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Tiered approach strategy for occupational risk assessment and management of innovative nanotechnology

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ABSTRACT
This work addresses the occupational and environmental risk assessment for the safe management of the metal matrix aluminum nanocomposites production (Al-MMNCs) in an industrial facility under an EU project using a tiered methodology approach. This structured strategy included the application of sequential nano specific tools with a life cycle perspective for the nanoproduct under development (Stoffenmanager Nano and Licara NanoScan tools), together with an exposure monitorization campaign of the industrial plant using two measurement equipments (Disc mini from Testo and NanoScan SMPS from TSI).

Key-words: Nanomaterials, Risk Assessment, Exposure Assessment, Tiered Approach, real-time monitoring equipment

1. Introduction

Nanotechnology as an emerging field has been revolutionizing the materials sector in a broad range of industrial and commercial applications, due to the nano-scale enhanced material properties. A high socio-economic impact is associated with nanotechnology, such as improvement of people's quality of life (*e.g.* cancer therapies) and the economic development (*e.g.* increased number of jobs) (1). The European Commission defines nanomaterial (NM) as '*a natural, incidental, or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm'* (2).

2. Risk assessment of nanocomposites pilot and industrial lines

2.1 Synthesis of the Al-7 wt% Si-10wt% nSiC, Al-30wt% nSiC and Al-45wt% TiC nanocomposites

The nanocomposites are intermediate species for the preparation of the nanoproducts. The aluminum metal matrix nanocomposites under study are Al-7 wt% Si-10wt% nSiC, Al-30wt% nSiC and Al-45wt% TiC, which are produced through a mechanical alloying process, high-energy ball milling (HEBM). Mechanical alloying (MA) is a solid-state powder processing technique involving repeated welding, fracturing, and rewelding of powder particles in a high-energy ball mil. The production of Al-SiC nanocomposites silicon carbide nano powder and aluminum powder are milled together. To produce the AL-Ti nanocomposites titanium carbide is synthesized during the HEBM process by Self-propagating High-temperature Synthesis (SHS) reaction using graphite and metal granular titanium. This combination of MA and SHS is denominated Mechanically Activated Self-propagating High-temperature Synthesis (MASHS). This manufacturing process starts with the weighing of the NM and metallic powders in proportion and then these materials are mixed in a closed tank to be homogenized. Then the mixed powder is loaded in the HEBM chamber for the mechanical alloying process by HEBM, which occurs inside an enclosed room. After the manufacturing of the nanocomposite through HEBM, the powder output is unloaded from a vial to a jar through a closed-loop inert gas suction system. Then, this powder goes through a sieving process and only the particles with dimensions >75µm are manually packaged into plastic bags, while the particles with dimensions <75µm are re processed. Plastic bags are then vacuum sealed in automatic packaging machinery.

2.2 Qualitative hazard identification of nano-powders

The first step of the risk assessment at a workplace begins with the qualitative hazard identification of the NMs and nanoproducts, which is accomplished by gathering information regarding their physic-chemical properties, hazard classification and exposure limits. The nanocomposites show a significant lack of data in terms of physico-chemical properties, toxicological effects and exposure limit values. Moreover, for the aluminium/silicon carbide (Al-SiC), the exposure limit values are related to the aluminum bulk material and not with the nanocomposite itself. Indeed, the exposure limit values both for the NMs and nanocomposites are in mass doses (mg/m^3), which do not distinguish the type of nano-forms.

2.3 Preliminary exposure assessment of nano-powders at the pilot and industrial lines

The preliminary occupational exposure assessment consists in establishing the scenarios and the potential routes of exposure to workers exposure to NMs during the manufacturing process(3). Therefore, it requires the characterization of the manufacturing process, as well as the identification of the physicochemical and hazardous properties of NMs. The activities in the manufacturing process that can potentially lead to release of NMs are the weighing, sieving, and packaging activities, as the mixing activity occurs inside a closed tank and the HEBM activity occurs inside an enclosed room. The workers are not allowed in the HEBM room while the HEBM process is running. Moreover, in this manufacturing process, several activities are performed manually, such as the NM weighing, transference tasks between some workstations, and pouring of the powder for mixing and packaging, which could potentially lead to the operator exposure.
The manufacturing process under study already has control measures implemented to mitigate the exposure, such as engineering control (*i.e.* general ventilation system and local exhaust ventilation (LEV)in some of the workstations), and personal protective equipment *(i.e.* operators wear disposable gloves and PPF3 masks).
The potential exposure routes are inhalation, dermal and ocular, with inhalation being considered to be the primary route by which NMs could enter the human body, as nano-powders are used in the manufacturing process line. Exposure by ingestion can also occur due to o unintentional transfer to mouth after dermal exposure.
The lack of hazards identification and occupational exposure limits (OELs) for the nanocomposite powders under analysis motivates the adoption of a structured approach for the exposure risk assessment and management of workers and the general public, i.e. the Tiered approach

3. Tiered Approach methodology

The tiered approach is a methodology to perform exposure assessments to nanomaterials in occupational scenarios. It consists of three hierarchy levels: initial assessment (tier1), basic exposure assessment (tier2) and expert exposure assessment (tier3) (fig). The uncertainty decreases as the method progresses along the chain. The tiers can be applied separately to obtain specific objectives(3,4)

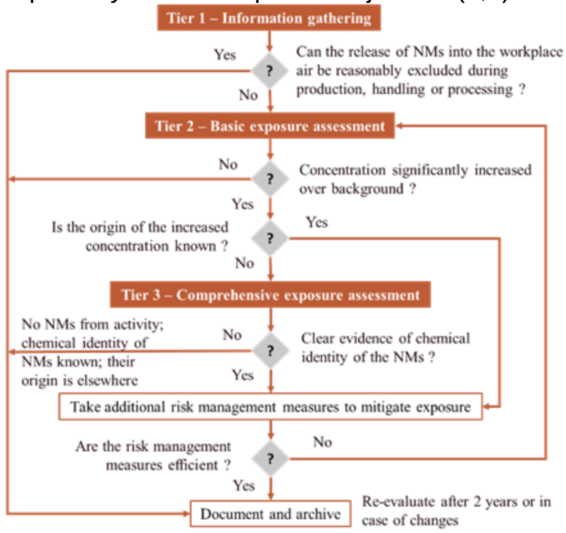

Figure 1: Schematic representation of the Tiered approach for exposure risk assessment to nanomaterials (adapted from (10)).

Application of Tier 1: Stoffenmanager Nano and Licara NanoScan tools

The initial assessment of the risk of exposure (Tier 1 of the Tiered approach) aims at evaluating the potential release and emission of airborne NMs based on information gathering in the qualitative hazard identification and the preliminary exposure assessment, to support the decision-making process regarding the need of an additional assessment. Among the range of tools available for risk screening and/or management of NMs, the Stoffenmanager Nano tool was selected to be used in Tier 1, as it enables to assess and manage the risk of inhalation exposure to NMs and nano products at workplace. Licara NanoScan tool was also selected for Tier 1, as it enables to screen the risks and benefits of nano products by establishing comparisons with conventional non nanoproducts within a life cycle perspective (5,6).

3.1 Application of Tier 2: exposure monitorization methodology

For the basic exposure assessment (Tier 2 of the Tiered approach), a quantitative risk analysis of workers exposure was implemented in the manufacturing process of nanocomposites in the industrial line to evaluate if there is a significant exposure of workers to nano-silicon carbide (nSiC) during the production of the nanocomposite powder (Al-30 wt% nSiC) and to propose appropriate control measures to mitigate exposure if necessary. The monitorization campaign took place in the industrial plant of the H2020 project partner in Venice (Italy) during 1 day in July 2022.

A multi metric approach was adopted, considering that it is the recommended approach to overcome the lack of consensus in the nanotechnology scientific community regarding the most suitable metrics to be use (7). Therefore, two different equipment were used in this study:

- The Disc mini 2.0 from Testo (Miniature Diffusion size charger Classifier), which measures the particle concentration (pt/cm3), the mean particle size diameter (nm), and the Alveolar Lung Deposition Surface Area (LDSA) ($\mu m2/cm^3$) of particles with a modal diameter in the range of 10-300 nm and with 1 s time resolution(8).
- The NanoScan SMPS (Scanning Mobility Particle Sizer) Nano particle Sizer 390 TSI, which measures the concentration distribution by size (pt/cm^3) with a modal diameter in the range of 10-420 nm and concentrations from 10-106 of particles (9).

Moreover, an anemometer Testo 410-1 was also used to measure temperature, relative humidity, and air flow in the working environment.

The relationship between the emission sources related with the manufacturing process represented, and the background (NMs emission from other sources than the target manufacturing process) was evaluated by performing background (BG) measurements before the manufacturing process begun at a point close that of the process (near field, NF, ≈ 3m) as well as far from the work area (far field, FF, ≈ 10 m), both inside the building. Background far field measurement was only performed for the packaging workstation.

Note that at the time of the monitorization campaign of the nanocomposites industrial line, the sieving activity was eliminated from the manufacturing process, as the H2020 project partner observed that the optimization of some of the nanocomposite product properties were being influenced by the sieving activity.

The industrial plant is divided in three rooms, which are inside the main building: room 1 where powders are weighted, room 2 where the HEBM takes place to produce the nanocomposites, and room 3 where the packaging of the nanocomposites occurs (room 3). The main building is equipped with a general ventilation system, while the three rooms are equipped with two types of local ventilation systems, *i.e*. flexible LEV and extraction workbench, which are connected in series between the rooms. During the manufacturing process only the operators were allowed in the HEBM room for the loading and unloading of the HEBM chamber.

To evaluate the potential exposure of workers to NMs during the nanocomposite manufacturing process, the recommendation of EN 17058 (10) was adopted, which states that the total particle concentration is considered to be significant if data fits equation 1.

$$M_{act} > M_{bgr} + 3 \times \sigma_{bgr} \qquad (1)$$

Where, M_{act} is the mean concentration of NM's during activity, M_{bgr} is the mean background concentration of NM's and σ_{bgr} is the standard deviation of the background concentration.

4. Results

4.1 Analysis of the Tier 1 results: Stoffenmanager Nano and Licara NanoScan tools

Hazard classifications depend on the available information regarding the hazard identification of the NMs and nanocomposites. For this reason, different hazard classifications were obtained for the different activities analyzed, depending on NMs or nanocomposites used/produced. The weighing activity of NMs was classified as average hazard class (B), which results from the hazard identification of the NMs and the application of the Stoffenmanager approach for hazard banding, where the NMs are attributed to be harmful/irritant. For the remaining activities where the mixture of materials and the nanocomposite is produced and used, the hazards are not identified and, as a consequence their hazard classification in the Stoffenmanager Nano tool is obtained based on the parent materials. Therefore, for these activities, a very high hazard band (D) was obtained, as these substances are not included in the list reported by OECD and their parent materials are not classified as carcinogenic,

mutagenic, toxic for reproduction or sensitizing. Finally, the hazard classification obtained for the activities of the pilot and industrial lines were the same, as the NMs and nanocomposites used were the same.
The exposure band score depends on several factors such as the existing control measures, the distance from the field source, use of PPE. For the pilot line the weighing and packaging activities obtained the high band for exposure while for the industrial line the medium band was obtained. The activities obtained the low band and HEBM and sieving obtained the high band for the pilot plant and for the industrial plant average. Mixing activity was given low band for both lines. The differences between the activities in the exposure bands may result from the fact that mixing, HEBM and sieving activities are performed with an enclosure of the source, *i.e*. in closed containers. Moreover, during HEBM activity no operators are allowed to enter the HEBM room.
The Stoffenmanager risk matrix combines the hazard and exposure bands to attribute a risk priority. As this tool follows the precautionary principle, the risk matrix is conservative in what concerns the uncertainty associated with the use of NMs(6). Thereby for the activities that a high hazard band is given a low-risk priority band cannot be assigned and the measure suggested by the tool often reduces the exposure and may lead to a lower exposure class but is insufficient for changing the risk priority. Given the effect on exposure, it is recommended to consider the application of control measures. Although the risk priority does not change with the application of risk measures it is recommended to apply control measures, in this a glove box in weighing and packaging activities to prevent emissions into the air and potential exposure to workers.
The Licara NanoScan tool requires the preliminary use of the Stoffenmanager Nano tool, to define the hazard and exposure bands to be used in the occupational health risks group of Licara NanoScan too(5)l. Therefore, three scenarios were established depending on the variation of hazard and exposure bands for the different activities of the manufacturing process under study in the industrial line to facilitate the application of the Licara NanoScan tool. The Licara NanoScan tool gives as an output the benefits and risks of the nanocomposite (new nanoproduct) comparatively to aluminum alloys (traditional non-nanoproduct). Moreover, a combination of total risks and benefits is also obtained as a final output for the decision-making process. In all the scenarios the overall benefits outweigh the risks which indicates that it is advisable to proceed with product development.

4.2 Analysis of the Tier 2 results

The results obtained through the monitorization campaign undertaken in the industrial line of nanocomposites production using both Disc mini 2.0 and NanoScan SMPS equipment are shown and discussed in the sections below. Additionally, a short comparative analysis between the metrics used by the two monitorization equipment used is also performed.
The ventilation systems in the weighing, HEBM and packaging workstations does not use HEPA filters, which enables a NMs collection efficiency close to 100 % in the NMs size range (11,12). As NMs filtration is not adequate there is the potential release of nano-powders into the outdoor environment. The average values of air flow rate measured near the extraction workbenches during the weighing and packaging activities was 1,9 m/s and 0,8 m/s, respectively. Based on the Health and Safety Authority (2014) (13), the weighing activity occurred with a high air flow rate, while the packaging activity with an average air flow rate. Note that the LEVs systems and extraction for the workbenches are connected in series between different rooms, which means that the air flow rate can vary. No glasses or coats were worn.

Figure 2 and Figure 3 shows the particle size measurements performed in the background near field (BG-NF) and/or far field (BG-FF), and for the weighing, HEBM and packaging activities, obtained with **disc mini 2.0**. According to the Commission definition of NM, (NMs were detected in the background measurements, as 100% of the constituent particle of the material in the background are in nanoscale dimension particles (1-100 nm). The particles detected by the disc mini equipment for weighing and packaging activities are NMs (100% of particles have a size lower than 100 nm). During the HEBM activity are below 100 nm, except during the HEBM unloading that shows a significant increase of particles dimensions. Note that during the HEBM activity, the nanocomposite powder is produced through repeated welding, fracturing, and re-welding of particles in a high energy ball mill. As a result, during the unloading of HEBM

chamber, coarser particles were released and detected by the disc mini equipment.
The lung deposited surface area (LDSA) considers the deposition efficiency of particles in different compartments of the lung-based model published by the International Commission for Radiological protection and defined for a reference working person (ICRP, 1994) (14). It has been shown that the LDSA given by a unipolar diffusion charging (*i.e.* Disc mini equipment) is associated to the fraction of the particle surface area concentration that would deposit in either the alveolar or the thoracic region of human lungs, for a particle size range of 20-400 nm (15). The particle size range covered by the disc mini 2.0 equipment is 10-300nm. LDSA reference values of 23 ± 8,4 $\mu m^2/cm^3$ and 16.9 ± 6,0 $\mu m^2/cm^3$ were proposed by Geiss et al. (2016) to be associated to a low-polluted outdoor and indoor environment and ambient air, respectively. The LDSA measurements performed in the background of the workstations inside the building, as well as outside the building are shown in Figure 4, and average values varies between 31,3 ± 2,9 µm2/cm3 to 33,4±1,5 µm2/cm3. Therefore, the LDSA values background measured inside the building are higher than the reference value associated to a low polluted indoor ambient air which may result from an inefficient ventilation system suitable for NMs. Figure 5 shows the LDSA measurements performed during the activities of weighing, HEBM and packaging. All activities show LDSA values higher than the low polluted indoor reference value proposed by (15) (16.9 ± 6,0 µm2/cm3). Moreover, the significant increase in the LDSA in the HEBM unloading results from the opening of the HEBM chamber and the consequent release of particles. Therefore, the high values of LDSA measured correspond to a high polluted ambient air, which may result from an inefficient ventilation system suitable for Ms.

Figure 6 shows concentration of each activity of the manufacturing and the sum of the average background concentration and three times their standard deviation measured in the corresponding workstation obtained the disc mini 2.0 and NanoScan SMPS equipment. The background corresponds to external sources other than the activities under study.
Considering the criteria established in Equation 1 worker exposure to NMs is not significant in weighing and packaging activities for the data obtained using the two monitorization equipment, which may result from the good control practices already implemented during the handling of nano-powders, *i.e*. combination of low energy with extraction workbench. For the HEBM loading and HEBM process, workers exposure is significant for the data obtained using the two monitorization equipment. Although, during the HEBM process workers are not allowed to be inside the room, which does not represent a risk for workers exposure. For the HEBM unloading, data obtained from the disc mini equipment evidence that workers exposure is significant, which is not verified for the data obtained with the NanoScan SMPS equipment. This difference in the data obtained between the two monitorization equipment may be a consequence of their positioning (both equipments are portable, but NanoScan needs to be placed over a flat surface during measurements). Since operators were allowed to enter the room, possibly equipments were placed in different positions. The significant exposure of the workers observed during HEBM activity may result from the lack of positioning of the flexible LEV over the HEBM chamber during the loading and unloading. The LEVs and extraction workbenches of the industrial facilities are connected in series and, consequently, possibly during the HEBM activity the air flow rate was low due to the high number of open gates in the same ventilation line.

Since HEBM where the only activity that the exposure was shown to be significant, the particle concentration distribution by size obtained with **NanoScan SMPS** will be presented below. Two peaks of particle number concentration are detected in 15,4 nm and approximately between 86,6 nm and 115,5 nm in the background and during the HEBM activity (Figure 7). Particle concentration during HEBM loading increases for 15,4 nm size comparatively with the background (Figure 7 a and b, respectively), while for HEBM unloading concentration increases for particles size of 15,4 nm and approximately between 86,6 nm and 115,5 nm (Figure 7d). These particles release result from the loading of the mixed materials into the HEBM chamber (i.e. mainly loose particles) and from the release of the nanocomposite produced during the HEBM process (i.e. loose and coarse particles).

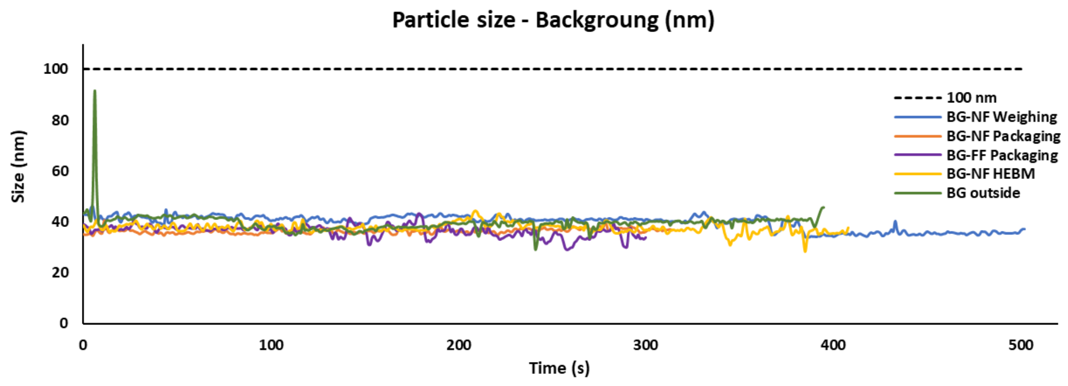

Figure 2: Background measurements in the near field (BG-NF) and/or far field (BG-FF) for weighing, HEBM, and packaging workstations, and outside of the building for particle size as a function of time.

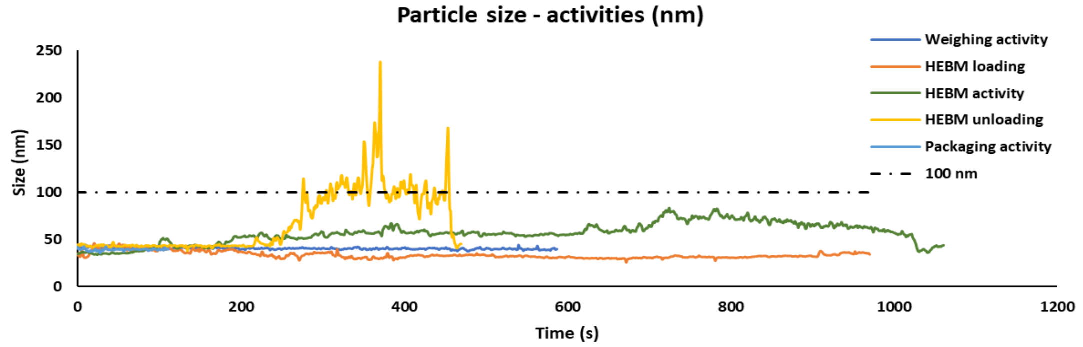

Figure 3: Particle size measurements as a function of time for three activities: weighing of SiC, packaging and high energy ball milling (HEBM), *i.e.* HEBM loading, HEBM process and HEBM unloading.

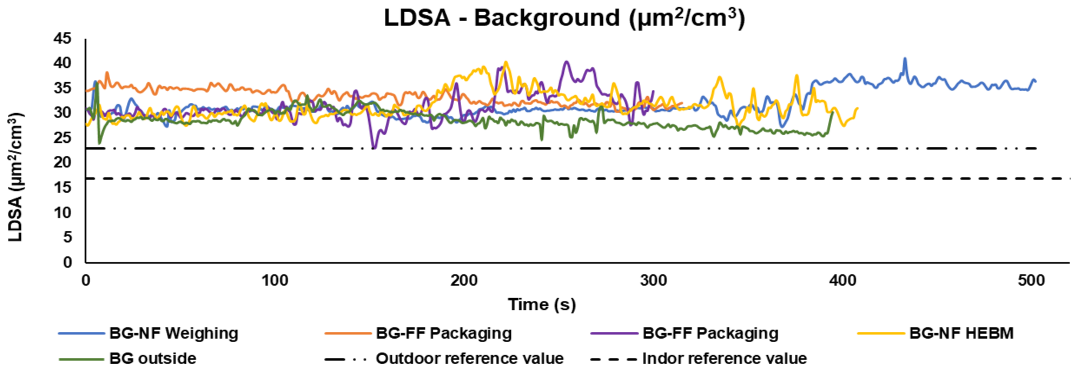

Figure 4: Lung deposition surface area (LDSA) as a function of time for the background measurements in the near field (BG-NF) and/or far field (BG-FF) for weighing, HEBM, and packaging workstations, and outside of the building.

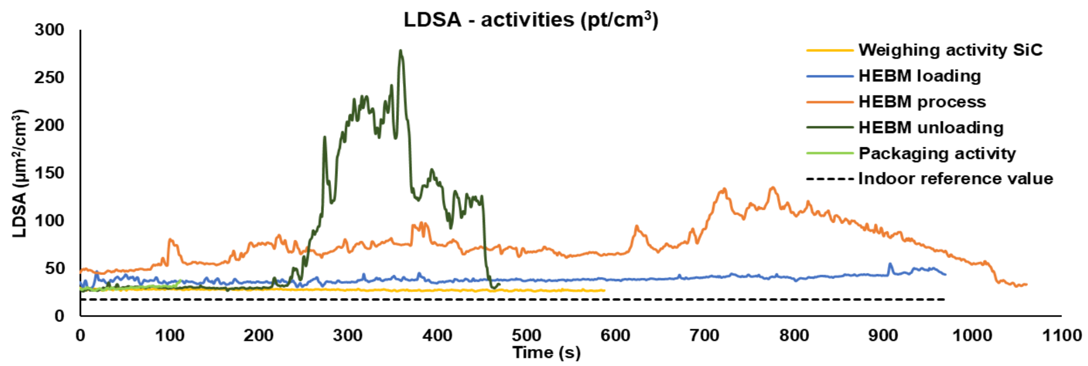

Figure 5: Lung deposition surface area (LDSA) measurements as a function of time for three activities: weighing of SiC, packaging and high energy ball milling (HEBM), *i.e.* HEBM loading, HEBM process and HEBM unloading.

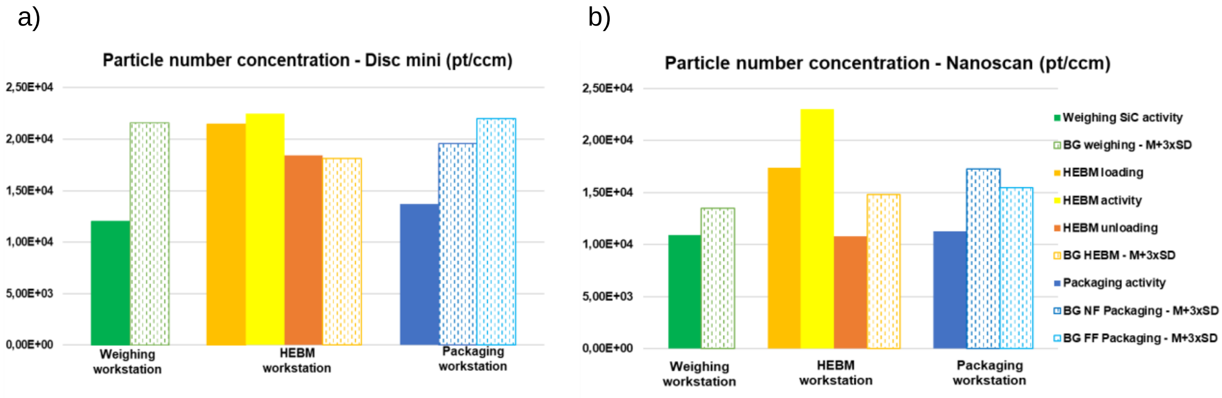

Figure 6: Particle average concentration during activities (full colored bars) and the average background concentration sum 3 times their standard deviation for each activity (dashed bars) obtained with: a) Disc mini and b) Nanoscan.

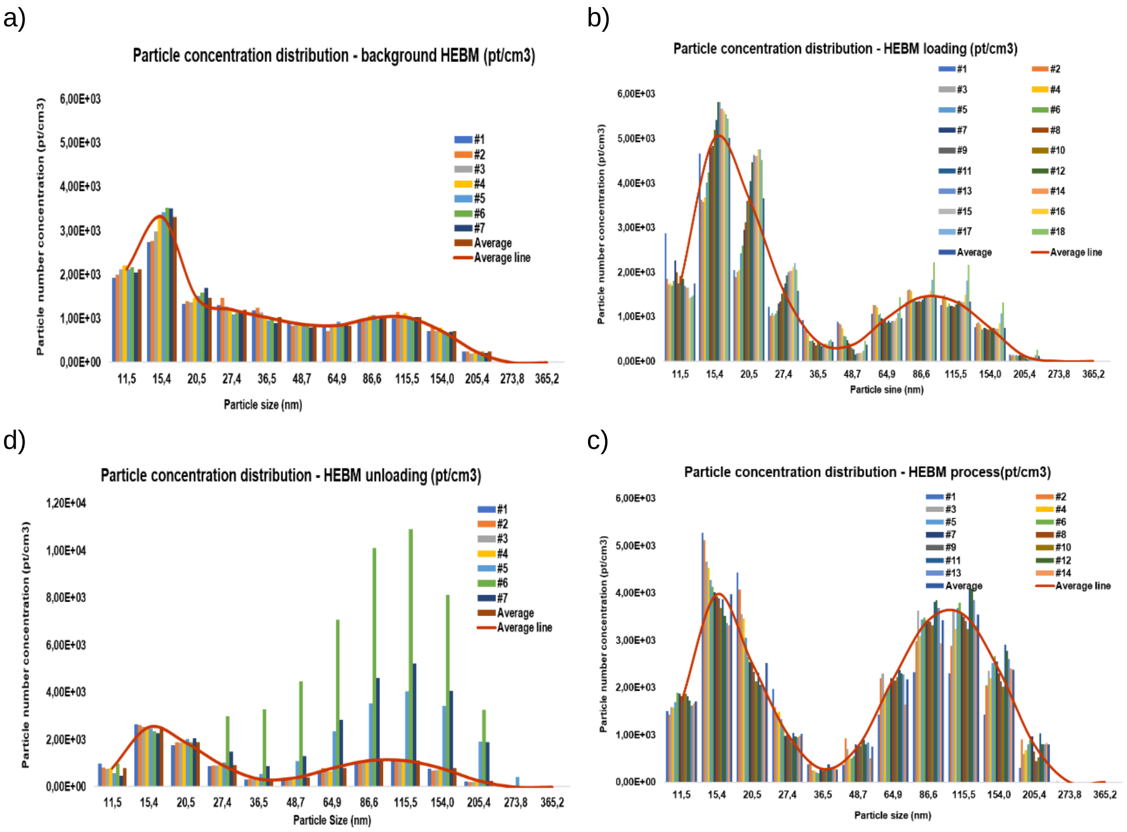

Figure 7:Particle number concentration distribution by size for HEBM: a) background, b) loading of the chamber c) process and d) unloading of the chamber.

5. Risk assessment and conclusions

5.1 Comparative analysis using metrics from the monitorization instruments

The two monitorization equipment used in Tier 2 operate differently and have slightly different NMs range (*i.e.* 10-300nm for disc mini 2.0 and 10-420nm for NanoScan), however, it is possible to make a

comparation in terms of the total particle concentration, particle size, as well as the results obtained in terms of determining if workers exposure is significant. The total particle concentration obtained with disc mini 2.0 and NanoScan SMPS equipment has the same order of magnitude, and both equipments detected the presence of NMs with particle size mainly below 100 nm in the background. Significant workers exposure was detected during HEBM loading and HEBM process with both monitorization equipments. Only the HEBM unloading demonstrated to have a significant worker exposure when measurements were done with the disc mini 2.0 equipment, while data obtained with the NanoScan SMPS equipment, indicate that the worker´s exposure was not significant. The distinct positions of equipment in the HEBM room may account to this discrepancy.

Overall, the results obtained with the monitorization equipment were similar allowing to propose risk control measures for the industrial process of nanocomposites production.

5.2 Comparative analysis of the results obtained from tiers 1 and 2

In tier 1 of the Tiered approach, the application of Stoffenmanager Nano tool recommended to implement a glovebox for the activities with the highest exposure potential in order to decrease the exposure band, namely for weighing and packaging activities for both lines. In tier 2, the application of the criteria established by OECD (2015) and EN 17058 (2018) (4,10) to evaluate workers exposure evidenced that workers exposure was only significant in the HEBM activity.

The comparison of the needs for additional risk control measures in tiers 1 and 2 seems to indicate that the preliminary recommendations obtained in tier 1 from the application of the Stoffenmanager nano tool for weighing and packaging activities are oversized. This results from the precautionary principle followed by the Stoffenmanager nano tool. Moreover, the lack of knowledge regarding the good control practices already implemented when handling the NMs and nanocomposites during these two activities such as the use of low energy in handling tasks, also contributed to an oversized result.

The low exposure potential obtained for the HEBM in tier 1activity resulted from the lack of understating of the potential exposure associated with the loading and unloading of NM powders. The implementation of tier 2 enables to propose more suitable recommendations, as it is more representative of the case study, rather than the application of tier 1 (isolated). However, higher costs are associated with the implementation of tier 2. The implementation of both tiers is relevant, considering the uncertainties related to the hazards and exposure to the nano-powders handled in the industrial facilities.

5.3 Overall risks identified and final recommendations of safety control measures

The main risk identified in specific activities of the industrial line of nanocomposite production is the inhalation of NMs when handling them, as it is known that aerosol particles in the range of 1 nm to 10 µm that are inhalable and deposit in the respiratory system may cause many diseases in the human respiratory tract (16). The HEBM activity, namely the loading of the HEBM chamber with the mixture of NM masterbatch and the metal alloy demonstrated a significant worker exposure to particles with a size lower than 100 nm. The LDSA in the HEBM room demonstrated to be higher than reference values associated to low polluted environments, which corresponds to the probability of the particles monitored to deposit in the alveolar region of human lungs, and consequently cause human respiratory diseases. High values of LDSA were detected in all the industrial facility monitored, even outside of the building. This indicates that the efficiency of the ventilation system should be improved, which is expected to be achieved through the implementation of several risk control measures, *i.e.*

•Provide the ventilation system of the industrial facility with suitable filters for NMs, such as HEPA filters with a class of H14, to minimize occupational exposure and the release of NMs into the outdoor environment. Even if the exhaust air is re-circulated into the workplace, HEPA filter class H14 should be used in order to adopt a conservative approach and face the lack of knowledge related to the hazards of the innovative nanocomposites. Moreover, a multi-filtration system could be implemented in the facilities of the manufacturing process under study to minimize NMs emission to the environment and minimize occupational exposures through the combination of coated fabric filters, to work as the primary filtration mechanism, and high efficiency particulate air (HEPA) filters of class H14,

namely in the workstations where NMs and nanoproducts are used;
•Development of a filters maintenance program to ensure an adequate cleaning of the filtration system;
•Automation of the HEBM loading and unloading process could also be an option to reduce the risk of workers exposure during these tasks. However, this would require higher technological costs;
•Positioning of the flexible LEV in the HEBM room over the HEBM chamber when it is opened for loading and unloading of the chamber;
•Implementation of the good control practices in the HEBM loading and unloading, which are already implemented during the weighing and packaging activity, such as use of low energy when handling nano-powders, and performance of the tasks as close of possible of the flexible LEVs;
•Management of the air ventilation system of the industrial facility to ensure an air flow rate equal or greater than 0.8 m/s (*i.e.* average air flow rate Health and Safety Authority (2014)), particularly when handling nano-powders, as LEVs systems and extraction for the workbenches are connected in series between different rooms. Thus, workers should be instructed to close the ventilation systems that could be unnecessary open, and an air flow sensor should be installed in the LEVs and extraction workbenches to control the air flow rate when handling NMs (*e.g.* anemometer).
•The release and emission of airborne NMs can result in their deposition in surfaces, which creates the risks of dermal and eye exposure of workers to NMs, as well as even NMs ingestion. In order to overcome these risks, besides FFP3 masks and latex gloves already in use, goggles and lab coats should also be used in the industrial facility to reduce the risks of workers exposure to NMs;
•Regular cleaning of ducts of air, surfaces and all points where particles (dust) accumulate to prevent dust explosion. The regular cleaning of the facilities should be performed using ATEX vacuum cleaners, which is recommended for NMs as they allow for the collection and safety of any residues and dust that would otherwise be dispersed in the air inside the workplace.

5.4 Conclusions

In conclusion hazards were identified for the NMs and aluminium nanocomposites under analysis based on a literature review, and it was observed a significant lack of data in terms of physico-chemical properties, toxicological effects, as well as exposure limit values. The lack of data was particularly significant for the aluminium nanocomposites as it is an innovative nanoproduct.

Potential exposure scenarios were identified in this study and risk management measurements were proposed to mitigate occupational exposure to NMs, as well as environmental release into the outdoor around the industrial facility. The application of the Licara NanoScan tool demonstrated that it is advisable to proceed with the development of the innovative intermediate nanoproduct compared with the conventional non-nanoproduct (*i.e.* aluminium alloys).

A monitorization campaign was carried out in the basic exposure assessment of tier 2 and it was verified that the existing control measures in weighing and packaging activities were sufficient to mitigate the inhalation risk of workers exposure to NMs. In the HEBM activity, workers exposure was significant, particularly during the loading and unloading of the HEBM chamber. LDSA values obtained for all workstations analyzed, as well as for outdoor measurements, were higher than reference values associated to a low polluted indoor and outdoor environment. Furthermore, it was detected that the filters used in the ventilation system of the industrial facility are not suitable for NMs filtration, which may result in the release of NMs into the outdoor environment. The existing ventilation system in the industrial facility was recommended to be improved through the implementation of several control measures.

Note that the environmental risk assessment was mainly focused on the indoor potential sources associated to the manufacturing of nanocomposites that could potentially lead to the release of NMs to the outdoor environment, such as the type filters used in the ventilation system. Moreover, based on the literature review limited information exist in terms of detection and quantification of NMs in the environment.

The adoption of this structured approach enabled to screen the potential risks to the workers exposure when handling nano-powders. The uncertainties and complexity associated with the use of NMs are parameters that significantly account for the risk. Therefore, the Tiered approach seems to be a suitable methodology to recognize the risks and design suitable and effective risk control solutions.

Several aspects related to this study still need further analysis and they could be analyzed in future work. As there is no consensus about the best metrics to assess exposure, harmonization of exposure metrics is needed to obtain more consistent results for exposure levels and enable the comparison of data. Toxicology-related studies about the innovative intermediate nanoproduct need further investigation. In what concerns the methodology applied for the occupational exposure a new monitoring campaign should be performed to evaluate whether the implementation of the proposed measures was sufficient to reduce the risks of worker exposure; It is advisable to conduct a tier 3 monitoring campaign in order to characterize the NMs detected in the occupational environment. Finally, more nanotools could be applied to the case study to test and validate results.

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