

La verifica delle condizioni di uso sicuro contenute nelle decisioni di rilascio di un'autorizzazione

Bologna, 22 Giugno 2018
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https://ec.europa.eu/docsroom/docu ments/28685

The screenshot shows a web browser window displaying the European Commission DocsRoom page for document 28685. The browser's address bar shows the URL <https://ec.europa.eu/docsroom/documents/28685>. The page header features the European Commission logo and navigation links such as 'A-Z Index', 'Sitemap', and 'About this site'. The main content area is titled 'Authorisation Decisions List' and includes the document date (08/03/2018) and creation information (GROW.DDG1.D.1). Under the 'Download links' section, there are two options: 'Original format' (selected) and 'PDF format with official reference'. A blue arrow points to the 'Original format' link, which is labeled 'Authorisation Decisions List' with a PDF icon and '(691 KB)'. On the right side of the page, there is a 'Stay connected' section with social media icons for Facebook, Google+, Twitter, and EU Tube, and a 'Document keywords' section listing 'special chemicals', 'chemical industry', and 'implementing decision'.



EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SME's
Consumer, Environmental and Health Technologies
REACH

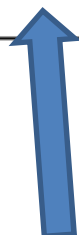
REACH Authorisation Decisions

List of authorisation decisions adopted on the basis of Article 64(8) of Regulation (EC) No 1907/2006 (REACH). The list also includes reference to related documentation concerning all applications for authorisation on which an opinion has been adopted by the Committee for Risk Assessment and the Committee for Socio-economic Analysis of ECHA on the basis of Article 64(5) REACH.

Substance name	Authorisation decision	Summary in OJ	Applicant(s)	Exposure scenario(s) from application (CSR)	Further details ¹
Bis(2-ethylhexyl) phthalate (DEHP)	C(2014) 5551 final	OJ C 260, 9.8.2014, p. 10	Rolls-Royce plc	DEHP 1-CSR-ES	ECHA documentation – DEHP1
	C(2016) 3549	OJ C 225, 22.5.2016, p. 3	Vinyloop Ferrara S.p.A. Stena Recycling AB Plastic Planet srl	DEHP 4-use-1-CSR-ES DEHP 4-use-2-CSR-ES	ECHA documentation - DEHP4 use 1 ECHA documentation - DEHP4 use 2
	Application withdrawn (2/12/2015)	NA	Arkema France	Application withdrawn (2/12/2015)	Application withdrawn (2/12/2015)

¹ Link to public versions of the application, results of public consultation and RAC and SEAC opinions on the ECHA website

Substance name	Authorisation decision	Summary in OJ	Applicant(s)	Exposure scenario(s) from application (CSR)	Further details ¹
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	Gentochema BV	Sodium dichromate-use1-2 Sodium dichromate-use3	Sodium dichromate – ECHA documentation-use1 Sodium dichromate – ECHA documentation-use2 Sodium dichromate – ECHA documentation-use3
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	Ilario Ormezzano Sai Spa	Sodium dichromate-Use1 Sodium dichromate-Use2	Sodium dichromate – ECHA documentation-Use1 Sodium dichromate – ECHA documentation-Use2
	C(2017)8331	OJ C 441 22.12.2017, p.15	Gruppo Colle.S.r.l.	Sodium dichromate	Sodium dichromate – ECHA documentation
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	ZF Luftfahrttechnik GmbH	Sodium dichromate	Sodium dichromate – ECHA documentation
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	Borealis Plastomers B.V.	Sodium dichromate	Sodium dichromate – ECHA documentation
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	Wesco Aircraft EMEA Limited	Sodium dichromate	Sodium dichromate – ECHA documentation
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	HAPOC GmbH & Co KG	Sodium dichromate	Sodium dichromate – ECHA documentation
Chromium trioxide	C(2017)663	OJ C 48 15.02.2017, p. 8	Grohe AG	Chromium trioxide	Chromium trioxide - ECHA documentation 1 Chromium trioxide - ECHA documentation 2



Substance name	Authorisation decision	Summary in OJ	Applicant(s)	Exposure scenario(s) from application (CSR)	Further details ¹
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	LANXESS Deutschland GmbH in its legal capacity as Only Representative of LANXESS CISA (Pty) Ltd. Atotech Deutschland GmbH Aviell Services Inc BONDEX TRADING LTD in its legal capacity as Only Representative of Aktyubinsk Chromium Chemicals Plant, Kazakhstan CROMITAL S.P.A. in its legal capacity as Only Representative of Soda Sanayii A.S. Elementis Chromium LLP in its legal capacity as Only Representative of Elementis Chromium Inc Enthone GmbH	Chromium trioxide-use1 Chromium trioxide-use2 Chromium trioxide-use3 Chromium trioxide-use4 Chromium trioxide-use5 Chromium trioxide-use6	Chromium trioxide - ECHA documentation 1 Chromium trioxide - ECHA documentation 2 Chromium trioxide - ECHA documentation 3 Chromium trioxide - ECHA documentation 4 Chromium trioxide - ECHA documentation 5 Chromium trioxide - ECHA documentation 6
	C(2017)6727 C(2017)6727 (FI) C(2017)6727(SV)	OJ C 348 17.10.2017, p.6-7	Oy Kromatek Ab; Kova-Kromi Oy; CrTe-Plating Oy; Saizeri Plating Oy; Turun Kovakromi Oy; Veljekset Wallenius Oy; Pirkan Kovakromaus Oy	Chromium trioxide	Chromium trioxide – ECHA documentation
	C(2017)3439	OJ C 172 31.05.2017, p.2	Rimex Metals (UK) Ltd	Chromium trioxide	Chromium trioxide - ECHA documentation
	C(2017)5001	OJ C 241, 26.07.2017, p.2	Nexter Mechanics	Chromium trioxide-Use 1 Chromium trioxide-Use 2 Chromium trioxide-Use 3 Chromium trioxide-Use 4	Chromium trioxide - ECHA documentation-Use 1 Chromium trioxide - ECHA documentation-Use 2 Chromium trioxide - ECHA documentation-Use 3 Chromium trioxide - ECHA documentation-Use 4
	C(2018)12	OJ C 16 18.01.2018, p.2	Abloy Oy	Chromium trioxide	Chromium trioxide – ECHA documentation

Substance name	Authorisation decision	Summary in OJ	Applicant(s)	Exposure scenario(s) from application (CSR)	Further details ¹
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	CROMOMED S.A., CRONOR S.A., Cromo Europa S.A., CHROMATLANTIQUE INDUSTRIEL and VILA ELECTROQUIMICAS.A.	Chromium trioxide	Chromium trioxide – ECHA documentation
	C(2018)654	OJ C 60 16.02.2018, p.8	Hoogovens Court Roll Surface Technologies V.O.F., WAVEC GmbH, Trattamento Cilindri Laminazione S.r.l., Walzen-Service-Center GmbH, NORD CHROME SAS, RHENAROLL SA, Texturing Technology Limited and NC POLAND Sp.z. o.o.	Chromium trioxide	Chromium trioxide – ECHA documentation
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	Sourisau sas, Amphenol Limited, Amphenol Socapex, ITT Cannon, Connecteurs Electriques Deutsch and Tyco Electronics UK Ltd	Chromium trioxide - uses 1-2-3	Chromium trioxide – ECHA documentation – Use 1 Chromium trioxide – ECHA documentation – Use 2 Chromium trioxide – ECHA documentation – Use 3
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	Topocrom GmbH	Chromium trioxide	Chromium trioxide – ECHA documentation
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	FN Herstal S.A., Manroy Engineering Ltd and Browning Viana - Fabrica de armas e artigos de desporto S.A.	Chromium trioxide – Uses 1-2	Chromium trioxide – ECHA documentation-use1 Chromium trioxide – ECHA documentation-use2
	C(2017)5880	OJ C 296 07.09.2017, p.15	Praxair Surface Technologies GmbH	Chromium trioxide – Uses 1-2	Chromium trioxide – ECHA documentation-use1 Chromium trioxide – ECHA documentation-use2
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	Federal Mogul Friedberg	Chromium trioxide	Chromium trioxide – ECHA documentation
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	Federal Mogul Valvetrain	Chromium trioxide	Chromium trioxide – ECHA documentation

Substance name	Authorisation decision	Summary in OJ	Applicant(s)	Exposure scenario(s) from application (CSR)	Further details ¹
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	Federal Mogul Burscheid	Chromium trioxide	Chromium trioxide – ECHA documentation
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	SNECMA	Chromium trioxide	Chromium trioxide – ECHA documentation
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	MTU Aero Engines AG	Chromium trioxide – Use1 Chromium trioxide – Use2	Chromium trioxide – ECHA documentation Chromium trioxide – ECHA documentation
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	Gerhardi Kunststofftechnik GmbH; C. Hübner GmbH; SAXONIA Galvanik GmbH; Karl Simon GmbH & Co. KG; Fischer GmbH & Co. surface technologies KG; Wafa Germany GmbH; Boryszew Oberflächentechnik Deutschland GmbH; Bolts Werke GmbH; Heinze Gruppe GmbH; C+C Krug GmbH; BIA Kunststoff- und Galvanotechnik GmbH & Co KG and Aludec Galvanic s.a.	Chromium trioxide	Chromium trioxide – ECHA documentation
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	CIRCUIT FOIL LUXEMBOURG SARL	Chromium trioxide	Chromium trioxide – ECHA documentation
	PENDING ADOPTION	PENDING ADOPTION OF DECISION	REACHLaw Ltd as Only Representative on behalf of Joint Stock Company "Novotroitsk Plant of Chromium Compounds"	Chromium trioxide – Use1 Chromium trioxide – Use2 Chromium trioxide – Use3 Chromium trioxide – Use4	Chromium trioxide – ECHA documentation-Use1 Chromium trioxide – ECHA documentation-Use2 Chromium trioxide – ECHA documentation-Use3 Chromium trioxide – ECHA documentation-Use4

USI

- FORMULAZIONE
- CROMATURA DECORATIVA
- CROMATURA FUNZIONALE
- ALTRI TRATTAMENTI SUPERFICIALI
(PASSIVAZIONE...)

Processi specifici per la cromatura funzionale

- PREPARAZIONE DI BAGNI
- Caricamento dei pezzi
- Pretrattamento chimico
- Cromatura per immersione
- Lavaggio-asciugatura
- Post-trattamento chimico
- Pulizia e scarico pezzi

processi

- Pulizia delle apparecchiature
- Manutenzione delle attrezzature
- Laboratorio analisi
- Stoccaggio articoli
- Gestione rifiuti

Criterion for the assessment of risk in exposure scenarios



1 (8)

Helsinki, 04 December 2013
RAC/27/2013/06 Rev.1
(Agreed at RAC-27)

APPLICATION FOR AUTHORISATION: ESTABLISHING A REFERENCE DOSE RESPONSE RELATIONSHIP FOR CARCINOGENICITY OF HEXAVALENT CHROMIUM

Workers

Based on a 40 year working life (8h/day, 5 days/week), the following risk estimates are used:

An excess lifetime lung cancer mortality risk = 4×10^{-3} per $\mu\text{g Cr(VI)}/\text{m}^3$

Table 19. Exposure concentrations and risks for workers – inhalation, local, long-term

Worker contributing scenario	PROC	Description	N*	Arithmetic Mean	Geometric Mean	90 th Percentile	RCR
WCS - 8	PROC 4	Loading of jigs	40	0.60 µg/m ³	0.33 µg/m ³	1.25 µg/m ³	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 5 per 1000 exposed workers
WCS - 9	PROC 13	Chemical pre-treatment					
WCS - 10	PROC 13	Other surface treatment by dipping/immersion					
WCS - 11	PROC 13	Rinsing/drying					
WCS - 12	PROC 13	Chemical post-treatment					
WCS - 13	PROC 4	Cleaning and unloading of jigs					
WCS - 14	PROC 8b	Cleaning of equipment					
WCS - 15	PROC8a	Maintenance of equipment					

Conclusion on risk characterisation

The 90th percentile value of the personal sampling data partially adjusted for respiratory protection of 1.25 µg Cr(VI)/m³ is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 5 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality.

DIRETTIVA (UE) 2017/2398 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO

del 12 dicembre 2017

che modifica la direttiva 2004/37/CE sulla protezione dei lavoratori contro i rischi derivanti da un'esposizione ad agenti cancerogeni o mutageni durante il lavoro

Valori limite e altre disposizioni direttamente connesse (Articolo 16)

A. VALORI LIMITE PER L'ESPOSIZIONE PROFESSIONALE

Nome agente	N. CE ⁽¹⁾	N. CAS ⁽²⁾	Valori limite ⁽³⁾			Osservazioni	Misure transitorie
			mg/m ³ ⁽⁴⁾	ppm ⁽⁵⁾	f/ml ⁽⁶⁾		
Polveri di legno duro	—	—	2 ⁽⁷⁾	—	—	—	Valore limite: 3 mg/m ³ fino a 17 gennaio 2023
Composti di cromo VI definiti cancerogeni ai sensi dell'articolo 2, lettera a), punto i), (come cromo)	—	—	0,005	—	—	—	Valore limite: 0,010 mg/m ³ fino al 17 gennaio 2025 Valore limite: 0,025 mg/m ³ per i procedimenti di saldatura o taglio al plasma o analoghi procedimenti di lavorazione che producono fumi fino al 17 gennaio 2025
Fibre ceramiche refrattarie definite cancerogene ai sensi dell'articolo 2, lettera a), punto i)	—	—	—	—	0,3	—	

Condizioni rilasciate contestualmente all'autorizzazione

- Adozione delle condizioni operative e delle misure di gestione del rischio indicate nei CSR
- Misure di esposizione occupazionale (periodicità annuale,, campionamenti personalie statici)
- Misure di emissione annuali nell'acqua e nell'aria