

Regulatory Affairs Data Sheet

Manufacture

All products are of Dutch origin and manufactured in the CurTec plant in Rijen (The Netherlands). The management system includes:

- NEN-EN-ISO 9001: 2015
- NEN-EN-ISO 14001: 2015
- FSSC 22000: Version 4.1
- NEN-EN-ISO 15378:2017

The management system is annually audited by Lloyd's Register Quality Assurance.

Food contact

All drums, Click Packs and Packos with a food safe logo comply with the following regulation:

- EC regulation 1935/2004 (Materials and articles intended to come into contact with food)
- EC regulation 10/2011 (on plastic materials and articles intended to come into contact with food including amendments. More detailed information can be found in the Declaration of Compliance, available on request.
- EC regulation 2023/2006 (Good Manufacturing Practice applicable to all food contact materials)
- EC directive 94/62
- FDA regulation CFR 21 177.1520 (Olefin polymers)

Toxins

Heavy metals

All drums, Click Packs and Packos comply with EC regulation 94/62. In addition, these products have the potential to be recycled according to these requirements.

Phthalates

All drums, Click Packs and Packos meet the requirements for phthalates. To the best of CurTec's knowledge (based on the available documentation from raw materials suppliers), phthalates are not intentionally used, or added, in the manufacture of our PE products. Thermoplastic elastomer sealing gaskets may contain traces of phthalates but fully comply with EU Regulation 10/2011 and EC Regulation 1907/2006 concerning REACH.

Bovine Spongiform Encephalopathy (BSE)**Transmissible Spongiform Encephalopathy (TSE)**

All drums, Click Packs and Packos are to be considered safe with respect to BSE and TSE.

Genetic Modified Organism (GMO)

All drums, Click Packs and Packos are to be considered safe with respect to GMO.

Bisphenol

All drums, Click Packs and Packos comply with EC regulation 10/2011. To the best of CurTec's knowledge, based on the declarations from our suppliers, Bisphenol is not intentionally added. Based on this information drums, Click Packs and Packos are considered to be in compliance with the French law no. 2012-1442 and Commission Regulation (EU) 2018/213.

BADGE, NODGE and BFDGE

Epoxy derivatives (BADGE, NODGE and BFDGE) are not intentionally added to the raw materials used for the production of drums, Click Packs and Packos.

Dimethyl fumarate (DMF)

Dimethyl fumarate is not intentionally added to the raw materials used for the production of drums, Click Packs and Packos.

Ozone depleting chemicals (ODCs)

Ozone depleting chemicals are not intentionally added to the raw materials used for the production of drums, Click Packs and Packos.

Melamine

Melamine is not intentionally added to the raw materials used for the production of drums, Click Packs and Packos.

Dioxins/ Furans/ PCBs

Dioxins/ Furans/ PCBs are not intentionally added to the raw materials used for the production of drums, Click Packs and Packos.

Pharma**US Food and Drug Administration (FDA)**

All drums, Click Packs and Packos with a food safety symbol comply with FDA Type III CFR 21 regulations and are included in the Drug Master File #16388.

REACH

CurTec's products do not contain items which fit the description of Substances of Very High Concern (SVHC) with more than 0.1 mass percentages, which are listed in the current (candidate) list which is published by the ECHA.

Responsibility and validity

It is the responsibility of the customer to determine whether their use of CurTec products is safe, lawful (except as provided in the above certifications) and technically suitable for their intended applications.

It is the responsibility of the customer to check compliance of their final products with the relevant legislation and applicable regulatory requirements including their restrictions.

This data sheet will be updated as needed. CurTec recommends that customers, who continuously use its products, frequently verify the status of this document.

This document has been automatically generated and is valid without signature.

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