



JOINT STOCK COMPANY

SIBUR-HIMPROM

(SIBUR-HIMPROM JSC)

Effective date: 06 May 2022

To whom it may concern.

Declaration on MDR list status of DOTP

We confirm that **BIS(2-ETHYLHEXYL) TEREPHTHALATE (dioctyl terephthalate, DOTP, CAS# 6422-86-2)** manufactured by “Sibur-Himprom” JSC, does not contain any intentionally added substances as listed in the Regulation (EU) No 2017/745 on medical devices (MDR), Annex I, Chapter II, item 10.4, therefore we do not expect any of these chemicals to be present in the product at levels greater than 0.1% (w/w), in particular:

- substances, classified as Carcinogenic, Mutagenic, Reprotoxic (CMR) 1a/1b under the Classification, Labelling and Packaging (CLP) Regulation (EC) No 1272/2008;
- human Endocrine Disrupting Chemicals (EDC), classified under the current Candidate EU-REACH SVHC List (Last Updated 17.01.2022; total 223 substances, <http://echa.europa.eu/web/guest/candidate-list-table>) or given in the following lists of endocrine disruptors (<https://edlists.org/the-ed-lists>):

List I: Substances identified as endocrine disruptors at EU level, updated April 2022 (<https://edlists.org/the-ed-lists/list-i-substances-identified-as-endocrine-disruptors-by-the-eu>),

List II: Substances under evaluation for endocrine disruption under an EU legislation, updated April 2022 (<https://edlists.org/the-ed-lists/list-ii-substances-under-eu-investigation-endocrine-disruption>),

List III: Substances considered, by the evaluating National Authority, to have endocrine disrupting properties, updated April 2022 (<https://edlists.org/the-ed-lists/list-iii-substances-identified-as-endocrine-disruptors-by-participating-national-authorities>);

- listed in the current Candidate EU-REACH SVHC List (Last Updated 17.01.2022; total 223 substances, <http://echa.europa.eu/web/guest/candidate-list-table>);

- phthalates (esters of ortho-phthalic acid);
- nanomaterials (substances with particles < 100 nm);
- derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable;
- tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable.

This statement does not cover:

Prepared by Gubina Olga (tel.: (342) 290-83-54)

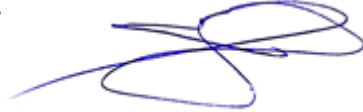
RNCBO	35305711	phone:	+7 (342) 290-82-16	98, Promyshlennaya Str., Perm
PSRN	1025901207804	fax:	+7 (342) 290-86-60	614055, Russia
ITIN	5905018998	e-mail:	mail-shp@sibur.ru	
IECC	XXX			

The information provided is not intended for public use. Any direct disclosure of the attached data through mass media, websites or otherwise is subject to prior consent of SIBUR LLC.

- any modification of our product by any addition of any other product to it,
- any modification of our product resulting from processing of the product, or
- an inadequate use and/or storage of our product or the finished articles by the end user.

Sincerely,

Yuri Belkin
Chief Process Engineer

A handwritten signature in blue ink, consisting of several overlapping loops and a long horizontal stroke extending to the left.