



Specification

| Concerning Product: | |
|-----------------------------------------|---------------------------------------------------------|
| Article number | 93141GIP |
| Trade name / designation / denomination | Guaifenesin |
| CAS number | 93-14-1 |
| Other names / synonyms | •3-(2-methoxyphenoxy)propane-1,2-diol; •guaifenesin; |
| EC number | 202-222-5 |
| Customs tariff number / CN code / TARIC | 29094980 |

| Parameter | Specification | Unit |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| Organoleptic test | | |
| Appearance of solution | clear and colourless | |
| Appearance | White or almost white, crystalline powder | |
| Physical parameter | | |
| Acidity/Alkalinity | Should comply as per BP | |
| Loss on drying | (In Vacuum 60° C/3h): ≤ 0,50 | % |
| Solubility | Sparingly soluble in water, soluble in alcohol | |
| Identity | | |
| Assay | By Chemical (on dry basis): 98,0 – 102,0 | % |
| Identification | By TLC: The principle spot in the chromatogram obtained with the test solution is similar in position and the size to the principle spot in the chromatogram obtained with the reference solution | |
| Identification | The IR absorption spectrum of the sample is concordant with the spectrum obtained with guaifenesin CRS / Working reference standard. | |
| Melting Point (identity) | 79 – 83 | °C |
| Impurities | | |
| Heavy Metals (as Pb) | ≤ 25 | ppm |
| Sulphated ash | ≤ 0,1 | % |
| Impurity | Total (excluding impurity B): ≤ 1,0 | % |
| Impurity | A: ≤ 0,10 | % |
| Impurity | Any other: ≤ 0,5 | % |
| Impurity | B: ≤ 1,0 | % |
| Residual Solvents | | |
| Residual solvents | Methanol ≤ 3000 | ppm |
| Residual solvents | Methylene Di Chloride ≤ 600 | ppm |
| Residual solvents | Toluene ≤ 890 | ppm |
| Elemental Impurities | | |
| Chlorides (Cl) | and monochlorhydrines: ≤ 250 | % |

Supplemental information:

Shelf life: 5 years

Packing: 25 kg HDPE

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 20. Nov. 2019

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