ORAFLEX® 11654

Characterization according to REACH Regulation

The product is an article within the meaning of the Regulation (EC) No 1907/2006 (REACH) Article 3.

Usage instructions

This product is not a hazardous substance or hazardous mixture according to the German Regulation "Gefahrstoffverordnung" or the European Regulation (EC) no. 1272/2008 (CLP Regulation). No hazards are expected, if the material is used as described in the respective Technical Data Sheet and Processing and Handling Instructions. When used as intended, our products do not release any substances expectedly or intentionally.¹

Substances of Very High Concern (SVHC) and REACH

Based on our supplier's declarations we can confirm that this product does neither contain any substances in a concentration greater than 0.1 weight-% listed in the Candidate List of Substances of Very High Concern (SVHC) published by the European Chemical Agency (ECHA) (https://echa.europa.eu/candidate-list-table, last updated on 23/01/2024) nor substances listed in Annex XIV of Regulation (EC) no. 1907/2006.

Synthetic polymer particles

The product does not contain microplastics according to REACH Annex XVII No. 78. The polymers contained are encapsulated by technical means to prevent release into the environment when used as directed during the intended end use, or are permanently integrated into a solid matrix during the intended end use.

RoHS Directive

The product does not contain any substances in a concentration above the maximum permitted concentrations defined in Annex 2 of the Directive 2011/65/EU ("RoHS 3", last amended by (EU) 2023/1526).

Ozone depleting substances - CFCS

According to the Regulation (EC) no. 1005/2009, the product does not contain the therein-listed substances, which deplete the ozone layer.

Packaging materials

Packaging materials used by ORAFOL for packing its products fulfil the requirements of the Regulation 94/62/EC and the German Regulation on prevention and recycling of packaging waste (VerpackV).

Disposal instructions

In Germany and in the EU, the product can be disposed of as household-type industrial waste (EU waste code number 20 03 01) if there are no other local or regional disposal rules. Otherwise, the disposal regulations of each country must be followed. Please ask your local waste disposal company, if siliconized release paper can be used for paper recycling.

Basis of Evaluation

The component-related statements in this document are based on the components and additives, which are used in the formulation of the product. These statements refer to the current condition of the product when leaving the factory site of ORAFOL Europe GmbH in Oranienburg. The information is based on our current knowledge and practical experience and relies further on the respective safety data sheets and declarations provided by the raw material producer or supplier. It cannot be excluded that minor traces are present in the product due to technically unavoidable contaminations of single raw material components. Routine analyses of our products concerning the content of such substances are not carried out. No guarantee and liability can be assumed for factors beyond our knowledge and control.

¹ The Technical Data Sheet and the Processing and Handling Instructions for this product can be downloaded from www.orafol.com .

