Buckton Scott Deutschland

# TECHNICAL DATA SHEET

## POMEGRANATE EPI 5% DE
## PR3014

**Botanical kind:** Lythraceae Punica granatum L.

**Part of the plant:** Epicarp

**Extraction solvent(s):** Ethanol, water 70:30 (V/V)

**Carrier(s):** Wheat maltodextrin

## DESCRIPTION

| | Specifications | Methods and references |
|---|---|---|
| **Appearance** | *Powder* | |
| **Color** | *Beige to brown* | |
| **Solubility** | *To be tested following the degree of incorporation* | |

## ANALYSES

| | Specifications | | Method and reference |
|---|---|---|---|
| | **Min** | **Max** | |
| **Ellagic acid content [%]** | *5.00* | - | *AE-156 - HPLC, internal method* |
| **Pyridine alkaloids content [%] (2)** | *Indicative value* | | *AE-133 - HPLC, internal method* |
| **Loss on drying [%] (11)** | - | *8.00* | *MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)* |
| **Bulk density** | *0.40* | *0.70* | *MO-181 - Eur. Ph. (04/2019:20934)* |
| **pH (1% in demineralized water) (11)** | *3.0* | *6.5* | *MO-03 - pH-meter, Eur. Ph. (07/2016:20203),"Potentiometric determination of pH" monograph* |
| **Screening [% < 500 µm]** | *95.0* | - | *MO-184 - Granulometer, internal method* |

## CONTAMINANTS

| | Specifications | | Method and reference |
|---|---|---|---|
| | **Min** | **Max** | |
| **Pb content [ppm] (2)** | - | *< 3.00* | *AE-01 - ICP, internal method* |
| **Cd content [ppm] (2)** | - | *< 1.00* | *AE-01 - ICP, internal method* |
| **Hg content [ppm] (2)** | - | *< 0.10* | *AE-01 - ICP, internal method* |
| **Pesticides content [ppm] (2)** | *< Residual Maximum Limit fixed in European Regulation 396/2005 and its modifications* | | *AE-02 - GC-MSMS/LC-MSMS, internal method* |

*Version: 2 of Wed, 19 Nov 2025*

*Document created on Mon, 13 Mar 2023*

***INFORMATION ABOVE AS RECEIVED FROM OUR SUPPLIER***

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| | | | |
|---|---|---|---|
| **Benzo(a)pyrene content [ppb] (2)** | - | *< 10.0* | *AE-03 - GC-MS-MS, internal method* |
| **Pahs (sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene) content [ppb] (2)** | - | *< 50.0* | *AE-03 - GC-MS-MS, internal method* |

| **MICROBIOLOGY** | **Specifications** | | **Method and reference** |
|---|---|---|---|
| | **Min** | **Max** | |
| **Total aerobic microbial count [CFU/g] (1)** | - | *< 10 000* | *AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)* |
| **Total yeasts/moulds count [CFU/g] (1)** | - | *< 100* | *AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)* |
| **Salmonella content [ /25g]** | *Absent* | | *AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)* |
| **Bile-tolerant Gram negative bacteria content [CFU/g]** | - | *< 100* | *AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)* |
| **Escherichia coli content [ /g]** | *Absent* | | *AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)* |
| **Staphylococcus aureus content [/g]** | *Absent* | | *AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)* |
| **Listeria monocytogenes content [/25g]** | *Absent* | | *AE-205 - ALOA One day* |

*(1) Acceptable maximal count: 5 times the acceptance criterion according to Eur. Ph. VIII° Ed. 5.1.8 Category B*
*(11) First ten batches*
*(2) On request with additional cost*

**Best before/ DMD (in months) :** *24*

**Storage conditions:** *Store in closed original packaging at 5 to 25°C in a dry place and protected from light.*

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**Complementary data**

*This reference is neither an Active Pharmaceutical Ingredient nor an excipient for pharmaceutical use. Responsibility of final labelling lies with the company placing the final product on the market.*
*- According to Regulation 1999/3/EC, and its modifications, product has not been ionized.*
*- According to the Regulations 2001/18/EC, 1829/2003 and 1830/2003, and its modifications, the product does not contain deliberately added GMO. (Fortuitous or technically inevitable traces could be detected at less than 0,9.)*
*- The product does not contain TSE/BSE substances.*