

BB DISTRIBE SAS  
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FRANCE

## Chemical analysis Report N° 1267120A01 v1

### BABY DIAPERS

27 October 2021

For the attention of **Franck BRUN PICARD**  
**BB DISTRIBE SAS**

Quotation 2021/68625 (DSP 858237)  
Reference Contre Analyses chimiques changes BB - Protocol de tests incluant la migration avec  
simulant d'urine ( note de L'ANSES de mars 2020 )

#### Tested products

FIXIES



Lucie VIENNE, *Study Manager*

*The copy of this report is only authorized by unabridged edition  
This edition includes 13 pages*

*The reported results relate exclusively to the tested samples. The samples will be kept only 2 months from the date of this report. The sample and the information regarding sample have been provided by the client. All information related to the sample are under liability of the client and have not been checked by the Eurofins ATS Company*

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S.A.S AU CAPITAL DE 714 050 euros  
N° SIRET : 33761796300117  
Code APE : 7120B

## SUMMARY

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## 1. FOREWORD

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The aim of this study is to analyse the chemical substances in baby diapers.

### TESTED PRODUCTS:



- FIXIES**  
COUCHES TAILLE 4+ MAXI+ 9-20KG X 44  
Reference:  
Supplier name: FRANCE  
Batch N°: 4AC 08:41 244 09/2021/FR  
Barcode N°: 3144030902242  
Provided by: BB DISTRIBE

The study is based on:

### Chemical analysis in a mix of all the components of the diaper

- EOX/AOX - (1T3VV)**  
SOP Reference: *INDIKATOR GmbH*
- Azo dyes: with extraction ISO 14362-1 :2017 – GC/MS - (YLN1C)**  
SOP Reference: *Eurofins Textile Testing Spain S.L.U.*
- Allergic and carcinogenic dyestuff DIN 54231 :2005 – LC/DAD - (YLT9Q)**  
SOP Reference : *Eurofins Textile Testing Spain S.L.U.*
- Bisphenol A and F in packaging material - LC-MS/MS - Internal - for plastics and packaging - (JJ0GR)**  
SOP Reference: *Eurofins Consumer Product Testing GmbH*

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- ❁ Copper (Cu) – ICP – MS – EN ISO 17294-2 mod.- (FIN0U)  
*SOP Reference: Eurofins Consumer Product Testing GmbH*
- ❁ Nickel (Ni) – ICP – MS – EN ISO 17294-2 mod.- (FIN0U)  
*SOP Reference: Eurofins Consumer Product Testing GmbH*
- ❁ Cobalt (Co) – ICP – MS – EN ISO 17294-2 mod.- (FIN0U)  
*SOP Reference: Eurofins Consumer Product Testing GmbH*
- ❁ Chromium (Cr) - ICP/MS - NF EN ISO 17294-2 - (JR0WK)  
*SOP Reference: Eurofins Consumer Product Testing GmbH*
- ❁ Lead (Pb) - ICP/MS - NF EN ISO 17294-2 - (JR0WI)  
*SOP Reference: Eurofins Consumer Product Testing GmbH*
- ❁ Cadmium (Cd) - ICP/MS - NF EN ISO 17294-2 - (JR0WG)  
*SOP Reference: Eurofins Consumer Product Testing GmbH*
- ❁ Mercury (Hg) - ICP/MS - NF EN ISO 17294-2 - (JR0WE)  
*SOP Reference: Eurofins Consumer Product Testing GmbH*
- ❁ Arsenic (As) - ICP/MS - NF EN ISO 17294-2 - (JR0WF)  
*SOP Reference: Eurofins Consumer Product Testing GmbH*
- ❁ Antimony (Sb) - ICP/MS - NF EN ISO 17294-2 - (JR0WH)  
*SOP Reference: Eurofins Consumer Product Testing GmbH*

**Chemical analysis post migration in a synthetic urine simulant (ANSES note dated the 9th of March 2020 - Demand N°2019-SA-0076)**

- ❁ Migration preparation test in simulated urine - Preparation - SCL Protocol - Test de préparation - (CH0B0)  
*SOP Reference: Eurofins ATS*
- ❁ Polychlorinated dibenzodioxins and -furans (17 PCDD/F): water, drinking water, sewage - GC/MS/MS – Internal method - (GFU02)  
*SOP Reference: Eurofins GfA*
- ❁ Polychlorinated biphenyls (12 WHO PCB): water, drinking water, sewage - GC-MS/MS - Internal (GFU07)  
*SOP Reference: Eurofins GfA*
- ❁ HAP EPA + EU - GC-MS/MS - Internal method (JC0L2)  
*SOP Reference: Eurofins WEJ Contaminants GmbH, Hamburg*
- ❁ Formaldehyde (free and bound) in materials - LC-UV – DNPH derivation (AW0XJ)  
*SOP Reference: Eurofins Consumer Product Testing A/S*
- ❁ Extractable content of dimethyl phthalate (DMP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW80)  
*SOP Reference: EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of diethyl phthalate (DEP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW81)  
*SOP Reference: EUROFINS PRODUCT TESTING A/S*

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- ❁ Extractable content of diisobutyl phthalate (DIBP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW82)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of dibutyl phthalate (DBP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW83)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of di-n-hexyl phthalate (DnHP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW84)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of benzylbutyl phthalate (BBP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW85)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of di(ethylhexyl) phthalate (DEHP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW86)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of di-n-octyl phthalate (DNOP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW87)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of diisononyl phthalate (DINP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW88)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of diisodecyl phthalate (DIDP) in materials - GC-MS - CPSC-CH-C1001-09.3 - (AWW89)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of other phthalate in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW90)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of di-n-pentyl phthalate (DNPP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW91)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of dicyclohexyl phthalate (DCP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW92)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of n-pentylisopentyl phthalate (PiPP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW93)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of diisopentyl phthalate (DIPP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW94)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of di(2-methoxyethyl) phthalate (DMEP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW95)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of diisooheptyl phthalate (DIHpP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW96)  
 SOP Reference: *EUROFINS PRODUCT TESTING A/S*

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- ❁ Extractable content of diheptylnonylundecyl phthalate (DHNUP) in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW98)  
*SOP Reference: EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of 1,2-Benzene dicarboxylic acid, dihexyl ester in materials - GC-MS - CPSC-CH-C1001-09.4 - (AW1FX)  
*SOP Reference: EUROFINS PRODUCT TESTING A/S*
- ❁ Extractable content of 1,2-Benzene dicarboxylic acid, dipentyl ester in materials - GC-MS - CPSC-CH-C1001-09.4 - (AW1G6)  
*SOP Reference: EUROFINS PRODUCT TESTING A/S*
- ❁ Di-C6-C10 alkylphthalates in materials - GC-MS - CPSC-CH-C1001-09.4 - (AWW1A)  
*SOP Reference: EUROFINS PRODUCT TESTING A/S*

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## 2. SYNTHESIS/CONCLUSION

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We detect the presence of the following chemical substances in a mix of all the components of the diaper:

- AOX (adsorbable organic halogens) 0,5 (LOQ = 0,5) mg/kg

For the analyses in post migration, no detection has been observed according to our LOQ with synthetic urine simulant (SCL PROTOCOL).

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### 3. RESULTS

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Chemical analysis in a mix of all the components of the diaper



ATS

Brand Manufacturer Denomination Batch n° Sample n°	FIXIES - COUCHES TAILLE 4+ MAXI+ 9-20KG X 44 4AC 08:41 244 09/2021/FR 836135
EOX/AOX	
	EOX (extractable organic halogens) mg/kg <2
	AOX (adsorbable organic halogens) mg/kg 0,5 (LOQ = 0,5)
Copper (Cu) - ICP-MS - DIN EN ISO 17294-2:2007-01 mod.	Copper (Cu) - CAS N°:7440-50-8 mg/kg <1
Nickel (Ni) - ICP-MS - DIN EN ISO 17294-2:2007-01 mod.	Nickel (Ni) - CAS N°:7440-02-0 mg/kg <1
Cobalt (Co) - ICP-MS - DIN EN ISO 17294-2:2007-01 mod.	Cobalt (Co) - CAS N°:7440-48-4 mg/kg <1
Chromium (Cr) - ICP-MS - DIN EN ISO 17294-2:2007-01 mod.	Chromium (Cr) - CAS N°:7440-47-3 mg/kg <1
Lead (Pb) - ICP-MS - DIN EN ISO 17294-2:2007-01 mod.	Lead (Pb) - CAS N°:7439-92-1 mg/kg <1
Cadmium (Cd) - ICP-MS - DIN EN ISO 17294-2:2007-01 mod.	Cadmium (Cd) - CAS N°:7440-43-9 mg/kg <0,1
Mercury (Hg) - ICP-MS - DIN EN ISO 17294-2:2007-01 mod.	Mercury (Hg) mg/kg <0,1
Arsenic (As) - ICP-MS - DIN EN ISO 17294-2:2007-01 mod.	Arsenic (As) - CAS N°:7440-38-2 mg/kg <1
Antimony (Sb) - ICP-MS - DIN EN ISO 17294-2:2007-01 mod.	Antimony (Sb) - CAS N°:7440-36-0 mg/kg <1
Determination of azo dyes - GC-MS - EN ISO 14362-1:2017 Annex F + ISO 14362-1:2017 + EN ISO 14362-1:2017	
	4-Aminobiphenyl - CAS N°:92-67-1 mg/kg <5
	Benzidine - CAS N°:92-87-5 mg/kg <5
	4-Chlorotoluidine - CAS N°:95-69-2 mg/kg <5
	2-Naphthylamine - CAS N°:91-59-8 mg/kg <5
	p-Chloroaniline - CAS N°:106-47-8 mg/kg <5
	2,4-Diaminoanisole - CAS N°:615-05-4 mg/kg <5
	4,4-Diaminodiphenylmethan - CAS N°:101-77-9 mg/kg <5
	3,3-Dichlorobenzidine - CAS N°:91-94-1 mg/kg <5
	3,3-Dimethoxybenzidine - CAS N°:119-90-4 mg/kg <5
	3,3-Dimethylbenzidine - CAS N°:119-93-7 mg/kg <5
	4,4-Diamino-3,3-dimethyl diphenylmethane - CAS N°:838-88-0 mg/kg <5
	p-Cresidine - CAS N°:120-71-8 mg/kg <5
	4,4-Methylene-bis-2-chloroaniline - CAS N°:101-14-4 mg/kg <5
	4-Aminophenyleter - CAS N°:101-80-4 mg/kg <5
	4,4-Thioaniline - CAS N°:139-65-1 mg/kg <5
	o-Toluidine - CAS N°:95-53-4 mg/kg <5
	2,4-Diaminotoluene - CAS N°:95-80-7 mg/kg <5
	2,4,5-Trimethylaniline - CAS N°:137-17-7 mg/kg <5
	o-Anisidine - CAS N°:90-04-0 mg/kg <5
	2,4-Xylydine - CAS N°:95-68-1 mg/kg <5
	2,6-Xylydine - CAS N°:87-62-7 mg/kg <5
	Aniline* - CAS N°:62-53-3 mg/kg <5
	1-4-phenylenediamine* - CAS N°:106-50-3 mg/kg <5
	4-Chloro-o-toluidinium chloride* - CAS N°:3165-93-3 mg/kg <5
	2-Naphthylammoniumacetate* - CAS N°:553-00-4 mg/kg <5
	4-Methoxy-m-phenylene Diammonium Sulphate* - CAS N°:39156-41-7 mg/kg <5
	2,4,5-Trimethylaniline hydrochloride* - CAS N°:21436-97-5 mg/kg <5
	HPLC Confirmation
Determination of allergic and carcinogenic dyestuff - LC-DAD - DIN 54231:2005	
	Disperse Blue 35 - CAS N°:12222-75-2 mg/kg <15
	Disperse Blue 1 - CAS N°:2475-45-8 mg/kg <15
	Disperse Blue 3 - CAS N°:2475-46-9 mg/kg <15
	Disperse Blue 106 - CAS N°:12223-01-7 mg/kg <15
	Disperse Blue 124 - CAS N°:61951-51-7 mg/kg <15
	Disperse Yellow 3 - CAS N°:2832-40-8 mg/kg <15
	Disperse Orange 3 - CAS N°:730-40-5 mg/kg <15
	Disperse Orange 37 - CAS N°:13301-61-6 mg/kg <15
	Disperse Red 1 - CAS N°:2872-52-8 mg/kg <15
	Disperse Yellow 39* - CAS N°:12236-29-2 mg/kg <15
	Disperse Brown 1* - CAS N°:23355-64-8 mg/kg <15
	Disperse Yellow 1* - CAS N°:119-15-3 mg/kg <15
	Disperse Orange 1* - CAS N°:2581-69-3 mg/kg <15
	Disperse Red 11* - CAS N°:2872-48-2 mg/kg <15
	Disperse Red 17* - CAS N°:3179-89-3 mg/kg <15
	Disperse Yellow 49* - CAS N°:54824-37-2 mg/kg <15
	Disperse Blue 7* - CAS N°:3179-90-6 mg/kg <15
	Disperse Blue 26* - CAS N°:3860-63-7 mg/kg <15
	Disperse Yellow 9* - CAS N°:6373-73-5 mg/kg <15
	Acid Red 26* - CAS N°:3761-53-3 mg/kg <15
	Basic Red 9* - CAS N°:596-61-9 mg/kg <15
	Direct Black 38* - CAS N°:1937-37-7 mg/kg <15
	Direct Blue 6* - CAS N°:2602-46-2 mg/kg <15
	Basic Violet 14* - CAS N°:632-99-5 mg/kg <15
	Disperse Orange 11* - CAS N°:82-28-0 mg/kg <15
	Direct Red 28* - CAS N°:573-58-0 mg/kg <15
	Basic Violet 3 (with Michler's Ketone > 0.1%)* - CAS N°:548-62-9 mg/kg <15
	Basic Blue 26 (with Michler's Ketone > 0.1%)* - CAS N°:2580-56-5 mg/kg <15
	Navy Blue* - CAS N°:118685-33-9 mg/kg <15
	Disperse Blue 102* - CAS N°:12222-97-8 mg/kg <15
	Disperse Orange 149* - CAS N°:85136-74-9 mg/kg <15
	Disperse Yellow 23* - CAS N°:6250-23-3 mg/kg <15
	Acid Violet 49* - CAS N°:1694-09-3 mg/kg <15
	Basic Violet 1* - CAS N°:8004-87-3 mg/kg <15
	Acid Red 114* - CAS N°:6459-94-5 mg/kg <15

**CHEMICAL ANALYSIS POST-MIGRATION WITH SYNTHETIC URINE SIMULANT**  
**Results expressed in mg / kg of baby diaper**

Brand Manufacturer Denomination Batch n°	FIXIES - COUCHES TAILLE 4+ MAXI+ 9 20KG X 44 4AC 08:41 244 09/2021/FR	Threshold concentration (issued from ANSES note dated the 9th of March 2020 - Demand N°2019-SA-0076)
<b>Migration preparation test in simulated urine - SCL Protocol</b>		
Average weight before impregnation g	39,24	
Average volume extracted from the diaper ml	261,1	
<b>Formaldehyde (free and bound) in materials - LC-UV - Internal Method DNPH derivation</b>		
Formaldehyde - CAS N°:50-00-0	< 2	3,05
<b>PAH acc. to EPA+EU (low LOQ) - GC-MS/MS - Internal Method</b>		
Phenanthrene - CAS N°:85-01-8	< 3,33.10 <sup>-3</sup>	
Anthracene - CAS N°:120-12-7	< 3,33.10 <sup>-3</sup>	
Fluoranthene - CAS N°:206-44-0	< 3,33.10 <sup>-3</sup>	
Pyrene - CAS N°:129-00-0	< 3,33.10 <sup>-3</sup>	
Benzo(a)anthracène - CAS N°:56-55-3	< 6,65.10 <sup>-4</sup>	2,85.10 <sup>-3</sup>
Chrysene - CAS N°:218-01-9	< 6,65.10 <sup>-4</sup>	2,85.10 <sup>-2</sup>
Benzo(b)fluoranthene - CAS N°:205-99-2	< 6,65.10 <sup>-4</sup>	2,85.10 <sup>-3</sup>
Benzo(k)fluoranthene - CAS N°:207-08-9	< 6,65.10 <sup>-4</sup>	2,85.10 <sup>-3</sup>
Benzo-(j)-fluoranthene - CAS N°:205-82-3	< 6,65.10 <sup>-4</sup>	2,85.10 <sup>-3</sup>
Benzo(a)pyrene - CAS N°:50-32-8	< 6,65.10 <sup>-4</sup>	2,85.10 <sup>-4</sup> (*)
Indeno-(1,2,3-cd)-pyrene - CAS N°:193-39-5	< 3,33.10 <sup>-3</sup>	2,85.10 <sup>-3</sup> (*)
Dibenzo(a,h)anthracene - CAS N°:53-70-3	< 6,65.10 <sup>-4</sup>	2,85.10 <sup>-4</sup> (*)
Benzo(ghi)Perylene - CAS N°:191-24-2	< 3,33.10 <sup>-3</sup>	2,85.10 <sup>-2</sup>
Dibenzo(a,i)pyrene - CAS N°:191-30-0	< 3,33.10 <sup>-3</sup>	2,85.10 <sup>-5</sup> (*)
Dibenzo(a,l)pyrene - CAS N°:189-55-9	< 3,33.10 <sup>-3</sup>	2,85.10 <sup>-5</sup> (*)
Dibenzo(a,h)pyrene - CAS N°:189-64-0	< 3,33.10 <sup>-3</sup>	2,85.10 <sup>-5</sup> (*)
Dibenzo(a,e)pyrene - CAS N°:192-65-4	< 3,33.10 <sup>-3</sup>	2,85.10 <sup>-4</sup> (*)
Cyclopenta(c,d)pyrene - CAS N°:27208-37-3	< 3,33.10 <sup>-3</sup>	2,85.10 <sup>-3</sup> (*)
5-Methylchrysene - CAS N°:3697-24-3	< 3,33.10 <sup>-3</sup>	2,85.10 <sup>-2</sup>
benzo[c]fluorene - CAS N°:205-12-9	< 3,33.10 <sup>-3</sup>	1,43.10 <sup>-5</sup> (*)
Benzo(e)pyrene - CAS N°:192-97-2	< 3,33.10 <sup>-3</sup>	2,85.10 <sup>-2</sup>
Perylene - CAS N°:198-55-0	< 3,33.10 <sup>-3</sup>	
Anthanthrene - CAS N°:191-26-4	< 3,33.10 <sup>-3</sup>	
Coronen - CAS N°:191-07-1	< 3,33.10 <sup>-3</sup>	
Benzo(b)naphtho(2,1-d)thiophene - CAS N°:239-35-0	< 3,33.10 <sup>-3</sup>	
Sum PAH 4	inapplicable	
Sum of all positive identified PAH	inapplicable	
<b>polychlorinated dibenzodioxins and -furans (17 PCDD/F): water, drinking water, sewage - GC-MS/MS - Internal</b>		
2,3,7,8-TetraCDD - CAS N°:1746-01-6	< 4,36.10 <sup>-9</sup>	1,43 .10 <sup>-8</sup>
1,2,3,7,8-PentaCDD - CAS N°:40321-76-4	< 5,81.10 <sup>-9</sup>	1,43 .10 <sup>-8</sup>
1,2,3,4,7,8-HexaCDD - CAS N°:39227-28-6	< 1,16.10 <sup>-8</sup>	1,43 .10 <sup>-7</sup>
1,2,3,6,7,8-HexaCDD - CAS N°:57653-85-7	< 1,16.10 <sup>-8</sup>	1,43 .10 <sup>-7</sup>
1,2,3,7,8,9-HexaCDD - CAS N°:19408-74-3	< 1,16.10 <sup>-8</sup>	1,43 .10 <sup>-7</sup>
1,2,3,4,6,7,8-HeptaCDD - CAS N°:35822-46-9	< 9,91.10 <sup>-9</sup>	1,43 .10 <sup>-6</sup>
OctaCDD - CAS N°:3268-87-9	< 6,99.10 <sup>-8</sup>	4,75 .10 <sup>-5</sup>
2,3,7,8-TetraCDF - CAS N°:51207-31-9	< 7,72.10 <sup>-9</sup>	1,43 .10 <sup>-7</sup>
1,2,3,7,8-PentaCDF - CAS N°:57117-41-6	< 1,04.10 <sup>-8</sup>	4,75 .10 <sup>-7</sup>
2,3,4,7,8-PentaCDF - CAS N°:57117-31-4	< 1,04.10 <sup>-8</sup>	4,75 .10 <sup>-8</sup>
1,2,3,4,7,8-HexaCDF - CAS N°:70648-26-9	< 9,65.10 <sup>-9</sup>	1,43 .10 <sup>-7</sup>
1,2,3,6,7,8-HexaCDF - CAS N°:57117-44-9	< 9,65.10 <sup>-9</sup>	1,43 .10 <sup>-7</sup>
1,2,3,7,8,9-HexaCDF - CAS N°:72918-21-9	< 9,65.10 <sup>-9</sup>	1,43 .10 <sup>-7</sup>
2,3,4,6,7,8-HexaCDF - CAS N°:60851-34-5	< 9,65.10 <sup>-9</sup>	1,43 .10 <sup>-7</sup>
1,2,3,4,6,7,8-HeptaCDF - CAS N°:67562-39-4	< 9,18.10 <sup>-9</sup>	1,43 .10 <sup>-6</sup>
1,2,3,4,7,8,9-HeptaCDF - CAS N°:55673-89-7	< 9,18.10 <sup>-9</sup>	1,43 .10 <sup>-6</sup>
OctaCDF - CAS N°:39001-02-0	< 1,94.10 <sup>-8</sup>	4,75 .10 <sup>-5</sup>
WHO(2005)-PCDD/F TEQ (lower-bound)	Not detected	
WHO(2005)-PCDD/F TEQ (upper-bound)	2,2.10 <sup>-8</sup>	
I-TEQ (NATO/CCMS) (lower-bound)	Not detected	
I-TEQ (NATO/CCMS) (upper-bound)	2,15.10 <sup>-8</sup>	

**CHEMICAL ANALYSIS POST-MIGRATION WITH SYNTHETIC URINE SIMULANT**  
**Results expressed in mg / kg of baby diaper**

Brand Manufacturer Denomination Batch n°	FIXIES - COUCHES TAILLE 4+ MAXI+ 9 20KG X 44 4AC 08:41 244 09/2021/FR	Threshold concentration (issued from ANSES note dated the 9th of March 2020 - Demand N°2019-SA-0076)
<b>polychlorinated biphenyls (12 WHO PCB): water, drinking water, sewage - GC-MS/MS - Internal</b>		
PCB 77 - CAS N°:32598-13-3	< 2,18.10 <sup>-7</sup>	1,43.10 <sup>-4</sup>
PCB 81 - CAS N°:70362-50-4	< 2,9.10 <sup>-8</sup>	4,75 .10 <sup>-5</sup>
PCB 105 - CAS N°:32598-14-4	< 4,72.10 <sup>-7</sup>	4,75.10 <sup>-4</sup>
PCB 118 - CAS N°:31508-00-6	< 5,69.10 <sup>-8</sup>	4,75.10 <sup>-4</sup>
PCB 114 - CAS N°:74472-37-0	< 1,7.10 <sup>-6</sup>	4,75.10 <sup>-4</sup>
PCB 123 - CAS N°:65510-44-3	< 4,84.10 <sup>-8</sup>	4,75.10 <sup>-4</sup>
PCB 126 - CAS N°:57465-28-8	< 2,78.10 <sup>-8</sup>	1,43.10 <sup>-4</sup>
PCB 156 - CAS N°:38380-08-4	< 2,66.10 <sup>-7</sup>	4,75.10 <sup>-4</sup>
PCB 157 - CAS N°:69782-90-7	< 4,96.10 <sup>-8</sup>	4,75.10 <sup>-4</sup>
PCB 167 - CAS N°:52663-72-6	< 1,33.10 <sup>-7</sup>	4,75.10 <sup>-4</sup>
PCB 169 - CAS N°:32774-16-6	< 1,45.10 <sup>-7</sup>	4,75.10 <sup>-7</sup>
PCB 189 - CAS N°:39635-31-9	< 4,84.10 <sup>-8</sup>	4,75.10 <sup>-4</sup>
WHO(2005)-PCB TEQ (lower-bound)	Not detected	
WHO(2005)-PCB TEQ (upper-bound)	7,25.10 <sup>-9</sup>	
<b>PCB (7 Indicateurs) ~ Environnement - Eaux</b>		
PCB 28	0.10 <sup>-6</sup>	1,43.10 <sup>-4</sup>
PCB 52	0.10 <sup>-6</sup>	4,75 .10 <sup>-5</sup>
PCB 101	0.10 <sup>-6</sup>	4,75.10 <sup>-4</sup>
PCB 118	0.10 <sup>-6</sup>	4,75.10 <sup>-4</sup>
PCB 138	0.10 <sup>-6</sup>	4,75.10 <sup>-4</sup>
PCB 153	0.10 <sup>-6</sup>	4,75.10 <sup>-4</sup>
PCB 180	0.10 <sup>-6</sup>	1,43.10 <sup>-4</sup>
Somme des 6 PCB (sauf le PCB 118) sans LOQ	0.10 <sup>-8</sup>	4,75.10 <sup>-4</sup>
Somme des 6 PCB (sauf le PCB 118) avec LOQ	0.10 <sup>-5</sup>	4,75.10 <sup>-4</sup>
Total 7 PCB indicateurs excl. LOQ	0.10 <sup>-8</sup>	4,75.10 <sup>-4</sup>
Total 7 PCB Indicateurs incl. LOQ	0.10 <sup>-5</sup>	4,75.10 <sup>-7</sup>
<b>TEQ-Totaux WHO-PCDD/F et PCB</b>		
Dioxine + PCB de type dioxine OMS 2005 TEQ sans LQ	0.10 <sup>-10</sup>	
WHO(2005)-PCDD/F+PCB TEQ (medium-bound)	0.10 <sup>-8</sup>	
Dioxine + PCB de type dioxine OMS 2005 TEQ avec LQ	0.10 <sup>-8</sup>	
<b>Extractable content of diethyl phthalate (DEP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Diethylphthalate - CAS N°:84-66-2	< 6,65.10 <sup>-2</sup>	16,3
<b>Extractable content of diisobutyl phthalate (DIBP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Di-isobutyl phthalate (DiBP) - CAS N°:84-69-5	< 6,65.10 <sup>-2</sup>	4,07.10 <sup>-2</sup> (*)
<b>Extractable content of dibutyl phthalate (DBP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Di-n-butylphthalate - CAS N°:84-74-2	< 6,65.10 <sup>-2</sup>	
<b>Extractable content of di-n-hexyl phthalate (DnHP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Dihexyl phthalate (DHXP) - CAS N°:84-75-3	< 6,65.10 <sup>-2</sup>	
<b>Extractable content of benzylbutyl phthalate (BBP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Benzyl butyl phthalate - CAS N°:85-68-7	< 6,65.10 <sup>-2</sup>	
<b>Extractable content of di(ethylhexyl) phthalate (DEHP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Bisethylhexylphthalate - CAS N°:117-81-7	< 6,65.10 <sup>-2</sup>	
<b>Extractable content of di-n-octyl phthalate (DNOP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Di-n-octylphthalate (DNOP) - CAS N°:117-84-0	< 6,65.10 <sup>-2</sup>	
<b>Extractable content of diisononyl phthalate (DINP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Diisononylphthalate (DINP) - CAS N°:68515-48-0	< 3,99.10 <sup>-1</sup>	
<b>Extractable content of diisodecyl phthalate (DIDP) in materials - GC-MS - CPSC-CH-C1001-09.3</b>		
Diisodecylphthalate (DIDP) - CAS N°:26761-40-0	< 3,99.10 <sup>-1</sup>	
<b>Extractable content of other phthalates in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Other phthalates	< 6,65.10 <sup>-1</sup>	
<b>Extractable content of di-n-pentyl phthalate (DNPP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Dipentylphthalate - CAS N°:131-18-0	< 6,65.10 <sup>-2</sup>	
<b>Extractable content of dicyclohexyl phthalate (DCP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Dicyclohexylphthalat - CAS N°:84-61-7	< 6,65.10 <sup>-2</sup>	
<b>Extractable content of n-pentylisopentyl phthalate (PIPP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
n-Pentylisopentyl phthalate - CAS N°:776297-69-9	< 6,65.10 <sup>-2</sup>	
<b>Extractable content of diisopentyl phthalate (DIPP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Di-(isopentyl)phthalate (DiPP) - CAS N°:605-50-5	< 6,65.10 <sup>-2</sup>	
<b>Extractable content of di(2-methoxyethyl) phthalate (DMEP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Di-(2-methoxyethyl)phthalate (DMEP) - CAS N°:117-82-8	< 1,33.10 <sup>-1</sup>	
<b>Extractable content of diisooheptyl phthalate (DIHP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
DiisoHeptylphthalate (DiHP) - CAS N°:41451-28-9	< 3,33.10 <sup>-1</sup>	
<b>Extractable content of diheptylnonylundecyl phthalate (DHNUP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Heptylnonylundecyl phthalate - CAS N°:68515-42-4	< 6,65.10 <sup>-1</sup>	
<b>Extractable content of 1,2-Benzene dicarboxylic acid, dihexyl ester in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Diisohexylphthalate - CAS N°:68515-50-4	< 3,33.10 <sup>-1</sup>	
<b>Extractable content of 1,2-Benzene dicarboxylic acid, dipentyl ester in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Phthalic acid, n-pentyl-isopentyl ester (DPP) - CAS N°:84777-06-0	< 3,33.10 <sup>-1</sup>	
<b>Di-C6-C10 alkylphthalates in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
C6-C10 Mixed phthalates	< 6,65.10 <sup>-1</sup>	
<b>Extractable content of dimethylphthalate (DMP) in materials - GC-MS - CPSC-CH-C1001-09.4</b>		
Dimethylphthalate - CAS N°:131-11-3	< 6,65.10 <sup>-2</sup>	

(\*)Today, the EUROFINS LOQ is superior to ANSES threshold

(&lt;) This value corresponds to the quantification limit

## 4. PROTOCOL

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### Chemical analysis in a mix of all the components of the diaper

#### **EOX/AOX**

The parameters AOX and EOX are sum parameters. Org. halogen compounds of Cl, Br and J are determined. These are in-house procedures based on the standards for AOX and EOX (see below).

##### AOX

The procedure for the determination of organic halogens in solids is as follows. First, the sample is eluted with hot water. Then the organic halogens dissolved in the water are determined using the methods standardized under the term AOX analysis (DIN EN ISO 9562). Water-soluble and thus mobile organic halogen compounds are thus detected. As this is a sum parameter, it is not possible to identify individual substances.

Alternative: For the determination of samples with an absorbent core we have developed a sample preparation variant. Here the aqueous extract is not prepared by hot water extraction but by elution over 8 hours at 40 °C using 2% sulfuric acid. The actual analysis of the aqueous extract according to DIN EN ISO 9562 is identical.

##### EOX

The sample is rubbed with silica gel and then extracted with ethyl acetate. The extract is burned in an oxygen stream according to DIN 38414-17. The halogen content is then determined microcoulometrically.

We are accredited for these process routes (determination of organic halogen compounds) according to DIN EN ISO/EC 17025.

#### **Azo dyes with extraction ISO 14362-1 :2017 – GC/MS**

Liquid extraction in a buffer solution and purified then measurement by GC-MS according to the standard ISO 14362-1 :2017.

According to the arylamine standard, the test consists of applying the Sample with a Buffer Solution at 70°C for half an hour, after that it is reacted with sodium dithionite, which reduces the amine for another half hour at that temperature.

After this time, the sample is cooled to stop the reaction and the extracting solution is done through diatomaceous earth cartridges, where aliquots of terbutyl are passed to make a liquid-liquid extraction. The amines turn from the aqueous solution (which is trapped in the column) to the terbutyl solution. Once the entire organic phase turns to a balloon, it is rotavaporated and its volume is reduced to 2ml - that extract is the one that is analyzed in GC-MS.

#### **Allergic and carcinogenic dyestuff DIN 54231 :2005 – LC/DAD**

Detection of disperse dyes according to standard DIN 54231

0.5±0.01 g of sample treated with methanol (7.5 ml) during 30 min at 70°C±2 with ultrasounds

#### **Heavy metals – ICP/MS**

Microwave decomposition. Internal method by ICP-MS

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S.A.S AU CAPITAL DE 714 050 euros

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Code APE : 7120B

## Chemical analysis post migration in a synthetic urine simulant (ANSES note dated the 9th of March 2020 - Demand N°2019-SA-0076)

### ❁ Migration preparation test in simulated urine - Preparation test - SCL Protocol

Random sampling of the diapers from the CUS provided. Impregnation of each diaper with 200 ml of simulated urine every 15 minutes until total volume to be injected according to the size tested (ex: 800 ml for size 4). The impregnated diapers are laid flat then covered and placed in an oven at 37°C for 16h. After these 16h, the diapers are pressed with a strength of 800 N for 5 min in order to collect the urine.

### ❁ Polychlorinated dibenzodioxins and -furans (17 PCDD/F): water, drinking water, sewage - GC-MS/MS - Internal

The aim of this method is to search and to quantify the dioxins (Polychlorinated dibenzodioxin / PCDD) and furans (Polychlorinated dibenzofuran / PCDF). This on a synthetic urine simulant obtained after migration (SCL protocol)

There are 75 PCDD and 135 PCDF but only 17 are recognized as toxics for man:

Tetrachlorodibenzodioxin, Pentachlorodibenzodioxin, Hexachlorodibenzodioxin (3 conformations), Heptachlorodibenzodioxin, Octachlorodibenzodioxin, Tetrachlorodibenzofuran, Pentachlorodibenzofuran (2 conformations), Hexachlorodibenzofuran (4 conformations), Heptachlorodibenzofuran (2 conformations), Octachlorodibenzofuran..

The extraction of PCDD and PCDF is carried out with toluene (Soxhlet method). The quantification is performed by gas chromatography combined with a mass spectroscopy (high resolution).

### ❁ Polychlorinated biphenyls: water, drinking water, sewage - GC-MS/MS - Internal

This analysis consists in determining the PCBs content on a synthetic urine simulant obtained after migration (SCL protocol). The method is by GC-MS. The extraction of Polychlorinated biphenyls is carried out with toluene (Soxhlet method). The quantification is performed by gas chromatography combined with a mass spectroscopy (high resolution).

### ❁ PAH acc. to EPA+EU (low LOQ) - GC-MS/MS - Internal Method

The aim of this method is to search and to quantify the polycyclic aromatic hydrocarbons (PAHs) on a synthetic urine simulant obtained after migration (SCL protocol)

Sample clean-up by automated solid-phase extraction (SPE) and measurement by GC-MS/MS.

### ❁ Formaldehyde (free and bound) in materials - LC-UV - Internal Method DNPH derivation Internal

The aim of this method is to search and quantify the formaldehyde (CMR substance: carcinogenic, mutagenic and reprotoxic) on a synthetic urine simulant obtained after migration (SCL protocol).

Liquid chromatography/UV detection using dinitrophenylhydrazine DNPH as derivative

### ❁ Extractable content of phthalates - GC-MS - CPSC-CH-C1001-09.4

Samples with expected high content is diluted before analysis.

The extract is injected to a gas chromatograph with mass selective detector (GC-MS), where the quantitative analyses of the components are performed from calibration standards in the same sequence. Control samples of both high and low levels and a method blank are also carried out.

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