local effects

For practical reasons, the choice was made to use one DN/MEL to set the potency score of a substance. A priori, there is no preference for the acute or chronic DN/MEL because the duration of exposure to articles and products is not defined and because both acute and chronic effects may occur. However, it is reasonable to assume that the chronic DN/MELs of a substance are lower than the acute ones. Following a conservative approach focusing on the lowest, i.e. chronic DN/MELs, is considered reasonable.
There is no preference for DN/MELs of a particular route of exposure. Exposure via each of the routes is possible, depending on the articles and products involved. Again, following a conservative approach, focusing on the lowest DN/MEL of all routes is considered reasonable. To enable comparison and categorisation, inhalation DN/MELs are converted to mg/kg body weight/day, by multiplying with the daily (24 h) respiration volume (20 m^3) of an average adult and dividing by the average human body weight (70 kg), as described by ECHA (ECHA, 2012).
The DN/MELs for the general population are used because they are relevant for consumer exposure.
Systemic DN/MELs are considered only because local DN/MELs cannot be converted to a standard unit that allows comparison with exposure.

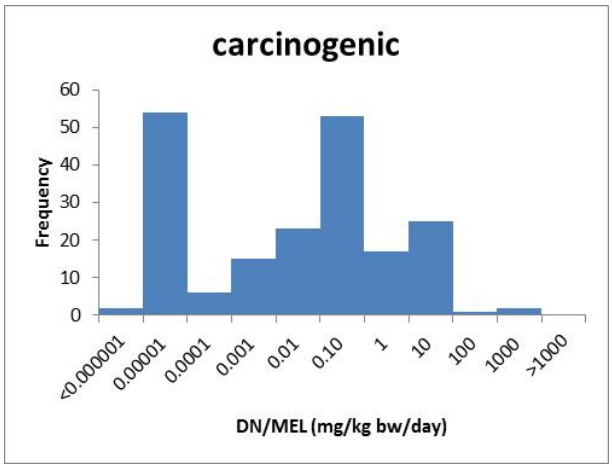
To summarise, the DN/MELs considered are for chronic, systemic effects in the general population and the route of exposure that gives the lowest value in mg/kg bw/day.
It should be noted that this DN/MEL is independent of the classification. For example, a substance may be selected on its classification for reproductive toxicity, but have a DNEL for neurotoxicity. Unfortunately, it is not possible to automatically find the effect for which the DN/MELs were derived.

Similar to the classifications, the DN/MELs were converted to numerical scores, as indicated below (Table 3). Schuur and Traas (2011) used a DN/MEL range from $<10^{-5}$ to >1 mg/kg bw/day, based on an expected DN/MEL range. Based on a preliminary analysis (Figure 1) of the DN/MELs available in the ECHA database, the potency categories were extended at the high DN/MEL end to enable a balanced (i.e. with equal group sizes) categorisation of less potent substances.

Table 3: Hazard potency scores

Category (mg/kg bw/day)	Score
DN/MEL ≤ 10^{-5}	10
10^{-5} < DN/MEL ≤ 10^{-4}	9
10^{-4} < DN/MEL ≤ 10^{-3}	8
0.001 < DN/MEL ≤ 0.01	7
0.01 < DN/MEL ≤ 0.1	6
0.1 < DN/MEL ≤ 1	5
1 < DN/MEL ≤ 10	4
10 < DN/MEL ≤ 100	3
100 < DN/MEL ≤ 1000	2
DN/MEL > 1000	1

Not all substances in the ECHA database have a DN/MEL. For substances without a DN/MEL, a low (5^{th}) non-parametric percentile of the available DN/MELs for a particular classification (see Figure 1) was used as a surrogate DN/MEL.



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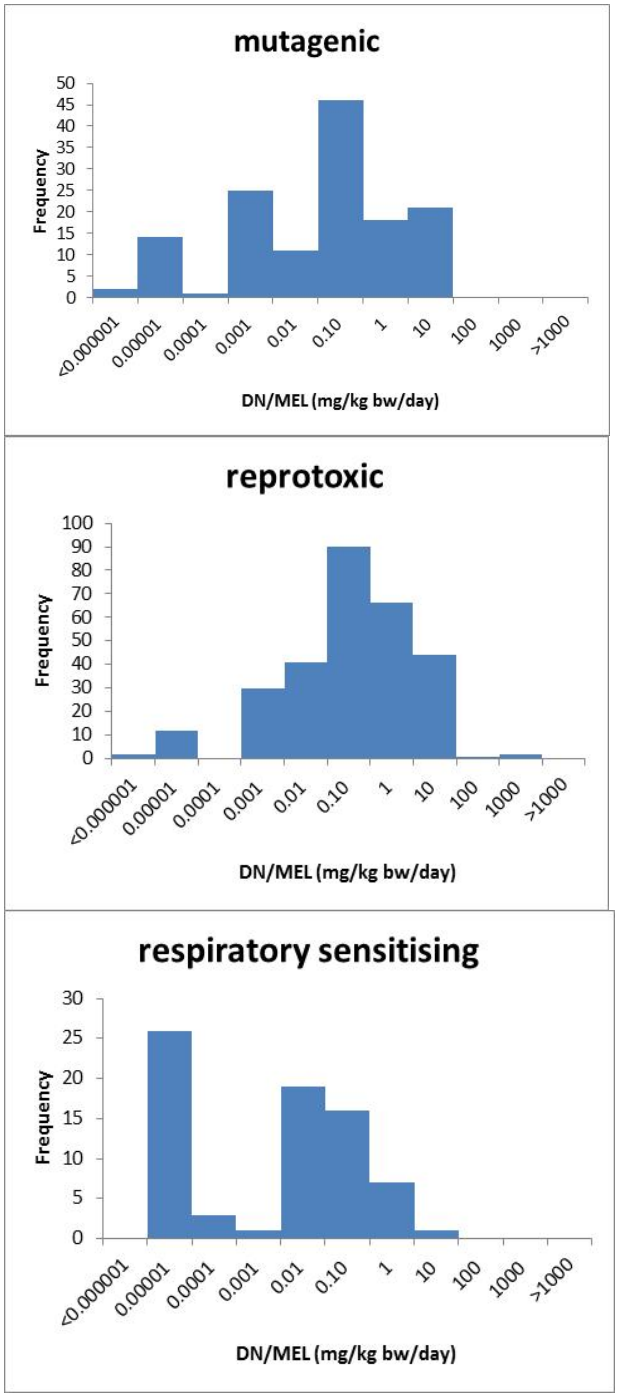

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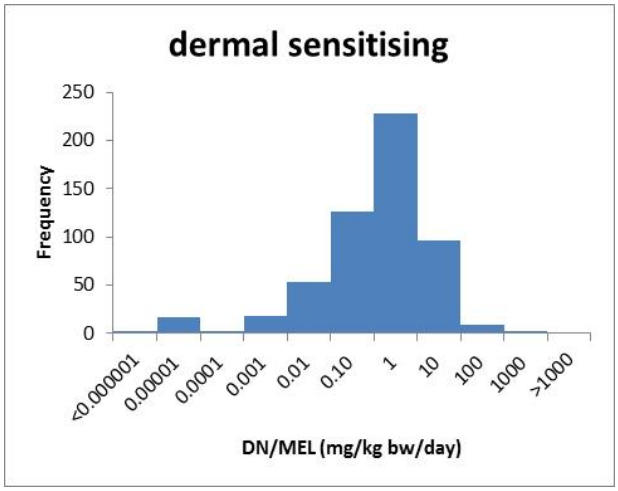

Figure 1: Histograms of the available DN/MELs (mg/kg bw/day; ECHA database, accessed March 2015) of substances classified as C, M, R, S_{resp} and S_{derm}. It should be noted that the presented DN/MELs are not necessarily based on the classified endpoints.

The 5th percentile is assumed to represent a reasonable worst-case DN/MEL for substances with a particular classification, but without a reported DN/MEL in the ECHA database. The percentiles are derived separately for substances with the classifications $CMRS_{resp}S_{derm}$ (Table 4). It should be noted that the DN/MEL of a specific substance may contribute to multiple classification-specific DN/MEL distributions when the substance has multiple classifications. For substances with multiple classifications, the potency score is based on the lowest corresponding surrogate DN/MEL.
In addition to the surrogate DN/MEL, another strategy was tested to fill in the gaps of missing DN/MELs, namely using the classification of specific thresholds of toxicological concern (TTC). However, this approach was abandoned because TTCs are not available for all classified hazards considered in this report. In addition, the TTC approach should not be used for a wide range of (categories of) substances with particular structural alerts for high potency (e.g. (EFSA, 2012)), which makes routine assignment of TTCs to the large list of currently assessed substances not feasible.

Table 4: 5th percentiles of available DN/MELs

Classification	Number of available DN/MELs	5th percentile of the available DN/MELs (mg/kg bw/day)	Potency score according to Table 2
C	198	5.7×10^{-6}	10
M	138	5.7×10^{-6}	10
R	288	1.5×10^{-4}	8
S_{resp}	73	4.3×10^{-6}	10
S_{derm}	553	8.6×10^{-4}	8

3.1.1.3 *Combining hazard endpoint and potency scores*

We are not aware of any arguments stating that the score representing the type of effect should contribute more to the overall hazard score, compared to the score representing the potency of a substance, or vice versa. We chose comparable ranges for both scores (i.e. from 1 to 10), and obtained the overall hazard score by adding the type of effect score to the potency score. As a result, the hazard score has a range of 2-20. Subsequently, we combined the overall hazard score (of each substance) with the exposure score (see Section 2.3).

Summary hazard score

Included

- **Effect score for C, M, R, S_{derm}, S_{resp}**
- **Potency, based on DN/MELs (for general population/chronic/systemic)**

Not included

- **All other classifications (Acute tox, STOT RE e.g.)**
- **No difference made on sub-categories of classifications (1A, 1B, 2)**
- **Hazards without classification (endocrine disruption)**
- **Occupational/environmental endpoints (Worker DNELs, OEL's, PBT/vPvB properties)**

3.1.2 *Exposure score*

As described for the hazard score, the exposure scores are also based on two components: the number of product and/or article categories (PC/ACs) in which a substance is used, and the relative exposure to the substance from the use of these products/articles.

3.1.2.2 *Number of Product/article categories*

Substances selected based on hazard classification can be divided in specific Product or Article Categories (PC/ACs)[1] in which they are used by selecting these PC/ACs in IUCLID (see Table 6 and Table 7).

In IUCLID it is possible to differentiate between user groups, namely workers and consumers. For this project, only the PC/ACs used by consumers were selected. The total (exact) number of PC/ACs in which a substance is used is determined and used as a score for the relative use of the substance. This number ranged from 1-41 for the current selection of substances.

[1] Articles are objects for which the shape and size is more important than the chemical composition for their function (for example a chair, car, book)
Products are mixtures, of which the function is determined by the chemical composition (usually products are fluids, for example paint, glue, cleaning products).

3.1.2.2 *Product exposure score*

A product exposure score is determined for products or articles semi-quantitatively. These product exposure scores are derived using the ECETOC-TRA consumer exposure tool in a similar way to that described by Schuur and Traas (2011) and based on expert judgment to interpolate from sub-PC to PC. This step is necessary because different sub-groups within PC/ACs, as used in ECETOC–TRA tool, cannot be found in IUCLID. The product exposure scores are determined either by multiplying three components: exposure estimation, exposure frequency, and usage versus consumption (gebruik vs verbruik in Dutch), which are each given 1-3 points, as depicted in Table 5. Thus, the product exposure scores range from 1 to 27 (Table 6 and Table 7).

Table 5: Components of the product exposure score

Parameter	Low	Medium	High
Exposure estimation	1: <100 mg/kg bw/d	2: 100-1000 mg/kg bw/d	3: ≥1000 mg/kg bw/d
Usage / consumption	1: usage		3: consumption
Frequency of exposure	1: accidental/ infrequent	2: occasionally	3: continuous/ frequent

The exposure estimation is based on the default values in the ECETOC-TRA tool and covers the combined exposure for all routes, calculated for a fictive substance with high vapour pressure. Implicitly, this gives relatively more weight to products for which the inhalation route of exposure is included, as the fraction released to air is set at 1. However, similar results are obtained when a low vapour pressure is assumed (results not shown).
The estimates from the ECETOC-TRA tool are event concentrations, rather than chronic concentrations, which would favour products with high quantities per event. As compensation, the usage/consumption and the frequency of exposure are taken into account. Usage/consumption reflects the difference between an article like a matrass, which releases less substance with every use (usage) and a product like paint, which is replenished with every use (consumption).
By including usage/consumption and use frequency, the scores of products with lower product amounts per event, but which are used up and are frequently used, are levelled. Cleaning products (PC35) are a good example. They have a moderate exposure estimation (score=2), but because they have a high exposure frequency and are consumed, they have a relatively high overall score.
Taking the exact outcome from the ECETOC-TRA tool was also considered, but discarded because it would provide a false sense of accuracy mismatching with the high level of abstraction of the information obtained from IUCLID. The product exposure score should therefore be seen as a screening.

In Schuur and Traas (2011), the number of PC/ACs in which a substance is used and whether it is used in children's products are also scored. In our methodology, the number of PC/ACs is used directly, as described in the previous section; the points given for use by children have been

omitted, as toys are only a sub-category and do not have their own PC/AC.

To move from the scoring system for subcategories from ECETOC–TRA tool to the main categories used in IUCLID, expert judgement was required. To derive the final scores, elements like 'which products within a main category are used the most', 'average scores of subcategories', and 'similarities across PC codes' were considered. The final product exposure score was determined by multiplying the three components. An expert elicitation was performed to see if other experts would derive similar scores. This did not result in any changes being made to the methodology; a more in-depth discussion is provided in the next section.

Table 6: Overview of the Product Categories and their exposure scores

Product Category	Exposure estima-tion 1-3	Usage / consump-tion 1 or 3	Frequency 1-3	Product exposure score
PC0: Other	2	3	1	6
PC1: Adhesives, sealants	2	3	2	12
PC2: Adsorbents	1	3	1	3
PC3: Air care products	1	3	2	6
PC4: Anti-freeze and de-icing	1	3	1	3
PC7: Base metals and alloys	1	1	1	1
PC8: Biocidal products	2	3	3	18
PC9a: Coatings, paints, thinners and removers	3	3	1	9
PC9b: Fillers, putties, plasters, modelling clay	3	3	1	9
PC9c: Finger paint	2	3	2	12
PC12: Fertilisers	2	3	1	6
PC13: Fuels	3	3	1	9
PC14: Metal surface treatment products	1	3	1	3
PC15: Non-metal-surface treatment products	1	3	1	3
PC17: Hydraulic fluids	1	3	1	3
PC18: Ink and toners	1	3	3	9
PC19: Intermediate	1	1	1	1
PC20: Products such as pH-regulators, flocculants, precipitants, neutralisation agents	1	3	1	3
PC21: Laboratory chemicals	1	3	1	3
PC23: Leather tanning, dye, finishing, impregnating products	3	3	2	18
PC24: Lubricants, greases, and release products	3	3	1	9

Product Category	Exposure estima-tion 1-3	Usage / consump-tion 1 or 3	Frequency 1-3	Product exposure score
PC25: Metal working fluids	1	3	1	3
PC26: Paper and board dye, including bleaches	3	3	2	18
PC27: Plant Protection Products	1	3	1	3
PC28: Perfumes, fragrances	3	3	3	27
PC29: Pharmaceuticals	1	3	1	3
PC30: Photo-chemicals	1	3	1	3
PC31: Polishes and wax blends	3	3	2	18
PC32: Polymer preparations and compounds	1	1	1	1
PC33: Semiconductors	1	1	1	1
PC34: Textile dyes, including bleaches	3	3	2	18
PC35: Washing and cleaning products (including solvent based products)	2	3	3	18
PC36: Water softeners	1	3	1	3
PC37: Water treatment chemicals	1	3	1	3
PC38: Welding and soldering products, flux products	1	3	1	3
PC39: Cosmetics, personal care products	3	3	3	27

Table 7: Overview of the Article Categories and their exposure scores

Article Category	Exposure estimation 1-3	Usage / consumption 1 or 3	Frequency 1-3	Product exposure score
AC 01: Other (not intended to be released)	2	1	2	4
AC 0-2: Other (intended to be released)	2	1	2	4
AC1: Vehicles	2	1	2	4
AC2: Machinery and electrical articles	2	1	2	4
AC3: Batteries	1	1	1	1
AC4: Stone, cement plaster	1	1	1	1
AC5: Fabrics, textiles and apparel	2	1	3	6
AC6: Leather articles	1	1	3	3
AC7: Metal articles	1	1	1	1
AC8: Paper articles	1	3	3	9
AC10: Rubber articles	3	1	2	6
AC11: Wood articles	2	1	3	6
AC13: Plastic articles	3	1	3	9
AC31: Scented clothes	3	1	3	9
AC32: Scented eraser, rubber	3	1	2	6
AC34: Scented toys	3	1	3	9
AC35: Scented paper	1	3	3	9
AC36: Scented CD	1	1	1	1
AC38: Packaging material for metal parts, releasing grease / corrosion inhibitors	1	1	1	1

3.1.2.3 *Expert elicitation PC and AC exposure scores*

In the previous section, it was decided to take the product of the scores per PC/AC for the priority setting. Although Schuur & Traas (2011) provide clear guidance on how to apply the exposure scoring approach, a certain level of personal judgment is required to derive the scores of the potential exposure per category. In addition, Schuur & Traas' proposal was setup at a level of subcategories. As the ECHA database only contains information at the level of the main PC/AC, the scoring was adapted to match the (lower) level of detail obtainable from the ECHA database. The quality of the scores derived by applying the approach and personal judgment was evaluated by comparison with scores assigned by experts who did not follow the exposure scoring approach.

By asking experts to elicit how they would scale the relative exposure to substances that may be present in a consumer product belonging to a PC or AC category, the scores can be put in broader perspective. Eight experts in the field of risk assessment were asked to score PCs and ACs from 1 to 9, where 9 indicated the highest exposure potential, and to

provide a rationale as to how they derived the given score. To avoid any bias, no information on possible consumer products or typical substances was given to the experts.

The results of the expert elicitation show that the individual expert scores vary on many PCs and ACs. Large differences in scoring were noted, where for one PC the scores ranged from 1 to 9. As a consequence, the score obtained by following the methodology often fell within the experts' range. A comparison was also made between the experts' average score per category and the methodology score. If the score differed by more than 6 points (to calculate the product exposure score scale, expert scores were multiplied by 3), the difference was considered to be large. This was the case in 23 of the 53 categories. Only four categories showed a small range and a small difference compared to the scores from the methodology, which in all four cases was within the range of the expert scores. The PCs involved were those not considered to have (much) consumer use (intermediates, semiconductors, pH-regulators) and one for which direct contact is inevitable, i.e. cosmetics.

These observed differences between experts may be the result of the wide range of products within a category and that experts visualised different products or routes of exposure per PC or AC. It has proven to be difficult to assign a characteristic score for an entire PC or AC. This clearly shows the difficulties in assessing the potential exposure from any consumer product on such limited information. Furthermore, within one PC or AC, products can have entirely different uses and exposures.

Also of note is the way the experts ranked the categories. Even though the specific scores may differ, the scores can show a high rank correlation. The experts were individually compared with the scores from the methodology to obtain the rank correlations (Spearman's rank correlation scores), where correlations of -1, 1 and 0 indicate (perfect) negative, positive or no correlation, respectively. In this case, the results show one correlation (-0.04) between -0.10 and 0.10 indicating no correlation, one correlation (0.27) between 0.10 and 0.30 indicating low correlation, and six moderate correlations (0.45, 0.47, 0.49, 0.61, 0.62, 0.63) between 0.30 and 0.70. No high correlations, i.e. score higher than 0.70, or negative correlations were observed.

Overall, it can be concluded that the expert exposure scores relate moderately well to the scores based on the methodology and personal judgement. Due to the wide ranges of the individual scores, it is not justifiable to change the methodology or the scores for specific categories. The elicitation exercise shows the complexity and diversity in screening for generic, i.e. substance independent, potential exposure from consumer products within the broad categories, without having knowledge of specific products. It underpins the uncertainty of the exposure scores for the specific Product and Article categories.

3.1.2.4 Combining Product/Article Categories and product exposure scores

The occurrence of a substance in PC/ACs and the corresponding product exposure scores can be combined in several ways.

In the chosen method, the highest product exposure score of a substance (1-27) is added to the total number of PC/ACs in which the substance is used (1-41). The resulting exposure thus scores the range from 2-68.
It is worth noting that, although the total number of PC/ACs is higher than the highest product exposure score, currently only nine of the 773 substances are used in more than 27 PC/ACs, while 159 substances have a highest product exposure score of 27. Thus, in general, the use in PC/ACs and the product exposure scores have approximately the same weight.

Summary exposure score

Included

- **Number of PC/ACs in which a substance is used**
- **A product exposure score as a measure for the exposure from the use of products/articles that contain the substance**

Not included

- **Tonnage**
- **Number of registrants**
- **Population size**
- **Function of the substance**
- **Physical chemical properties**

3.2 Combining the hazard and exposure scores

The total scores for hazard and exposure were combined to rank both the selected substances and the PC/ACs (see the overviews in Figure 2 and Figure 3).

3.2.1 Prioritisation of substances

All parameters discussed in section 3.1 were combined to gain a ranking of the substances, as depicted in Figure 2. As there was no reason to value either hazard or exposure higher, both scores were weighted similarly. Since the hazard scores of the current selection range from 2-18 and the exposure scores from 2-68, the hazard scores were multiplied by 3.5 to place them in the same order of magnitude. Finally, both scores were added to reach the final score. In the text box below, zinc oxide is given as an example to illustrate how the total score was calculated.

In summary:

- Hazard score= hazard endpoint score + hazard potency score
- Exposure score= number of PC/ACs + product exposure score
- Total score = hazard score * 3,5 + exposure score

Example: Zinc Oxide

Hazard score

- **Endpoint score = 3 (R only)**
- **Potency score = 5 (DNEL 0.7 mg/kg/d)**
- **Hazard score = 3 + 5 = 8**

Exposure score

- **Number of PC/ACs = 23**
- **Highest Product exposure score = 27**
- **Exposure score = 23 + 27 = 50**

Total score

- **8 x 3.5 + 50 = 78**

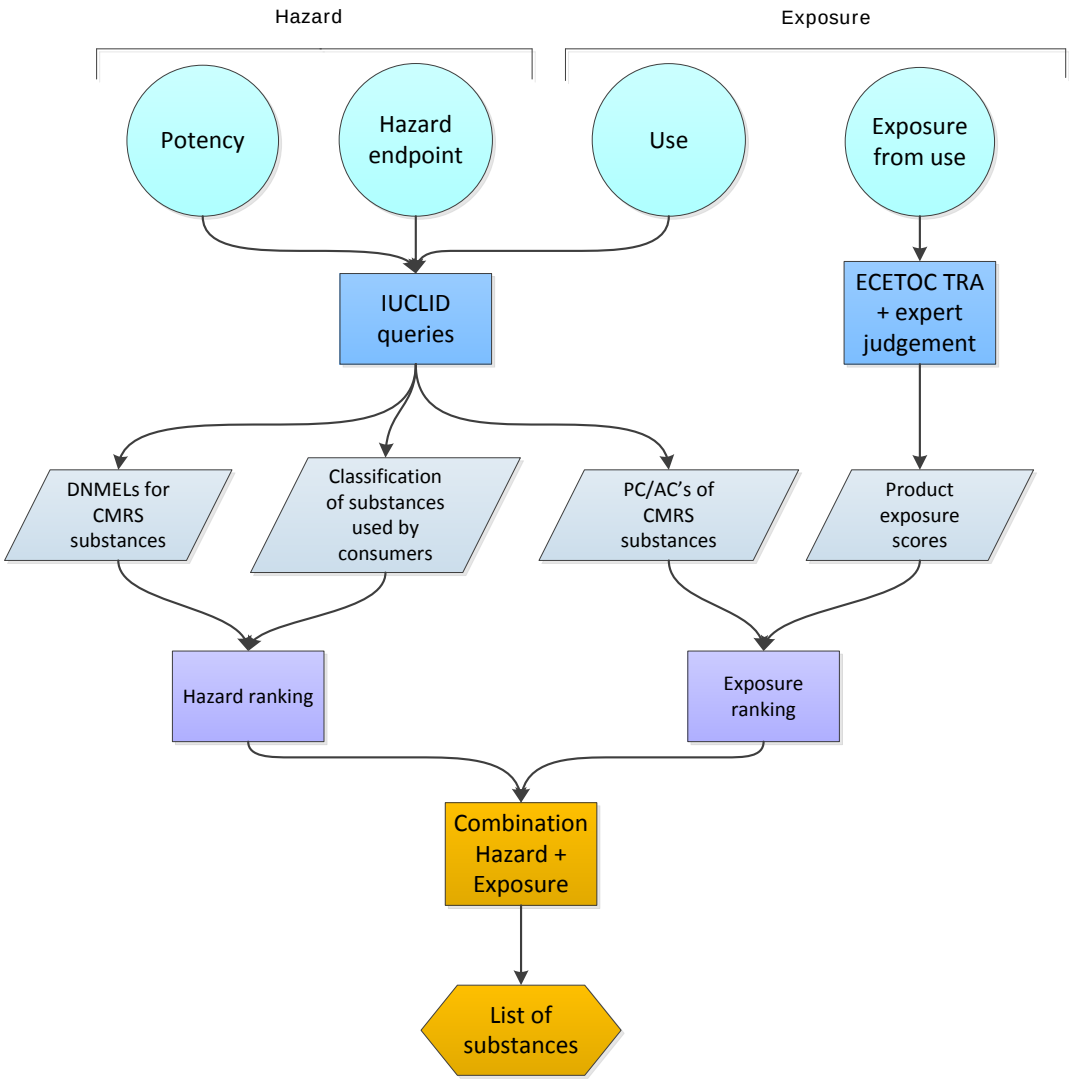

Figure 2: Overview of the prioritisation of the substances. The input parameters are DN/MELs, classification, Product/Article Categories (PC/ACs) and product exposure scores. The parameters are combined resulting in a scored list of substances.

3.2.2 *Prioritisation of PC/ACs*

The ranking of the PC/ACs is based on the number of substances in each PC/AC, their hazard endpoint scores, and the product exposure score of that PC/AC (see *Figure 3*). Unfortunately, it is currently not feasible to also link the potency scores to the PC/ACs.
Similar to the ranking of the substances, hazard and exposure scores were given equal weight. The hazard score was derived by taking the sum of all hazard endpoint scores for all substances in a PC/AC. The exposure score was derived by multiplying the number of substances with the product exposure score belonging to the specific PC or AC, It was decided to multiply the hazard score by 2 to give hazard and exposure equal weight. Exposure and hazard scores are added together to calculate the total score. In the text box below, PC12: Fertilisers is given as an example to illustrate the calculation of the total score.

In summary:

- Hazard score = sum hazard endpoint scores
- Exposure score = product exposure score x number of substances
- Total score = hazard score * 2 + exposure score

Example: PC12: Fertilisers

Hazard score

- **Sum endpoint scores = C (46x4) + M (1 x 4) + R (54 x 3) + S_{resp} (0 x 2) + S_{derm} (26 x 1) = 378**

Exposure score

- **Number of substances = 128**
- **Product exposure score = 6**
- **Exposure score = 128 x 6 = 768**

Total score

- **378 x 2 + 768 = 1524**

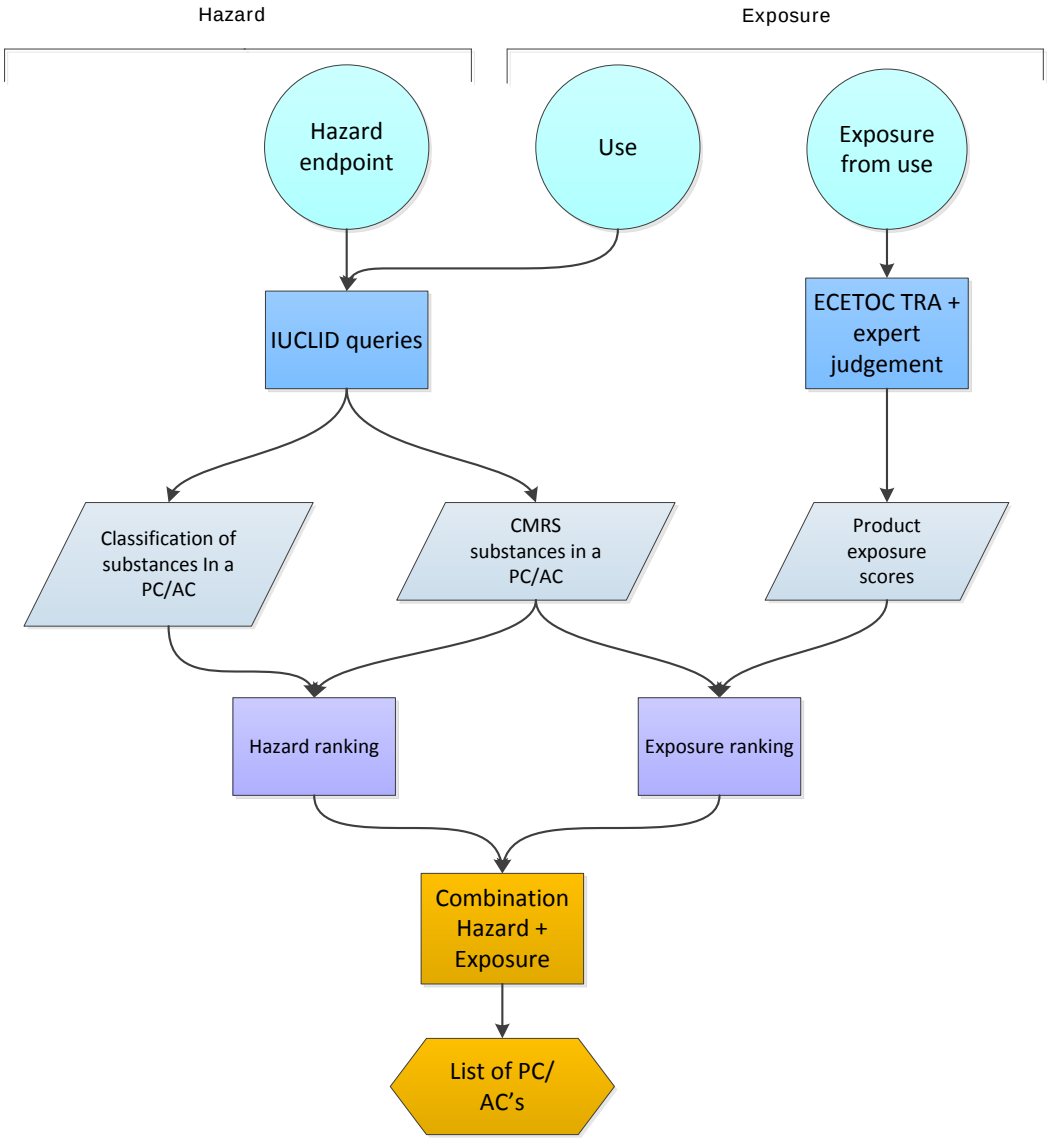

Figure 3: Overview of the prioritisation of the PC/ACs. The input parameters are classification, number of substances and product exposure scores. The parameters are combined resulting in a scored list of PC/ACs.

4 Results

The Excel tables with the substances and PC/ACs can be found in Annex A and confidential Annex B. Both files are essentially the same, except that the names, CAS-, and EC-numbers of substances with individual submissions have been replaced with a random number in Annex A. This is necessary to comply with the confidentiality requirements. A more thorough explanation of confidentiality issues is given in Chapter 5.
The IUCLID queries were performed from June 2014 until March 2015 in the following order: Dermal sensitisers (June 2014) - Carcinogens (August 2014) - Mutagens (October 2014) – Reproductive toxicants (February 2015) - Respiratory sensitisers (March 2015).
The substances and the PC/ACs were scored as described in the previous chapter. The rankings resulting from these scores are described in the first two sections of this chapter. In the second part of the chapter, the results of this methodology are compared with the prioritisation for the ILT (Inspectorate Environment and Transport) and the SIN (Substitute It Now) list.

4.1 Results presented for substances

THE RESULTS ARE PRESENTED IN THE EXCEL FILES IN ANNEX A

www.rivm.nl/bibliotheek/rapporten/2015-0194.xlsx

The list with all the selected substances and their respective scores for the different parameters is given on the tab ‘Substances’. The different parameters are in the coloured columns, and by using the filter options it is possible to sort the list or select a specific group of compounds, depending on the question of interest. A few examples:

- To select reproductive toxicants sorted on their use in PC/ACs: select substances with ‘Repro’ = 3 (column O), ‘Sum PCs and ACs’ = sort largest to smallest (column G)
- To select only carcinogens with DMELs, sorted from lowest to highest DMEL: select substances with ‘Carc.’ = 4 (column M), ‘DNEL/DMEL’ = DMEL (T), ‘DN/MEL converted to oral’ = sort smallest to largest (S)
- To select only substances with a DN/MEL, sorted on the total hazard score: unselect blanks in ‘DN/MEL converted to oral’ (column S), ‘Total hazard score’ = sort largest to smallest (F)

Table 8 summarises a few highlights from the results. Figure 4 shows a frequency plot of the total scores of the substances. As can be seen in the Excel table and in Figure 4, there are groups of substances that have the same scores, and thus essentially have the same ranking. These rankings can be found in the Annexes in column L, and range from 1 to 121.

Table 8: Highlights results substances

Number of substances	773
Carcinogens	248
Mutagens	151
Reprotoxicants	297
Sensitisers Respiratory	38
Sensitisers Dermal	461
Highest score	106 (Aluminium Oxide)
Median score	53 (various compounds)
Lowest score	19.5 (Phenol, isobutylated, phosphate (3:1))
Number of rankings	121*
Number of DN/MELs	420
Highest DNEL	196.5 mg/kg bw/day (Antimony Trisulfide)
Lowest DMEL	$2.87*10^{-7}$ mg/kg bw/day (Petroleum pitch)
Median DNEL	0.25 mg/kg bw/day

*The method for scoring substances results in many substances with the same total score. Thus, 773 selected substances were ranked and divided over 121 positions in the ranking.

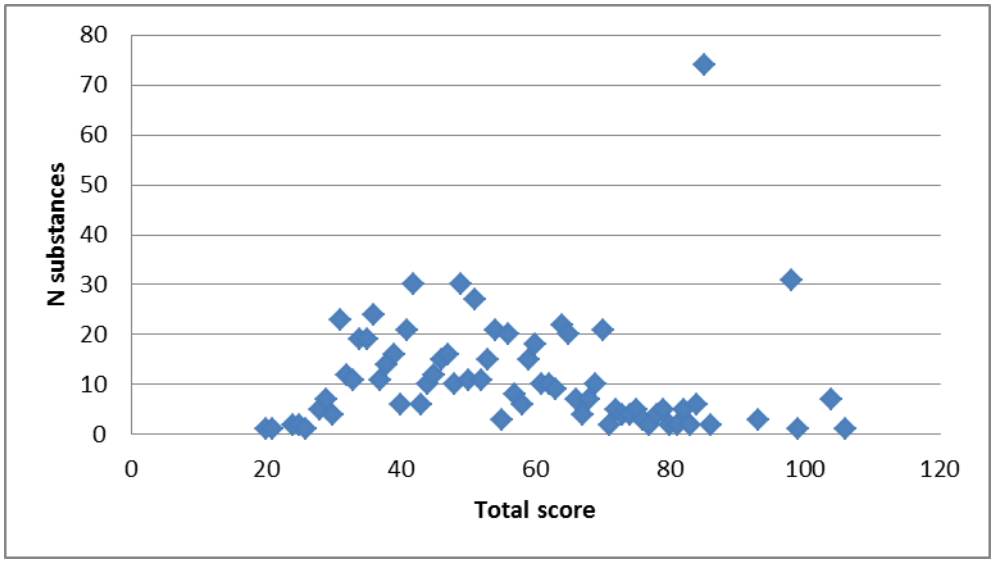

Figure 4: Frequency plot of the total scores of the substances. This plot shows the number of substances (y-axis) for every total score (x-axis)

The substance with the highest score is Aluminium Oxide which is used in a large number of PC/ACs (30), including cosmetics, and has been selected for carcinogenicity. It should be noted that Aluminium Oxide is not carcinogenic itself, but is probably classified based on the presence of an impurity. Unfortunately, it is currently not possible to make this distinction in the IUCLID search.
As can be seen in Figure 4, the number of substances with the same score varies widely. At rank 2, 4, and 8 (scores of 103.5, 97.5, and 84.5 points) are three groups of substances that are exceptionally large. With the exception of a few fragrances in the 84.5 group, these substances are all petroleum and gas derivatives, including petrolatum, slack wax,

naphtha, residual oil, and similar products. The many different entries are often similar substances that are, for example, produced with slightly different processes.
These substances have high total scores, because they have high hazard scores (CMR, no DN/MEL) and are used in many PC/ACs, including some with high product exposure scores. The situation with these compounds is complex as they are often produced in two or more variants, which differ in the presence/absence of CMR impurities and thus classification, but share one IUCLID entry. In their dossiers, it is stated that only the purified variant, without CMR classification, may be used in consumer products. However, this differentiation cannot be made in an automatic search, as only the worst-case classification is selected.

Another interesting group of compounds are the (meth)acrylates, which occupy rank 3 and 12 amongst others. The methacrylates are classified for skin sensitisation, and are used in a wide range of products. When the substances are sorted on the highest number of PC/ACs, the six highest scoring compounds are all methacrylates, with, on top, butyl- and isobutyl methacrylate that are used in 41 PC/ACs.

There are 187 substances with the maximum potency score of 10. However, most of these are carcinogenic/mutagenic/resp. sensitisers missing a DNEL for the general population. If the substances without DNEL are removed from the list, 13 compounds with a potency score of 10 remain; that is a DN/MEL ≤ 10^{-5} mg/kg bw/day. Of these, nine have a DMEL and four a DNEL.

There are only four compounds with a hazard endpoint score of 10, thus a classification for all endpoints except they can be either carcinogenic or mutagenic. All four are cobalt compounds. This group of compounds does not score particularly high overall (rank 29-37), because they are only used in a few PC/ACs (max. 7), with low product exposure scores (max. 9) and have DNELs around 0.01 mg/kg bw/day (potency score = 6/7).

4.2 Results presented for PC/ACs

The list with PC/ACs and their scores can be found on the tab ‘PCACs’. The column with the total score is marked in red, while the sub-scores are yellow.
The list of results for PC/ACs shows the product category with the highest total score, which is the sum of the scores of all substances used in that category. The results also show the number of compounds with a specific classification in a PC or AC. The list of PC/ACs can also be sorted on, for example, the number of substances, the number of carcinogens, or their hazard score.

Table 9 summarises selected highlights of the results. The total scores for all PC/ACs are included in Table 12. The highest scoring group is PC35: Washing and cleaning products, which contains a relatively large number of substances (463), including many carcinogens (127) and reprotoxicants (133), and, as product category, has a higher product exposure score than the numbers two and three (PC9a: Coatings and paints and PC13: Fuels).

Table 9: Highlights results PC/ACs

Number of PC/ACs	57
Highest total score	11052 (PC35: Washing and cleaning products)
Lowest total score	7 (PC11: Explosives)
Highest hazard score	1746 (PC13: Fuels)
Highest exposure score	8334 (PC35: Washing and cleaning products)
Highest number of substances per PC/AC	553 (PC9a: Coatings and paints)
Lowest number of substances per PC/AC	1 (PC11: Explosives)
Highest number of carcinogens	177 (PC13: Fuels)
Highest number of mutagens	121 (PC13: Fuels)
Highest number of reprotoxicants	172 (PC13: Fuels)
Highest number of skin sensitisers	152 (PC9a: Coatings and paints)
Highest number of respiratory sensitisers	16 (PC9a: Coatings and paints)

In general, PCs score higher than ACs; a result of the lower exposure scores for articles and because ACs tend to contain less of the selected compounds (from the current ECHA database). The highest scoring AC is AC13: Plastic articles, in position 19.

4.3 Comparison of the results with other prioritisations

4.3.1 Comparison of the results with results from the ILT prioritisation

The ILT prioritisation tool was developed to help the Dutch Human Environment and Transport Inspectorate (ILT) prioritise the supervision/enforcement of hazardous substances. For the present study, the results from the ILT prioritisation were used for comparison as they also prioritise substance categories based on the risk inventory for consumers. The ILT project was also one of the reasons for building the current methodology as it demonstrated the value of a prioritisation tool, but provided insufficient detail on consumer use to cover the needs of the NVWA. However, although consumers are included in the ILT tool, they were not its main focus, as risks for workers and the environment were also considered. The methodology behind the ILT list can be found in the RIVM report 'Risk inventory of groups of hazardous substances' (Zweers P.G.P.C. et al., 2014). The results described below are from an update made in 2015 (Zweers P.G.P.C., de Groot G.M., & Bakker J., 2015).
In the ILT project, 55 product groups based on Use Categories (UC), were categorised in three different risk classes. The categorisation was performed by taking 4-8 representative substances per group and determining their hazardous properties and likelihood of exposure. The hazard properties included physical-chemical, human health, and environmental hazards. The results were divided in risks for the protection targets environment (including man indirectly exposed via the environment), workers, and consumers. In this report, only the risk for consumers is considered.

The ILT list distinguishes between low, medium and high risk groups for consumers, based on human health hazard and consumer exposure. Human health hazard was considered high when ≥10% of the volume (as tonnage on the market) of the 4-8 representative substances was classified as CMR 1A/1B or placed on the REACH candidate list for equivalent concern. The hazard was average if ≥ 10% of the volume was classified or labelled for other adverse effects. The low hazard category contained UCs of which >90% of the substance volume had no classification and labelling.
The score for consumer exposure was derived from the use in consumer products or articles, the availability for exposure, and the likelihood and duration of exposure, see Table 10.
The total score for consumer risk was determined by combining the scores for hazard and exposure according to the decision tree depicted in Table 11.

Table 10: Determination of the exposure scores in the ILT project

Use in consumer products / articles	Availability for exposure	Likelihood and duration of exposure	Exposure score
+	+	+	+
+	+	-	+/-
+	-	+	+/-
+	-	-	-
-			-

(Table adapted from Zweers et al., 2014)
+ = high, +/- = middle, - = low

Table 11: Determination of the consumer risk scores in the ILT project

Human hazard	Consumer exposure	Consumer risk
+	+ / +/-	+
+ / +/-	+	+
+/-	+/-	+/-
+ / +/- / -	-	-
-	+ / +/- / -	-

(Table adapted from Zweers et al., 2014)
+ = high, +/- = middle, - = low

To be able to compare our ranking of PC/ACs with the ranking of UCs for consumer exposure, PCs were matched with their UC counterparts. For the PCs with no UC equivalent, such as PC9a Coatings and paints, the average score of the components was used, for example Colourants, Solvents, Surface active agents etc. If five or more UCs were used to derive an average, the score was marked with an asterisk*. The results are given in Table 12. For PC0 (others), PC19 (Intermediate), or any of the ACs, there is neither a matching UC nor are there fitting components; for this reason these were removed from the list.

Table 12: Overview of the PC scores from the prioritisation project and ILT list for consumer risk

Product Categories	PC scores	ILT scores
PC 35: Washing and cleaning products (including solvent based products)	11052	+/-
PC 9a: Coatings and paints, thinners, paint removes	8109	+/-*
PC 13: Fuels	8064	+
PC 38: Welding and soldering products (with flux coatings or flux cores.), flux products	7778	+/-
PC 24: Lubricants, greases, release products	6375	+
PC 31: Polishes and wax blends	5516	+
PC 1: Adhesives, sealants	5500	+/-
PC 39: Cosmetics, personal care products	5330	+
PC 3: Air care products	5124	+/-
PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids	4238	+/-*
PC 4: Anti-freeze and de-icing products	3633	+
PC 28: Perfumes, fragrances	3357	+
PC 23: Leather tanning, dye, finishing, impregnation and care products	3310	+/-*
PC 9b: Fillers, putties, plasters, modelling clay	3075	+/-
PC 18: Ink and toners	2789	+/-
PC 9c: Finger paints	2668	+
PC 8: Biocidal products (e.g. disinfectants, pest control)	2610	+
PC 12: Fertilisers	1524	+/-
PC 15: Non-metal-surface treatment products	1246	-*
PC 27: Plant protection products	1044	+/-
PC 16: Heat transfer fluids	851	-
PC 17: Hydraulic fluids	831	-
PC 37: Water treatment chemicals	628	+/-
PC 32: Polymer preparations and compounds	541	+/-
PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids	494	+/-*
PC 30: Photo-chemicals	189	+/-
PC 21: Laboratory chemicals	177	-
PC 20: Products such as pH-regulators, flocculants, precipitants, neutralisation agents	174	-
PC 14: Metal surface treatment products, including galvanic and electroplating products	165	-*
PC 2: Adsorbents	164	-
PC 29: Pharmaceuticals	133	+
PC 25: Metal working fluids	79	-
PC 36: Water softeners	53	+

PC 7: Base metals and alloys	46	-
PC 33: Semiconductors	34	-
PC 11: Explosives	7	+

* The ILT score for these PCs is the average of ≥5 UCs

As can be seen, both scores show much the same trend, with all low-scoring UCs in the lower half of the PC ranking, and most high scoring UCs in the upper half of the PC ranking.
Notable exceptions are PCs 29, 36, and 11 (Pharmaceuticals, water softeners, and explosives), which rank low in the current method, but high in the ILT prioritisation. One reason for this difference is that the ILT methodology works with a small group of representative compounds for each UC, and does not consider the total number of compounds used in a group. In the current methodology, the number of compounds is an important factor, as it influences both the total hazard and exposure scores of the PCs.
Another factor is the difference in expected exposure for these three PCs, which was at least average in the ILT methodology, and low (product exposure scores of 1-3) in the current method. As became apparent in the expert elicitation, exposure estimations vary widely depending on the expert, even when using the same scoring system. In this case, different methods and experts resulted in different estimations of exposure.
On the other hand, three of the four PCs with the highest scores were ranked as average in the ILT list, namely PC 35, 9a, and 38 (Washing and cleaning products, Coatings and paints, and Welding and soldering products). The average score of Washing and cleaning products in the ILT list is the result of average hazard and exposure scores. The latter is interesting, as the exposure was average because two high volume compounds scored low for ‘Likelihood and duration of exposure’, while the other six compounds had a high score. In the current methodology, all compounds within a PC/AC are given the same product exposure scores, regardless of their volume or function. Both methods have their merits and limitations, but it is important to be aware of this difference.
The difference in score for Coatings and paints can be attributed to the fact that there is no UC equivalent of this PC. Thus, the ILT score used is the average of various UC scores, which hampers the comparison as it dilutes the scores of the different parameters.
Welding and soldering products score high in the current list on the combination of a relatively high number of compounds, product exposure score, and hazard score. In the ILT project, this PC was represented by two UCs: Welding and soldering agents and Flux agents for casting. Both UCs scored average on hazard and exposure, which was related to the compounds chosen as being representative for these UCs.

In conclusion, both methods give comparable results, with a few notable exceptions. Some different outcomes are related to difficulties in the match between UCs and PCs, others to differences in the methodology. The latter are related to the different purposes of the tools: the current tool focusses specifically on consumer exposure, while the ILT risk inventory has a broader scope that includes workers and the environment. This results in differences in emphasis, for example on tonnage of a few compounds, in contrast to the total number of

compounds. Tonnage has a strong correlation with emission to the environment, but not with the exposure of consumers using these products (Meek M.E., 2008).

4.3.2 Comparison of the results with the SIN list

The SIN (Substitute It Now) list contained 830 substances in July 2015 selected by ChemSec as being Substances of Very High Concern (SVHC) (Chemsec, 2015). This selection is based on the criteria used under REACH and thus overlaps with the candidate list under REACH, but also contains substances that have not yet been identified as SVHC under REACH. These criteria are given in the REACH regulation under article 57 and include substances which are CMR, PBT, vPvB, or of equivalent concern. The latter can be for example endocrine disruptors or respiratory sensitisers. The aim of the SIN list is to speed up the recognition of SVHCs and to encourage companies to replace these compounds.
The list is freely available in Excel format and contains information on the reason for selection, as well as the classification, tonnage and PC/ACs in which the substances are used. However, they are not ranked on these properties. Nevertheless, a comparison with the SIN list is useful to identify hazardous substances not included in our selection, and to determine why they were not found.
A summary of the results of the comparison is given in Table 13.

Table 13: Overview of the comparison of the substance list with the SIN list

N substances on prioritisation list	773
N substances on SIN list	830
N substances on both lists	202
S_{derm} substances from the prior list not on SIN	383
SIN subs. not on prior list without CMR class.	71
SIN subs. not on prior list without PC/AC	396
SIN subs. not on prior list without both CMR and PC/AC	40

Although the SIN list and the prioritisation list are of comparable length, only 202 substances occur on both lists which represents 26% of the SIN list and 24% of the prioritisation list. It is noteworthy that of these 202 substances, 91 belong to the top-100 of the prioritisation list. These are mainly petroleum compounds registered for consumer use. This indicates that at least the high ranking substances are also considered of high priority by Chemsec.
Most of the differences between the lists can be explained by the different inclusion criteria, which are linked to the respective aims of the lists.
Of the substances not on the SIN list, a majority of 67% (383 substances) consists of skin sensitisers, as this is not an SVHC selection criterion. Another difference is that the SIN list only includes compounds with a harmonised classification, instead of also including the self-classification of the registrants.

When looking at the substances on the SIN list that are not on the prioritisation list, the largest group (63%) consists of compounds not registered for use in a PC or AC. This is actually an underestimation of

the total number of substances not included for this reason, as there is no distinction between worker and consumer PC/ACs in the SIN list. Thus, substances can have a PC/AC in the SIN list, but not be found in IUCLID when searching only for consumer PC/ACs.
A smaller group (13%) of substances was not included in the prioritisation list because they have no CMRS classification. These were either endocrine disruptors or PBT/vPvB compounds.

5 Disclaimer

When using the prioritisation methodology and/or the resulting lists of substances and PC/ACs, a few factors should be kept in mind which may influence the accuracy of the tool. This chapter gives a concise evaluation of the accuracy of the ECHA database and the methodology. Additionally, an overview of confidentiality issues and the way they are handled is provided.

5.1 Inaccuracies in the ECHA database

The outcome of the methodology is highly dependent on the quality of the data in the ECHA substance database. Errors or omissions in the information provided by the registrants might lead to missing substances if either the (CMRS) classification or consumer use is not filled in, or to substances being included that do not have CMRS properties or consumer use, but have been marked as such by mistake. The latter can be corrected on an individual basis by verification of the substance dossier, but the first can only by detected if missing substances are picked up on CMRS properties and consumer use in another context.
Additionally, it is known that there are inaccuracies in the IUCLID query tool and/or the IUCLID database. For example, some substances or PC/AC codes on the ECHA website cannot be found in IUCLID and vice versa. This issue has been reported to ECHA, as they are the only organisation that can solve this issue.

5.2 Disclaimer development of the methodology

During the development of the methodology, several concessions had to be made due to limitations in the database and the large variety of substances included. The approach with the combination of different input parameters presented in this report was based on experience with previous methods and expert judgment, with due consideration for the uncertainties in the data. However, it should be kept in mind that the values chosen for the product exposure, hazard endpoint, and potency scores are arbitrary values, which may be changed if new insights arise.

Product exposure score

In the case of product exposure scores, the broad definition of most PC and ACs made it very difficult to derive consistent scores that covered large groups of substances, as already noted in the expert elicitation (see 3.2.2.3.).
To enable more precise exposure estimations, the function of substances in products could be added to the IUCLID queries. However, this entry is incomplete and the data interpretation would become complex, as substances can have different functions in different PCs. The best way to gain more precise knowledge on the use of a substance in specific products is to check this manually in the Chemical Safety Reports (CSR). However, this is only doable for individual substances, and is not feasible for an automatic screening.

Hazard endpoint score

To a lesser extent, the situation of the hazard endpoint scores is similar to that of the product exposure scores, as again one score was determined for a range of effects. For example, not all forms of reproduction toxicity are equally severe (see 3.2.1. Hazard endpoint).

Hazard potency score

The potency scoring using DNELs has the added difficulty that not all selected substances have general population DNELs available in the ECHA database. The use of the 5th upper percentile to fill in missing DNELs inevitably results in less accurate potency scores, compared to substances with DNELs provided by the registrant.
Additionally, the DNELs derived by the registrants vary in their reliability (Schenk L., Palmen N., & Theodori D., 2014). Furthermore, the potency score is based on the lowest DNEL which might have been derived for a different endpoint than those used for the selection. For example, a substance that has been selected for its classification as mutagen may have a lowest DNEL based on its neurotoxic properties.
It was for these reasons that the scores were derived on relatively global scales, as this lowers the risk of attaching unjustifiable accuracy to the scoring system.

Number of PC/ACs

The number of PC/ACs in which a substance is used is not a score, however this number is not always accurate, as is known from the Substance Evaluation process and the Textile prioritisation project (oral communication). Some registrants may include future uses in a registration that are not relevant at the present time, or leave uses in the dossier that have become obsolete.

As a last remark, although the datasheets have been error and quality-checked, the risk of introducing mistakes or errors during the combination and analyses of the Excel-files remains.

5.3 Confidentiality

One of the disadvantages of the ECHA database is that it is not publicly available, as part of the information is confidential. Registrants can use flags in IUCLID to show whether a particular field is confidential or not. However, this is not permitted for all fields: classification and DNELs always have to be publicly available. Of the information used in the prioritisation methodology, only the PC/ACs in which a substance is used may be confidential. However, as registrants have to submit valid justification and payment to be allowed to claim confidentiality for PC/ACs, PC/ACs are also publicly available on the ECHA website.
Due to the large number of substances included, it is not possible to confirm for which substances PC/ACs are confidential. For this reason there are two separate versions of the data-sheets. In the public version, only total numbers of PC/ACs are reported for every substance, without giving the exact PC/ACs in which the substances are used. For substances that have only one registrant, or for which it is not known whether it is an individual or joint submission, a random number has replaced the substance name, CAS- and EC-number. This was necessary

as otherwise it might be possible to derive information on the use of that particular registrant by using the number of PC/ACs and the maximal product exposure score.
In the confidential version, full information is available on all substances, including the use in specific PC/ACs and the random number to substance conversion.

6 Discussion and evaluation

6.1 The methodology

In the development of the methodology for the prioritisation tool, various choices had to be made which influence the outcome of the prioritisation tool. The first, and probably most important, choice was to use the ECHA database as a data source. Not only did this determine which substances could be found, but it also set the boundaries for the subsequent methodology.
The advantages of the ECHA database are the large number of substances included, the possibility to select substances with specific properties by using automated queries, and the relative objectivity of these searches; i.e users are not dependent on pre-selection by a third party.
The most important disadvantages are the confidentiality of the data and the limited control of inaccuracies, as discussed in the previous chapter. Note also that the deadline for registration of the lower tonnages under REACH is in 2018, which means that both the number of substances and the information on use in PC/ACs in the ECHA database will grow in the coming years. For this reason, it would be valuable to repeat the queries and subsequent ranking either every year or at least after the 2018 deadline, to also include the lower tonnage substances and uses.

The current methodology is based on the method described by Schuur and Traas (2011) for the prioritisation of substances under REACH. However, the proposed scoring system had to be adapted to match with the information available from the IUCLID queries. In particular, the division of the product exposure scores in sub-categories had to be changed to only main PC/ACs, as subcategories are not included in the ECHA database (section 3.2.2). As became clear from the expert elicitation on exposure scoring, most PC/ACs are very broad, which makes it difficult to assign a single exposure product score.

It was intended to give the hazard and exposure scores a similar weight as well as the scores within hazard and exposure. At the same time, it is important to maintain sufficient resolution of the final scores.
This is particularly well illustrated by the number of PC/ACs, which is not scored, but is an exact number that depends on the substances selected. As this number did not exactly match with the product exposure scores, lengthy discussions took place before the current calculation of the (total) exposure score was agreed on. One option was to also assign a score to the number of PC/ACs, by giving one point for every five PC/ACs. However, this resulted in too little weight for this parameter and a very low resolution, as the upper 50% of the scores were included in only 3% of the substances, while 62% of the substances would get a score of one.
For this reason, the current method in which the total number of PC/ACs is added to the highest product exposure score was chosen. As only six substances are used in more than 30 PC/ACs, and for all others the scores are well balanced, it turned out to be the best solution. In addition, including hazard helped to balance the total scores, by reducing the weight of each individual score.

It should be kept in mind that after the next 2018 REACH registration deadline, the number of substances in the ECHA database will be higher. If this leads to an increase in the number of substances used in more than 27 PC/ACs, it may be necessary to reconsider the scoring method. Otherwise, the use will gain disproportionate weight, compared to the product exposure scores.

Initially, the average instead of highest product exposure scores per substance were used, but this was changed during the process of developing the tool. The reason was that averaging actually reduced the total score of substances used in many different PC/ACs. As an illustration; if a substance is used in both cosmetics (score=27) and metal articles (score=1), the average product exposure score would be 14, while a substance only used in cosmetics has a score of 27. By taking the highest product exposure score of all PC/ACs, this effect is avoided.

The derivation of the total hazard score, including a potency and endpoint score was more straightforward than for the exposure score, as these fitted well in a scoring system from one to ten. The classification categories (1A, 1B, 2) were not taken into account, as these are measures of the burden of proof rather than the severity of the effect for most classifications. The exception is sensitisation, but as the number of compounds with a subcategory (1A or 1B) is still very small, as this was only introduced in 2011, this has not been taken into account for the time being. Of course, this might be changed in the future as more compounds are classified in subcategories.

The methodology allows the selection of the hazard endpoint of interest. In future iterations of this methodology, it is thus possible to include other hazard endpoints.
One example of an endpoint that is worth considering is long-term repeated exposure (classification STOT RE), which includes effects such as neuro- and immunotoxicity.
Another interesting candidate is endocrine disruption, which could not be included as this endpoint is not yet sufficiently or officially defined, and it is also not included in the ECHA database. Possibly this will be added to the ECHA database in a future update, or else a selection of these compounds might be taken from another source.
If other endpoints are added, it will be necessary to add these to the hazard endpoint scores without changing the weight of the summed hazard score.

6.2 Overall use and other methods

This prioritisation methodology is explicitly aimed at risks to consumers. This sets it apart from most other prioritisation methods, such as the ILT and SIN list, which also take into account environmental and/or occupational risks. These lists are nevertheless used for comparison, because they are performed in a sufficiently similar way and because, in both cases, it is possible to make a sub-selection on endpoints that are relevant to consumers.

The prioritisation tool discussed in this report has the purpose of identifying and ranking substances and product groups most relevant to

consumers. Thus, only human endpoints are included, with a focus on hazards that require repeated, long-term exposure, and that can occur at low doses, namely $CMRS_{resp}S_{derm}$. Substances are only included when used in consumer products or articles according to their REACH registrants.

The ILT prioritisation focusses more on emission to the environment and transport, where tonnage and hazards like explosiveness are of higher importance.
The SIN list is maintained by an NGO and is meant to be a broad collection of high risk chemicals. As they aim to include compounds not yet identified as SVHCs under REACH, some of their endpoints cannot be found in the ECHA database. Endocrine disruption (ED) is the best example of an endpoint that is not yet defined under REACH and in the EU, but one that may be included in the future.
Another study that should be mentioned in this context was performed by Goldsmith et al., who also looked specifically at substances in consumer products (Goldsmith M. R. et al., 2014).
The Goldsmith database is a collection of substances used in consumer products from Walmart in the USA. The substance data were gathered from material safety data sheets (MSDSs). Substances were ranked on their concentration and occurrence in products, which were divided in use categories. This categorisation was based on the retailer's product categories, thus these use categories are not comparable with the PC/ACs used in our study.
No hazard is included in either the selection or ranking. As a result, many substances are included that are not classified as CMRS; for example, the most used substance is water.
Considering these differences, it was decided not to use the Goldsmith database for a direct comparison. Although it would be interesting, the only additional information it would generate would be the occurrence of the overlapping compounds in consumer products of an American retailer.

The lists of ILT, SIN and Goldsmith illustrate that the choice for the division in product types or categories is a difficult point in all prioritisation methods, and that every method has chosen a different option. As PC/ACs were already defined and used under REACH, this was the logical choice for the current methodology. However, they are not always very specific; especially the ACs can be very general, such as wood articles or plastic articles. The function of the substance is also not taken into account, while this is an important factor for the concentration in and release from the product. In the adaptation of the ECETOC TRA tool used for the determination of the product exposure scores, all substances within a PC/AC are given the same (worst case) function, concentration, and release.
Unfortunately, no more precise method for exposure estimations could be found or invented, without resorting to manual screening.

While the methodology is primarily intended to be used by the NVWA as an aid in the prioritisation of their enforcement activities, it might also be useful for other purposes. Of course, other groups can use it if they are specifically interested in consumer risks or a specific selection criterion. It might also be useful as an additional aid for the selection of high-priority substances for risk management under REACH or other legislative frameworks.

7 Conclusions and recommendations

The new tool enables the selection and prioritisation of substances and product/article categories from an extensive and growing amount of information on industrial chemicals in Europe on their risk to consumers. The methodology allows the addition of other endpoints in the selection if required by the enforcement authorities. As such, it facilitates the use of information in the ECHA registered substance database for a risk based prioritisation of enforcement activities.

Method

The ECHA database is used as data source from which all substances are selected with a $CMRS_{resp}S_{derm}$ classification, and with registered use in consumer products or articles. Additionally, all DNELs and DMELs for general population/long-term/systemic effects were retrieved from the ECHA database.
Scores were assigned to substances and product/article categories (PC/ACs) for both hazard and exposure parameters. The hazard score consist of an endpoint score based on the estimated severity of the effect for which the substance is classified, and a potency score based on the DN/MEL. Substances for which no DN/MEL is available are given the potency score of the 5^{th} percentile of all substances with the same classification.
The exposure score consists of the number of PC/ACs in which a substance is used, and a score for the exposure from these products/articles.

Results

The results include two extensive lists in Excel, one with ranked substances and the second with ranked product and article categories in which they are used.
As it is possible to select and/or adjust the different parameters separately, the ranking can be easily modified to answer different questions. Thus, this new prioritisation tool is able to rank both the substances in consumer products and categories of consumer products, and can be used for selection of specific substances or products for further consideration.

Results from the first execution of the tool show that cleaning agents have the highest total score of the PC/ACs, followed by coatings/paints and fuels.
The substance with the highest score is Aluminium oxide, which was classified as carcinogen, probably due to an impurity. Noteworthy are the three large groups of petroleum derivates with the same scores, at the upper end of the ranking. These compounds are complex cases because their dossiers in the ECHA database include multiple variants, some of which have CMR classifications and different ones used in consumer products.
The methacrylates have the highest exposure scores. These compounds are classified for skin sensitisation and are used in a very wide range of

products. Only four compounds, all cobalt salts, had a hazard endpoint score of 10, meaning they are classified as C and/or M, R, S_{resp}, and S_{derm}. The results of the PC/ACs were compared with the ILT prioritisation and the substances with the SIN list. Although both comparisons are limited by differences in purpose and methodology, most of the high scoring PC/ACs and substances also scored high in the other methods. The most important difference between the methods lies in the exposure information used. This is caused by both the difference in scope of the tools and the information available.

Recommendations

The prioritisation tool selects and ranks the substances in consumer products based on many assumptions and estimations. It would be interesting to perform a more in-depth examination of a selection of substances. This could be achieved by thoroughly examining their REACH dossiers and checking all information on hazard and exposure, to gain a more complete understanding of the risk of these substances. The selection criteria for the substances examined might be:

- The substances with the highest scores
- A selection of substances with high, middle, and low scores
- The highest scoring substances with a specific hazard endpoint (for example skin sensitisers)
- Substances from the product category(ies) with the highest score (such as cleaning agents)
- A group of substances with similar structures/mode of action/use that are of particular interest (for example petroleum derivates or methacrylates)
- A combination of the previous options.

The information gained from this action can be used to evaluate the prioritisation tool and determine whether the chosen parameters are representative for the information available in the dossier.
Based on these results, the methodology could be improved if necessary and/or relevant. It could also be used as an extra motivation to take certain substances under further scrutiny.
If there are doubts on the validity of the information in the REACH dossiers, or if the dossiers are incomplete, other sources might be searched, for example the US household products database, to determine in which products a substance is really used.

If the outcome of this evaluation indicates that the high scoring substances and/or product categories give reason for concern, it can also be used as a basis for enforcement actions. The enforcement actions in turn are an important source of feedback on the functioning of the tool. Additionally, the tool may be used for prioritisation under legislative frameworks such as REACH.

One of the strengths of the tool is that it is possible to add additional hazard endpoints such as repeated dose toxicity (classified as STOT-RE) or endocrine disruptors, once the criteria are agreed on. These may be included in future iterations.

To ease the search for substances in a specific product/article category, it is possible to create additional tables with the substances for every PC/AC, for example, all substances in cosmetics with their respective rankings. Currently, this has not yet been included in a way that allows a quick and easy search, but this would be valuable if there is concern about specific products.

It should also be considered that only REACH registered compounds are included and the deadline for the lower tonnages has not yet passed. Thus it is advisable to repeat the retrieval of the substances at a later time (autumn 2018), to update the list. At that time, a new version of IUCLID will be available (IUCLID 6), which may include additional search criteria.

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Annex I Overview of substance lists

REACH-lists - Candidate list and authorisation list

REACH is the European Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals (EC/1907/2006). Under REACH, the industry is obliged to provide information to the ECHA for all industrial chemicals that are produced or imported in volumes of ≥1 ton/year. REACH requires industry to generate information on the intrinsic properties of substances, assess these properties, determine D(M)NELS, and perform a chemical safety assessment if the substance fulfils certain requirements.
In article 57 of the REACH legislation, criteria (CMR, PBT, vPvB or with equivalent level of concern) are defined for identification of substances as Substances of Very High Concern (SVHC) (REACH, art 57). Once identified as SVHC substances, they may be included on the Candidate List. Currently (2014) 151 chemicals are included on the Candidate list. Inclusion on the Candidate list requires agreement of the Member State Committee of the European Chemical Agency (ECHA). At present, several substances have an ECHA recommendation for being on the list (Candidate-list, ECHA-website).
Identification of an SVHC substance and its inclusion in the Candidate List is the first step of the authorisation procedure. The authorisation list (Annex XIV of REACH) contains substances prioritised from the Candidate List based on the available information on intrinsic properties, wide dispersive use, and volumes of the substances on the EU market. Currently, 22 chemical substances are included on the list, but authorisation requests and their assessment is ongoing (Authorisation list, 2014).

CLP-lists - Classification and Labelling inventory & Annex VI

The Classification and Labelling (C&L) Inventory is a database which contains classification and labelling information on substances notified under Classification Labelling and Packaging (CLP) Regulation and registered under the REACH Regulation. Producers and importers themselves determine the classification of substances and mixtures, and are required to submit all self-classifications to ECHA for inclusion in the C&L Inventory. ECHA maintains the inventory, but does not review or verify the accuracy of the information. At present, the Inventory consists of more than 90,000 substances (C&L Inventory, 2014).

Member States, manufactures, importers and downstream users may propose a harmonised classification and labelling for a substance, which is then added to Annex VI of the CLP regulation. Usually this applies to carcinogenic (C), mutagenic (M), or reproduction toxic substances (R) or respiratory sensitisers (S). The decision making for harmonised classification takes place at Community level. Currently, Annex VI contains 4485 substances (CLP, Annex VI; table 3.1).

Dutch-substance lists - ZZS-list & ILT-list

On request of the Dutch government (Ministry of Infrastructure and Environment), RIVM made a list with substances of very high concern for humans and the environment (ZZS-list). The substances on the list are evaluated with priority and the aim is to either ban these priority substances from the (living) environment or to reduce their concentrations to ensure a negligible risk level (ZZS-list, 2014). The 371 substances on this list are selected based on their presence on other lists (from European legislation), such as: Annex VI of CLP (CMR 1A or 1B classified substances), Candidate List for REACH, EU Persistent Organic Pollutants (POP-) regulation (EC 850/2004), Water Directive (2000/60/EC) and substances listed by the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) for priority action.

In 2012, RIVM made the list 'Dangerous substances', on request of the 'Inspectie Leefomgeving en Transport' (ILT). To a large extent, this list overlaps the ZZS-list, but it excludes the substances from the Water Directive and OSPAR list. It includes hazardous chemicals from the Prior Informed Consent (PIC-) Regulation (chemicals from Part I, II, III and Annex III), chemicals listed and proposed by the Stockholm Convention on POPs, and chemicals from the Convention on Long-Range Transboundary Air Pollution (CLRTAP) directed by the United Nations Economic Commission for Europe (UNECE). The ILT-list consists of almost 1500 substances and substance groups. Amongst them are approximately 660 petroleum and coal derivatives (Personal communication with J. Bakker (RIVM-VSP)).

International list - Domestic substance list and Priority substance list

In 1994, Environment Canada published Part II of the *Canada Gazette*, (1994) the Domestic Substance List (DSL). This is an inventory of approximately 23,000 substances manufactured in, imported into, or used in Canada on a commercial scale. It is based on substances present in Canada, under certain conditions between January 1, 1984 and December 31, 1986 (DSL-website, 2014). This list however, is dated and no longer represents current commercial activity in Canada. Therefore, the Canadian Ministry of the Environment and Health has asked Health Canada to revise the DSL, by using prioritisation tools, to form a 'Priority Substance List' (PSL).

NGO driven list - SIN-list

The SIN (Substitute It Now) List is an NGO (ChemSec) driven project to speed up the transition to a world free of hazardous chemicals. The SIN List 2.1, updated February 2013, consists of 626 chemicals (554 CMRs, 20 PBT/vPvBs and 52 substances of equivalent level of concern) that ChemSec has identified as Substances of Very High Concern based on the same criteria established by the EU chemical regulation REACH (SIN-list, 2014).
The SIN List is a living, ongoing, multi-stakeholder project that will evolve according to new developments and findings. It will be continuously updated as new information on dangerous chemicals becomes available (SIN-list, 2014).

Table A1. Overview of all substance lists with their properties

	Who	Aim	Hazard criteria	Number of chemicals	Regulatory context	References/links
Candidate list (REACH)	ECHA/Member States	Inclusion on this list is the first step in the authorisation process	Art. 57 of REACH (CMR, PBT, vPvB, equivalent concern)	151	Yes, REACH	Candidate-list, ECHA-website; http://echa.europa.eu/regulations/reach/authorisation/the-candidate-list
Authorisation list (REACH)	ECHA/Member States	Authorisation of substances	Art. 57 of REACH (CMR, PBT, vPvB, equivalent concern)	22	Yes, REACH	Authorisation list, REACH; http://echa.europa.eu/en/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list
C&L Inventory	Self-classification by industry; ECHA maintains inventory	Inventory ensures classification and labelling of hazardous substances	All substance properties, according to CLP criteria	> 90,000	Yes, REACH en CLP	C&L Inventory, 2014; http://echa.europa.eu/regulations/clp/cl-inventory
Annex VI of CLP	ECHA/Member States	Harmonised classification and labelling of hazardous substances	All substance properties, according to CLP criteria with a focus on CMR properties	4485	Yes, CLP	CLP, Annex VI; http://echa.europa.eu/en/addressing-chemicals-of-concern/harmonised-classification-and-labelling/annex-vi-to-clp

	Who	Aim	Hazard criteria	Number of chemicals	Regulatory context	References/links
SIN	ChemSec (NGO)	To increase the number of substances on the REACH Candidate list	Comparable with REACH criteria	626	No	SIN-list; http://www.chemsec.org/what-we-do/sin-list
Priority Substance List	Canadian Ministry of the Environment and Health, Heath of Canada	Identification of hazardous substances to be assessed on a priority basis	‘ toxic’ (see above)	69 *(including group or class of chemicals, effluents or wastes)*	Canadian Environ-mental Protection Act, 1999	Priority Substance List; http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=C6C230D5-1
ZZS lijst	RIVM	Exclude substances of very high concern from the environment	CMR 1A & 1B (CLP/EU-GHS); PBT/vPvB (REACH Annex XIV); POP; OSPAR	371	Yes, Dutch ministry I&M	ZZS-list; http://www.rivm.nl/Documenten_en_publicaties/Algemeen_Actueel/Nieuwsberichten/2013/Lijst_Zeer_Zorgwekkende_Stoffen_beschikbaar
ILT-list	RIVM		See above	~1500	No	Not publicly available

Annex II Link between substance and consumer product

ECHA substances database

The ECHA substances database captures, stores, maintains and exchanges data on intrinsic and hazard properties of chemical substances registered under REACH.
The industry has to register all new and existing industrial chemicals in Europe under the REACH-legislation. At present, all industrial substances with a production or importation volume of >100 ton/year should be registered. The last deadline for all substances above 1 ton/year is 31 May 2018 (IUCLID, 2014), therefore substances produced or imported between 1 and 100 ton/year are now missing from the database.

The amount of information the industry has to provide in the database depends on the volume of a substance that is produced or imported in Europe.
The properties that can be found in the database include among others;

- General information (e.g. chemical name, CAS No., synonyms, impurities, additives)
- Physical-chemical data
- Manufacture and use (e.g. production processes, use in products/articles)
- Toxicological information (e.g. humane toxicity studies, classifications, DNELs)
- Environmental fate and pathways (e.g. photo-degradation, distribution, biodegradation)
- Ecotoxicity

The ECHA substances database is available in IUCLID (International Uniform Chemical Information Database), which has a query tool that makes it possible to search for substances on specific properties, for example, all substances that have been classified as carcinogenic. However, the ECHA substances database contains confidential information, and access to the database is limited to the ECHA and the competent authorities of member states (IUCLID, 2014).

National Poison Information Centre (NVIC-database)

Companies are required by law (CLP regulation) to provide detailed information about hazardous products (based on their classification; composition e.g.) to the National Poison Information Centre (NVIC). It should be noted that, in general, the information is similar to the information on a product's Material Safety Data Sheets (MSDS). The NVIC collects this information in an extensive toxicological database which can be accessed by medical professionals. In the case of poisoning, professional health care takers can ask for detailed information about the toxic components in the products concerned. Based on patient data and exposure data (age, weight, amount of product) a risk analysis can be made of the poisoning. Like the ECHA substances database, access to the NVIC-database is restricted (NVIC-database).

Household Product Database

The US Household Products Database (HPD) of the National Library of Medicine is based on the Consumer Product Information Database © by DeLima Associates. It includes information on household product types, brand names, chemical constituents, health-related information, and related exposure minimisation techniques.
Products in the database are selected based on market share in each of nine product categories, and on shelf presence in retail stores such as drugstores, supermarkets, auto parts stores, building supply stores, office supply stores, craft stores and pet stores.

The Household Product Database links over 14,000 consumer brands to the health effects listed in Material Safety Data Sheets (MSDS) provided by manufacturers on a voluntary basis. The database is designed to answer the following 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 toxicology-related database of the National Library of Medicine?

The information in the Household Product Database comes from a variety of publicly available sources, including brand-specific labels and MSDS when available from manufacturers and manufacturers' web-sites (US Household Product Database, 2014).

Dangerous substance database

In 2012, the RIVM drew up, on behalf of ILT (Inspectie Leefomgeving en Transport), the list 'Dangerous Substances' (ILT-list).
The ILT-database can couple approximately 400 substances from the ILT-list (substances that are most relevant to the ILT) to Use Categories (UCs). UCs can be linked with SBI-codes[2] which provides information on which branches produce, import, process, or distribute a specific substance. As a result, the ILT can use the database to quickly select the applications of a substance, and the relevant industries that produce, import or process the substance (Personal communication J. Bakker (RIVM-VSP)).

Consumer Product Chemical Profile database (Goldsmith et al., 2014)

Recently, a study was published in which data was collected on concentrations of substance in products from Wallmart (Goldsmith et al., 2014). Material Safety Data Sheets (MSDSs) were used to obtain toxicological information on the chemicals used in consumer products.

[2] SBI is de Standaard Bedrijfsindeling, zoals onder andere gebruikt door het Centraal Bureau voor de Statistiek (CBS), en is een Europees geharmoniseerde indeling van bedrijven en instellingen in sectoren en branches.

The database represents 1797 unique chemicals used in 8921 consumer products. These consumer products were grouped in 353 'use categories' within a total of 15 top-level categories. This information was used to identify chemicals present at high concentrations across multiple consumer products and use categories that have a high exposure potential (Goldsmith et al., 2014).

SPIN-list

The Substances in Preparations in Nordic Countries (SPIN) list is a database of substances in products in the Nordic countries. The database is based on data from the Product Registries of Norway, Sweden, Denmark and Finland. The intention behind the SPIN database is to make available as much data as possible from the Product Registers to the public.
The database is financed by the Nordic Council of Ministers, Chemical group. Industries in the Nordic countries are obliged to notify their substances. However there are slight differences between the countries about which chemicals must be declared (Nordic product registers, 2007). In general, the registration scheme applies to notifiable products that are produced or imported for industrial use in quantities of 100 kg or more per year, and chemicals that are classified as dangerous for health or the environment, or as causing fire and explosion hazards. In addition, a substance must be used by more than three different producers to avoid a confidentiality breach. Furthermore, it should be noted that, at least from Denmark, the information involves professionally used products only.
All the data used in the SPIN database is summarised data and no references can be made to specific concentrations of any given substance in any kind of product. The information included is, for example, the Industrial Use categories (NACE) and Use Category (UC62) codes (see Annex IV of this report for an overview), the annual tonnage used in each country, and the presence or absence of the substance in consumer products (SPIN-list, 2014; Nordic product registers, 2007).

Other specific product type databases

Below are a selection of other databases, sometimes only containing information on specific product categories:

<u>Skin Deep database</u>
The Environmental Working Group (EWG) launched Skin Deep in 2004 to create online safety profiles for cosmetics and personal care products, with the aim to 'fill in where industry and government databases leave off.'
EWG staff scientists compared the ingredients on personal care product labels and websites to information in nearly 60 toxicity and regulatory databases. Skin Deep contains information and online safety assessments for 69,378 products and 2,274 brands, and was searched 232,955,554 times since 2004 (Skindeep, 2014).

<u>Dutch information website</u>
This information website is an initiative of the NVZ (Dutch Association of Soap Manufacturers) in collaboration with Milieu Centraal and IVAM BV.

The Dutch government financially supported this project as one of the Test Projects under the SOMS programme (Strategy handling Substances).
The purpose of the website is to provide information to consumers and professional users of consumer products (e.g. bakers, butchers and catering businesses) on the safe handling of laundry and cleaning products.
Some information is provided on substances present in laundry and cleaning products (*Isditproductveilig, 2014*).

Annex III Prioritisation tools

Prioritisation under REACH and CLP (Schuur & Traas, 2011)

Schuur & Traas developed a system to prioritise substances within policies related to the various work process under the REACH and CLP regulations.
The purpose is to prioritise which substances are selected for consideration under various REACH processes. The selection of substances may differ depending on the REACH process involved. The substances are prioritised on exposure by using a system of points awarded for various exposed populations: consumers, workers, environment, and man indirectly exposed via the environment. Substances in consumer products can receive a higher priority depending on:

- the number of product categories they are used in
- when applied in products made to be used by children
- when exposure levels are high

Hazard is taken into consideration by the identification and evaluation of CMRS substances. Three criteria are set, namely classification category, threshold/non-threshold effect, and potency (on the basis of a Derived No-Effect Level (DNEL) or Derived Minimum Effect Level (DMEL)). The following choices were made to weight the criteria:

- A priori no weight differences in hazard criteria C, M, R or S
- Category 1A, 1B C/M/R will receive higher priority than Category 2 C/M/R
- Genotoxic carcinogens get higher priority than substances classified otherwise
- A substance is given a higher priority if its potency is higher

Although potential risk of substances is always an important factor, the REACH regulation under consideration also determines the priority given to substances.

Risk-inventory of User Categories

In 2012, the RIVM together with TNO-Triskelion, requested by ILT, published a “Risico-inventarisatie milieugevaarlijke stofgroepen t.b.v. de VROM-Inspectie” (Zweers et al., 2012; TNO Triskelion, 2012). It describes a risk assessment of substance groups and was developed in collaboration with the Inspectorate. The risk assessment was intended for a first prioritisation within the ILT programme on environmentally hazardous substances. The method was applied on groups of substances conform the classification in ‘User Categories’ (UCs). These UCs were used in the risk assessment of ‘Bestaande Stoffen’ (EEG/793/93). At first, 10 substance groups were used; later (TNO report) another twenty substances groups were used. Within each substance group, 4 to 8 representative substances with different production volumes, hazard properties and exposure levels were scored.

The CLP classifications were used as a starting point to determine hazard properties. The harmonised classification was used when

available; otherwise, the self-classifications from the classification and labelling inventory (C&L inventory) were used.
In order to assess the possibility and level of exposure of consumers, the following sub-parameters were assessed:

- Presence of a substance in a consumer product or article
- Chance of primary exposure
- Probability, duration and frequency of exposure

Based on decision rules, scores were given to the representative substances. These individual scores were used to derive scores for the substance groups. The result is a risk inventory for each substance group. However, no analyses have yet been performed to assess the robustness of the results of this method of risk assessment (TNO Triskelon report, 2013).

Method to prioritise chemical risks in food (Mengelers & Jeurissen, 2013)

The RIVM has developed a test method which is intended to be a tool to qualitatively prioritise chemical risks in food. In consultation with the Dutch Food and Consumer Product Safety Authority (NVWA), it was decided that the method should have the following properties:

- Suitable for chemical risks in food
- Based on the probability and severity of the risks
- Qualitative risk estimation
- Prioritising with a simple tool
- Accessible to the NVWA, RIVM and third parties

Additionally, two assumptions were made regarding exposure:
1. Exposure is long term
2. Exposure is based on an adult with an average consumption

A questionnaire for professionals was prepared in which chemical risks (substances) in food were scored based on the answers of the participants. The participants had to answer four specific questions: three questions designed to estimate their exposure, and one question about the toxicity (potency) of the substance. Each answer is linked with a score, and the final score (0-20) is the sum of all scores (see figure A2).

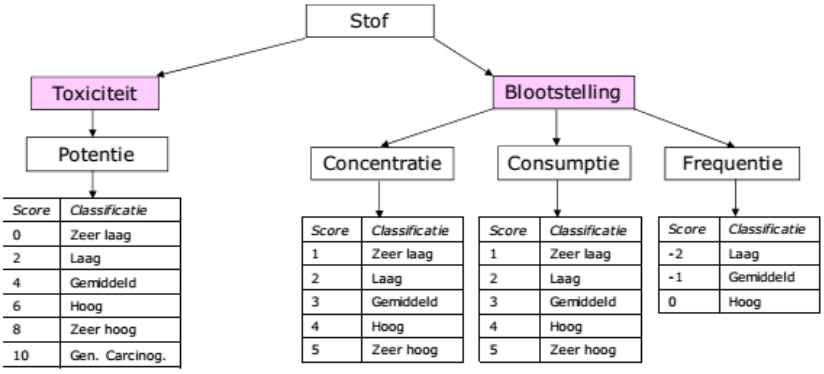

Figure A2. Schematic representation of the prototype for the prioritising of chemicals in food

Prioritisation tool within the Domestic Substance List (Health Canada)

Health Canada, in collaboration with Environment Canada, developed a set of tools with which substances from the DSL can be prioritised, resulting in the PSL (Health Canada website, 2014). The developed tools are:

- SimET; Simple Exposure Tool
- SimHaz; Simple Hazard Tool
- ComHaz; Complex Hazard Tool
- ComET; Complex Exposure Tool

For a description of the tools, see the report by Tiesjema et al. (2011).

Annex IV Use categories (UC 62) for chemical substances and preparations

The table below is copied from the report “The Nordic product registers”. The table lists 62 use categories (UC 62) for chemical substances and preparations. The UC 62 are developed on the basis of the 55 use categories used in EU for new substances (Nordic product registers, 2007).

Code	Text	Description
01	Absorbents and adsorbents	Solid substances/materials used to absorb or adsorb gases or liquids: filter materials/media, molecular sieves, silica gel.
02	Adhesives, binding agents	Materials which are applied to two surfaces causing them to adhere: dispersion based adhesives, hot-melt, resins for polymer based hardening adhesives, solvent based adhesives.
03	Aerosol propellants	Compressed or liquefied gases within which substances are dissolved or suspended and expelled from a container upon discharge of the internal pressure through expansion of the gas.
04	Anti-condensation agents	Substances/materials used to avoid condensation on surfaces and in the atmosphere: anti-dim agents, condensation removers.
05	Anti-freezing agents	Substances/materials used to prevent and remove ice formation: antifreeze liquids, de-icing agents.
06	Anti-set-off and anti-adhesive agents	Substances/materials used to prevent set-off and adhesion: spraying powder and anti-set-off additives for printing, oils and waxes for laths and shuttering, casting slip, etc.
07	Anti-static agents	Substances/materials used to prevent or reduce the tendency to accumulate electrostatic charges: anti-static additives, materials for surface treatment against static electricity.
08	Bleaching agents	Substances/materials used to whiten or decolourise materials. Not: cosmetics, photographic bleaches, optical brighteners.
09	Cleaning/washing agents	Substances/materials used to remove dirt or impurities from surfaces: detergents, soaps, dry cleaning solvents, optical brighteners in detergents, paint removers.

Code	Text	Description
10	Colouring agents	Substances used to impart their colour to other materials: dyestuffs, pigments, colour forming agents, fluorescent brighteners (but see below re detergents). Not: cosmetics, photochemicals, optical brighteners used exclusively in detergents, reprographic agents.
11	Complexing and flocculating agents	Substances used to combine with other substances (mainly metal ions) to form complexes or precipitates or induce coagulation.
12	Conductive agents	Materials used to conduct electrical current: electrolytes, electrode materials. Not: semi-conductors.
13	Construction materials	Substances/materials used as building materials and constructional articles: wall construction materials, road surface materials, ceramic, metal, plastic and wooden construction materials, moulding materials.
14	Corrosion inhibitors	Substances/materials used to prevent corrosion: corrosion-inhibiting additives, rust preventives.
15	Cosmetics	Cosmetic and toiletry formulations.
16	Dust binding agents	Substances/materials used to control finely divided solid particles of powdered or ground materials to reduce their discharge into the air.
17	Electroplating agents	Substances/materials used as a source for a layer of metal deposited on another surface, or that aid in such a deposition.
18	Explosives	Substances/materials characterised by chemical stability, but with the ability to undergo chemical change, rapidly producing a large quantity of energy and gas accompanied by bursting or expansion: blasting agents, detonators, incendiaries.
19	Fertilisers	Substances added to soil to supply chemical elements needed for plant nutrition.
20	Fillers	Materials used to fill cavities or tighten joints, or relatively inert and normally non-fibrous, finely divided substances added to elastomers, plastics, paints, ceramics, etc. usually to extend volume and sometimes to improve desired properties, such as whiteness, lubricity, density or tensile strength.
21	Fixing agents	Substances/materials used to interact with a dye on fibres to improve fastness on fibres. Not: photo chemicals.

Code	Text	Description
22	Flame retardants and extinguishing agents	Substances/materials incorporated into or applied to, a surface of materials, or distributed in the air, to slow down or to prevent combustion: flame retardants, fire preventing and/or extinguishing agents.
23	Flotation agents	Substances/materials used to concentrate and obtain minerals from ores: flotation oil, flotation depressants.
24	Flux agents for casting or joining materials	Substances/materials used to promote the fusing of minerals or prevent oxide formation.
25	Foaming agents	Substances/materials used to form physically, by expansion of compressed gases or vaporisation of liquid, or chemically by decomposition evolving a gas, a foam or cellular structure in a plastic or rubber material: chemical or physical blowing agents, expanding agents, frothers.
26	Food/feedstuff flavourings and nutrients	Substances used in food or animal feedstuffs to produce or enhance taste or odour or nutritional value.
27	Fuels	Substances/materials used to evolve energy in a controlled combustion reaction: gasoline, kerosene, gas oil, fuel oil, petroleum gas, non-mineral oil.
28	Fuel additives	Subcategories: anti-fouling agents, antiknock agents, deposit modifiers, fuel oxidisers.
29	Heat transferring agents	Substances/materials used to transmit or to remove heat from another material: cooling agents, heating agents.
30	Hydraulic fluids and additives	Fluids used for transmitting pressure and EP-additives.
31	Impregnation materials	Substances/materials used to admix with solid materials, which retain their original form: impregnating agents for leather, paper, textile and wood. Not: flame retardants, conserving agents, pesticides.
32	Insulating materials	Substances/materials used to prevent or inhibit the flow of electrical current, heat and light and the transmission of sound.
33	Intermediates	Substances used for synthesis of other chemicals: monomers, prepolymers.
34	Laboratory chemicals	Substances/materials used in laboratories for analytical purposes.
35	Lubricants and additives	Substances/materials entrained between two surfaces and thereby used to reduce friction: oils, fats, waxes and friction reducing additives.
36	Odour agents	Substances/materials used to produce, enhance, or mask odour. Not: food additives, cosmetics.

Code	Text	Description
37	Oxidising agents	Substances that give up oxygen easily, remove hydrogen from other compounds, or accept electrons in chemical reactions, and are used for such purposes.
38	Pesticides, agricultural	Active ingredients and preparations containing one or more active ingredient(s), intended to protect plants or plant products against harmful organisms, or prevent the action of such organisms, influence the life processes of plants, preserve plant products, destroy undesirable plants or destroy parts of plants. Not: nutrients, fertilisers.
39	Non-agricultural pesticides and preservatives	Active ingredients and preparations containing one or more active ingredients intended to render harmless, destroy or prevent the action of harmful or nuisance animal or plant organisms or microorganisms: disinfectants, preservatives.
40	pH-regulation agents	Substances used to alter or stabilise the hydrogen ion concentration (pH): acids, alkalis, buffers.
41	Pharmaceuticals	Medicinal preparations and active ingredients: medicines, veterinary medicines, hormones, diagnostic remedies, dietetics, and other therapeutic preparations.
42	Photo chemicals	Substances/materials used to create a permanent photographic image: desensitisers, developers, fixing agents, photosensitive agents, sensitisers, anti-fogging agents, light stabilisers, intensifiers.
43	Process regulators	Substances used to regulate the speed of a (chemical) process: accelerators, activators, catalysts, hardeners, inhibitors, siccatives, cross linking agents etc. Not: stabilisers.
44	Reducing agents	Substances used to remove oxygen, hydrogenate, or, in general, act as electron donors in a chemical reaction.
45	Reprographic agents	Substances/materials used to reproduce a permanent image: toners and developers for photocopying, toner additives, printing ink, and developers for printing forms. Not: photo chemicals, fixing agents.
46	Semiconductors	Substances having resistivities that are between those of insulators and metals, and are usually changeable by light, heat or electrical or magnetic field, or generate electromotive force upon the incidence of radiant energy: semiconductors, photo-voltaic agents.

Code	Text	Description
47	Softeners	Substances/materials used for softening materials to improve feel, to facilitate finishing process, or to impart flexibility or workability: coalescing agents, bates (leather technology), devulcanising agents, emollients, swelling agents, water softeners, plasticisers.
48	Solvents	Substances/materials used to dissolve, thin, dilute, and extract: extraction agents, solvents and thinners for paints, lacquers, adhesives and other materials.
49	Stabilizers	Substances/materials used to prevent or slow down spontaneous changes in and ageing of materials: antioxidants, anti-siccatives, heat stabilisers, light stabilisers, scavengers, charge stabilisers.
50	Surface-active agents	Substances/materials used to lower the surface and/or interfacial tension of liquids and promote cleaning, wetting, dispersion etc.
51	Tanning agents	Substances/materials used for treating hides and skins.
52	Viscosity adjustors	Substances/materials used to modify the flow characteristics of other substances, or mixtures, to which they are added: pour point depressants, thickeners, thixotropic agents, turbulence suppressor, viscosity index improvers.
53	Vulcanizing agents	Substances/materials added to rubber to aid and speed up vulcanisation: vulcanising accelerators and vulcanisation assistants.
54	Welding and soldering agents	Materials used for welding and soldering: electrodes, flux, powdered metal, wire etc.
55	Others	Substances/materials whose technical functions are not described elsewhere.
56	Cutting fluids	Preparations used to facilitate cutting and other deformation of metal: cutting lubricants, drilling oil and other fluids used for cutting, drilling, grinding, honing, milling, punching, rolling or stamping metal. (Might be covered by Lubricants and/or Heat transferring agents?).
57	Friction agents	Materials used to enhance friction.
58	Grinding materials	Subcategories: glass pellets, steel pellets, sand(paper), emery(cloth).
59	Paints, lacquers and varnishes	Materials which form a surface coating: Covering and protecting lacquers, solid colour or pigment either dry or with a vehicle, primers, anti-fouling, anticorrosive, damp proofing, or fire retarding paints, wood staining agents, etc.

Code	Text	Description
60	Radioactive agents	Radioactive substances/materials.
61	Surface treatment	Materials used to treat surfaces for purposes not elsewhere described: metal-hardening agents, chromatising agents, rust removers, gum, glass etching agents, glazing agents (for paper, textiles, leather, ceramics), gloss reducing agents, dressing agents (for textiles), polishing agents (car wax, stove polish, wax and other polish for floors, furniture, metal, etc.), protective colloids. Not: anti-set-off, anti-static, bleaching, cleaning and colouring agents, corrosion inhibitors, dust binding and electroplating agents, flame retardants, flux agents, impregnation materials, paints and lacquers.
62	Electromechanical components	Materials used as electromechanical components not elsewhere described: commutators, transformers. Not: semiconductors, conductive agents.

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