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RAW MATERIAL IDENTIFICATION DATA

PHARMACEUTICAL INGREDIENTS

Cf. Procedure N° GRRAF004

SIMULSOL M45 PHA PREMIUM

PRODUCT CODE: 80134U

PREAMBLE

This document aims to facilitate the information exchanges related to SEPPIC's chemical raw materials (herein after referred to as the "Materials"). Such exchanges shall occur between SEPPIC, supplier of the Materials, and its customers.
In the framework of these exchanges, SEPPIC offers to sale such Materials for the preparation of pharmaceutical formulations. The final use of the Materials supplied by SEPPIC remains the sole responsibility of SEPPIC's customer.
In case of direct importation, SEPPIC's customers are responsible for the compliance of the imported Material with the local pharmaceutical regulations.
The final use of the Material and the compliance with associated regulations remains the sole responsibility of the customer. SEPPIC commits to supply Materials that are in conformity with the application claimed.
Each Material is associated to a commercial reference, to a packaging unit, and to contractual specifications, to which the data supplied in this document are linked. The information provided in this document cannot be taken as specifications. The only specifications on the Material are information included in its certificate of analysis.
The data comprised in this document are deemed to be valid at the date of its signature, at the best of SEPPIC's knowledge, but might be updated. SEPPIC does not commit itself to automatically update this document and to automatically communicate the updated document to its customers.
The information comprised in this document and related to the Material is submitted by SEPPIC to his prospects and/or customers for their own development and/or the manufacturing of its pharmaceutical formulations.
This document and the information contained in this document cannot be communicated by SEPPIC's prospects and/or customers to any third party without the prior written agreement of SEPPIC, at the exception of the communication and/or the disclosure to legal authorities which remains of the prospects and/or customers' sole responsibility.

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SUMMARY

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I - GENERAL INFORMATION

- Commercial name: SIMULSOL M45 PHA PREMIUM
- Product code: 80134U
- Supplier: SEPPIC S.A.
  22 Terrasse Bellini
  Paris La Défense
  92800 PUTEAUX
  France
  Tel: +33 (0)1 42 91 40 00 / Fax: + 33 (0)1 42 91 41 41
- Manufacturer: SEPPIC S.A.
  127, chemin de la poudrerie
  81100 Castres
  France
  Tel: +33 (0)5 63 72 69 69 / Fax: + 33 (0)5 63 72 69 70
- Harmonized Customs number: 340213

I.1 - Product use

- Grade: Pharmaceutical
- Type of material:
  ☒ Pharmaceutical Excipient
  ☐ Active pharmaceutical ingredient
  ☐ Colour ☐ Active Nutritional/Food ingredient
  ☐ Flavour ☐ Other:
- Type of application:
  ☒ Oral ☒ Topical
  ☐ Injectable ☐ Inhaled
- Type of functionality: Hydrophilic emulsifier
- Chemical name or usual name or description: polyoxyethylenated stearic acid (8 EO)

I.2 - Composition

Usual name (chemical name)	CAS No.	EC No.	Equivalent to E-No.	%
Polyoxyl 8 stearate (polyoxyethylene 8 stearate)	9004-99-3	-	-	100%

I.3 - Declaration of origin

☐ Animal or human (see IV/ 1)*
☒ Vegetal (see IV/ 2)
☐ Mineral
☒ Synthetic

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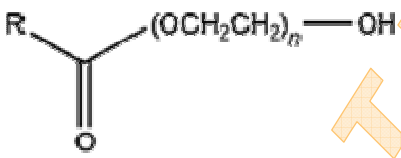
☐ Other: fermentation, biotechnology, culturing cells, ...

II - MATERIAL SPECIFICATION DATA

II.1 - Structural and molecular formula of the material's components

Components	Structural formula	Molecular formula	Molecular weight
Polyoxyl 8 stearate	 where R is $CH_3(CH_2)_{16}$ and n = 8	$C_{34}H_{68}O_{10}$	636.91

II.2 - Regulatory status of the material's components

Pharma Status	Material
Conform to EP (European Pharmacopeia) monograph N°	Yes 1234 (magrocol stearate)
Conform to USP/NF (US Pharmacopeia) monograph	Yes Polyoxyl stearate
Conform to JP (Japanese Pharmacopeia) monograph	No
Conform to other Pharmacopoeias:	Not yet identified

II.3 - Additives

The material contains additives (antioxidant, preservatives…): ☐ Yes ☒ No

Additives	Function	E-number	Concentration (unit)

II.4 - Analytical data

- Data controlled and reported on the certificate of analysis (CoA) are: See the CoA
- All data listed in the CoA is examined in every batch delivered: ☐ Yes ☒ No

If not, it is indicated in the certificate of analysis: ☒ Yes No

- Tests are carried out by independent laboratories: ☐ Yes ☒ No

If yes, the type(s) and scope of testing(s) are:

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II.5 - Microbiological analysis NA

- Microbiological analysis are done on: ☐ Starting material ☐Material

Microorganisms	Concentration	Method	Comments

- The limits are reported on the CoA: ☐Yes ☐ No

II.6 - Stability & Shelf life

- Stability data are based on: ☒ Standard storage conditions
  ☐ ICH Q1 ☐ Other:
- Expiry date: 2 years (unopened packaging in the recommended storage conditions)
- Expiry date starts from: ☒ Date of production ☐ Date of analysis
  ☐ Purchase date ☐ Delivery date

III - REGULATION FILES

The material holds:

☐ A Certificate of Suitability of the EP monograph (CEP-Chemical) issued by the EDQM

☐ A US DMF

☐ A European DMF less than 5 years old registered in these countries

☐ Others

☒ None

IV - DETAILS ON ORIGIN

The following information come from data obtained until today from our current suppliers.

Starting materials involved in the process	Source[1]
Stearic acid	Vegetal (palm oil)
Ethylene oxide	Synthetic

[1] Synthetic; Human; Animal (specify*), Vegetal (specify), Mineral; Others (specify**)
* Avian, Porcine, Bovine, Caprine, Ovine …
** Fermentation, biotechnology, culturing cells …

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IV.1 - In case of animal or human origin: TSE & Viral risk NA

- The material holds a CEP for the TSE risk complying with the guideline EMEA/410/01 Rev. 3 — March 2011: ☐ Yes, CEP No.: ☐ No

If not, list of the animal species, tissues, country of origin and material used: ex: bone, skeletal muscles, tongue, heart, tendon, skin, trachea, adipose tissue, testis, ovary, uterus, foetal tissue, milk, colostrums, cord blood, urine

Tissues	Animal specie	Country of origin

- The manufacturing process involves source materials, material into contact, or reagents (e.g. lubricants, cleaning agents, filtering agents, processing aids, enzymes or culture media) that are of human or animal origin: ☐ Yes ☐ No
- In accordance with the Note of Guidance ref. CPMP/BWP/268/95 on Viral Safety Studies, validation studies on inactivation & removal of viruses are available: ☐ Yes ☐ No

IV.2 - In case of vegetable origin: GMO status

- The material contains or consists of GMOs and is produced from or contains ingredients produced from GMOs according to European Regulation 1829/2003/EC: ☐ Yes ☒ No
- The material requires GMO-labelling according to European Regulations 1829/2003/EC & 1830/2003/EC: ☐ Yes ☒ No
- The manufacturing process includes recombinant technologies: ☐ Yes ☒ No
- There is a procedure to check the PCR negative status: ☐ Yes ☒ No

V - IMPURITIES AND CONTAMINANTS

V.1 - Solvents

- There are solvents used during the manufacturing of the material: ☐Yes ☒No
- Residual solvents based on the Note for Guidance EMA/CPMP/ICH/283/95 (ICHQ3C) and USP <467>:
  - o There are solvents likely to be present in the material: ☒ Yes ☐ No

Solvent name	Class (1/2/3)	ICHQ3C's limit (ppm)	Concentration (ppm)	Origin*	Analysis method	Comments
1,4-dioxane	2	< 3	< 380	Process	EP 2.4.25	Statistical analysis
Ethylene glycol	2	< 620	< 620	Process	EP 2.4.24	Results on 3 batches
Confidential	3	< 5000	< 5000	Process		

*process, starting material, cleaning, cross contamination

  - o Levels of residual solvents are monitored in starting materials: ☐ Yes ☒ No

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V.2 - CMR (carcinogenic, mutagenic, reprotoxic) & PGIs

- The material contains substances listed in Chapter IV, article 15 of the European Cosmetic Regulation 1223/2009/EC of 30 November 2009: ☐ Yes ☒ No
- The material is concerned by the European Guideline on the limits of genotoxic impurities CPMP/SWP/5199/02: ☐ Yes ☒ No

V.3 - Elemental Impurities

- Elemental impurities levels on starting materials are: ☐ monitored by SEPPIC ☒ from supplier data
- Elemental impurities levels on material are (ICH Q3D):

Elemental Impurities	Class	**Level of Elemental Impurities according to analysis performed of 3 batches of the most representative product (µg/g)**	**Permitted concentrations of Elemental Impurities for option 1 (ICH Q3D) in Drug Products** **Oral concentration (µg/g)**	**Analytical Method Used**
As	1	< 0,15	1,5	ICP-MS
Cd	1	< 0,05	0,5	ICP-MS
Hg	1	< 0,3	3	ICP-MS
Pb	1	< 0,05	0,5	ICP-MS
Co	2A	< 0,5	5	ICP-MS
Ni	2A	< 2	20	ICP-MS
V	2A	< 1	10	ICP-MS
Ag	2B	< 1,5	15	ICP-MS
Au	2B	< 1	10	ICP-MS
Ir	2B	< 1	10	ICP-MS
Os	2B	< 1	10	ICP-MS
Pd	2B	< 1	10	ICP-MS
Pt	2B	< 1	10	ICP-MS
Rh	2B	< 1	10	ICP-MS
Ru	2B	< 1	10	ICP-MS
Se	2B	< 1,5	15	ICP-MS
Tl	2B	< 0,08	0,8	ICP-MS
Ba	2B	< 14	140	ICP-MS
Cr	2B	< 110	1100	ICP-MS
Cu	3	< 30	300	ICP-MS
Li	3	< 5,5	55	ICP-MS
Mo	3	< 30	300	ICP-MS
Sb	3	< 12	120	ICP-MS

Sn	3	< 60	600	ICP-MS

V.4 - Residual metal catalysts

Residual metal catalysts based on the European Guideline EMEA/CPMP/SWP/4446/2000 and ICH Q3D

- Metal catalysts or reagents are used in the synthesis process: ☐ Yes ☒ No
- Metal catalysts or reagents are likely to be present in the material: ☐ Yes ☒ No
- Levels of residual metals are monitored in starting materials: ☐ Yes ☒ No

Metals	Class (1-2-3)*	Concentration (ppm)	Guideline limit (ppm)	Methods used	Comments

*class 3 (Fe, Zn), class 2 (Cu, Mn), class 1 (Pt, Pd, Ir, Rh, Ru, Os, Mo, Ni, Cr, V)

V.5 - Contaminants

To our current knowledge of process, starting materials (based on our suppliers' statements) and equipment, the following substances are not likely to be contained, intentionally added or generated at our facility in the material		**Comments**
Aflatoxins B1, B2, G1, G2	☒	
Antibiotics	☒	
Antineoplastic agent	☒	
Asbestos	☒	
Cytotoxic agents	☒	
Dioxins and PCB	☒	
Ethylene oxide	☐	Used as raw material. Residual value < 1 ppm (in statistic analysis)
Formol	☒	
Fungi	☒	
Melamine	☒	
Mycoplasma	☒	
Mycotoxins	☒	
Narcotic	☒	
Nitrates	☒	
Ochratoxins	☒	
Pesticides (ethoxyquin included)	☒	
Phthalates	☒	
Plant hormones	☒	
Polycyclic Aromatic Hydrocarbons (PAH)	☒	
Psychotropic agents	☒	
Sewage sludge	☒	
Steroids, hormones, growth promoter	☒	
Other contaminants[1] [2]:	☒	

[1]according to European Regulation 1881/2006/EC

[2]according to the last edition of the California proposition 65

V.6 - Allergens

To our current knowledge of process, starting materials (based on our suppliers' statements) and equipment, the material does not contain or is not derived from any of the following		Comments
Allium Genus (garlic, onion, chives, leeks)	☒	
Azo dyes (E102, E110, E122, E123, E124, E129, E151)	☒	
Bee products, pollen and products thereof (royal jelly, honey)	☒	
Benzoates, benzoic acid and parabens (E210-E219)	☒	
BHA/BHT (E320-E321)	☒	
Cardamom (ginger)	☒	
Caroten	☒	
Cinnamon	☒	
Cocoa	☒	
Egg / Egg derivatives	☒	
Gelatine	☒	
Glutamates and glutamic acid (E620-E625)	☒	
Gluten and cereals containing gluten and products thereof (wheat, rye, barley, oats, spelt, kamut or their hybridised strains):	☒	
Jatropha plant	☒	
Latex (natural or synthetic)	☒	
Lecithin	☒	
Lupin	☒	
Maize / Corn and product thereof	☒	
Milk and milk derivatives (lactose, lactic acid, casein, whey, etc.)	☒	
Seed Oil, Mustard	☒	
Sesame seeds and products there of	☒	
Sweeteners (including aspartame and polyols: Isomalt, Lactitol, Mannitol, Erythriol, Sorbitol, Xylitol)	☒	
Pepper	☒	
Peanuts and tree nuts and by extension their oils and derivative products (specify type: almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamTOXia nuts and Queensland nuts, coconuts, nutmeg):	☒	
Phenylalanine	☒	
Phosphates	☒	
Phytosterol	☒	
Quinine	☒	
Seafood (Crustaceans, Molluscs, Fishes) and derivates	☒	
Silicones	☒	
Sorbates and sorbic acid (E200 - E203)	☒	
Soybeans and products thereof (bulking or anti-dusting agents, emulsifiers, hydrolysed vegetable protein)	☒	
Sugar (Fructose, Glucose)	☒	

To our current knowledge of process, starting materials (based on our suppliers' statements) and equipment, the material does not contain or is not derived from any of the following		Comments
Sulphites and Sulphur dioxide (SO2) – at conc. of more than 10 mg/kg or 10 mg/L expressed as SO2:	☒	
Sunflower products and derivates	☒	
Umbelliferae (angelica, aniseed, caraway, carrot, celery, chervil, coriander, dill, fennel, lovage, myrrh, parsley)	☒	
Vanillin	☒	
Vegetable protein derivatives	☒	
Others[1]:	☒	

[1]according to European food regulation 1169/2011/EU , US FALCPA 2004 and European cosmetic regulation 1223/2009/EC

V.7 - Virus

- Virus contamination based on:

- Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EC,

- Recommendation CDC (US) regarding highly pathogenic avian influenza (HPAI) from H5N1 virus.

- The material is free from any starting material originating from birds, pork and has not been in contact with birds and pork and then is not concerned by the regulations above: ☒ Yes ☐ No

VI - OTHER CONFORMITIES

VI.1 - Animal testing

Based on European Regulation 1223/2009/EC of 30 November 2009 on cosmetic products – Chapter V – Art. 18.

- The material has been tested on animals for cosmetic purposes ☐ Yes ☒ No

VI.2 - Conflict metals

Based on US Dood-Franck Wall Street Reform and Consumer Act of July 10, 2010.

- The material contains and/or uses in its manufacturing process 3TG metals (Tin, Tungsten, Tantalum, Gold) and these metals are intentionally added in the material ☐ Yes ☒ No

VI.3 - Nanomaterials

Nanomaterials based on European Commission Recommendation 2011/696/EU of 18 October 2011 and French Decree n° 2012-232 of 17 February 2012.

- The material contains particles, in an unbound state or as an aggregate or as an agglomerate, with a minimum proportion of the particles in the distribution size have one or more outer dimensions between 1 nm and 100 nm in number: ☐ Yes ☒ No

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- The material contains particles, in an unbound state or as an aggregate or as an agglomerate, with a proportion of 50% of the particles in the distribution size have one or more outer dimensions between 1 nm and 100 nm in number: ☐ Yes ☒ No
- The material is intentionally nanoscale produced: ☐ Yes ☒ No
- The material is free of compound defined as a nanoparticle: ☒ Yes ☐ No

VI.4 - Doping substances

The material or components of the material consist in or contain substances listed in the current prohibited list of WADA (World Anti-Doping Agency): ☐ Yes ☒ No

VII - SUBCONTRACTING

- SEPPIC is the manufacturer of the product (totally or partially): ☒ Yes ☐ No

	Seppic	Subcontractor
Manufacturing	☒	☐
Packaging	☒	☐
Labelling	☒	☐
Analysis/control of final material	☒	☐
Release	☒	☐
Others: - Storage and logistic for starting and final materials	☐	☒

- SEPPIC establishes specific purchase requirements ☒ Yes ☐ No ☐ NA
- SEPPIC audits or assesses its subcontractor: ☒ Yes ☐ No ☐ NA
- The certificate of analysis supplied for each batch of delivery states where the manufacturing has been performed: ☐ Yes ☒ No

VIII - MATERIAL MANUFACTURING QUALITY

VIII.1 - Quality assurance of the manufacturing site

- For further information on the manufacturing site quality systems, see the Quality manual of the manufacturing plant

VIII.2 - Description of the manufacturing process

Reaction of stearic acid with ethylene oxide in order to obtain polyoxyl 8 stearate.

VIII.3 - Manufacturing standards of the material

- These standards or guidelines are followed for the manufacturing of the material:

☒ ISO 9001
☒ ISO 14001
☒ OHSAS 18001
☐ GMP part II Guidelines / ICH Q7a
☐ ISO 22000
☒ IPEC Guidelines

- Certificates are held for the manufacturing of the material:

☒ ISO 9001 certificate delivered by SGS
☒ ISO 14001 certificate delivered by AFAQ
☒ OHSAS 18001 certificate delivered by AFAQ
☐ Certificate of Manufacturing Authorization delivered by ANSM
☐ GMP part II certificate delivered by ANSM
☒ GMP attestation of inspection delivered by ANSM
☐ EXCIPACT, International excipient certification delivered by SGS
☐ RSPO (Roundtable on Sustainable Palm Oil) ordinary member

- The manufacturing plant has been inspected by the local authority ☒ Yes ☐ No
- The manufacturing plant has been inspected by FDA ☐ Yes ☒ No
- The material is made by a: ☒ Batch process ☐ Continuous process
- Critical parameters of production are recorded continuously: ☒ Yes ☐ No
- Batch records are done on the material: ☒ Yes ☐ No
- Batch records are checked and signed: ☒ Yes ☐ No
- Batch records are kept during: 10 years
- The person in charge of checking and signing the batch records is the Production Workshop Manager
- The person in charge of releasing batch is Quality control manager
- In case of deviation, the person in charge of releasing batch is the Quality assurance manager
- There is a change control program (formula, processing, and starting materials): ☒ Yes ☐ No

VIII.4 - Quality of the manufacturing water

	Manufacturing	Cleaning
Tap water	☒	☒
Demineralised or purified water	☐	☐
Sterilised water	☐	☐
Water for injection	☐	☐

The water used in processing steps meets the standards for potable water:

☒ Yes ☐ No

VIII.5 - Microbiological quality of the material

- The material has been sterilized: ☐ Yes ☒ No
- The material is treated to reduce microbiological contamination by irradiation/ionisation: ☐ Yes ☒ No
- The material is treated to reduce microbiological contamination by ethylene oxide treatment: ☐ Yes ☒ No
- The material is treated to reduce microbiological contamination ☐ Yes ☒ No
- The air cleanliness class in final processing and packaging rooms is: NA
  ☐ Class 100 ☐ Class 10 000 ☐ Class 100 000

VIII.6 - Cross contamination

- The workshop is used exclusively for the material ☐ Yes ☒ No
- The equipment used for the material is: ☐ Single material ☒ Multiple material

In case of multiple material equipment:

- Other materials manufactured on this equipment are chemically dissimilar to the material:
  ☐ Yes ☒ No
- Highly effective and/or sensitizing (medicinal) substances (ex antibiotics) are manufactured on this equipment: ☐ Yes ☒ No
- There is a cleaning procedure to remove the previous material: ☒ Yes ☐ No

In case of use of storage tanks: **NA**

- Storage tanks are dedicated to specific chemicals: ☐Yes ☐ No
- Storage tanks are cleaned and inspected before filling: ☐ Yes ☐ No

In all cases:

- Starting materials or components used in manufacturing are stored in distinct area: ☒ Yes ☐ No
- Cross contamination with allergens and GMOs can occur: ☐ Yes ☒ No
- There is a procedure to prevent contamination: ☒ Yes ☐ No

VIII.7 - Batch & Label

- Definition of a batch: a batch corresponds to a manufacture order. A batch can also be the content of a finishing reactor. Thus, a batch is a quantity of homogeneous product obtained at the last manufacturing step.

  Batch numbering system: see the Quality manual of the manufacturing plant
- Couples “product code and batch number” are unique: ☒ Yes ☐ No

- Starting materials can be traced by their batch number to all batches of final material where they may have been used : ☒ Yes ☐ No
- Batch records specify the amount and batch number of starting material used: ☒ Yes ☐ No
- Batch records specify which machine/equipment are used: ☒ Yes ☐ No
- Manufacturing batch size for the material: 4600 kg
- Final materials are properly identified, labelled and stored: ☒ Yes ☐ No
- Final material labels are: ☒ Printed as needed ☐ Purchased pre-printed
- Reconciliation on labels is done on each bath: ☒ Yes ☐ No
- There are written procedures for receipt and testing of packaging materials: ☒ Yes ☐ No
- Indications on the label of the delivered final material:

☒ Product name
☒ Product code
☒ Supplier (name and address)
☒ Manufacturing site (name and address)
☒ Batch number
☐ Order number
☒ Net weight, product quantity
☒ Type of packaging (code)
☐ Quality specifications
☒ Manufacturing date (YYYY-MM)
☐ Shelf life
☐ Retest date
☒ Expiry date
☒ Compulsory notes related to safety work, environment and transport
☒ Precaution of use and handling (including storage conditions)
☐ Others:

- A new packaging or new labelling is carried out for the material, after it has left the production area: ☐ Yes ☒ No
- The label is in conformity with the European regulation 1272/2008/EC concerning classification and labelling (Globally Harmonized System (GHS)) ☒ Yes ☐ No

VIII.8 - Sampling, testing and recording

- The testing samples represent the whole batch: ☒ Yes ☐ No
- Retain samples are stored from all manufacturing batches for future reference: ☒ Yes ☐ No For 3 years (expiry date + one year)

- Records of the tests performed are maintained: ☒ Yes ☐ No
- Test methods are fully documented & controlled: ☒ Yes ☐ No
- Calibration certificates for primary standard weights and primary standard instruments are available and traceable to National/International standards (NIST): ☒ Yes ☐ No
- Written procedures for final product inspection, testing & release are in place: ☒ Yes ☐ No
- An annual review of products is performed: ☐ Yes ☒ No

IX - PACKAGING AND STORAGE

IX.1 - Packaging

OTP30	Primary packaging	Secondary packaging	Pallet*
Type of Material	Plastic drum	-	Wood
Size (cm) :	31,5 x51,7 (Dxh)	-	114 x 114
Specifications (weight, …)	25 kg	-	600 kg 24 plastic drums/pallet

*standard packaging. This packaging could be changed without any prejudice to the material

- Batch separation is maintained during packaging: ☒ Yes ☐ No
- Final material packing operations are segregated: ☐ Yes ☒ No
- Material packaging is sealed (pilfer-proof) closed with a special link: ☒ Yes ☐ No
- Silica Gel Desiccant is used during packaging: ☐ Yes ☒ No
- The packaging material complies with European Regulation 1907/2006/EC on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and later amendments: ☒ Yes ☐ No
- The packaging material complies with European Regulation 1935/2004/EC on materials in contact with food and later amendments: ☒ Yes ☐ No
- The packaging material complies with European regulation 10/2011/EU on plastic materials in contact with food and later amendments: ☒ Yes ☐ No
- Appropriate controls & measures taken on containers & closures of sterile drug substances are: NA
- There is a quarantine system for final material: ☒ Yes ☐ No
- New packaging or new labelling is carried out after the material has left the manufacturing site: ☐ Yes ☒ No

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IX.2 - Storage

Storage recommendations: Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials, food and drink. Keep container tightly closed and sealed until ready for use.
Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

- SEPPIC applies good storage practices: ☒ Yes ☐ No
- Good storage practices are: Traceability, closed and covered premises, temperature recordings, segregated areas (quarantine, conform, not conform), etc...
- The facilities used to store or release material awaiting shipment are in good conditions (clean, maintained): ☒ Yes ☐ No
- Shipping containers are marked to identify their contents: ☒ Yes ☐ No

X - ETHNIC AND DIET CONCERNS

	Yes	No
The material is Kosher certificated:	☐	☒
The material is suitable for Kosher products	☒	☐
The material is Halal certificated:	☐	☒
The material is suitable for Halal products	☒	☐
The material is suitable for vegans:	☒	☐

XI - INTELLECTUAL PROPERTY

Patents:

SEPPIC patent: none

SEPPIC owns industrial property related to this product. According to the continuous enlargement of this industrial property and the regular evolution of associated examination procedures, SEPPIC will provide patents application and/or patent publication numbers upon request.

This information constitutes the knowledge of SEPPIC at this date.

It remains of the customer's responsibility to assess the freedom to operate the material within the formulation it intents to develop and/or place onto the market.

Document approved on the 21 August 2017

By Sandra PAUMIER

Pharmaceutical Regulatory Affairs Manager