

# Product Information Package

|              |                                    |
|--------------|------------------------------------|
| PRODUCT NAME | IPASEPT 0,2µM FILTR/NS+SPRAY(6X1L) |
| PRODUCT CODE | 93002                              |
| GRADE        | 0,2µm Filtrated, not irradiated    |
| VERSION      | 2                                  |
| DATE         | 09-01-2026                         |

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## 1. General Information

|                  |                                    |
|------------------|------------------------------------|
| VWR Part Number  | 93002                              |
| VWR Product Name | IPASEPT 0,2µM FILTR/NS+SPRAY(6X1L) |
| CAS number       | 67-63-0                            |
| Origin           | synthetic                          |

## 2. Regulatory Information

|                                                                                   |                       |
|-----------------------------------------------------------------------------------|-----------------------|
| Is the finished product compliant with the following Pharmacopoeia monographs?    |                       |
| • Ph. Eur.                                                                        | Not tested            |
| • USP                                                                             | Not tested            |
| • JP                                                                              | Not tested            |
| • BP                                                                              | Not tested            |
| • NF                                                                              | Not tested            |
| • Other (see statement)                                                           | Conform specification |
| Does VWR hold any regulatory file on the product?                                 |                       |
| <a href="#">EU Biocidal Products Regulation (BPR)</a> (Regulation (EU) 528/2012)) | EU-0020460-0001 1-1   |

## 3. Supply Chain

|                                                                                                                                                                      |     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|
| With respect to the product in question, does VWR perform:                                                                                                           |     |
| • Production                                                                                                                                                         | Yes |
| • Filling, packaging, relabeling                                                                                                                                     | Yes |
| • Quality Control                                                                                                                                                    | Yes |
| • Storage and Distribution                                                                                                                                           | Yes |
| State the name and address of the original manufacturer<br>VWR International bv - Part of Avantor, Researchpark Haasrode 2020,<br>Geldenaaksebaan 464, B-3001 Leuven |     |
| If VWR is not the original manufacturer, is the product delivered to VWR:                                                                                            |     |
| • Directly from manufacturer?                                                                                                                                        | N/A |
| • Always from the same manufacturing site?                                                                                                                           | N/A |
| • From an approved supplier                                                                                                                                          | N/A |
| For a detailed supply chain description see the Supply chain statement in attachment                                                                                 |     |

## 4. Manufacturer

|                                                                                                          |                   |
|----------------------------------------------------------------------------------------------------------|-------------------|
| Is the manufacturer certified according to                                                               |                   |
| • ISO 9001                                                                                               | Yes               |
| • ISO 14001                                                                                              | Yes               |
| • GMP                                                                                                    | See GMP statement |
| • EXCiPACT                                                                                               | No                |
| • Other                                                                                                  | N/A               |
| Is the production site dedicated for the product?                                                        |                   |
| No                                                                                                       |                   |
| If not, other products?                                                                                  | Fine chemicals    |
| • Are materials that are high effective substances and/or toxic produced on the same manufacturing site? | No                |
| • Are hormones produced on the same manufacturing site?                                                  | No                |
| • Are beta-lactam antibiotics produced on the same manufacturing site?                                   | No                |
| • Are cytostatics produced on the same manufacturing site?                                               | No                |
| Is the production process continuous or batch driven?                                                    |                   |
| Batch driven                                                                                             |                   |

## 5. Filling and Packaging

|                                                                                                 |                   |
|-------------------------------------------------------------------------------------------------|-------------------|
| State the VWR Filling and Packaging site:                                                       |                   |
| VWR International bvba, Researchpark Haasrode 2020, Geldenaaksebaan 464, B-3001 Leuven, Belgium |                   |
| What quality system is applied to this product?                                                 |                   |
| • ISO 9001                                                                                      | Yes               |
| • ISO 14001                                                                                     | Yes               |
| • ISO 45001                                                                                     | Yes               |
| What level of GMP is applied to this product?                                                   | See GMP statement |
| All certifications of the production site:                                                      |                   |
| • ISO 9001                                                                                      | Yes               |
| • ISO 14001                                                                                     | Yes               |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| • ISO 45001                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Yes                                  |
| • EU-GMP (limited product scope)                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | See GMP statement                    |
| • ISO17034 (limited product scope)                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Yes, not applicable for this product |
| <b>Describe the quality management system:</b><br>The Quality Management System is described in detail in our Self Assessment.                                                                                                                                                                                                                                                                                                                                                                         |                                      |
| <b>Is the product filled under controlled conditions?</b>                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                      |
| • At least Cleanroom ISO Class 8 at rest (0.5µm; 5µm)                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Yes                                  |
| • Laminar flow                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | No                                   |
| <b>Is the filling process automated or manual?</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Automated or semi-automated          |
| <b>Is the filling room dedicated or multiproduct during filling?</b>                                                                                                                                                                                                                                                                                                                                                                                                                                   | Dedicated                            |
| <b>Is a gowning procedure followed to enter the cleanrooms?</b>                                                                                                                                                                                                                                                                                                                                                                                                                                        | Yes                                  |
| <b>Do you have a system for reconciliation of labels?</b>                                                                                                                                                                                                                                                                                                                                                                                                                                              | Yes                                  |
| <b>Can a batch be traced back to :</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                      |
| • The bulk material                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Yes                                  |
| • QC release                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Yes                                  |
| • Filling documents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Yes                                  |
| <b>How long are batch records retained?</b><br>Records are retained for at least one year past the expiry date.                                                                                                                                                                                                                                                                                                                                                                                        |                                      |
| <b>What type of water is used for cleaning purposes?</b><br>Potable water and final rinse with Purified water compliant to EP and USP                                                                                                                                                                                                                                                                                                                                                                  |                                      |
| <b>What is your definition of a batch?</b><br>A batch is defined as a product volume produced from one manufacturer batch during a fixed period of time                                                                                                                                                                                                                                                                                                                                                |                                      |
| <b>Lot number system?</b><br>VWR lot numbers are unique nine digit alpha-numeric codes comprised of the following: The first two numbers are the last two digits of the year of issuing the filling order. The letter indicates the month (A=Jan, B=Feb, etc.) in which the filling order was issued. The next two numbers indicate the day of printing of the filling order. Finally, the last four digits increase sequentially. This allows to estimate the period in which the product was filled. |                                      |

## 6. Certificate of Analysis (COA)

|                                            |     |
|--------------------------------------------|-----|
| Which information is stated on the VWR COA |     |
| • VWR Article number                       | Yes |
| • Product name                             | Yes |
| • Batch number                             | Yes |
| • Expiry date                              | Yes |
| • Production date                          | No  |
| • Filling date                             | No  |
| • Specifications                           | Yes |
| • Results                                  | Yes |
| • Electronic signature of QC Manager       | Yes |

## 7. Shelf Life

|                                        |                                              |
|----------------------------------------|----------------------------------------------|
| What is the shelf life of the product? | 24 months                                    |
| How is the expiry date attributed?     | 24 months after release of the bulk material |
| Is the stated shelf life based on      |                                              |
| • Stability testing                    | No                                           |
| • Retesting retained samples           | No                                           |
| • Literature                           | Yes                                          |
| • Historical data                      | Yes                                          |

## 8. Label

|                                                       |     |
|-------------------------------------------------------|-----|
| Which information is stated on the VWR product label? |     |
| • VWR product code                                    | Yes |
| • Product name                                        | Yes |
| • Batch number                                        | Yes |
| • Expiry date                                         | Yes |
| • Production date                                     | No  |
| • Filling date                                        | No  |
| • Address of the VWR filling site                     | Yes |
| • Specifications                                      | No  |
| • Results                                             | No  |

## 9. Product Information

We point out that VWR International does not perform these specific testing on the product. But to the best of our knowledge, taking into consideration the raw materials used and/or the manufacturing process, the product is expected to be free from:

|                                                   |                          |
|---------------------------------------------------|--------------------------|
| Dioxines                                          | Yes                      |
| Mycotoxins                                        | Yes                      |
| Phtalates                                         | Yes                      |
| Melamine                                          | Yes                      |
| Aflatoxin                                         | Yes                      |
| Nanomaterials                                     | Yes                      |
| Asbestos                                          | No information available |
| Latex                                             | Yes                      |
| Carcinogenic, mutagenic and reprotoxic substances | Yes                      |
| Pesticide                                         | Yes                      |

## 10. Product Documentation

|                                                  |                                                           |
|--------------------------------------------------|-----------------------------------------------------------|
| Specification                                    | Available on <a href="http://www.VWR.com">www.VWR.com</a> |
| SDS                                              | Available on <a href="http://www.VWR.com">www.VWR.com</a> |
| BSE/TSE Statement                                | Available                                                 |
| GMO Statement                                    | Available                                                 |
| Residual solvent Statement                       | Available                                                 |
| Residual Metal Catalyst and Elemental Impurities | Available                                                 |
| GMP Statement                                    | Available                                                 |
| Nitrosamine statement                            | Available                                                 |
| Allergen Statement                               | Available                                                 |
| VWR Filling and Packaging Process Flow           | Available                                                 |
| Manufacturing Process Flow                       | Available                                                 |
| Supply chain statement                           | Available                                                 |
| Packaging specifications                         | Available                                                 |
| Other                                            | N/A                                                       |

## Product Statements

93002 IPASEPT 0,2µM FILTR/NS+SPRAY(6X1L)

### BSE/TSE

With reference to guideline EMA/410/01 Rev. 3 of the EC, we declare that this product is manufactured without the use of raw materials of animal or human origin. During processing the product does not come in contact with animal material. Therefore the product is considered safe regarding TSE and BSE.

### GMO

With reference to Regulation 1829/2003 and 1830/2003 concerning the labeling and traceability of genetically modified organisms (GMO) and of food and feed produced from genetically modified organisms, we hereby declare that this product is neither produced from, nor consists of genetically modified organisms. Hence, to the best of our knowledge, there is no objective reason to suspect a risk associated with GMO in the product.

### Allergen

To the best of our knowledge, taking into consideration the raw materials used and the manufacturing process, allergenic products according to Regulation (EU) No 1169/2011 Annex II are not expected to be present in the final product except for

None ;

For your information, the allergenic products included in Regulation (EU) No 1169/2011 Annex II are:

- Cereals containing gluten and products thereof;
- Crustaceans and products thereof;
- Eggs and products thereof;
- Fish and products thereof;
- Peanuts and products thereof;
- Soybeans and products thereof;
- Milk and products thereof (including lactose);
- Nuts and products thereof;
- Celery and products thereof;

- Mustard and products thereof;
- Sesame seeds and products thereof;
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg;
- Lupin and products thereof;

We point out that VWR International does not perform any testing on allergens in the product.

## **Residual Solvents**

With reference to guideline ICH Q3C, we hereby confirm that residual solvents are not likely to be present.

Except for;

- class 2 solvent, t-Butanol ( < 100 mg/kg),
- class 3 solvent: n-Propanol, 2-Butanol, Ethanol and Acetone which are are likely to be present, and
- 2-propanol (class 3) which is inherent to the product

Residual Class 3 solvents (excluding 2-propanol) are below 0.5%

## **Residual Metal Catalyst and Elemental Impurities**

Based on the implementation of ICH Q3D into the European Pharmacopoeia and US Pharmacopoeia, all elements from ICH Q3D Class 1 and 2A (i.e. Cd, Pb, As and Hg plus Co, V and Ni) are analyzed on the raw materials used. Those elements are analyzed by atomic absorption spectroscopy or inductively coupled plasma using optical emission spectroscopy or mass spectroscopy detection. In addition, no elements are intentionally added in the manufacturing process.

Based on the results gathered so far, we implemented skip lot testing for the metal catalyst residues. This means we will perform a full analysis on the residues of metal impurities every 5 lots or at least every 2 years if not ordered at high frequency. In case skip lot testing is applied for metal catalyst analysis of a concerned lot, the results of the latest performed analysis will be copied.

The specifications were set based on our quantitation limits of the ICP method. The risk of having a non-compliant result reported is mitigated by;

- Qualified source (compendial grade) with ICH Q3D statement
- Enough data have been gathered over the last 5 years to support skip lot testing
- A full analysis is performed every 5 lots or at least every 2 years for less frequent orders
- In case a metal of class 1 and 2A is a specification set by the monograph, we will test it and not apply skip lot testing

The ICHQ3D guideline does not state that we need to measure the residues of metal catalysts on each lot

## **GMP**

Our pharma-grade materials are prepared according to principles of good manufacturing practice (GMP). These principles are expected to be applied for the manufacture and repack of products with a designation of a pharmacopoeia in the title of the substance. The applied principles of GMP for pharmaceutical products are based on IPEC - PQG Joint Good Manufacturing Practices Guide for Pharmaceutical Excipients. The IPEC - PQG GMP Guide is also the basis for our supplier audits. Processes are verified to comply with an adequate quality level of manufacturing and quality control. We trust that the applied GMP principles cover the quality management system and the extent of GMP necessary throughout manufacturing processes for pharma-grade products.

## **Nitrosamine**

Following an internal evaluation in accordance with regulatory authority guidance and as outlined in the ICH Q9 guideline on quality and risk management, VWR International bv ("VWR") has determined that nitrosamines and related compounds are not likely to be present above reportable limits in this product.

VWR's review of the products for risk of nitrosamines included the assessment of potential nitrogen sources and other chemistries with potential for nitrosamine impurity formation. Following such assessment, in line with the CHMP Assessment report of Article 5(3) of Regulation EC (No) 726/2004 (EMA/369136/2020) by the European Medicines Agency, dated 25 June 2020, VWR is able to confirm the following:

1. None of our manufacturing processes utilize sodium nitrite or other nitrosating agents as intentionally added ingredients in the presence of secondary, tertiary amines or quaternary ammonium salts within the same or different manufacturing step.
2. None of our manufacturing processes utilize sodium nitrite or other nitrosating agents as intentionally added ingredients in combination with reagents, solvents or catalysts, which are susceptible to degradation to secondary or tertiary amines, within the same or different manufacturing step.
3. During our manufacturing process the products are not coming into contact with nitrosamines or nitrosamines containing products.

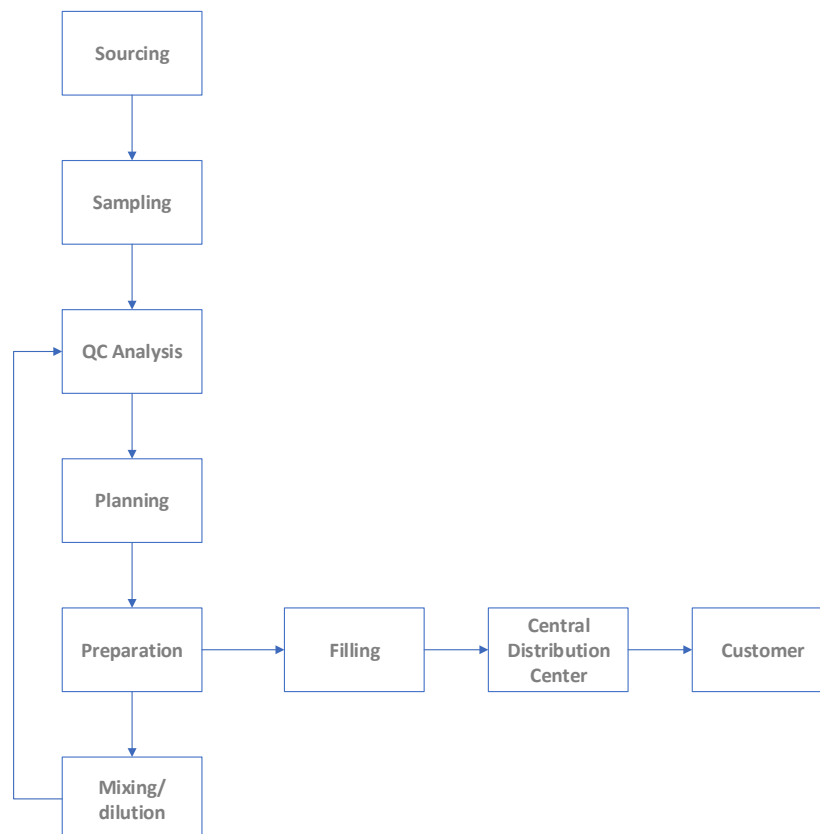
4. During our manufacturing process the products are not coming into contact with equipment used to handle nitrosamines or nitrosamines containing products.
5. We do not outsource any nitrogen containing solvents or other nitrogen containing reagents to 3rd parties for recovery or reprocessing.
6. None of our products are sold in blister packaging containing nitrocellulose printer primer that may react with amines in printing ink to potentially generate nitrosamines.
7. The water used to manufacture the products and clean the equipment has not been treated with chloramine or chlorine.

Considering the very low potential for the presence of nitrosamine in VWR manufactured and/or repacked products as set forth above, no specific testing was or is intended to be performed by VWR to confirm the absence of nitrosamine or related compounds in the products. VWR makes no warranties or representation, express or implied, related to the presence or absence of nitrosamines or related compounds in any of the products.

## VWR Filling and Packaging Process Flow

93002 IPASEPT 0,2µM FILTR/NS+SPRAY(6X1L)

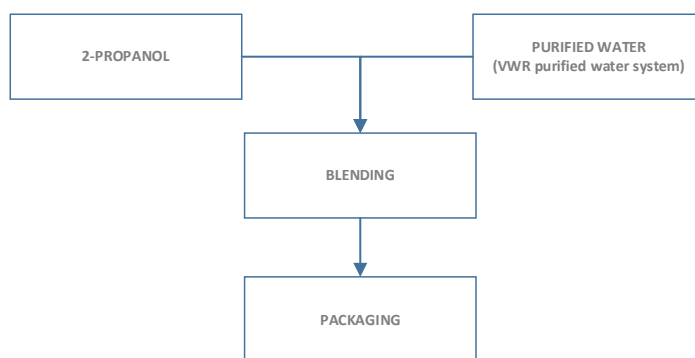
The flowchart below gives an overview of the filling and packaging flow at VWR International.



## Manufacturing Process Flow

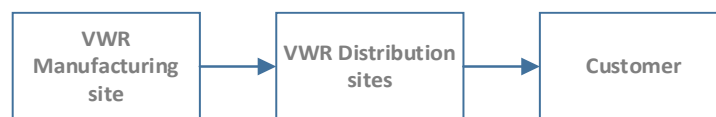
93002 IPASEPT 0,2µM FILTR/NS+SPRAY(6X1L)

The flowchart below gives an overview of the manufacturing process at the manufacturer.



## Supply chain Flow

93002 IPASEPT 0,2µM FILTR/NS+SPRAY(6X1L)



| Company                                                                                              | Activity                                                                      |
|------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| VWR International bv<br>Researchpark Haasrode 2020,<br>Geldenaaksebaan 464, B-3001 Leuven<br>Belgium | QC testing ;Manufacturing ;Labelling ;Packing<br>;Warehousing ;Distribution ; |
| VWR<br>Distribution Warehouses                                                                       | Warehousing ; Distribution ;                                                  |

Depending on the customer requirements, various VWR warehouse can be added to the supply chain.

## Packaging Specifications

93002 IPASEPT 0,2µM FILTR/NS+SPRAY(6X1L)

|                                |                              |
|--------------------------------|------------------------------|
| Part number:                   | VWRC93002.1016 + SPRAYPISTOL |
| Packed quantity:               | 6 x 1 L with SPRAYPISTOL     |
| Primary Container              |                              |
| Type                           | BOTTLE LIQUIDS               |
| Measurements                   | 1L DIN28                     |
| Material                       | HDPE NAT (Eu No. 1935/2004)  |
| Secondary Container            |                              |
| Type                           | Carton box                   |
| Material                       | Carton                       |
| Closure at delivery            |                              |
| Type                           | SCREW CAP                    |
| Measurements                   | DIN28                        |
| Material                       | PE                           |
| Added closure for customer use |                              |
| Type                           | SPRAY PISTOL                 |
| Measurements                   | DIN28                        |
| Material                       | PP, PE, LLDPE, POM           |

This document is created based on the information kept in our quality database.

By *QA VWR chemicals - Lies Fierens*

On *January 13, 2026*