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Summary of European Commission Decisions on authorisations for the placing on the market for the use and/or for use of substances listed in Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(Published pursuant to Article 64(9) of Regulation (EC) No 1907/2006 ([1]))

(Text with EEA relevance)

(C/2026/736)

Decision granting an authorisation

Reference of the decision ([1])	Date of decision	Substance name	Holder of the authorisation	Authorisation number	Authorised use	Date of expiry of review period	Reasons for the decision
C(2026) 595	4 February 2026	bis(2-ethylhexyl) phthalate (DEHP) (EC No 204-211-0; CAS No117-81-7)	Baxter S.A., Boulevard René Branquart 80, 7860 Lessines, Belgium	REACH/26/2/0	Formulation of bis(2-ethylhexyl) phthalate (DEHP) mixtures for application in immediate packaging of medicines and medical device	14 December 2031	In accordance with Article 60(4) of Regulation (EC) No 1907/2006, the socio-economic benefits outweigh the risk to human health and the environment from the use of the substance and there are no suitable alternative substances or technologies.
			Vantive Manufacturing Limited, Moneen Road, Mayo, F23 XR63 Castlebar, Ireland	REACH/26/2/1			
			Baxter (Malta) Trading Co Ltd, A47 Marsa Industrial estate, MRS3000 Marsa, Malta	REACH/26/2/2			
			Gambro Dasco SpA., Via Modenese 66, 41036 Medolla, Emilia-Romagna Italy	REACH/26/2/3			

([1]) OJ L 396, 30.12.2006, p. 1.

Reference of the decision (1)	Date of decision	Substance name	Holder of the authorisation	Authorisation number	Authorised use	Date of expiry of review period	Reasons for the decision
			Baxter S.A., Boulevard René Branquart 80, 7860 Lessines, Belgium	REACH/26/2/4	Use of bis(2-ethylhexyl) phthalate (DEHP)-containing plastics for immediate packaging of medicinal products		
			Vantive Manufacturing Limited, Moneen Road, Mayo, F23 XR63 Castlebar, Ireland	REACH/26/2/5			
			Baxter (Malta) Trading Co Ltd, A47 Marsa Industrial estate, MRS3000 Marsa, Malta	REACH/26/2/6			
			Gambro Dasco SpA., Via Modenese 66, 41036 Medolla, Emilia-Romagna Italy	REACH/26/2/7			
			Baxter S.A., Boulevard René Branquart 80, 7860 Lessines, Belgium	REACH/26/2/8	Use of bis(2-ethylhexyl) phthalate (DEHP)-based mixtures as a lubricating/ sealing agent for the insertion of port closures into empty bags and assembly/connection of parts, that are used in immediate packaging of medicines	14 December 2028	
			Vantive Manufacturing Limited, Moneen Road, Mayo, F23 XR63 Castlebar, Ireland	REACH/26/2/9			
			Baxter (Malta) Trading Co Ltd, A47 Marsa Industrial estate, MRS3000 Marsa, Malta	REACH/26/2/10			
			Gambro Dasco SpA., Via Modenese 66, 41036 Medolla, Emilia-Romagna Italy	REACH/26/2/11			

(1) The decision is available on the European Commission website at: Authorisation (europa.eu)

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