

PVC COMPOUND WES7851/E MTS FOR FOOD CONTACT APPLICATIONS

INEOS Compounds Aycliffe Limited

School Aycliffe Lane Newton Aycliffe Co Durham DL5 6EA United Kingdom

Tel: +44 1325 300555 Fax: +44 1325 303001 www.ineos.com

The above PVC compound has been formulated and manufactured by INEOS Compounds Ltd for anticipated use in low toxicity applications such as food contact packaging for foodstuffs. As such, special quality control release tests (e.g. aqueous extract testing for heavy metals) are applied by INEOS Compounds to each production batch.

The monomer used to produce the base polymer is listed in EU Directive 2011/10/EC (FCM Substance No. 127) and also in Schedule 1 Part 1 Section A of UK Statutory Instrument 1998 No. 1376 where it is listed as item 220, PM/Ref No. 26050 CAS No. 000075-01-4. Specific migration requirements are detailed in S.I. 2005 No. 898 - see paragraph 4 below.

All other raw materials used in WES7851/E MTS Clear compounds are listed in EU Directive 2011/10/EC with the exception of the pigments. Pigments are selected from the French positive list for food contact.

All ingredients are also listed in the US Code of Federal Regulations In particular the ingredients are listed under paragraphs; 178.2010, 181.27 and 178.3297 of Title 21 Chapter 1 of the US Code of Federal Regulations, Food and Drug Administration. The only ingredient not to be listed is the PVC itself which has prior sanction to these regulations

The base PVC resin is selected to ensure that at the outset residual VCM is no more than one part per million (ppm). As supplied by INEOS Compounds the PVC compound itself therefore contains well below 1ppm residual VCM - typically less than 0.1ppm. This should enable food contact products made from the compound to comply with regulations such as EC Directive 78/142/EEC and its updates including 93/8/EEC and 97/48/EEC as well as UK Statutory Instrument No. 898 (2005) [Part 3 Requirements for Vinyl Chloride].

However, due to the fact that the PVC compound undergoes conversion operations that are outside INEOS Compounds control, it must be emphasised that responsibility for demonstrating suitability of a finished product for a specific intended application always rests with the end customer. As an example of this principle, it is a requirements of S.I. No. 1523 that there is no deterioration of organoleptic characteristics of food when in contact with materials and articles as outlined in Article 3 of the Framework Regulation (EC) No 1935/2004. Also UK S.I. No. 1376 and Directives 2011/10/EC and 78/142/EEC require Overall and Specific Migration Test Limits to be met for finished product in contact with foodstuffs. Such requirements can only be demonstrated by appropriate testing commissioned by the end user.

Substances for which an SML applies.

WES7851/E MTS contains Di 2 Ethylhexyl Terephthalate (FCM substance No. 798) for which a Specific Migration limit of 60 mg/kg is given

WES7851/E MTS contains monomethyltin tris(ethylhexyl mercaptoacetate) (FCM Substance No. 697 for which there is a group migration limit of 0.18 mg/kg, expressed as Tin

WES7851/E MTS contains dimethyltin bis(ethylhexyl mercaptoacetate) (FCM Substance No. 698 for which there is a group migration limit of 0.18 mg/kg, expressed as Tin

P R Law

Regulatory Affairs Manager

March 2014

INEOS Compounds Aycliffe Limited Registered in England No. 8651343 Registered Office INEOS Compounds Aycliffe Limited School Aycliffe Lane Newton Aycliffe Co Durham DL5 6EA



Laboratoire agréé par les Ministères chargés de la Santé et de l'Environnement (détails sur demande)



V/Réf.: Commande M. COURTIN du 15/09/2015

N/Réf.: DA-15/08115 du 17/09/2015

Your Ref.: Order Mr COURTIN of 15/09/2015 Our Ref. : DA-15/08115 of 17/09/2015

RAPPORT D'ESSAIS N°RE-15/18299 du 27 Octobre 2015

TESTS REPORT N°RE-15/18299 of October 27, 2015

1. OBJET / OBJECT

Examen de l'inertie d'un matériau devant entrer en contact avec des aliments. Essai de migration globale. Inertia's examination of a material intended to come into contact with foodstuffs. Overall migration test.

2. DOCUMENTS DE REFERENCE

- Norme NF EN 1186, parties 1 et 3
- Directive européenne n°82/711/CEE du 18/10/82, modifiée
- Directive européenne n°85/572/CEE du 19/12/85, modifiée
- Règlement (CE) n°1935/2004 du 27 octobre 2004
- Règlement (UE) n°10/2011 du 14 Janvier 2011, modifié
- Note d'information DGCCRF 2004/64

3. DESCRIPTION DE L'ECHANTILLON

Echantillon réceptionné au laboratoire le 17/09/2015

- Plaque de PVC

Référence : Lanière Polar - Grand Froid

REFERENCE DOCUMENTS

- Standard NF EN 1186, parts 1 and 3
- Modified European directive n°82/711/EEC of 18/10/82
- Modified European directive n°85/572/EEC of 19/12/85
- Regulation (EC) n°1935/2004 of October 27, 2004
- Modified Regulation (EU) n°10/2011 of January 14, 2011
- DGCCRF information notice 2004/64

SAMPLE DESCRIPTION

Sample receptionned at Laboratory on 17/09/2015

- PVC sheet

Reference : Lanière Polar - Grand Froid

L'accréditation du COFRAC atteste de la compétence des laboratoires pour les seuls essais couverts par l'accréditation. La reproduction de ce rapport d'essais n'est autorisée que sous sa forme intégrale. Il comporte 2 page(s). Les résultats mentionnés ne sont applicables qu'aux échantillons soumis à IANESCO.

The accreditation of COFRAC tests section attests the competence of laboratories for the exclusive tests covered by accreditation. The reproduction of this document is allowed only as a whole 2 page(s). The mentioned results apply only for the samples submitted to IANESCO.



4. CONDITIONS D'ESSAIS ET RESULTATS / TEST CONDITIONS AND RESULTS

Conditions de contact sur l'échantillon	Simulant	Observations des éprouvettes	Observations du liquide simulateur	Valeurs individuelles de migration globale en mg/dm²	Valeur moyenne en mg/dm²
Test conditions	Simulant	Observations on the sample	Observations on the simulant	Individual values of overall migration in mg/dm²	Mean value in mg/dm²
MG2 : 10 jours à 40°C	A : Ethanol 10%	Matériau opaque après	Limpide	1.5 1.7 1.7	
OM2 : 10 days at 40°C	A : 10% ethanol	contact Material opaque after contact	Limpid		1.6
MG2 : 10 jours à 40°C	B : Acide acétique 3%	Matériau opaque et décoloré après contact	Limpide	3.9 2.6 3.3	3.3
OM2 : 10 days at 40°C	B : 3% acetic acid	Material opaque and discolored after contact	Limpid		
MG2 : 10 jours à 40°C	C : Ethanol 20%	Matériau opaque après contact	Limpide	4.7 3.5 3.2	
OM2 : 10 days at 40°C	C : 20% ethanol	Material opaque after contact	Limpid		3.8

Notes : Rappel des limites maximales autorisées

Pour les simulants aqueux : 10 mg/dm² avec un écart analytique de 2 mg/dm²

Pour le simulant gras : 10 mg/dm² avec un écart analytique de 3 mg/dm²

Recall of the authorized maximal limits :

For aqueous simulants : 10 mg/dm² with an analytical tolerance of 2 mg/dm² For fatty simulant : 10 mg/dm² with an analytical tolerance of 3 mg/dm²

Date de début d'analyse / Date of analysis beginning : 09/10/2015

5. CONCLUSION / CONCLUSION

Dans les conditions d'essai indiquées dans le tableau ci-dessus, la migration globale de ce matériau est inférieure à la limite fixée par la réglementation dans les simulants A, B, C du règlement n°10/2011 modifié.

In the test conditions indicated in the above table, the overall migration of this material is within the limit set by regulation in the simulants A, B, C of modified regulation 10/2011.

NB: Le matériau doit être conforme aux exigences de composition définies aux chapitres II et III du règlement 10/2011 modifié.

NB: The material has to be in compliance with the requirements of composition defined in chapters II and III of the modified regulation 10/2011.

Maryse FAVARD

Responsable Matériaux et Emballages

Head of Department Packaging and Materials