### Clwyd Compounders Ltd

### Since 1979

### 40 years of compounding excellence

A Compounders Approach to Raw Material and Data Management for Safe, Compliant and Premium Rubber Compounds for a Wide Range of Applications.



Adrian Barlow Technical Compliance & Support

Elastomeric Compounding Specialists, from Formulation to Application



### Excellence in Rubber Compounding

# We are specialists in custom rubber compounds, where performance is critical.

Clwyd Compounders has over 40 years experience of supplying quality compounds to industry.

We understand rubber in-depth - from formulation to application and can supply compounds to meet the most demanding of end-user specifications in industries ranging from oil & gas to food processing.

We also understand the needs of downstream processors, working closely with our customers to ensure the compounds we supply process efficiently thus minimising waste.



## The Benefits of Working with Clwyd Compounders

We offer a comprehensive compounding service, from Formulation to Application.

✓ Technical support and unbiased advice
 ✓ Use majority of advanced materials available today
 ✓ Facilities for development and production
 ✓ Control of Intellectual Property (IP) for your products
 ✓ De-risking supply chains



### In the Old Days

- Customer looking to make bicycle handles
- ✓ No particular requirements black
- ✓ What is lying about leftover tyre compound
- ✓ MSDS why do I need that rubber is safe







### Rubber Safe?

- ✓ Rubber gloves part of PPE
- ✓ Accepted safe by industry
- Change in times and attitudes
- Companies still living in the past?



### Lifetime and Beyond

- ✓ Some hazards are negated
- ✓ Is it the case for entire life and beyond?
- ✓ What forces could be applied frictional?
- ✓ Polymer degradation



Signal word Danger

Hazard Statements H372 - Causes damage to lung through prolonged or repeated exposure by inhalation

Precautionary Statements P260 - Do not breathe dust P501 - Dispose of contents/containers in accordance with local regulations

Voluntary label element In case of inadequate ventilation wear respiratory protection





REACH – polymers exempt from registration, so safe?
 REACH showing more and more interest in polymers for future
 REACH Annex XVII – restriction, not safe
 Encapsulated / Not bio-available – no longer acceptable



## Typical Enquiry Details Today

- ✓ Polymer type, Hardness, Colour
- Physical and Processing properties (Specification)
- Special requirements
- ✓ Regulations

# Actual Enquiry

- Customer supplied specification
- ✓ One of seven pages
- EU 10/2011 + EC 282/2008
  only apply to plastics
- ✓ Too much detail yes and no
- ✓ Not enough fine detail

Regulation						
1.	EC 1935 / 2004	(EU Food Contact)	Have to comply with.			
2.	EC 2023/2006	023/2006 (Good Manufacturing Practice)				
3.	EC 282/2008	(Recycled Plastic )	Have to comply with.			
4.	EU 10/2011	(FOOD CONTACT – plastics)	Have to comply with.			
5.	EC 450/2009	C 450/2009 (FOOD CONTACT - Active & Intelligent Materials & Articles)				
6.	EC 1907/2006	(REACH)	Have to comply with.			
7.	German Consume	Have to comply with.				
8.	German Food, Sup	Have to comply with.				
9.	BfR (D, Recomme fur Risikobewertu Recommendatior	Have to comply with.				
10.	DIN 11483 Part 2 Cleaning and Disin the impacts to ela	Especially have to comply with.				
11.	ADI free (free of a	Especially have to comply with.				
12.	Food, Drug and Co Regulations, Title (RUBBERS)	Especially have to comply with.				



### **Resources Required**

- $\checkmark$  To provide accuracy and detail of information
- ✓ Comprehensive systems
- ✓ Experienced personnel
- ✓ Basic tools no longer good enough
- ✓ Volume and detail of information



### MSDS Considerations

- ✓ Generic MSDS with generic information
- ✓ MSDS for every compound
- One ingredient or difference in quantity can change hazard rating
- Complex software for complex calculations
- Even greater complexity due to ingredients being mixtures



### **Raw Materials**

#### Example of a Fluoroelastomer

- ✓ Section 3.2 MSDS
- ✓ One raw material 6 ingredients
- ✓ 15 to 20 raw materials in a compound
- Actual ingredients 50 to100
- Number of hazard
  calculations possibly +1k

Ingredient	CAS Nbr	EC No	REACH Registration No.	% by Wt	Classification
Vinylidiene fluoride-	9011-17-0			90-99	Substance not classified
hexafluoropropylene polymer					as hazardous
1. 1.1 [222 trifluoro 1					Aquatic Chronic 1, H410,
4, 4 – [2,2,2 – timuolo- i-	1478-61-1	216-036-7		0.1-2	M=1 Eye Dam. 1, H318;
(trinuorometriyi) etriyildenej					Repr 1B, H360F; STOT
aipnenoi					RE 2 H373
Dic //, chlorophonyl) culphono	80-07-9	201-247-9	<1	- 1	Aquatic Chronic 2, H411
Bis (4-chiorophenyi) sulphone				< 1	Eye Irrit. 2, H319
Benzyltriphenylphosphonium,					Dopr 1P H260E Aquatic
salt with 4, 4′ [2, 2, 2-	75768-65-9	278-305-5		<1	Acuto 1, H400, Acustic
trifluoro-1- (trifluoromethyl)					Acute 1, H400; Aqualic
ethylidene] bis [phenol] (1:1)					Chronic 1, H410
	7631-86-9	231-545-4		<1	Substance with a
Ciliana distridu					community level
Silicon dioxide					exposure limit in the
					workplace
Tetrahydrothiophene 1, 1-	126-33-0	20/ 702 1		0.2 -	Acute Tox. 4, H302
dioxide		204-783-1		0.4	Rper. 1B, H360D



### Scale of Task

- Investment in systems & resources necessary to meet documentation legal requirements
- ✓ Over 700 active raw materials
- ✓ 1000's of rubber compounds
- Ensure safety of operators
- ✓ Provide in the spoken language of the customer



### Impact of REACH

- ✓ REACH and nowUK REACH
- ✓ What do customers really know?
- ✓ Annex XVII
- ✓ SVHC / Authorisation

#### REACH Annex XVII Entries common to the rubber industry

Entry 28 – Substances which are classified as carcinogen category 1A or 1B in Part 3 of
Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 1 or Appendix 2,
respectively.
Entry 29 – Substances which are classified as germ cell mutagen category 1A or 1B in
Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 3 or
Appendix 4, respectively.
Entry 30 – Substances which are classified as reproductive toxicant category 1A or 1B in
Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 5 or
Appendix 6, respectively.
Entry 50 – Polycyclic-aromatic hydrocarbons (PAH)
Entry 52 – Phthalates - DINP, DIDP, DNOP
Entry 68 – Perfluorooctanoic acid (PFOA)



### Understanding Substances and SVHCs

- ✓ SVHC actual situations
- Substances Di Octyl Phthalate (DOP), Ethylene ThioUrea (ETU), Litharge
- ✓ Additives anti-degradants added to product (Millable Poly Urethane, Poly Acrylate)
- By products / impurities branched 4-nonyl phenol in Tris(NonylPhenyl) Phosphite (TNPP)
- ✓ Unreacted monomer Poly Siloxanes D4, D5 & D6



### **Customer Regulatory Requirements**

- ✓ PolyAromatic Hydrocarbons (PAH) REACH EU8, EPA16, GS18
- ✓ REACH Annex XIV & XVII
- ✓ RoHS III Electrical & electronic equipment
- California 65 Safe Drinking Water and Toxic Enforcement Act of 1986
- ✓ Food Regulations FDA, BfR, EC 1935/2004



### **Compound PAH levels**

### <u>PAH Levels Table</u> <u>Compound</u>: 9053B/005 (9053911108) <u>Date</u>: 19/10/2020

These results are probably not the maximum as this is only an estimation. The calculated value is established on a small sampling base of raw material information.

The only way to know for certain is to carry out the PAH extraction testing on the compound itself.

РАН Туре	EU8	EPA16	GS18
Acenaphthene		0.004	(0.004)
Acenaphthylene		0.089	(0.089)
Anthracene		0.045	0.045
Benzo(a)anthracene	0.036	0.036	0.036
Benzo(b)fluoranthene	0.134	0.134	0.134
Benzo(j)fluoranthene	0.134		0.134
Benzo(k)fluoranthene	0.031	0.031	0.031
Benzo(ghi)perylene		3.122	3.122
Benzo(a)pyrene	0.611	0.611	0.611
Benzo(e)pyrene	0.745		0.745
Chrysene	0.040	0.040	0.040
Dibenzo(a,h)-anthracene	0.018	0.018	0.018
Fluoranthene		1.204	1.204
Fluorene		0.004	(0.004)
Indeno(1,2,3-cd)pyrene		0.491	0.491
Naphthalene		0.045	0.045
Phenanthrene		0.268	0.268
Pyrene		4.014	4.014
Total	1.749	10.156	11.035



# Compound Annex XVII levels

Substance Requirement	Part number(s)	Relevant substance(s) Chemical name	Relevant substance(s) CAS number	Relevant substance(s) Content (weight %)
D4 & D5 siloxanes (Entry 70 Annex XVII)	867430XXXX	Octamethylcyclotetrasiloxane (D4) Decamethylcyclopentasiloxane (D5)	556-67-2 541-02-6	0.666 0.419
SVHC list	867430XXXX	Octamethylcyclotetrasiloxane (D4) Decamethylcyclopentasiloxane (D5) Dodecamethylcyclohexasiloxane (D6)	556-67-2 541-02-6 540-97-6	0.666 0.419 0.499
Reproductive Toxicity Category 1B (Entry 30 Annex XVII)	906395XXXX	4,4'-[2,2,2-trifluoro- 1(trifluoromethyl)ethylidene]diphenol	1478-61-1	2.50
Reproductive Toxicity Category 1B (Entry 30 Annex XVII)	906365XXXX	4,4'-[2,2,2-trifluoro- 1(trifluoromethyl)ethylidene]diphenol Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2- trifluoro-1(trifluoromethyl)ethylidene]bis[phenol] (1:1) tetrahydrothiophene-1,1-dioxide	1478-61-1 75768-65-9 126-33-0	1.43 0.71 0.29
Reproductive Toxicity Category 1B (Entry 30 Annex XVII)	907395XXXX	4,4'-[2,2,2-trifluoro- 1(trifluoromethyl)ethylidene]diphenol	1478-61-1	2.06
Reproductive Toxicity Category 1B (Entry 30 Annex XVII)	907305XXXX	Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2- trifluoro-1(trifluoromethyl)ethylidene]bis[phenol] (1:1)	75768-65-9	0.92
Reproductive Toxicity Category 1B (Entry 30 Annex XVII)	907365XXXX	4,4'-[2,2,2-trifluoro- 1(trifluoromethyl)ethylidene]diphenol Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2- trifluoro-1(trifluoromethyl)ethylidene]bis[phenol] (1:1) tetrahydrothiophene-1,1-dioxide	1478-61-1 75768-65-9 126-33-0	0.77 0.51 0.15



### Compound Annex XVII levels – continued –

Substance Requirement	Part number	Relevant substance(s) Chemical name	Relevant substance(s) CAS number	Relevant substance(s) Content (weight %)
Reproductive Toxicity Category 1B (Entry 30 Annex XVII)	907355XXXX	Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro- 1(trifluoromethyl)ethylidene]bis[phenol] (1:1)	75768-65-9	0.93
	907365XXXX	4,4'-[2,2,2-trifluoro-1(trifluoromethyl)ethylidene]diphenol	1478-61-1	0.75
Reproductive Toxicity Category 1B (Entry 30 Annex XVII)		Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro- 1(trifluoromethyl)ethylidene]bis[phenol] (1:1)	75768-65-9	0.50
		tetrahydrothiophene-1,1-dioxide	126-33-0	0.15
Reproductive Toxicity Category 1B (Entry 30 Annex XVII)	907305XXXX	Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro- 1(trifluoromethyl)ethylidene]bis[phenol] (1:1)	75768-65-9	0.94
Reproductive Toxicity Category 1B (Entry 30 Annex XVII)	907335XXXX	Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro- 1(trifluoromethyl)ethylidene]bis[phenol] (1:1)	75768-65-9	1.15
Reproductive Toxicity Category 1B (Entry 30 Annex XVII)	908365XXXX	4,4'-[2,2,2-trifluoro-1(trifluoromethyl)ethylidene]diphenol	1478-61-1	1.03
Phthalates (Entry 52 Annex XVII)	9083651XXXX	Di-IsoNonyl Phthalate	28553-12-0 & 68515-48-0	0.54
Reproductive Toxicity Category 1B (Entry 30 Annex XVII)	907355XXXX	Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro- 1(trifluoromethyl)ethylidene]bis[phenol] (1:1)	75768-65-9	0.93
	907365XXXX	4,4'-[2,2,2-trifluoro-1(trifluoromethyl)ethylidene]diphenol	1478-61-1	0.75
Reproductive Toxicity Category 1B (Entry 30 Annex XVII)		Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro- 1(trifluoromethyl)ethylidene]bis[phenol] (1:1)	75768-65-9	0.50
		tetrahydrothiophene-1,1-dioxide	126-33-0	0.15



### Generated information

Reliant on supplier information
 Annex XVII enquiry involved 92 compounds
 Generated 24 pages of tabulated information
 Significant resource

### Understanding Change – Original example

- Issues with using a tyre compound
- ✓ Natural Rubber allergies
- ✓ Aromatic process oil & carbon black carcinogenic & PAH
- Para-phenlyenediamine Skin sensitizer (Cat 1) + Reproductive Toxicant (Cat 1B)
- Sulphur accelerators Skin sensitizer (Cat 1) + Skin irritant (Cat 2) + Eye irritant (Cat 2)

### **Understanding Change - Limitations**

- ✓ Annex XVII restrictions
- ✓ Entry 28 Carcinogenic (Category 1A; ≥ 0.1%)
- ✓ Entry 30 Reproductive Toxicant (Category 1B; ≥ 0.3%)
- ✓ Entry 50 PAH (Child bicycle; ≥ 0.5 ppm, Adult bicycle; ≥ 1 ppm)
- ✓ OPTION NOT SUITABLE



### Understanding Change – A Better Option



# Summary



The design of a rubber compound today not only requires the Rubber Technologist to have the age old traditional technical knowledge of what the individual ingredients deliver to the overall rubber compound in terms of its processing and physical properties. Today, they also need to be aware of the restrictions that those materials can have on the applications for the finished parts, based on their individual and combined hazard ratings.



### Conclusion

Clwyd Compounders recognise the issues facing the compounding industry and have invested in significant resources to cover this, and provide information for our customer base.

This not only gives our customers the confidence in compliance. If there is a need to develop alternatives, Clwyd are orientated to work quickly at developing alternative compounds to ensure continuity of material supply.





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