ISOPA interpretation on selection of Use Descriptors:

We refer to the Guidance on Information requirements and Chemical Safety Assessment (CSA), Chapter R12 – Use Descriptor System. Reference: ECHA – 2010 – G-05-EN, dated 26.03.2010

[Link: *http://guidance.echa.europa.eu/guidance4_en.htm*]

Sectors of Use [SU]

1. There are 3 Main User Groups, being **SU 3** [industrial uses], **SU 21** [consumer uses] and **SU 22** [Professional uses]. All other sectors of use at industrial level, including **SU 8** and **SU 9** [Manufacturing of Chemicals/Fine chemicals] and **SU 10** [Formulation/repackaging/chemical], are sub sectors of SU3 and are not strictly required to describe. If they are described as a use they should be described in addition to **SU 3**, e.g. **SU 3/SU 10**, and not as sector of use on its own, e.g. **SU 10**.

2. **SU8** and **SU9** [Manufacturing of Chemicals/Fine chemicals] is **only** related to the synthesis of MDI/TDI/polyols, i.e. members of ISOPA. Eventually, it applies to producers of chemically modified isocyanates, e.g. specialised system houses, who then become substance manufacturers and may have their own REACH obligations. In general, **SU8** and **SU9** will not be relevant to the "common" downstream user of Isocyanates and polyols who is making Polyurethane products/articles.

3. The "common" downstream user of MDI, TDI or polyol should select between **Sector of Use SU 3/SU 22/SU 21** depending whether uses are Industrial, Professional or Consumer. We consider all other SU's to be covered by these main group of Sectors of Use applicable for PU (Polyurethanes) downstream, i.e. **SU 3** (Industrial Uses) may include: SU 10 SU 11, SU 12, SU 13, *SU14*, SU 16, SU 17, SU 18, SU 19, SU 20, SU 23 applications. **SU 22** (Professional Uses) may include: SU 2, SU 12, SU 13…

4. ISOPA considers **SU 10** as only applicable for formulators, repackers/distributors or producers of modified isocyanates (e.g. specialised system houses) and manufacturers of other products containing MDI/TDI/polyol, e.g. resin makers, who also should consider whether they are manufacturers themselves of substances and have a REACH registration obligation. It is not considered relevant for downstream users that self-formulate preparations for internal consumption for manufacturing PU products and/or articles, these are considered as **SU 3**, e.g. manufacturing of coatings or adhesives is considered to be covered under **SU 3**.

5. For **SU 3** (Industrial Uses), the necessary PROC's and ERC's are included to cover for in-house formulation of preparations prior to the manufacture further downstream.

6. Following the guidance of the Use Descriptor System [R12] for **SU3/SU10/SU22** only PROC's and ERC's are assigned and for **SU 21** [Consumer Use] only PC's and ERC's.

7. The manufacturing of prepolymers based on MDI/TDI or polyols would be covered by ISOPA under SU3 (industrial use) and SU22 (professional use) for each application.

Process Categories [PROC]

1. **PROC 2**, **PROC 3** and **PROC 4** are normally intended for manufacturing chemical products and not for manufacturing articles. However, ISOPA believes that these PROCs represent at best the reflection of typical PU processes, e.g. occasional interventions of enclosed panel production [**PROC 2**], closed molding [**PROC 2 or 3**], open molding [**PROC 4**] processes manufacturing.

2. **PROC 5** related to mixing and blending in batch processes for formulation of preparations and articles (multistage and/or significant contact). ISOPA regarded PROC 5 as representative for mixing processes, where significant exposure could occur, e.g. open mixing processes.

3. **PROC 7 is** related to industrial spraying activities. These activities can occur in a closed environment in closed well ventilated cabinets, e.g. for spraying adhesives on a substrate. It is also regarded applicable for spraying MDI on a substrate in a partially enclosed setting where very efficient ventilation is used, e.g. spraying on a stream of particles as is used sometimes for dry blending systems for the production of wooden boards. Finally, it is also regarded applicable for cleaning areas where particles could be coated with MDI by the use of high pressure. This cleaning technique occurs when vacuum cleaning techniques fail to clean properly in difficult to reach locations. The technique will create airborne particles coated with MDI and can therefore be regarded as similar to a spraying activity, although the percentage of MDI on these particles is typically quite low (<10% on dry weight)

4. **PROC 10 is** related to rolling and brushing activities. These is considered suitable for low energy spreading activities such as using One Component Foam for insulating small cavities, windows at professional level, for cleaning surfaces contaminated with non fully cured low residual MDI containing particles, for rolling uncured films etc.

5. **PROC 12** related to the use of blowing agents forwarded by trade associations or individual customers is not considered as relevant for the ISOPA end uses since the ISOPA end uses only cover MDI/TDI/polyol substances, excluding other additives, such as blowing agents. **PROC 12** forwarded by trade associations or individual customers for request to be included as part of ISOPA intended use is considered not relevant and pose no obligation to ISOPA members to adopt **PROC 12** in the ISOPA use descriptors.

6. **PROC 15** related to laboratory activities is considered to be relevant for all PU applications at **industrial level [SU3]**.

7. **PROC 19** related to intended and intimate contact and forwarded by trade associations or individual customers is not considered as an intended use at industrial level [SU3] or professional level [SU22], sine this PROC is intended for uses where manual contact with substances is considered as intentional or general practice, e.g. hair dresser, artists working with clay. For manual activities **PROC 5** [“mixing or blending in batch processes for formulation of

preparations and articles (multistage and/or significant contact)"] has been regarded as representative for these exposure scenarios.
PROC 19 forwarded by trade associations or individual customers for request to be included as part of intended use will not be considered as intended use in the ISOPA use descriptors and pose no obligation to ISOPA members to adopt **PROC 19** in the ISOPA use descriptors.

8. **PROC 21** at **industrial level or professional level [SU 3/SU 22**] related to low energy manipulation of substances bound in other materials and/or articles.
ISOPA regards **PROC 21** applicable for post foaming/curing handling activities such as demoulding, trimming, manual cutting etc. ISOPA regards **PROC 21** as NOT applicable for fully cured PU products. ISOPA regards fully cured PU products as products which are 24 hours old post production and/or PU products which are no longer hot or sticky or otherwise proved that residual monomeric diisocyanates do not pose a risk. Fully cured products do not require exposure scenarios.
PROC 21 forwarded by trade associations or individual customers for request to be included as part of intended use for scenarios including fully cured PU products will not be considered as intended use in the ISOPA use descriptors and pose no obligation to ISOPA members to adopt **PROC 21** for these uses in the ISOPA use descriptors.
Automatic cutting operations typically occurring immediately after foaming/pressing are considered to be exposure scenario's covered under **PROC 2**, **PROC 3** or **PROC 4** since workers are believed only occasionally to be located at those areas.

9. ISOPA regards **PROC 24,** high energy work-up like sawing or milling activities of massive metals or substances bound in materials and/or articles and possibly resulting in exposure to dusts containing very low residual amount of MDI due to the incompleteness of curing process. High energy cutting is only applied for cutting hard surfaces and this is a scenario applicable for ES 9 where wooden boards for which MDI has been used as a bonding agent MDI PROC 24 is also applied for cleaning blenders/vessels/containers where the MDI has become solid and hammering techniques are required for cleaning purposes. These activities normally occur on weekly to monthly basis. This activity can occur in manufacturing (ES1) or in Composite Wood facilities (ES9)

Article Categories [AC]

1. Following the ECHA guidance of the Use Descriptor System [R12] **Article Categories** are only relevant when the **service life** of article is of relevance for exposure. Exposure during service life is considered relevant when the substance is intended to be released from an article or when the substance is still present at levels > 0.1% in article with no intended release.

   Based on current available data, ISOPA does not consider both conditions relevant for fully cured PU products because the substances covered [MDI, TDI, and polyols] are chemically reacted upon use and are not becoming part of an article and therefore are no longer available for further life cycle steps, i.e. consumer/worker service life cycle stage, or emission to the environment.

For this reason, **Article Categories** are not used. **Article Categories** forwarded by association or customers do not pose an obligation to ISOPA members to adopt these in the ISOPA use descriptors. Unless it can be demonstrated that PU articles are produced with intended release of substances being part of that article.

Product categories [PC]:

1. Following, ***the Guidance on Information requirements and Chemical Safety Assessment (CSA), Chapter R12 – Use Descriptor System. Reference: ECHA – 2010 – G-05-EN, dated 26.03.2010*** for **SU21** [Consumer Use] only PC and ERC's are required.
2. **PC 10**, Building and Construction Preparations not covered elsewhere, has been deleted as PC in ***the Guidance on Information requirements and Chemical Safety Assessment (CSA), Chapter R12 – Use Descriptor System.*** *This PROC was assigned to the consumer use of One Component Foam and has now been assigned PC32 "Polymer preparations and compounds".*

Environmental release categories [ERC]:

1. **ERC 5**: ERC 5 describes industrial use of substances in articles with a specific function and substances remaining in the article after having been used as processing aids for some PU applications like Flexible Foam, Rigid foam, elastomers and TPU and part of other PU composites applications, MDI/TDI/polyols do not have a specific function, such as e.g. a fire retardant. For the other applications MDI/TDI has a particular function as a binding/curing agent and can be regarded in some occasions as processing aid.

2. ***ERC 6a:*** *ERC6a describes the industrial use of a substance resulting in manufacturing another substance. ISOPA regards it as possible that MDI/TDI/polyol can be used by formulators or resin manufacturers whereby they are transformed to other substances and whereby the original MDI/TDI/polyol are below 0.1% of the final material/product/substance.*

3. ***ERC 12a:*** *ERC12a describes the (low) release of substances (intended or not) from materials or articles as a result of processing these articles/materials by workers. Typical operations are cutting, grinding etc related to PROC21, PROC24 and PROC25.*
   Since a PU product is fully cured, i.e. 24 hours old, not hot or sticky anymore [see position on PROC2, PROC21 and PROC24 and Article Categories above],it is regarded as an article to be used by consumers and not workers, therefore this ERC12a is regarded as not applicable. PROC21 is related to not fully cured PU products and is still in the process of becoming an article and therefore not linked to ERC12a.

Downstream Aassociations are requested to contact ISOPA In case of discrepancies with use descriptors to ensure continued alignement with downstream.