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CHARACTERIZATION OF NONEXTRACTABLE RESIDUES FOR THEIR RISK ASSESSMENT IN SOIL WITH SPECIAL REGARD TO PHARMACEUTICALS

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Currently a standardized or commonly accepted analysis technique for the evaluation of non-extractable residues (NER) of different groups of substances and active agents does not exist. Within the framework of the market approval of pharmaceutics, concerning the evaluation of biodegradation of the substance in the soil also the fraction of NER is taken into account. Therefore there is urgent need for the development of an extraction method.

The state of knowledge on the evaluation of NER in soils was identified through a comprehensive literature research. Focus lay on techniques to quantify the NER on the one hand, and on methods to characterize the residues on the other hand. It was demonstrated that NER can be present in soil in four different forms regarding the binding, the remobilization and the hazardous potential: The substances can be present heavily sorbed (NER-type 1) and in this form they are potentially remobilizable. They can originate from physical inclusion in the soil matrix (NER-type 2). These NER are potentially remobilizable as well and thus represent a possible risk. The substances can be covalently bound by irreversible bindings (NER-type 3). It is to be assumed that these NER cannot be released again. Also the fourth type, the biogenic-fixed parts (NER-type 4), are considered to be securely bound in terms of risk evaluation.

The state of the published methods for the characterization of NER was analyzed and evaluated in their entirety and according to different forms of specification. A preliminary leveled sequential extraction method was derived from the results and will be discussed for the characterization of NER from Pharmaceuticals.