

技术说明书 : MERCKINADE™ SDA 4580 (等同 IMS 251C)

Eq. IMS 251C

1. 疫苗制备

SDA 4580 (等同 IMS 251C) 为矿物油基佐剂 , 适用于制备约 80 nm 的微型油包水 (O/W) 乳液。由高纯度注射级矿物油与高度精制的植物来源乳化剂 (甘露醇、山梨醇、聚乙二醇、纯化油酸) 组成 , 不含动物源成分。

典型组成比例 (以质量计) : MERCKINADE™ SDA 4580 (等同 IMS 251C) : 水性抗原介质 = 1 : 4-9 (相当于样例 “ 100 g : 400-900 g ”) 。

在室温或更低温度下 , 将水性介质逐步加入 MERCKINADE™ SDA 4580 (等同 IMS 251C) 中 , 以高速剪切搅拌直至形成稳定、均一的乳液 ; 建议使用高剪切分散设备以获得最佳稳定性与免疫效果。

2. 乳液特性 (基于安慰剂抗原介质)

类型	黏度 (mPa · s, 25 ° C)	电导率 (mS/cm)	液滴尺寸 (nm)	稳定性 (贮存)
O/W (油包水)	约 25 (25 ° C)	约 10 (以安慰剂 抗原介质测得)	约 80	4 ° C : > 12 个月 ; 25 ° C : 约 6 个月

37 ° C 加速稳定性 : > 100 天。

3. 免疫应答

MERCKINADE™ SDA 4580 (等同 IMS 251C) 可显著增强疫苗效力 , 诱导强烈且持久的免疫反应 ; 已证实可同时促进体液与细胞免疫 , 适用于细菌、支原体、病毒与寄生虫等多类抗原。

4. 适用动物

推荐用于 : 牛、家禽、猪及小反刍动物等疫苗。

5. 优势

适合免疫原性较低或抗原介质对乳化体系有干扰的场景 ; 可在降低注射剂量或稀释抗原的同时保持防护水平。

6. 安全性与法规

毒理学试验 (Berlin 试验、口服 LD50 、腹腔

LD50 、眼 / 皮肤刺激、致热原性) 表明本系列佐剂无毒且耐受性良好。Merckinade™ 为 SDA BIO 品牌 ; 其微量成分 (Span 、 Tween 、 Pluronic 共聚物、矿物油) 已被 CVMP 认定可用于免疫制品 , 并列入 USDA APHIS 与 CDA 已注册兽用商业产品的附件中。

关键要点 (Key Points)

- 即用型油佐剂 , 工艺友好
- 形成极稳定的微型 O/W 乳液 , 注射顺畅
- 诱导强烈且持久的免疫反应
- 同时刺激体液与细胞免疫
- MERCKINADE™ (SDA BIO) 已列入 USDA / CDA 注册产品



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 (mPa.s)	CONDUCTIVITY (mS/cm)	DROPLET SIZE (micron)	STABILITY		
				After storage at 4°C	After storage at 25°C	After storage at 37°C
O/W (oil-in-Water)	About 25 at 25°C	~10 (placebo antigenic medium)	~ 80nm	More than 12 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



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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
SDA BIO 331 Goldsboro Avenue,
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

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

Result quality : **Good**

