



VITALOGRAPH (IRELAND) LIMITED, GORT ROAD BUSINESS PARK, ENNIS, CO. CLARE, IRELAND.
TELEPHONE: (065) 6864100. FAX: (065) 6829289.

To whom it may concern:

Per the REACH regulation, Regulation (EC) No 1907/2006 of the European Parliament and of the Council and amendment 552/2009, Vitalograph does not manufacture, import or distribute chemicals.

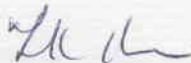
Note: Vitalograph does not mix substances and/or preparations to make preparations for placement on the market. I.e. Vitalograph is not a formulator, per the regulation.

Per the Candidate List {decision # ED/67/2008} published by the European Chemicals Agency on October 28th 2008, Vitalograph does not include the substances of very high concern {SVHC} in its products in a concentration above 0.1% (w/w). These chemical include:

Substance Name	CAS No.	Reason for Inclusion
Triethyl arsenate	427-700-2	Carcinogenic (article 57a)
Anthracene	204-371-1	PBT (article 57d)
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	Carcinogenic (article 57a)
Dibutyl phthalate (DBP)	201-557-4	Toxic for reproduction (article 57c)
Cobalt dichloride	231-589-4	Carcinogenic (article 57a)
Diarsenic pentaoxide	215-116-9	Carcinogenic (article 57a)
Diarsenic trioxide	215-481-4	Carcinogenic (article 57a)
Sodium dichromate	234-190-3 (7789- 12-0 and 10588-01-9)	Carcinogenic, mutagenic and toxic to reproduction (articles 57a, 57b and 57c)
5-tert-butyl-2,4,6-trinitro-m- xylene (musk xylene)	201-329-4	vPvB (article 57e)
Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	Toxic to reproduction (article 57c)
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: Alpha- hexabromocyclododecane Beta- hexabromocyclododecane Gamma- hexabromocyclododecane	247-148-4 and 221- 695-9 (134237-50-6) (134237-51-7) (134237-52-8)	PBT (article 57d)
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	PBT and vPvB (article 57d - e)
Bis(tributyltin)oxide (TBTO)	200-268-0	PBT (article 57d)
Lead hydrogen arsenate	232-064-2	Carcinogenic and Toxic to reproduction (articles 57a

Benzyl butyl phthalate (BBP)	201-622-7	and c) Toxic to reproduction (article 57c)
---------------------------------	-----------	--

As a medical device manufacturer Vitalograph also complies with the Medical Device Directive in the EU, the US Food & Drug Administration, and Canadian Medical Device Regulations for medical devices. These regulations require us to evaluate the safety of all of our devices prior to placing these devices on the market. Vitalograph achieves this through extensive risk management and product testing to ensure the safety and performance of our devices.

Signed: 
Frank Keane
General Manager
Vitalograph (Ireland) Ltd.

Date: 13/11/2009