



Animal species



## Technical Bulletin

### Key Points :

- Ready to use oil adjuvant
- For very stable *m* - O/W emulsion
- Easy to inject vaccines
- Induces a strong and long lasting immune response
- Known to stimulate humoral and cellular responses
- MERCKINADE™ listed on USDA and CDA as SDA BIO

## SDA 4580 (Eq IMS 251C)

### Ready to use oil adjuvant for veterinary vaccines

SDA 4580 is a mineral oil based adjuvant which has been developed for the manufacture of micro (~80nm) O/W emulsions. It comprises a high grade injectable mineral oil and extremely refined emulsifiers obtained from mannitol, sorbitol, polythylene glycol and purified oleic acid of vegetable origin. SDA 4580 is free of animal origin ingredients.

Vaccine formulations with MERCKINADE SDA 4580 induce a strong and long term immunity. Compared to traditional oil emulsions, MERCKINADE™ SDA 4580 emulsions are **very stable** and **easy to inject**.

#### 1. VACCINE PREPARATION:

To prepare 100 g of vaccine, a typical preparation is made of:

|                           |          |
|---------------------------|----------|
| • MERCKINADE SDA 4580     | 100g     |
| • Aqueous antigenic media | 400-900g |

Stable preparations are obtained by mixing the aqueous medium into the MERCKINADE™ SDA 4580, at room temperature or less, under vigorous stirring. The use of a high shear mixer is necessary to prepare a stable and efficient vaccine.

#### 2. EMULSION CHARACTERISTICS: (on placebo antigenic medium)

| TYPE                  | VISCOSITY<br>(mPa.s) | CONDUCTIVITY<br>(mS/cm)              | DROPLET SIZE<br>(micron) | STABILITY               |                          |                          |
|-----------------------|----------------------|--------------------------------------|--------------------------|-------------------------|--------------------------|--------------------------|
|                       |                      |                                      |                          | After storage<br>at 4°C | After storage at<br>25°C | After storage at<br>37°C |
| O/W<br>(oil-in-Water) | About 25<br>at 25°C  | ~10<br>(placebo antigenic<br>medium) | ~ 80nm                   | More than 12<br>months  | About 6 month            | > 100 days               |

**3. IMMUNE RESPONSE:** MERCKINADE™ SDA 4580 is able to improve vaccine efficacy via the induction of a strong short term and long lasting immunity. It has been demonstrated that it is an excellent adjuvant to stimulate humoral and cellular responses. This product is similar with MERCKINADE™ SDA 4580, and is recommended for bacterial, mycoplasma, viral or parasite antigens

**4. ANIMAL SPECIES:** MERCKINADE™ SDA 4580 adjuvant is recommended for different vaccines notably those for **cattle**, poultry, porcine, and **small ruminants**.

**5. STRENGTH:** MERCKINADE™ IMS adjuvant is especially recommended for emulsion with disturbing antigenic media. MERCKINADE™ SDA 4580, it is suitable when antigen immunogenicity is intrinsically low. It offers the possibility to reduce the injected dose or to dilute antigenic media while keeping the same level of protection.

**6. SAFETY AND REGULATORY:** The toxicological tests made on MERCKINADE™ SDA range (Berlin test, Oral LD 20 6, IP LD 50, ocular irritation test, dermal irritation test, pyrogenicity) conclude to the non-toxicity and favourable tolerance of these adjuvants.

Merckinade™ adjuvants is SDA BIO brand and their components, in trace amount of span, tween, Pluronic copolymer, mineral oil, have been considered as safe by the Committee for Veterinary Medical Products (CVMP) for use in immunological products and are included as authorized substances in the annex in the USDA APHIS and CDA registered veterinary commercial products.

The properties of the antigenic media are crucial for the vaccine efficacy but also for its safety. Each team developing a vaccine will have to study the safety and efficacy profile of the underdevelopment formula according to local market acceptance criteria.

**For more information on this product or for any advice regarding the optimization of your vaccine, please contact our teams on [www.sdabio.com](http://www.sdabio.com)**



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MERCKINADE SDA 4580  
NanolImmunoComplex Type  
IMS Vaccine Adjuvant

Product ID: SDA4580  
Manufacturing Date: 09/22/2025  
Expiry Date: 09/21/2027

Batch Number: SDA458020250209B  
Batch Quantity: 3000 Litter

| Analysis  | Specification | Result    |
|---|---------------|-----------|
| Emulsion Type   | Oil-in-Water  | Confirmed |
| Emulsion Viscosity (mPa.s)                                    | < 20          | 18        |
| Emulsion Conductivity (mS/cm)                                 | 8-14          | 9.4       |
| Emulsion Particle Size (μm)                                   | < 0.5         | 0.04      |
| Emulsion Dispersion   | < 0.25        | 0.16      |
| Emulsion Stability (1: 9 PBS, Centrifuge at 3000 RPM, 30 min) | No Separation | Confirmed |
| Sulfide Residue (%)   | < 0.05        | 0         |
| Heavy Metal (ppm)   | < 0.10        | 0         |
| Abnormal Toxicity   | None          | Confirmed |
| Peroxide Value (mMoles/kg)                                    | < 3.0         | 0.4       |
| Acid Value (mg KOH/g)   | < 1.0         | 0.4       |
| Iodine Value (g/100g, %)                                      | 0.5-1.0       | 0.8       |
| Saponification Value (mg KOH/g)                               | 15-20         | 17.0      |
| Hydroxyl Value (FFA %)  | 0.1-0.2       | 0.17      |

I hereby certify that this batch of product was manufactured and quality control tested in full compliance with the current manufacturing and QC procedures, with internal requirements and with specifications.

Jasmine Nee

Quality Assurance Department  
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Sanfrd, NC

Date: 09-27-2025

# Size Distribution Report by Intensity

v2.2



## Sample Details

**Sample Name:** SDA4580

**SOP Name:** SDA1023

**General Notes:**

**File Name:** InstantFECT.dts

**Dispersant Name:** Water

**Record Number:** 28

**Dispersant RI:** 1.330

**Material RI:** 1.59

**Viscosity (cP):** 0.8872

**Material Absorbtion:** 0.010

**Measurement Date and Time:** 2025/01/03 12:04:09

## System

**Temperature (°C):** 25.0

**Duration Used (s):** 80

**Count Rate (kcps):** 148.4

**Measurement Position (mm):** 4.65

**Cell Description:** Disposable sizing cuvette

**Attenuator:** 6

## Results

|                          |       | <b>Size (d.nm):</b> | <b>% Intensity:</b> | <b>St Dev (d.n...</b> |
|--------------------------|-------|---------------------|---------------------|-----------------------|
| <b>Z-Average (d.nm):</b> | 67.47 | Peak 1:             | 80.05               | 98.4                  |
| <b>Pdl:</b>              | 0.198 | Peak 2:             | 4549                | 1.6                   |
| <b>Intercept:</b>        | 0.953 | Peak 3:             | 0.000               | 0.0                   |

**Result quality :** **Good**

