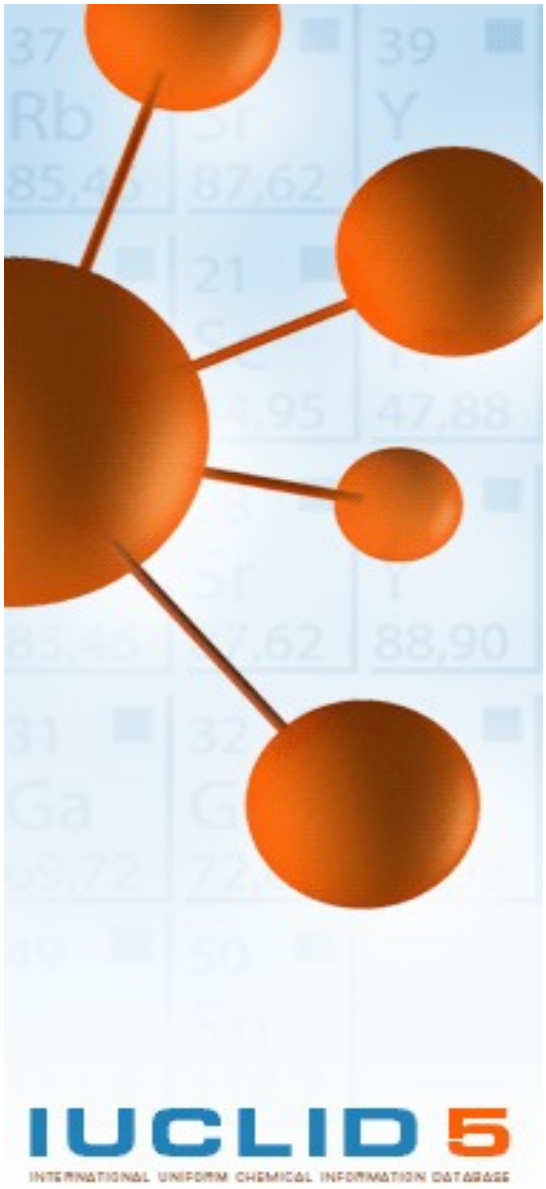

IUCLID 5
Guidance and Support

How to report identified uses for REACH in IUCLID 5.0

July 2008 v 1.0

IUCLID 5 has been developed by the European Commission in association with the OECD and is supported by ECHA

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1. Scope

The purpose of this document is to advice any user of IUCLID 5 on how to fill in use and exposure information to the current IUCLID 5 sections 3.5. This is a temporary procedure until this section is changed in the next release of IUCLID 5. Please note that section 3.6 will also be changed accordingly and therefore the instruction given below also applies to that section.

2. Background

Under REACH each manufacturer and importer of substances will have to develop and assess exposure scenarios for his own markets. It would be efficient for him to work out or use a suite of generic exposure scenarios for the different markets and products, which can be modified case by case if necessary. In doing so, he may be able to link the internal information related to products, markets and customers to exposure and product safety information.

For downstream users it would be efficient to receive standardised exposure scenarios for the relevant applications of the substances in their sector, and not a wide range of different scenarios from different suppliers. In order to i) facilitate standardisation of exposure scenarios and ii) support the "recycling" of exposure scenarios, a **use descriptor system** has been developed and implemented in the "Guidance on information requirements and chemical safety assessment" (published on ECHA website on May 29; http://echa.europa.eu/reach_en.html).

This use descriptor system will also serve as a basis for deriving a short title for exposure scenarios and can be used to identify the suitable exposure estimation entries in the available Tier 1 exposure estimation tools.

The use description is based on four elements:

- sector of use (SU)
- chemical product category (PC)[1]
- process category (PROC)
- article category (AC).

More guidance on the use of those use descriptors is available in the Guidance on information requirements and chemical safety assessment, chapter R12, available on ECHA website (http://echa.europa.eu/reach_en.html, click on guidance and then guidance document).

The descriptors are reported in the Appendices to this document. The lists have been copied from Appendix R. 12-1 to R.12-5 of the Guidance on Information Requirements and Chemicals Safety Assessment, where the derivation and the meaning of the categories is explained in more detail. Chapter R.12 also provides advice on how to describe uses for which no suitable entry can be identified in the pick-lists.

Compared to R.12 (as published on May 29) the descriptor pick-lists have been "cleaned" from elements actually being part of the Guidance:

- The process categories (PROC) related to operation of metals and other minerals have been included into the PROC numbering system.
- In the "sector of use" descriptor (SoU), the column with the conversion to NACE entries has been deleted.
- The guidance on how to describe uses under the entry "others" have been removed from the list. Nevertheless it is recommended that any use that cannot be described in sufficient detail based on the existing entries in the pick-lists should be described in standard terminology in the free-text field "others", based on the systems specifically recommended in R.12. Here reference is made for example to NACE (for Sector of Use), TARIC (for Article Category) and the Nordic UCN system or the ConsExpo system (for Chemical Product Categories).
- SU 10 has been slightly re-phrased.
- "PC 39, personal care products" and "PC 40 extraction agent" have been added.
- Pulp has been added in SU 6 and a subdivision has been made related to "other" production or services (0-1 for "other economic activities related to chemicals" and 0-2 for "other economic activities, not related to chemicals"
- The sub-headlines in the article descriptor for intended release have been removed. Sub-numbering has been added to cover all the categories and to allow for subdivision if relevant, e.g. the registrant sees the need to develop a particular exposure scenario for one of the article sub-categories.

[1] Most of the descriptors refer to preparations for end use.

- AC 33 “candles” has been removed from the descriptors for substances in article with intended releases. The use of substances in candles can be described with a PC category or under “others”.
- All “other” has been moved from the last position in the pick-list to the first position.

3. How to report identified uses in the current version of IUCLID 5.0

Uses have to be reported in IUCLID 5 in the field “3.5 Identified uses and exposure scenarios”. The current structure does not yet contain the descriptors consistently with the *Guidance on information requirements and chemical safety assessment* (developed within REACH Implementation Project 3.2 which was still in progress at the time defining the final version of IUCLID 5.0). It is planned that appropriate changes will be implemented in the next version of IUCLID, expected to be released in early 2009[2].
It is foreseen that section 3.5 (and 3.6) of IUCLID 5 should be modified in the following way[3]:

- introduction of the possibility for “Confidentiality flags”
- Restructuring the section on “identified use and exposure scenario”:
    - Introduce a new pick-list for the application technique (named *process category* in the future) and change of the content of the pick-lists for the other use descriptor
    - Remove the imbrications of the use descriptors
    - Link exposure scenarios to the identified uses (including to attached documents when available)
    - Introduce a confidentiality flag per identified use.

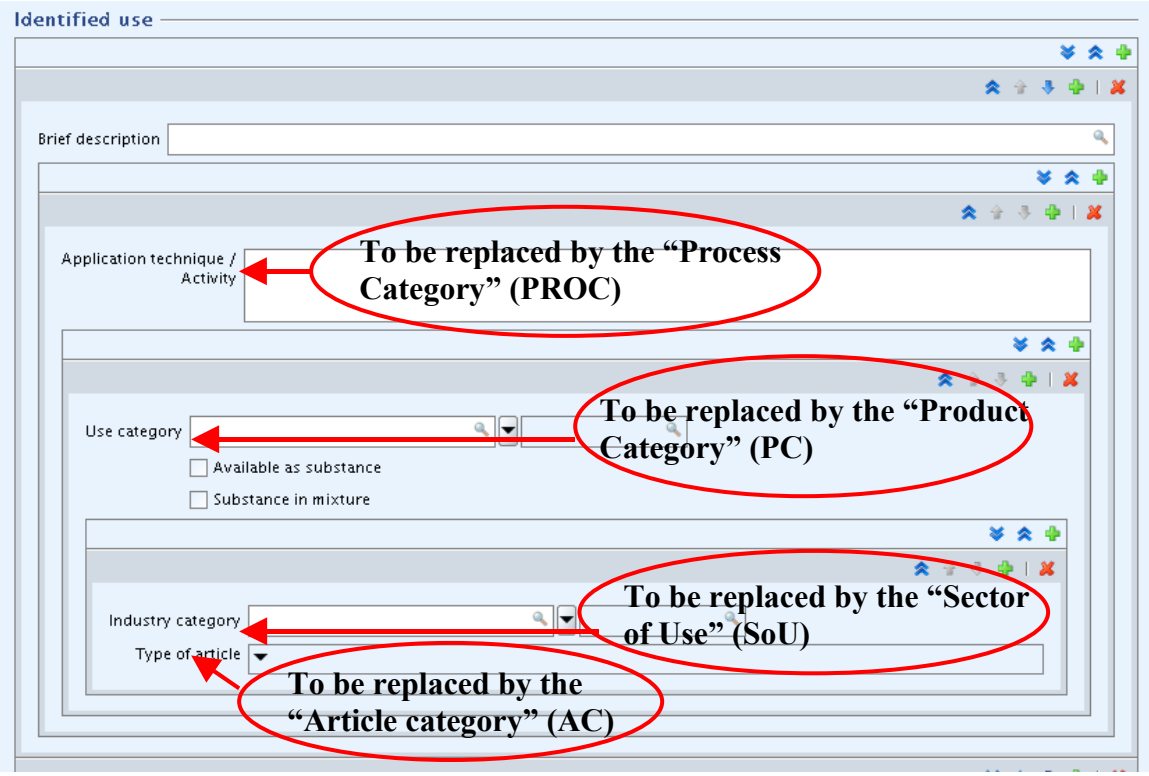
Therefore, a temporary procedure is proposed, so that the users can fill in their current use and exposure information consistently with the *Guidance on information requirements and chemical safety assessment* and in view of the future version of IUCLID. The following advice is given to the users to fill in section 3.5 (and 3.6 when appropriate) of IUCLID:

- The **Application technique** will be replaced by the **Process Category**. It is therefore advised to enter in this field one of the descriptors reported in Appendix 3.
- The **Use Category** will be replaced by the Chemical **Product Category**. As no automatic migration of data will be possible for this field it is advised to select “other products:” and to type in a descriptor of Appendix 2, as this will facilitate the update of the section once the next version of IUCLID 5 is released. Please note that the second part of the picklist on use categories in IUCLID 5 and the chemical product categories in Appendix 2 are to a large extend identical.
- The **Industry category** will be replaced by the **Sector of Use**. In the attached excel table, the conversion between the Industry category and the Sector of use is given. If an Industry category exists with an identified *Sector of Use* this item should be chosen. In this case an automatic migration of the descriptor will be possible when a new version of IUCLID is released. Otherwise it is advised to select “other (NACE code to be used only):” and to type in a descriptor of Appendix 1.
- The **Type of article** will be replaced by the **Article Category**. In the attached excel table, the conversion between the Article type and the Article category is given. If an Article type exists with an identified *Article Category* this item should be chosen. In this case an automatic migration of the descriptor will be possible when a new version of IUCLID is released. Otherwise it is advised to select “C18 - Other (no intended release); specify:” and to type in a descriptor of Appendix 4a or select “Other articles; specify:” and type in a descriptor of Appendix 4b, as this will facilitate the update of the section once the next version of IUCLID 5 is released.

The following screenshot describes the change of fields:

[2] In order to harmonise as far as possible with OECD, a proposal to change the use descriptor system as explained in this paper will be made to OECD (both to the SIAM and the Task force on environmental exposure assessment)

[3] It could happen that slight modifications to the proposal here are introduced, after OECD consultation.

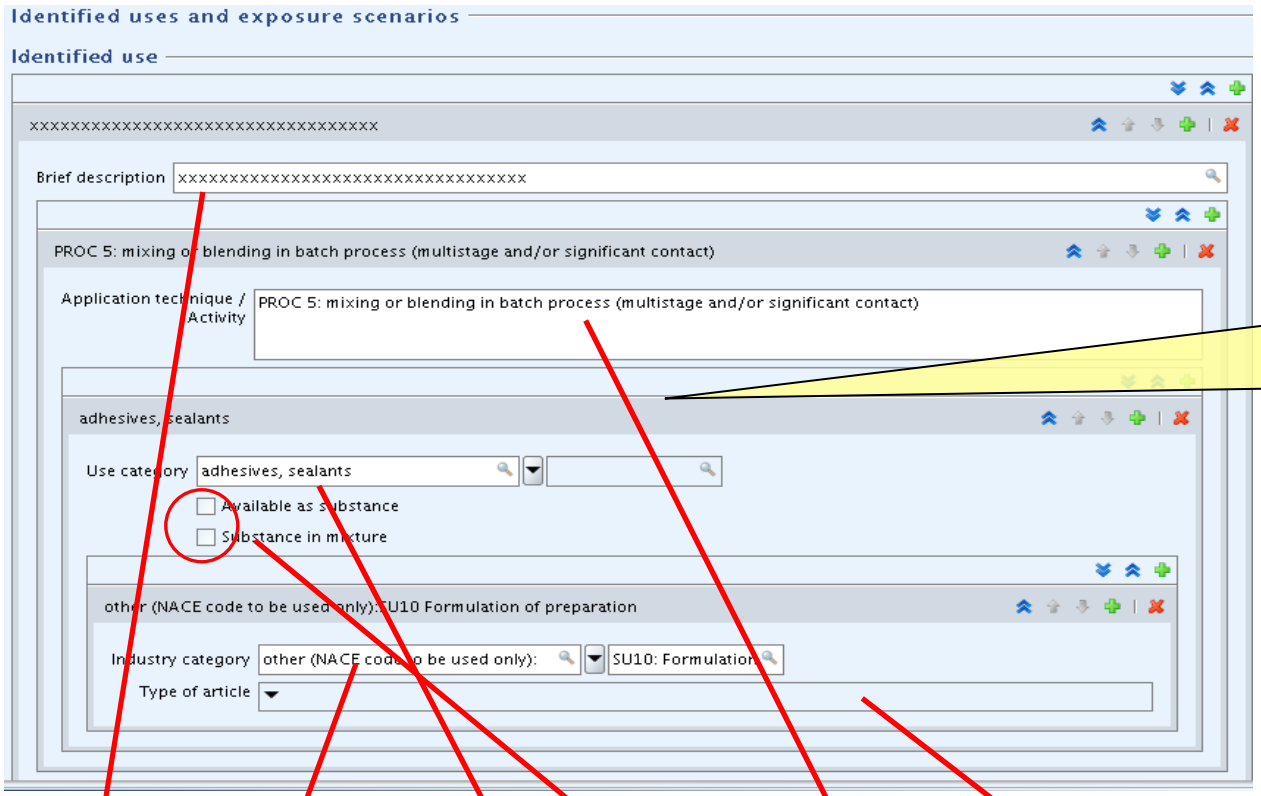


Please note that the "overall use and exposure" section should only be filled for registration under REACH under 10 tonnes.

4. Transfer of the information on the identified uses from IUCLID 5.0 to IUCLID 5.1

Subject to potential additional modifications in the foreseen changes of IUCLID, the following figures show how the information filled in the actual version of IUCLID 5.0 will be transferred in the future version of IUCLID 5.1. The screenshots of the future version of IUCLID 5 are not real and can be subject to revisions.

4.1. Use description

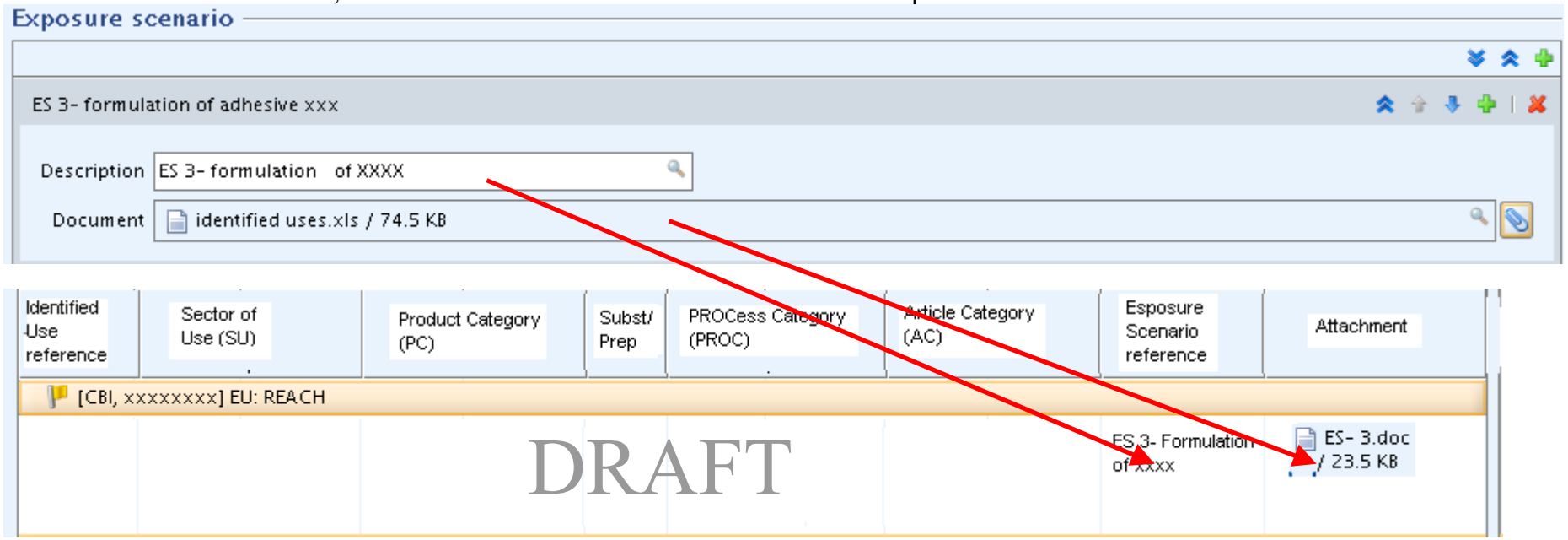


If the registrant chooses to include three different use categories [in future chemical *product category* or *preparation category*] in one use, he should add three different repeatable blocks for "Use category".

Identified Use reference	Sector of Use (SU)	Product Category (PC)	Subst/ Prep	PROCess Category (PROC)	Article Category (AC)	Esposure Scenario reference	Attachment
[CBI, xxxxxxx] EU: REACH							
XXXXXXXXXXXX	SU 10: Formulation of preparation	PC 1: adhesives PC 9: coatings PC32 : polymer preparation	P	PROC 5: mixing or blending in batch processes			

4.2. Exposure Scenarios

When an ES has been attached, then a row in the table will be created. It will not be possible for the transfer of data to link an ES to an identified use.



Appendices

Appendix 1: - Descriptors for Sector of use (SoU) (from Appendix R.12-1 of the Guidance on information requirement and chemical safety assessment)

	Sector of use (SoU)
SU 0-1	Other activity related to manufacturing of chemical products
SU 0-2	Other activity related to manufacture and services
SU 1	Agriculture, forestry, fishery
SU 2	Mining, (including offshore industries)
SU 3	Industrial Manufacturing (all)
SU 4	Manufacture of food products
SU 5	Manufacture of textiles, leather, fur
SU 6	Manufacture of pulp, paper and paper products
SU 7	Printing and reproduction of recorded media
SU 8	Manufacture of bulk, large scale chemicals (including petroleum products)
SU 9	Manufacture of fine chemicals
SU 10	Formulation [mixing] of preparations and/or re-packaging
SU 11	Manufacture of rubber products
SU 12	Manufacture of plastics products, including compounding and conversion
SU 13	Manufacture of other non-metallic mineral products, e.g. plasters, cement
SU 14	Manufacture of basic metals
SU 15	Manufacture of fabricated metal products, except machinery and equipment
SU 16	Manufacture of computer, electronic and optical products, electrical equipment
SU 17	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment.
SU 18	Manufacture of furniture
SU 19	Building and construction work
SU 20	Health services
SU 21	Private households (= general public = consumers)
SU 22	Public domain (administration, education, entertainment, services, craftsmen)
SU 23	Recycling

When an appropriate descriptor does not exist in the above list, “other” should be selected and a NACE code (available at http://ec.europa.eu/comm/competition/mergers/cases/index/nace_all.html) should be used.

Appendix 2: - Descriptor for Types of Chemical Product [PC = Product Category] (from Appendix R.12-2 of the Guidance on information requirement and chemical safety assessment)

PC 0	Other products
PC 1	Adhesives, Sealants
PC 2	Adsorbent
PC 3	Air care products
PC 4	Anti-Freeze and De-icing products
PC 5	Artists Supply and Hobby preparations
PC 6	Automotive Care Products
PC 7	Base metals and alloys
PC 8	Biocidal Products (e.g. Disinfectants, pest control)
PC 9	Coatings and Paints, Fillers, Putties, Thinners
PC 10	Building and construction preparations not covered elsewhere
PC 11	Explosives
PC 12	Fertilizers
PC 13	Fuels
PC 14	Metal surface treatment products, including galvanic and electroplating products,
PC 15	Non-metal-surface treatment products
PC 16	Heat Transfer Fluids
PC 17	Hydraulic Fluids
PC 18	Ink and Toners
PC 19	Intermediate
PC 20	Products such as ph-regulators, flocculants, precipitants, neutralization agents, other unspecific
PC 21	Laboratory Chemicals
PC 22	Lawn and Garden Preparations, including fertilizers
PC 23	Leather tanning, dye, finishing, impregnation and care products
PC 24	Lubricants, Greases and Release Products
PC 25	Metal Working Fluids
PC 26	Paper and Board dye, finishing and impregnation products
PC 27	Plant Protection Products
PC 28	Perfumes, Fragrances
PC 29	Pharmaceuticals
PC 30	Photochemicals
PC 31	Polishes and Wax Blends
PC 32	Polymer Preparations and Compounds

PC 33	Semiconductor
PC 34	Textile dyes, finishing and impregnating products
PC 35	Washing and Cleaning Products (including solvent based products)
PC 36	Water softeners
PC 37	Water treatment chemicals
PC 38	Welding and soldering products, flux products
PC 39	Cosmetics, personal care
PC 40	Extraction agents

When no appropriate descriptor is available “other product” should be selected and a category should be specified in the free text field.
It is recommended to make reference to sub-categories covered in the ConsExpo fact sheets (consumer products, http://www.rivm.nl/en/healthanddisease/productsafety/ConsExpo.jsp) or in one of the Nordic use categories (UCN, http://195.215.251.229/fmi/xsl/spin/SPIN/guide/menuguide.xsl?-db=spinguide&-lay=overview&-view#)

Appendix 3: - Descriptor for process categories [PROC] (from Appendix R.12-3 of the Guidance on information requirement and chemical safety assessment)

Descriptor		Examples and explanations
PROC 0	Other process	
PROC 1	Use in closed process, no likelihood of exposure	Use of the substances in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems.
PROC 2	Use in closed, continuous process with occasional controlled exposure	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. It is not high integrity and occasional expose will arise e.g. through maintenance, sampling and equipment breakings.
PROC 3	Use in closed batch process (synthesis or formulation)	Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, e.g. through enclosed transfers, but where some opportunity for contact with chemicals occurs, e.g. through sampling
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	Use in batch manufacture of a chemical where significant opportunity for exposure arises, e.g. during the charging, the sampling or discharge of material, and when the nature of the design is likely to result in exposure.
PROC 5	Mixing or blending in batch processes (multistage and/or significant contact)	Manufacture or formulation of chemical products or articles using technologies related to mixing and blending of solid or liquid materials, and where the process is in stages and provides the opportunity for significant contact at any stage.
PROC 6	Calendering operations	Processing of product matrix Calendering at elevated temperature an large exposed surface
PROC 7	Industrial spraying	Air dispersive techniques Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting; Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls; in case of coating, overspray may lead waste water and waste.
PROC 8	Transfer of chemicals from/to vessels/large containers at non dedicated facilities	Sampling, loading, filling, transfer, dumping, bagging in non dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.
PROC 9	Transfer of chemicals into small containers (dedicated filling line)	Filling lines specifically designed to for both, capturing vapour and aerosol emissions and minimise spillage
PROC 10	Roller application or brushing	Low energy spreading, Including cleaning of surfaces. Substance can be inhaled as vapours, skin contact through droplets, splashes, working with wipes and handling of treated surfaces.
PROC 11	Non industrial spraying	Air dispersive techniques Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting; (also includes manufacture of foam, including blowing operations) Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls; in case of coating, overspray may lead waste water and waste.
PROC 12	Use of blow agents for foam production	

PROC 13	Treatment of articles by dipping and pouring	Immersion operations Treatment of articles by dipping, pouring, immersing, soaking, washing out or washing in substances; including cold formation or resin type matrix. Includes handling of treated objects (e.g. after dying, plating,), Substance is applied to a surface by low energy techniques as dipping the article into a bath or pouring a preparation onto a surface.
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelettisation	
PROC 15	Use of laboratory reagents in small scale laboratories	Use of substances at small scale laboratory (< 1 l or 1 kg). Larger laboratories and R+D installations should be treated as industrial processes.
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	Covers the use of material as fuel sources (including additives) where limited exposure to the product is its unburned form is expected. Does not cover exposure as a consequence of spillage or combustion.
PROC 17	Lubrication at high energy conditions and in partly open procecc	Lubrication at high energy conditions (temperature, friction) between moving parts and substance; significant part of process is open to workers or to the environment The metal working fluid may form aerosols or fumes due to rapid moving metal parts; exhausted cutting fluids need to be disposed off as waste
PROC 18	Greasing at high energy conditions	Use as lubricant where significant energy or temperature is applied between the substance and the moving parts.
PROC 19	Hand-mixing with intimate contact (only PPE available	Addresses occupations where intimate and intentional contact with substances occurs without any specific exposure controls than PPE.
PROC 20	Heat and pressure transfer fluids (closed systems) in dispersive use	Motor and engine oils, brake fluids Also in these applications, the lubricant may be exposed to high energy conditions and chemical reactions may take place during use. Exhausted fluids need to be disposed of as waste. Repair and maintenance may lead to skin contact. Leakage during use may lead to environmental exposure.
PROC 21	Low energy manipulation of substances bound in materials and/or articles	Manual cutting, rolling or assembly of material/article, possibly resulting in the release of fibres or rubber fumes;
PROC 22	Potentially closed operations with minerals at elevated temperature	Activities at smelters, furnaces, refineries, coke ovens. Exposure related to dust and fumes to be expected. Emission of direct cooling may be relevant.
PROC 23	Open processing and transfer of minerals at elevated temperature	Sand and die casting, tapping and casting melted solids, raking melted solids paving; Exposure related to dust and fumes to be expected. Emission of direct cooling may be relevant.
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	Substantial thermal or kinetic energy applied to substance by grinding, mechanical cutting, drilling or sanding. Release of solids (dust) or fumes to be expected
PROC 25	Hot work operations with metals	Welding, soldering, gouging, brazing, flame cutting Exposure due to the release of fumes to be expected.

Appendix 4a: - Descriptors for substances in articles with no intended release [AC] (from Appendix R.12-4 of the Guidance on information requirements and chemical safety assessment)

AC 0	Other Articles
AC 1-1	Passenger cars and motor cycles
AC 1-2	Other vehicles: Railway, aircraft, vessels, boats, trucks, and associated transport equipment
AC 2	Machinery and mechanical appliances thereof
AC 3-1	Electrical and electronic products, e.g. computers, office equipment, video and audio recording, communication equipment
AC 3-2	Electrical batteries and accumulators
AC 3-3	Electrical and electronic products: Household appliances (white ware)
AC 3-4	Photographic and reprographic articles: cameras, video cameras
AC 4	Glass and ceramic products: dinner ware, pots, pans, food storage containers
AC 5-1	Fabrics, textiles and apparel: bedding and clothing
AC 5-2	Fabrics, textiles and apparel: curtains, upholstery, carpeting/flooring, rugs,
AC 6	Leather products: apparel and upholstery
AC 7-1	Metal products: cutlery, cooking utensils, pots, pans,
AC 7-2	Metal products: toys
AC 7-3	Metal products: furniture
AC 8-1	Paper products: tissue, towels, disposable dinnerware, nappies, feminine hygiene products, adult incontinence products, writing paper
AC 8-2	Paper products: newspaper, packaging
AC 9	Photographic and reprographic articles: films, printed photographs
AC 10-1	Rubber products: tyres
AC 10-2	Rubber products: flooring
AC 10-3	Rubber products: footwear
AC 10-4	Rubber products: toys
AC 10-5	Other general rubber products
AC 11-1	Wood and wood furniture: flooring
AC 11-2	Wood and wood furniture: furniture
AC 11-3	Wood and wood furniture: toys
AC 12-1	Constructional articles and building material for indoor use: wall construction material ceramic, metal, plastic and wood construction material, insulating material.
AC 12-2	Constructional articles and building material for outdoor use: wall construction material, road surface material, ceramic, metal, plastic and wood construction material, insulating material.
AC 13-1	Commercial/consumer plastic products like disposable dinner ware, food storage, food packaging, baby bottles
AC 13-2	Plastic products: Flooring
AC 13-3	Plastic products: Toys

Appendix 4b: - Descriptors for substances in articles with intended release [AC] (from Appendix R.12-5 of the Guidance on information requirement and chemical safety assessment)

AC30	Other articles with intended release of substances
AC31	Scented clothes
AC32	Scented eraser
AC34	Scented toys
AC35	Scented paper articles
AC36	Scented CD
AC37	Other scented articles
AC38	Packaging material for metal parts, releasing grease/corrosion inhibitors
AC39	Other articles releasing grease or corrosion inhibitors

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