

## TECHNICAL DATA SHEET

### WHITE WILLOW BA 2-4 % DE PR967

|                        |                          |
|------------------------|--------------------------|
| Botanical kind:        | Salicaceae Salix alba L. |
| Part of the plant:     | Bark                     |
| Extraction solvent(s): | Water                    |
| Carrier(s):            | Wheat maltodextrin       |

#### DESCRIPTION

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

#### ANALYSES

|                                                               | Specifications   |         | Method and reference                                                                       |
|---------------------------------------------------------------|------------------|---------|--------------------------------------------------------------------------------------------|
|                                                               | Min              | Max     |                                                                                            |
| Total salicylic derivatives, expressed as salicin content [%] | 2.00             | 4.00    | MO-243 - HPLC, Eur. Ph. (04/2008:2312), "Willow bark dry extract" monograph                |
| Salicin content [%] (4)                                       | Indicative value |         | AE-130 - HPLC, internal method                                                             |
| Identification (finished product) (4)                         | Complies         |         | MO-110 - TLC, Eur. Ph. (04/2008:2312), "Willow bark dry extract" monograph                 |
| Loss on drying [%] (11)                                       | -                | 8.00    | MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)                                      |
| Bulk density                                                  | 0.30             | 0.70    | MO-181 - Eur. Ph. (04/2019:20934)                                                          |
| Total ash content [%] (11)                                    | -                | < 12.00 | MO-01 - Muffle furnace, Eur. Ph. (01/2008:20416), "Total ash" adapted monograph            |
| pH (1% in demineralized water) (11)                           | 5.0              | 10.0    | 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] (4) | -              | < 3.00 | AE-01 - ICP, internal method |
| Cd content [ppm] (4) | -              | < 1.00 | AE-01 - ICP, internal method |
| Hg content [ppm] (4) | -              | < 0.10 | AE-01 - ICP, internal method |

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|                                                                                                      |                                                                                      |        |                                          |
|------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------|------------------------------------------|
| As content [ppm] (4)                                                                                 | -                                                                                    | < 1.00 | AE-01 - ICP, internal method             |
| Pesticides content [ppm] (4)                                                                         | < Residual Maximum Limit fixed in European regulation 396/2005 and its modifications |        | AE-02 - GC-MSMS/LC-MSMS, internal method |
| Benzo(a)pyrene content [ppb] (4)                                                                     | -                                                                                    | < 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] (4) | -                                                                                    | < 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) |

(1) Acceptable maximal count: 5 times the acceptance criterion according to Eur. Ph. VIII° Ed. 5.1.8 Category B

(11) First ten batches

(4) HACCP based control plan defined annually according to risk analysis

Best before/ 24

DMD (in months) :

Storage conditions: Store in closed original packaging : 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.*

- *Complies with French decrees (2006-352 and 24th June 2014)*
- *According to Regulation 1999/3/EC, and its modifications, has not been ionized.*
- *According to the Regulations 2001/18/EC, 1829/2003 and 1830/2003, and its modifications, the above mentioned item 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*