

Bagian : QC

ANALISA PERMINTAAN BARANG

Due date : 18 Maret 2026

Tanggal : 18 Februari 2026

No	Kode Barang	Nama Barang	Satuan	Stok Saat Ini (A)	Rencana Kebutuhan (B)	Kekurangan (A -B + C)	Pending Penerimaan (C)	Jumlah	Realisasi Pembelian	Realisasi Penggunaan
1	IMO10028	Jasa Analisa Parameter Etilen Oksida Bahan Baku Kollicoat IR	Js	0	1	-1	0	1	0	0
1	IMO10028	Jasa Analisa Parameter Dioksan Bahan Baku Kollicoat IR	Js	0	1	-1	0	1	0	0

Catatan :

- Penggunaan jasa untuk pemenuhan pemeriksaan parameter Etilen Oksida dan Dioksan pada bahan baku Kollicoat IR, dengan No. Batch:

1. Batch: 65296136W0 Ex. BASF SE

- Estimasi harga pengujian: Rp.1.300.000 / batch.

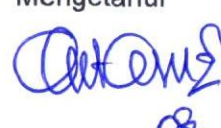
Latar belakang permintaan:

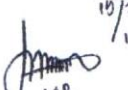
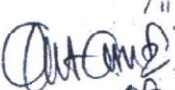
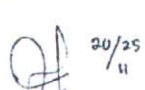
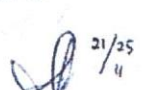
- Parameter tersebut belum dapat dilakukan analisa secara internal dikarenakan belum terdapat metode yang tervalidasi di PT. Mersifarma.
- Sebagai pemenuhan data untuk perilsan bahan baku.
- Analisa menggunakan metode HS-GC-FID. Saat ini Dept. R&D belum melakukan pengembangan metode dan belum tersedia juga kolom GC.
- Pengujian dilakukan di PT. Eurofins Angler Biochemlab
- Terlampir Spesifikasi bahan awal, Penawaran harga dan CoA Kollicoat IR.

Dibuat

 18/26
1005/02

Mengetahui

 18/26
02

 mersi <i>Good Quality Improves Life's Quality</i> PT. MERSIFARMA TM. SUKABUMI-INDONESIA	SPESIFIKASI PENGUJIAN BAHAN AWAL KOLLIKOAT IR RAW MATERIAL SPECIFICATION OF KOLLIKOAT IR		Halaman : 1 of 5 Pages : 1 dari 5							
			No. Dokumen : RD.02-SBP/042.01 Document No.							
			Tanggal Dokumen Disetujui : 22 OCT 2025 Document Approval Date							
			Menggantikan No. : RD.02-SBP/042.00 Supersedes Number							
Disusun Oleh: <i>Prepared by:</i>	Diperiksa Oleh: <i>Reviewed by:</i>		Disetujui Oleh: <i>Approved by:</i>							
Tanda tangan, tgl. <i>Sign, date</i>  18/11/25 Staf AD	Tanda tangan, tgl. <i>Sign, date</i>  19/11/25 Supervisor AD	Tanda tangan, tgl. <i>Sign, date</i>  21/11/25 Asst. Mgr. QC	Tanda tangan, tgl. <i>Sign, date</i>  20/11/25 Manager AD	Tanda tangan, tgl. <i>Sign, date</i>  21/11/25 Manager QC	Tanda tangan, tgl. <i>Sign, date</i>  21/11/25 Manager QA					
PUSTAKA <i>REFERENCES</i>		1. USP 47 Tahun 2024 Monografi Ethylene Glycol and Vinyl alcohol Graft Copolymer <i>USP 47, 2024 Ethylene Glycol and Vinyl alcohol Graft Copolymer Monograph</i> 2. Suplemen I Farmakope Indonesia VI Tahun 2022 Hal. 290-291 <i>Supplement I Indonesia Pharmacopeia VI, 2022 pages 290-291</i> 3. Sertifikat analisis Kollicoat IR dari BASF. <i>Certificate of Analysis from BASF.</i>								
PEMERIAN⁽¹⁾ <i>DESCRIPTION</i>		Serbuk hablur berwarna putih kekuningan. <i>White to faintly yellow powder</i>								
KELARUTAN⁽¹⁾ <i>SOLUBILITY</i>		Sangat larut dalam air, larut dalam asam encer dan alkali hidroksida encer, praktis tidak larut dalam alkohol anhidrat dan aseton. <i>Very soluble in water, soluble in dilute acid and dilute alkali hydroxide, practically insoluble in anhydrous alcohol.</i>								
IDENTIFIKASI⁽¹⁾ <i>IDENTIFICATION</i>		Spektrum inframerah sampel sama seperti pada standar Kollicoat IR. <i>The infrared spectrum of sample same as Kollicoat IR standard.</i>								
VISKOSITAS⁽¹⁾ <i>VISCOSITY</i>		25 - 250 mPas 25 - 250 mPs								
pH⁽¹⁾ <i>pH</i>		5.0 - 8.0 5.0 - 8.0								
SISA PEMIJARAN⁽¹⁾ <i>RESIDUE ON IGNITION</i>		≤ 3.0% ≤ 3.0%								
SUSUT PENGERINGAN⁽¹⁾ <i>LOSS ON DRYING</i>		≤ 5.0 % ≤ 5.0 %								
		<table border="1"> <tr> <td>Tanggal Berlaku <i>Effective Date</i></td> <td>Review ke-1 <i>1st Review</i></td> <td>Review ke-2 <i>2nd Review</i></td> </tr> <tr> <td>24 NOV 2025</td> <td></td> <td></td> </tr> </table>			Tanggal Berlaku <i>Effective Date</i>	Review ke-1 <i>1st Review</i>	Review ke-2 <i>2nd Review</i>	24 NOV 2025		
Tanggal Berlaku <i>Effective Date</i>	Review ke-1 <i>1st Review</i>	Review ke-2 <i>2nd Review</i>								
24 NOV 2025										


13/11/25
OR.

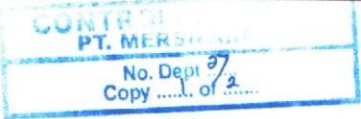


Good Quality Improves Life's Quality

PT. MERSIFARMA TM.
SUKABUMI-INDONESIA

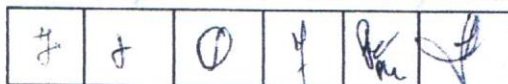
**SPESIFIKASI PENGUJIAN BAHAN
AWAL KOLLI COAT IR**
**RAW MATERIAL SPECIFICATION OF
KOLLI COAT IR**

Halaman : 2 of 5
Pages : 2 dari 5
No. Dokumen : RD.02-SBP/042.01
Document No.
Tanggal Dokumen Disetujui : 22 OCT 2025
Document Approval Date
Menggantikan No. : RD.02-SBP/042.00
Supersedes Number

BILANGAN ESTER ⁽¹⁾ <i>ESTER VALUE</i>	10.0 - 75.0 mg KOH/g 10.0 - 75.0 mg KOH/g
CEMARAN ETILEN GLIKOL DAN DIETILEN GLIKOL ⁽³⁾ <i>ETHYLENE GLYCOL AND DIETHYLENE GLYCOL IMPURITY</i>	≤ 400 ppm (0.04 %) 
CEMARAN ORGANIK ⁽³⁾ <i>ORGANIC IMPURITY</i>	Eilen Oksida ≤ 1 ppm <i>Ethylene Oxide</i> ≤ 1 ppm Dioksan ≤ 10 ppm <i>Dioxane</i> ≤ 10 ppm
UJI MIKROBIOLOGI ⁽²⁾ <i>MICROBIOLOGICAL TESTS</i>	Angka Lempeng Total ≤ 10 ³ koloni/g <i>The Total Aerobic Microbial Count</i> ≤ 10 ³ colonies/g Angka Kapang Khamir ≤ 10 ² koloni/g <i>The Total Combined Molds and Yeasts Count</i> ≤ 10 ² colonies/g
WADAH DAN PENYIMPANAN ⁽¹⁾ <i>PACKAGING AND STORAGE</i>	Dalam wadah tertutup rapat pada temperatur ≤ 25°C. <i>Preserve in tight containers at temperature ≤ 25° C.</i>

SEJARAH PERUBAHAN
HISTORY OF CHANGE

No. No.	No. Dokumen Document No.	Tanggal Berlaku Valid Date	Deskripsi Perubahan Description of Changes
1.	2RD20/SPBAP/042.00	08 September 2016 <i>September 08th, 2016</i>	a. Menggantikan no. 3VA00/SPSBP/001.00 <i>Replaced Standard Procedured no. 3VA00/SPSBP/001.00</i> b. Mengganti nama Divisi dan Departemen <i>Changed Division and Department name</i> c. Melakukan update pustaka <i>Update literature</i>
2.	2RD20/SPBAP/042.01	08 Oktober 2016 <i>October 08th, 2016</i>	a. Menggantikan no. 2RD20/SPBAP/042.00 <i>Replaced Standard Procedured no 2RD20/SPBAP/047.00</i> b. Melakukan update pustaka <i>Update literature</i>



Antoni 13/12/26
09/

Contact

Eurofins Angler Biochemlab
Jl. Raya Sawo No. 17-19
Jawa Timur
ID - 60218 Surabaya
Tel: +62317456111
Eurofins_Angler_CustomerService@eurofinsasia.com

PT. MERSIFARMA TIRMAKU MERCUSANA
Reza Herlambang
JL. RAYA PELABUHAN KM. 18 CIKEMBAR
ID - 43161 SUKABUMI
Admin_RD@mersifarma.com

Quotation number MMD215250446-01

Please indicate this reference for all correspondence

Surabaya, 02/09/2025

Project quotation - Ethylene Glycol dan Vinyl Alcohol Graft Copolymer

Account: A01786234UBQ

Tax N°: 0017924341441000

Dear Customer,

We hereby provide the enclosed quotation as follows :

Price without tax in IDR					
Code	Analyses/packages	TAT	Unit price	Qty.	Total
AAA	Ethylene Glycol dan Vinyl Alcohol Graft Copolymer	7d	1,300,000.00	2	2,600,000.00 (1)
DLQUQ-2	Ethylene Oxide (HS-GC-FID)				(1)
DL09B-2	1,4 Dioxane (HS-GC-FID) (A)				(1)

(1) A tax rate of 11.00% applies for this service. The tax rates displayed are not binding but provided merely as an indication

TAT Turnaround time.

(A) This Test is accredited. If the symbols (A) or (S) are present, restrictions exist for certain types of samples or test parameters.

Total before tax IDR	2,600,000.00
Tax rate (1)	+11.00%
Total price (incl. tax) IDR	2,886,000.00

Due to the rounding rules applied, the total, sub-totals and sum of the lines might slightly differ.

For your cooperation and coordination, we thank you

Payment terms and conditions

Invoice must be paid no later than thirty (30) calendar days after the invoice was issued.

By placing an order or sending samples to our laboratory the customer accepts this quotation and our General Terms and Conditions of Sale referenced therein. Our General Terms and Conditions of Sale are attached to this quotation

Please send your samples to this address

Quotation number MMD215250446-01

PT Eurofins Angler Biochemlab
JL. SAWO NO. 17-19, Desa/Kelurahan Beringin,
Kec. Sambikerep, Kota Surabaya, Provinsi Jawa
Timur
ID -

www.anglerlab.com
Tel +62317456111
Eurofins_Angler_CustomerService@eurofinsasia.com

Handwritten signature and date:
13/6/2025
OR



We create chemistry

Certificate of Analysis

BASF SE

Attention! Please note that the certificates of analysis are also conveniently available on your BASF online portal.

PT. IMCD INDONESIA

2025-12-29

Certificate No 2243

Page 2 of 2

RT.005 RW.001, Kembangan Utara,

11610 Jakarta Barat
Kembangan, DKI JAKARTA
Indonesia

EN - Nutrition & Health
ENT/QA
QAL-Release@basf.com

Inspection Certificate 3.1 according to EN 10204

Kollicoat® IR

20KG Plastic drums
Purchase order/Customer material
23345 OP
55554797

Material	55554797
Order	6013375055 000050
Delivery	3550597480 000010
Batch	65296136W0
Batch/Qty	640.000 KG
Total	640.000 KG
Transport	MRSU4407942

Characteristic Method	Unit	Value	Lower Limit	Upper Limit
--------------------------	------	-------	----------------	----------------

*Not routinely tested

Kollicoat IR may contain traces of colloidal anhydrous silica.

The product meets the requirements of the monograph:

"Macrogol Poly(vinylalcohol) Grafted Copolymer" Ph.Eur. 11th edition

"Ethylene Glycol and Vinyl alcohol Graft Copolymer" USP-NF 2025, Issue1

"Polyvinyl alcohol - polyethylene glycol graft copolymer" of JPE 2018

Specification for food additives of EU regulation "E 1209, Polyvinyl alcoholpolyethylene glycol-graft-copolymer"

Manufacturer: BASF SE
Carl-Bosch-Str.38
67056 Ludwigshafen
Germany

BASF SE
Quality Assurance - Release

The above-mentioned data describes the relevant parameters of the product at the time of issuing this certificate of analysis (CoA). The data is controlled at regular intervals as part of our quality assurance program and is provided for reference only. The contractually agreed quality of the product at the time of passing of risk is exclusively determined by our product specification. Unless specifically agreed by the Parties in writing signed by authorized representatives, no suitability for a particular use shall be presumed or implied based on the CoA and the customer is solely responsible for determining and verifying the suitability of the use of the product for any purpose.

This is a computer-generated document. No signature is required.

Antoni 13/02/26
082



We create chemistry

Certificate of Analysis

BASF SE

Attention! Please note that the certificates of analysis are also conveniently available on your BASF online portal.

PT. IMCD INDONESIA

2025-12-29

Certificate No 2243

Page 1 of 2

RT.005 RW.001, Kembangan Utara,

11610 Jakarta Barat
Kembangan, DKI JAKARTA
Indonesia

EN - Nutrition & Health
ENT/QA
QAL-Release@basf.com

Inspection Certificate 3.1 according to EN 10204

Kollicoat® IR

20KG Plastic drums
Purchase order/Customer material
23345 OP
55554797

Material 55554797
Order 6013375055 000050
Delivery 3550597480 000010
Batch 65296136W0
Batch/Qty 640.000 KG
Total 640.000 KG
Transport MRSU4407942

Manufacturing date : 19.09.2025
Release date : 21.11.2025
Retest date 18.09.2030

Characteristic Method	Unit	Value	Lower Limit	Upper Limit
Appearance		Conforms	white to faintly yellow powder	
Identification (IR)		Conforms	must conform	
Identification (film)		Conforms	must conform (transparent film)	
Viscosity (Brookfield, Spindle 2)	mPa*s	112	50	250
Heavy metals		conforms*	must conform (max. 20 mg/kg)	
pH-value		6,7	5,0	8,0
Sulphated ash / Residue on ignition	g/100g	0,9		2,0
Ester value	mgKOHg	17,3	10,0	70,0
Loss on drying	g/100g	1,0		5,0
Vinyl acetate (Ph.Eur. impurity A)	mg/Kg	< 5		20
Acetic acid (Ph.Eur. impurity B)	mg/Kg	6300		15000
Ethylene oxide	mg/Kg	< 1		1
1,4-Dioxane	mg/Kg	< 10		10
Ethylene glycol	mg/Kg	< 50		400
Diethylene glycol	mg/Kg	< 50		400
Sum of Ethylene glycol/Diethylene glycol	mg/Kg	< 100		400
Arsenic	mg/Kg	< 1		3
Lead	mg/Kg	< 1		1
Mercury	mg/Kg	< 1		1
Cadmium	mg/Kg	< 1		1
Total aerobic microbial count (TAMC) Ph. Eur. 2.6.12	CFU/g	30		200
Total combined yeasts/moulds count (TYMC) Ph. Eur. 2.6.12	CFU/g	< 10		20

The above-mentioned data describes the relevant parameters of the product at the time of issuing this certificate of analysis (CoA). The data is controlled at regular intervals as part of our quality assurance program and is provided for reference only. The contractually agreed quality of the product at the time of passing of risk is exclusively determined by our product specification. Unless specifically agreed by the Parties in writing signed by authorized representatives, no suitability for a particular use shall be presumed or implied based on the CoA and the customer is solely responsible for determining and verifying the suitability of the use of the product for any purpose.

This is a computer-generated document. No signature is required.

15/12/24
082