

# Refined Soybean Oil IV



## Description

Our refined Soybean Oil IV is a highly purified soybean oil intended for use in the manufacture of parenteral preparations, and complies with:

- European Pharmacopoeia
- US Pharmacopeia
- Chinese Pharmacopoeia
- Japanese Pharmacopoeia

## Application areas

Refined Soybean Oil IV can be used as an active pharmaceutical ingredients (API), in parenteral nutrition (e.g. large volume lipid emulsion) or as an excipient for human and veterinary applications.

## Regulatory environment

Refined Soybean Oil IV is manufactured according to c-GMP Guidance for Active Pharmaceutical Ingredients. The quality of the substance is suitably controlled according to the current version of the monograph Soybean Oil, refined <1473> of the European Pharmacopoeia, including supplements (certificate of suitability CEP delivered by EDQM, European Directorate for the Quality of Medicines & HealthCare).





## Manufacturing process

The refining process used is an advanced purification process, designed to purify and to provide a high quality product. The process enables production of oils with low level of impurities and trans fatty acids, while maintaining the excellent stability of the end product.

## Packaging

Refined Soybean Oil IV is available in 60L or 225L tight head metal drums.

## High level of quality

- Quality procedures system & management
- Personnel training
- Sourcing and control of raw materials
- Validated manufacturing process
- Validated analytical procedures
- Control of critical steps and risk assessments
- Control of impurities
- Appropriate packaging and labeling
- Documented stability data

## Contaminants

- Control of bacterial endotoxins
- Heavy metals  $\leq 10\text{ppm}$
- Residual solvents: compliance with ICH Q3C and EP 5.4 requirements
- Residues of metal catalysts or metal reagents: compliance with guideline EMEA/CHMP/4446/2000 and EP 5.20 requirements
- Absence of TSE/BSE risk
- Absence of mycotoxins and genotoxic impurities

*To find out how we can help you create innovative products, contact us today:*

ADM - SIO  
2 Rue George Sand - Bat A  
78112 Fourqueux  
France  
sio-orders@adm.com  
+ 33 (0)1 74 08 03 00  
+ 33 (0)1 39 21 01 40  
www.admsio.com

