



## Specification

| Concerning Product:   |  |
|---|--|
| Article number  | 562107MPEG   |
| Trade name / designation / denomination   | Doxylaminsuccinat  |
| CAS number  | 562-10-7   |
| Other names / synonyms  | •Doxylamine succinate; •butanedioic acid; N,N-dimethyl-2-[1-phenyl-1-(2-pyridinyl)ethoxy]ethanamine; •doxylamine hydrogen succinate; |
| EC number   | 209-228-7  |
| Customs tariff number / CN code / TARIC   | 29333999   |
| Molecular weight [g / mol]  | 388.45742  |
| Formula   | C <sub>21</sub> H <sub>28</sub> N <sub>2</sub> O <sub>5</sub>  |
| <b>Warning</b>  |  |
| Harmful if swallowed. Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. |  |

| Parameter                        | Test Method             | Specification            | Unit   |
|----------------------------------|-------------------------|--------------------------|--------|
| <b>Organoleptic test</b>         |                         |                          |        |
| Appearance of solution           | visual                  | clear and colourless     |        |
| Colour                           | visual                  | white or almost white    |        |
| <b>Physical parameter</b>        |                         |                          |        |
| Form                             | visual                  | powder                   |        |
| Water content                    | KF                      | ≤ 0,5                    | %      |
| <b>Identity</b>                  |                         |                          |        |
| Assay                            | Titration               | 99,0 – 101,0             | %      |
| Infrared absorption spectrometry | IR                      | conform to the reference |        |
| <b>Impurities</b>                |                         |                          |        |
| Sulphated ash                    |                         | ≤ 0,1                    | %      |
| Impurity                         | Related Substances (CG) | (C): ≤ 0,5               | %      |
| Impurity                         | Related Substances (CG) | any: ≤ 0,1               | %      |
| Impurity                         | Related Substances (CG) | total: ≤ 0,7             | %      |
| <b>Residual Solvents</b>         |                         |                          |        |
| Isopropylalcohol                 | Residual Solvents       | ≤ 5000                   | l/hlpa |
| Toluene                          | Residual Solvents       | ≤ 450                    | ppm    |

### Regulatory information:

**Registration status:** This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICH Q7).

### Supplemental information:

**Shelf life:** 5 years

**Complies with monographie:** Ph.Eur.

**Regional origin:** ES

Chemische Werke Hommel GmbH & Co.KG

*This document was generated electronically and is valid without signature.*

Waltrop, 19. Apr. 2023

We only confirm that we took over the data from our supplier accordingly. Despite careful working, errors in the takeover are not totally excluded. Some or all parts of the document may be translated due to our best knowledge from the original to give a better understanding. If you have any questions about specific details, please call us directly. Unless otherwise marked, these data do not originate from us and have not been tested by us on the correctness. The above information corresponds to the present state of our knowledge and is intended as a general description of our products and their possible applications. We make no warranties, expressed or implied, as to the information's accuracy, adequacy, sufficiency or freedom from defect and assumes no liability in connection with any use of this information. Any user of this product is responsible for determining the suitability of our products for its particular application. The foregoing information does not absolve the buyer of its own tests. Observing existing laws and regulations, is the responsibility of the buyer of our product. Nothing included in this information waives any of our General Terms and Conditions of Sale, which control unless it agrees other in writing. Any existing intellectual/industrial property rights must be observed. Due to possible changes in our products and applicable national and international regulations and laws, the status of our products could change. Material Safety Data Sheets providing safety precautions, that should be observed when handling or storing our products, are available upon request and are provided in compliance with applicable law. The user should obtain and review the applicable Material Safety Data Sheet information before handling any of these products. For additional information, please contact us.