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TECHNICAL DATA SHEET Review date:

Version: **3.0** 

# 94424 - TRICHLOROACETIC ACID

### 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

### 1.1 Identification of the substance or preparation

Name: Trichloroacetic acid Bulk code: 94424 Internal code: 405340

#### 1.2 Synonyms

TCA.

# 2. DESCRIPTION

Appearance: Crystals Colour: White Odour: Characteristic Origin: Synthetic

### 3. COMPOSITION/INFORMATION ON COMPONENTS

Formula: C<sub>2</sub>HCl<sub>3</sub>O<sub>2</sub> CAS: 76-03-9 EINECS: 200-927-2 Molecular weight: 163.39 g/mol

# 4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: Soluble in water.

Highly deliquescent.

#### 5. PROPERTIES/USES

Excipient for pharmaceutical use.

# <u>6. DOSAGE</u>

No information available.

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## 7. REMARKS

### STORAGE:

Store at room temperature in a cool, dry place in a tightly closed container away from sunlight and moisture. Due to its deliquescence, it is recommended to store it in a laboratory desiccator.

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

### BSE/TSE:

The product and the raw materials from which this product was obtained are not of animal origin. Therefore, it is not subject to the BSE regulation, according to EMEA/410/01, final Rev. 03.

In addition, no animal material is present at any time during production.

### GMOs:

The product and the raw materials from which this product has been obtained do not contain genetically modified organisms (GMOs). Therefore, it is compliant with the applicable European Regulations (EC) 1829/2003 and 1830/2003 of the Spanish state and European Directive (EC) 2001/18.

# SVHC:

The product does not contain any of the substances listed in Article 57 of REACH.

#### **RESIDUAL SOLVENTS:**

The product meets the requirements for residual solvents according to the CPMP/ICH/283/95-ICH Q3C guideline. Residual solvents are tested and guaranteed in accordance with USP chapter <467>.

No Class 1, 2 solvents are used in the manufacturing process.

#### ELEMENTAL IMPURITIES:

The product meets the elemental impurity requirements (of the ICP) according to ICH Q3D.

No impurities from the ICH Q3D list are added to the process in the form of catalyst or metal reagent.

# CONTAMINANTS:

Based on the manufacturing process, the product does not contain:

- Dioxins
- Aflatoxins

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#### - Latex

- DEHP and DINP phthalates
- Melamine

### ALLERGENS:

- **Food allergens:** The product does not contain lactose or derivatives. The product does not contain gluten and gluten has not been present in any manufacturing process. Neither the product nor its starting materials contain any of the allergenic substances listed in Annex II to Regulation (EU) 1169/2011.

#### HALAL:

The product is not Halal certified.

### KOSHER:

The product is not Kosher certified.

### **REACH:**

Exempt from registration under Article 2 of REACH (EC) 1097/2006.

### TARIFF ITEM NUMBER:

2915 40 00 00