

**Refining & Chemicals**

Total Research & Technology Feluy  
Regulatory Affairs  
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PLASTRIBUTION LTD  
For the attention of Dan Jarvis  
Clinitron House , Excelsior Road  
LE65 1JG Leicestershire  
GB - Great Britain

Letter: ARP/20L00606

Feluy, 12/05/2020

Dear Sir,

Concern: POLYPROPYLENE LUMICENE® MR 10MX0

**NITROSAMINES (EMA/189634/2019)**

This statement is in response to your request regarding the Nitrosamines impurities as mentioned in EMA/189634/2019 from the European Medicines Agency (EMA) in the here above-mentioned product. In September 2019 EMA began a review under Article 5(3) of Regulation (EC) No 726/2004 to provide guidance to marketing authorisation holders on how to avoid the presence of nitrosamine impurities in human medicines.

We can hereby confirm that we do not intentionally use the substances listed below in the manufacturing of here above-mentioned product.

We hereby inform you that to the best of our knowledge nitrosamines compounds would not be present in the here above-mentioned product sold and supplied by Total Refining & Chemicals.

However, we inform you that some traces of amines (primary, secondary or tertiary), at a ppb level, may be present in the here above-mentioned product.

However, since we do not perform specific tests to verify the potential presence of nitrosamines compounds, amines, nitrosating agents and substances listed in the here above-mentioned product, we cannot guarantee that there is no trace amount of some of nitrosamines compounds, amines, nitrosating agents and substances listed below as impurity or otherwise, in the here above-mentioned product.

Our certificate does not cover :

- any modification of the warranted product by any addition of any other product to it,
- any prejudicial modification of the warranted product resulting from a processing of the product,
- an inadequate use and/or storage of the material and of the finished articles.

The present certificate is valid for a period of one year starting from the date first above written. It can then be renewed upon request.

We are at your disposal for any further information you may need and remain,

Yours faithfully,  
Total Research And Technology Feluy

B. KLUYSKENS  
Regulatory Affairs

F. RADERMACHER  
Regulatory Affairs, Manager

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**List of Substances:**

- Sodium Nitrite ( $\text{NaNO}_2$ , CAS 7632-00-0)
- Nitrocellulose (EC 936-908-7)
- Ozone (CAS 10028-15-6)
- Nitrous Acid ( $\text{HNO}_2$ , CAS 7782-77-6)
- Nitric Acid ( $\text{HNO}_3$ , CAS 7782-77-6)
- Nitric Oxid ( $\text{NO}$ , CAS 10102-43-9)
- Nitrosyl halides (e.g.  $\text{ClNO}$ ,  $\text{BrNO}$ )
- Dinitrogen trioxide ( $\text{N}_2\text{O}_3$ , CAS 10544-73-7)
- Dinitrogen tetroxide ( $\text{N}_2\text{O}_4$ , CAS 10544-72-6);
- Organic nitrites (e.g.  $\text{t-BuONO}$ )
- Formaldehyde (CAS 50-00-0)
- Amide solvents
- N,N-dimethylformamide (DMF, CAS 68-12-2)
- N-Methylpyrrolidone (NMP, CAS 120-94-5)
- N,N-dimethylacetamide (DMA, CAS 127-19-5)
- Hydroxylamine ( $\text{NH}_2\text{OH}$ , CAS 7803-49-8)
- N-nitro-N-methyl-4-aminobutyric acid (NMBA, CAS 61445-55-4)
- N-nitrosodiméthylamine (NDMA, CAS 62-75-9)
- N-nitrosométhyléthylamine (CAS 10595-95-6)
- N-nitrosodiethylamine (NDEA, CAS 55-18-5)
- N-nitrosodipropylamine (CAS 621-64-7)
- N-nitrosodibutylamine (CAS 924-16-3)
- N-nitrosomorpholine (CAS 59-89-2)
- N-nitrosopiperidine (CAS 100-75-4)
- N-nitrosopyrrolidine (CAS 930-55-2)
- N-nitrosodiethanolamine (CAS 1116-54-7)
- N-Methyl-N'-Nitro-N-Nitrosoguanidine (CAS 70-25-7)
- N-Nitrosoethyl-n-butylamine (CAS 4549-44-4)
- N'-Nitrosoanabasine (CAS 37620-20-5)
- 4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanol (CAS 76014-81-8)
- 4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone (CAS 64091-91-4)
- N-Nitrososarcosine (CAS 13256-22-9)
- N-Nitrosornicotine (CAS 16543-55-8)
- 3-(N-methylnitrosamino) propionic acid (CAS 10478-42-9)
- 4-(N-methylnitrosamino) butyric acid
- Nitrosoazetidine-4-carboxylic acid (CAS 30248-47-6)
- N-nitrosodiphenylamine (CAS 86-30-6)
- Nitroso-diisopropylamine (CAS 601-77-4)
- N-nitroso N-methyl N phenylamine (CAS 614-00-6)
- N-nitroso N-ethyl N-phenylamine (CAS 612-64-6)
- N-nitroso dibenzylamine (CAS 5336-53-8)
- 1-nitroso-2,3-dihydropyrrole (CAS 37449-28-8)
- N-nitrosodicyclohexylamine (CAS 947-92-2)
- N-nitrosodiisononylamine (CAS 643014-99-7)
- N-Nitrosodimethylamine (NDMA, CAS 62-75-9)
- N-Nitrosodiethylamine (NDEA, CAS 55-18-5)
- N-Nitro-N-methyl-4-aminobutyric acid (NMBA, CAS 61445-55-4)



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- N,N-diethylacetamide (DEA, CAS 685-91-6)
- Triethylamine (CAS 121-44-8)
- Diethylamine (CAS 109-89-7)
- Monoethylamine (CAS 75-04-7)
- Dimethylamine (CAS 124-40-3)
- Trimethylamine (CAS 75-50-3)
- Dibutylamine (CAS 111-92-2)
- Tributylamine (TBA, CAS 102-82-9)
- Tetra Butyl Ammonium Bromide (TBAB, CAS 1643-19-2)3
- N-Methylmorpholine (NMM, CAS 109-02-4)
- N,N-Diisopropylethylamine (DIPEA, CAS 7087-68-5)
- Diethanolamine (CAS 111-42-2)