

Easy safety when designing and outfitting dedusting technology for intermediates acc. to REACH using strictly contained systems by TRM Filter

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In acc. with REACH Regulation (European regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals), the intermediates take on a key role in the location-based production network of process industries. With respect to the products transported beyond the location boundaries, the requirements on their evaluation are lower under the provision that they are handled in a strictly contained system in the production network. The filtration of process dusts often constitutes the third largest mass stream beyond the boundaries of a process, after the supply and removal of production materials. Strictly-contained filtration is achieved with the explosion pressure resistant filter systems where dust collection and filter replacement are carried out under adequate conditions of containment. TRM Filter, a Slovenian specialist for dust removal systems, developed explosion pressure resistant filter systems available in proven scaled containment versions and are upgradeable during their entire life cycle within the scope of containment.



FIGURE 1: ECR Filter system

In previous years, the implementation of REACH Regulation involved significant organizational effort relating to the data collection and documentation, but also toxicological evaluation of chemicals. To focus the flood of elicitation and logically ensuing evaluations relating to industrial hygiene, the intermediates within a production network of a location were at least met with simplified evaluations under the condition that they are handled in a strictly contained environment. Strict containment is, for instance, outlined in ECHA guidance (European Chemicals Agency) and references to other sources in progressive steps (3-5). With the strict containment, these substances need to be handled in isolators »open« (Strategy 3) or »closed« (Strategy 4).

TRM Filter meets the strict containment requirements for dedusting filter systems with our product ranges ECH for the distributed dedusting of mostly individual process machines in solids handling, and ECR for dedusting of higher process air streams. Both ranges can be upgraded in stages during their entire process life cycle in strict containment. Concerning the residual leakage, they both achieve quantitatively measured containment objectives in all handling steps and therefore provide reliable design of the dust removal function, even with increasing evaluation quality of the dedusted processes and process materials regarding industrial hygiene. The quantitative measurement of the residual leakage of the staged design variations was carried out by applying measurement methods used in the pharmaceutical industry, i.e. the so-called APCPPE (Assessing the Particulate Containment Performance of Pharmaceutical Equipment), better known in this context by its predecessor's name SMEPAC (Standardized Measurement of Particulate Airborne Concentration). The measurement results are also applicable under REACH to the evaluation methods of process industries. The method measures the leakage and surface contamination of the instruments by using the thoroughly-described and analytically-validated substitutes such as lactose. Furthermore, both ECH and ECR dedusting filter systems are designed to be explosion pressure resistant acc. to the rigorous tests with the Research Establishment for Applied System Safety and Health (FSA). This way, even in the event of explosion, the contamination of the environment is strictly prevented.

In the basic configuration, Enduro, both ECH and ECR systems (Fig. 1: ECR) are comprised of one cleanable primary filter stage H13 and one secondary filter stage H13. The dusts cleaned by the primary filter stage are collected in a dust collection container. Optionally, the systems may be outfitted with the integrated fans. They are available either as powder-coated steel systems, or stainless steel systems.



FIGURE 2: Bag with Lid



FIGURE 3: Bag-in/Bag-out filter replacement



FIGURE 4: Safe bag



FIGURE 5: Dust collection in continuous foils

In accordance with the ECHA strategy recommendations for strict containment in isolators with open handling (Strategy 3), TRM Filter recommends the configuration Novento for both ECH and ECR. In this configuration, the handling operations of the dedusting filter system are closed and protected with simple versions of protective foil technologies. The collection of dust occurs in a bag with lid (Fig. 2: The occasional replacement of both filter elements is achieved by employing the bag-in/bag-out method (Fig. 3: Bag-in/Bag-out). As a result, the service life of a cleanable primary filter is up to 3 years, depending on the dust load.

Strict containment in isolators with closed handling (Strategy 4) is accomplished with the configuration Practico for both ECH and ECR. In this configuration, the handling operations of the dedusting filter system are closed and protected with protective foil technologies. The collection of dust occurs in a safe bag (Fig. 4: safe-bag).

When specific, more severe reasons for strict containment in isolators with closed handling under Strategy 4 are present, the configuration Optimo of both ECH and ECR systems offers an even greater level of protection. The cleaned dust is collected in the continuous foil compartments that are sealed on both sides. The deposits of dust on filter elements can be immobilised prior to their replacement.

Both TRM filter's ECH and ECR dedusting filter systems feature complete protection under strict containment of substances in all normal handling operations. Moreover, the systems remain closed against the environment in case of explosions, rendering any environmental contamination impossible. The systems are upgradeable during their entire service life at the said protection levels. For this reason, they offer confidence when deciding on investments in dedusting technologies in view of the ever developing toxicological process risk assessment.



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Established in 1982, TRM Filter is based in Ljubljana, Slovenia. The company focuses on the development and production of innovative pharmaceutical dust removal systems in the domains of pharmacy, chemistry and food industry. Rotatronic Technology developed by TRM Filter meets the high requirements for explosion-protected High Containment filter systems, offering the best filter performance while also being low-maintenance. TRM Filter's solutions are implemented by leading pharmaceutical companies. The company is run by Peter Tomšič.