	GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.	
	Type of document:	
	<b>TECHNICAL DATA SHEET</b>	
	Review date: 19.04.2024	Version: 12.0
<b>86776- TRIETHANOLAMINE</b>		

## 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

### 1.1. Identification of the substance or preparation.

Name: Triethanolamine

Code: 86776

Internal code: 405395

### 1.2. Synonyms.

TEA, Trolamine.

## 2. DESCRIPTION

Appearance: Transparent viscous liquid.

Colour: Slightly yellowish.

Origin: The product is produced from petrochemical raw materials. The materials used can be traced back to petroleum or gas derivatives, therefore there are no materials of animal or biological origin. Auxiliary chemicals used in production and processes are synthetic and therefore no animal or biological materials are used or expected to be present.

Geographical origin: Product manufactured in France/USA.

## 3. COMPOSITION/INFORMATION ON COMPONENTS.

CAS number: 102-71-6

EINECS number: 203-049-8

Formula:  $N(CH_2CH_2OH)_3$

Molecular weight: 149.19g/mol

INCI: Triethanolamine


DEA content < 0.5%

MEA content < 0.1%

### Composition:

The DEA content is less than 0.5% and the purity of TEA99 is at least 99 percent. The presence of NDELA has been tested and no significant quantities have been detected. The limit of detection of the method used is 25 ppb.

**Method of production:** The production process is by reaction of ammonia with ethylene oxide. Subsequently, the final product is separated and purified by means of a distillation process.

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#### 4. PHYSICO-CHEMICAL DATA.

For further information, see the analysis report.

**Solubility:** Miscible with water and ethanol.

#### 5. PROPERTIES/USES.

Cosmetic use.

Industrial use.

The product is listed in the following cosmetics regulations, although it is the customer's responsibility to check the suitability of the finished item for the intended use in cosmetics and its compliance with relevant legislation and applicable requirements:

European Union – Regulation No 1223/2009

Restrictions: III / 62

Positive lists: Not approved as colourant, preservative or UV filter

Identified functions: buffer, surfactant, emulsifier, masking agent

United States – FD&C Act

Restrictions: /

Positive lists: Not approved as colour additive

CIR Ingredient Status Report: Safe for use in rinse-off products:

- Limited to 5% in no-rinse cosmetic products
- Should not be used in products containing N-nitrosating agents.

Reference: JACT 2 (7): 183-235 (1983)

China – FD&C Act


IECIC 2015: listed as 05819

Technical and safety standards for cosmetics (2015): Chapter 1.8

#### 6. DOSAGE.

Restriction III/62 of Regulation 1223/2009 applies to triethanolamine:

- (a) No-rinse products
  - Maximum concentration to be used: 2.5%
- (b) Rinse-off products

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Specifying further that the following restrictions apply to both types of products:

- Should not be used with nitrosating systems.
- Minimum purity: 99%
- Maximum secondary amine content: 0.5%
- Maximum nitrosamine content: 50 µg/kg
- Keep in nitrite-free environments.

## 7. REMARKS.

### STORAGE:

Protect from sunlight and keep in a tightly closed container.

The product may freeze at low temperatures and its melting point range is 17.9–21°C. In these cases, it is recommended to gently heat the uncovered container in a water bath, using caution as it can be flammable.

Colour values may increase during the product's lifetime, which is natural.

The documentation available related to the product's regulatory compliance is included below.

### BSE/TSE:

The materials used are derived from petroleum or gas, therefore there are no materials of animal or biological origin. Auxiliary chemicals used in production are synthetic and therefore no animal or biological materials are used. The product is determined to be bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathy (TSE) free.

### GMOs:

The materials used are derived from petroleum or gas, therefore there are no materials of animal or biological origin. Auxiliary chemicals used in production are synthetic and therefore no animal or biological materials are used. The product is free from genetically modified organisms (GMOs).

### CMR:

The product contains diethanolamine, which is registered as toxic for reproduction, category 2, according to European Regulation 1272/2008/EC.

### NANOMATERIALS:

The product does not contain nanomaterials (nanoparticles, nanoscale substances).

### VOCs:

The product is, according to the following definitions:  
Physicochemical properties of triethanolamine:

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- Vapour pressure: 0.0003 hPa

- Boiling point: 336.1°C

Solvent Directive (Directive 2010/75/EU):

Definition of VOC: Any organic compound having at 293.15K a vapour pressure of 0.01kPa or more, or having a corresponding volatility under the particular conditions of use.

VOC status TEA: 0% VOC

Paint Directive (Directive 2004/42/EU):

Definition of VOC: Any organic compound having an initial boiling point less than or equal to 250°C measured at a standard atmospheric pressure of 101.3 kPa.

VOC status TEA: 0% VOC

Ordinance on the Incentive Tax on Volatile Organic Compounds (SR814018; 01/01/2017)

Definition of VOC: Organic compounds with a vapour pressure of at least 0.1 mbar at 20°C or a boiling point of maximum 240°C at 1013.25 mbar.

VOC status TEA: 0% VOC

EU Ecolabel – Paints and Varnishes (Directive 2015/886/EU):

Definition of VOC: Any organic compound having an initial boiling point less than or equal to 250°C measured at a standard pressure of 101.3 kPa as defined in Directive 2004/42/EC and which, in a capillary column, are eluting up to and including n-tetradecane (C<sub>14</sub>H<sub>30</sub>).

Definition of SVOC: Any organic compound having an initial boiling point greater than 250°C and lower than 370°C measured at a standard pressure of 101.3 kPa and which, in a capillary column, are eluting with a retention rate after n-tetradecane (C<sub>14</sub>H<sub>30</sub>) and up to and including n-docosane (C<sub>22</sub>H<sub>46</sub>).

VOC status TEA: 100% SVOC

EU Ecolabel: All-purpose Cleaners and Sanitary Cleaners (Directive 2011/383/EU):

Definition of VOC: Any organic compound with a boiling point below 150°C.

VOC status TEA: 0% VOC


### IONISING RADIATION:

The product has not been irradiated/exposed to any type of radiation.

### RESIDUAL SOLVENTS:

The product meets the ICH Harmonised Tripartite Guidelines for Residual Solvents as per CPMH/ICH/283/95. No Class 1, Class 3 or Class 4 solvents are used in the manufacturing process, so they are not expected to be present.


As a Class 2 solvent, ethylene glycol (MEA) < 0.5% by weight may be present.

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#### IMPURITIES:

Although they are not routinely tested, the manufacturer indicates that none of the following products are used at any stage of the manufacturing process, nor have any been observed to have been produced within the process itself. Therefore, the following impurities are not expected to be present:

- 1,4-Dioxane
- 2,4-Toluene diisocyanate
- Acrylic compounds and derivatives.
- AHTN (6-acetyl-1,1,2,4,4,7-hexamethyltetralin)
- Aldehydes (formaldehyde and acetaldehyde if stored under appropriate conditions).
- Alkylphenol and alkylphenol ethoxylates (APEO) and their derivatives (nonylphenol / octylphenol and ethoxylates, etc.)
- Alpha-isomethyl ionone
- Antioxidants, preservatives, inhibitors and stabilisers.
- Any bacteriological or enzymatic contamination.
- Aromatic compounds (including phenylpropanolamine) — Polycyclic aromatic compounds — Aromatic nitrogen compounds rTD laboratory
- CFC
- CMRs as per European Regulation 67/548/EEC.
- Components listed as SVHC
- Compounds prohibited by RoHS (Restriction of Hazardous Substances) and WEEE (Waste Electrical and Electronic Equipment) Directives 2011/65/EC and 2002/96/EC
- Cresol and derivatives
- Dimethyl fumarate (CAS No 624-49-7) as per Directive 2009/251/EC
- Dioxins as per European Regulation 2375/2001/EC
- EDTA (ethylene-diamine-tetra-acetate) and its salts
- Esters of any alcohol or acid.
- Flame retardant
- Furfural
- Gluten
- Glycerine
- Type E and P glycolates
- Halogenated, inorganic and organic derivatives.
- Harmful components according to any of the Nordic listings or one of the priority lists
- Heavy metals, including catalyst residue: Aluminium (Al), Arsenic (As), Barium (Ba), Beryllium (Be), Boron (B), Cadmium (Cd), Calcium (Ca), Cobalt (Co), Chromium (Cr), Copper (Cu), Iron (Fe) TEA85 and TEA99 <5 ppm, Lead (Pb), Manganese (Mn), Mercury (Hg), Molybdenum (Mo), Nickel (Ni), Potassium (K), Selenium (Se), Silver (Ag), Tin (Sn), Titanium (Ti), Vanadium (V), Zinc (Zn)
- HHCB (1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta-γ-2) benzopyran)

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- Hydroxyisohexyl-3-cyclohexane carboxaldehyde
- Maleic anhydride
- Melamine
- Mercaptans
- Mesylate and derivatives (methylsulphonic acid derivatives)
- Mycotoxins as per European Regulation 466/2001/EC.
- Nanoparticles or materials produced through nanotechnology.
- Naphthalene
- NTA (nitrile-tri-acetate)
- PCP (pentachlorophenol)
- Perfluor tensides
- Pesticides as per European directive 86/363/EC.
- Phenolic compounds
- Phthalates as per European Regulation EP 2005/84.
- Pyridine
- Quaternary ammonium salts.
- Residual propylene oxide and ethylene oxide.
- Silicone and COC derivatives — Ethanolamines\_Impurities\_2015.doc
- Silica gel
- Sulphur-based components
- Synthetic rubber
- Trichlorethylene
- Unreacted alcohols.
- Vulcanisation aids.
- Xylene

EU Water Directive 2000/60 and amendments:

- Chlorinated organic compounds.
- Organobromine compounds.
- Organotin compounds.
- Asbest
- Azo-compounds
- Polyvinyl chloride compounds and mixtures.
- Perfluorooctane sulphonates (PFOS)

#### Nitrosamines:

No sodium nitrite ( $\text{NaNO}_2$ ), other nitrites or other nitrosating agents are used at any stage of the manufacturing process as reagents/catalysts. They are also not used for the preparation of the starting material or as intermediates in the manufacturing process, nor as reaction, catalysts or processing aids during the manufacturing process, nor are they produced as impurities derived from the production process.

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The product is analysed using the LC/MS/MS method to check the nitrosamine content (nitrosodiethanolamine < 20 ppb). The product is not tested for nitrites or nitrates.

During the manufacturing process, secondary and tertiary amines are generated as intermediates and as reagents. These are diethanolamine (DEA) and triethanolamine (TEA), which is a tertiary amine in itself.

Monoethanolamine (MEA) is also used as a reagent.

The solvents used in the manufacturing process are neither recycled nor reconverted and the product is not manufactured in a multi-purpose unit.

### ELEMENTAL IMPURITIES:

The product complies with the Elemental Impurities Guidelines derived from the Harmonisation Conference (ICH – <http://www.ich.org/>). The data detailed below are the result of the limit of the analytical method report.

Class 1 elemental impurities:

- Cadmium (Cd) < 1.0 mg/kg
- Lead (Pb) < 1.0 mg/kg
- Arsenic (As) < 1.0 mg/kg
- Mercury (Hg) < 0.10 mg/kg

Class 2A elemental impurities:


- Cobalt (Co) < 1.0 mg/kg
- Vanadium (V) < 1.0 mg/kg
- Nickel (Ni) < 1.0 mg/kg

Class 2B elemental impurities:

- Thallium (Tl) < 1.0 mg/kg
- Gold (Au) < 0.050 mg/kg
- Palladium (Pd) < 0.050 mg/kg
- Iridium (Ir) < 0.50 mg/kg
- Osmium (Os) < 0.050 mg/kg
- Rhodium (Rh) < 0.50 mg/kg
- Ruthenium (Ru) < 0.050 mg/kg
- Selenium (Se) < 1.0 mg/kg
- Silver (Ag) < 1.0 mg/kg
- Platinum (Pt) < 0.050 mg/kg

Class 3 elemental impurities:

- Lithium (Li) < 1.0 mg/kg

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- Antimony (Sb) < 1.0 mg/kg
- Barium (Ba) < 1.0 mg/kg
- Molybdenum (Mo) < 1.0 mg/kg
- Copper (Cu) < 1.0 mg/kg
- Tin (Sn) < 1.0 mg/kg
- Chromium (Cr) < 1.0 mg/kg

#### CALIFORNIA 65 PROPOSITION:

The product is not listed in Proposition 65, the State Drinking Water and the Toxic Enforcement Act. However, as by-products recognised in the state of California for causing cancer or reproductive toxicity, diethanolamine (CAS 111-42-2) is found at trace levels below 0.4% by weight.

Heavy metals (specifically arsenic, lead and mercury) are not present above 5 ppm, which is the limit of detection of the analytical method.

#### ALLERGENS

- **Food allergens:** The product is free of allergens described in ANNEX II to Regulation No 1169/2011, such as animal and fish products, shellfish, nuts, peanuts, eggs, milk, wheat, soybeans, celery, mustard, sesame, gluten, lupin, SO<sub>2</sub> and sulphites.
- **Cosmetic allergens and impurities:** The production route does not involve the use of these products at any stage of the manufacturing process, nor has it been observed that these are produced within the process. Therefore, the following impurities/allergens are not expected to be present:


Products listed as allergenic:

- European Commission Directive 2000/13 – amended 2006/142
- European Commission Directive 2003/15/EC – amending 76/768 EEC
- European Commission Directive 2003/89/EC
- ALBA List, August 2001 version, page 10 of 13, 26 of allergenic components
- Latex
- Moskene: 1,1,3,3,5-pentamethyl-4,6-dinitroindan
- Musk ambrette: 4-tert-butyl-3-methoxy-2,6-dinitrotoluene
- Musk ketone: 4-tert-butyl-2,6-dimethyl-3,5-dinitroacetophenone
- Musk tibetine: 1-tert-butyl-3,4,5-trimethyl-2,6-dinitrobenzene
- Musk xylene: 5-tert-butyl-2,4,6-trinitro-m-xylene
- Nitromusks and/or polycyclic musks.
- Parabens

#### HALAL:

The product meets the requirements, but does not have a Halal certificate.



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**KOSHER:**

The product meets the requirements, but does not have a Kosher certificate.

**VEGAN/VEGETARIAN:**

The product is suitable for vegan/vegetarian use.

**ANIMAL TESTS:**

Animal testing is not performed for use in cosmetics only. Any such testing on substances used in cosmetic products is only carried out to meet explicit legal or regulatory requirements where animal testing is required (e.g. REACH).

**REACH:**

01-2119486482-31-XXXX

**Tariff item number:**

2922150000

**CSAR Code:**

005819-06680-9649