DOKUMENTATION FOR INDHOLD

ARKEMA

SAFETY DATA SHEET

Product: **EVATANE® HT - 24-33% VA** Page: 1 / 7

SDS No.: 00901-007 (Version 1.5) Date 14.05.2021 (*Cancel and replace* : 13.03.2019

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Generic Safety Data Sheet

Identification of the mixture: EVATANE® HT - 24-33% VA
Other means of identification: -
UN number: -

Grades : EVATANE® 24-03 / EVATANE® 28-03 / EVATANE® 28-05 / EVATANE® 28-150 / EVATANE® 28-25 / EVATANE® 28-25 PV / EVATANE® 28-40 / EVATANE® 28-420 / EVATANE® 28-800 / EVATANE® 33-25 / EVATANE® 33-400 / EVATANE® 33-45 / EVATANE® 33-45 PV /

Recommended use of the chemical and restrictions on use :

Use of the Substance/Mixture : Hotmelt adhesives and coatings, Coextrusion, Foam, Compounds

Company/Undertaking Identification:

Supplier
ARKEMA - France
420 rue d'Estienne d'Orves
92705 Colombes Cedex, FRANCE
Telephone: +33(0)1 49 00 80 80
Telefax: +33(0)1 49 00 83 96
E-mail address: pars-drp-fds@arkema.com
http://www.arkema.com

Agent
Bostik Australia Pty Ltd
Level 1, 6 English Street
Essendon Fields. VIC 3041, Australia
Telephone: 1800267845
Telefax: (03)93515294

DOKUMENTATION BPA TEST

Test Report **No: SHCPCH210605989E** **Date: Jun 16 2021**

The test results are as follows:

Remarks :
(1) 1 mg/kg = 0.0001%
(2) MDL = Method Detection Limit
(3) ND = Not Detected (< MDL)

Bisphenol-A
Test method: With reference to US EPA 3550C: 2007, analysis was performed by HPLC-DAD-MS.

Test Item(s)	Unit(s)	MDL	Test Result(s)
Bisphenol-A	mg/kg	1	ND

Sample Description: Mouth guard/Mouth gray/Mouthpiece

The test report shall only be used for client scientific research, teaching, internal quality control, product research and development, etc.

*** End of Report***

DOKUMENTATION FOR CE-GODKENDELSE

Product(s):	Mouth Tray/Mouth Piece/Mouthpiece/Mouth Guard/Mouthguard
Type(s):	SG01/I-MT03B/I-MT01B/I-MT02C/I-ASTB02/YYDE004/ YYDE005/YYDS006/YYSY001/YYDE001/YYDE003/YYDS005/ YYDS004/YYDY004/YYDY005/YYDY006/YYDE002/I-MT04/ NV02/NV01/TI01/NV03/NV04/I-TWL-LT
Product Classification:	Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Medical Device Directive (93/42/EEC).

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

Standard(s): EN ISO 14971:2012; EN ISO 15223-1:2016; EN 1041:2008+A1:2013; EN ISO 10993-12009/AC:2010; EN ISO 10993-5:2009; EN ISO 10993-10:2013

The review result of the technical files and test report support the self declaration for the devices listed above. Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

SUNGO Cert GmbH

CE

Sungo global service

SUNGO
Executive Director
Issued: Jan. 6 2020
Cert. No.: EU164518
Expiration Date: Jan. 5 2025
Sungo
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