Updates in materia di biocidi

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Delegated act about ED evaluation for biocides

- The European Commission has published its delegated Regulation setting out the criteria for identifying endocrine disrupting chemicals (EDCs) under the biocidal products Regulation (BPR) in the EU *Official Journal*.
- The criteria will apply from 7 June 2018

Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council

The Commission has returned the following active substances to ECHA for an ED assessment:

- cyanamid;
- chlorophene;
- salicylic acid;
- 2-phenoxyethanol;
- formaldehyde;
- MBO;
- HPT;
- carbendazim;
- active chlorine generated from sodium chloride by electrolysis and active chlorine released from hypochlorous acid.
- In total 32 opinions have now been returned

The ED Guidance on endocrine disruptors

- A guidance document for the identification of substances with endocrine disrupting properties in pesticides and biocides is now available (7 June 2018).
- A public consultation on the draft Guidance was open from 7 December 2017 to 31 January 2018
- The Guidance document has been developed by the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) with the support of the European Commission Joint Research Centre (JRC) and a selected panel of experts from MSs .

The ED Guidance on endocrine disruptors

- This Guidance was developed jointly by ECHA and the European Food Safety Authority (EFSA) with support by the Joint Research Centre (JRC).
- It describes how to identify endocrine disruptors in the context of the Biocidal Products Regulation (EU) No 528/2012 and the Plant Protection Products Regulation (EC) No 1107/2009 in accordance with the scientific criteria for the determination of endocrine disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100 and Commission Regulation (EU) 2018/605.
- The guidance document has been published in the EFSA Journal

New additional guidelines

Guidance on micro-organisms : This Guidance provides technical advice on the information requirements, the hazard and exposure assessment, the risk characterisation and the evaluation of the active substances and biocidal products in accordance with Annex II, Title 2 and Annex III, Title 2 of the BPR for micro-organisms. (29/03/2017)

Guidance on Disinfection By-Products : This guidance document deals with the risk assessment for human health and the environment of Disinfection By-Products that is applicable for the authorisation of products under the EU Biocidal Products Regulation (BPR, Regulation (EU) 528/2012). (23/01/2017)

Guidance on active substance suppliers: This Guidance describes the obligations under Article 95 of the BPR and explains the regulatory consequences.

Guidance on applications for technical equivalence: (Version 2.0 of this Guidance replaces the document "Recommendations for applicants on information requirements for technical equivalence Tier II"). This Guidance informs potential applicants about their obligations resulting from the provisions of Article 54 of the BPR: when they need to apply for an assessment of technical equivalence and on the procedural steps in making that application. The Guidance also informs potential applicants about the assessment conducted by the Agency and the approach used for assessing the technical equivalence of the alternative source of an active substance versus its reference source. (12/07/2018)

Biocides IT tools updated

The latest version of the biocides submission tool R4BP 3 provides improved workflows and notification systems and an enhanced user experience. The updated SPC Editor now makes it easier to compare summaries of product characteristics (SPCs).

- The new features in R4BP 3 include:
- improved search filters with automatically saved results;
- the option to save draft applications;
- improved application wizards and more informative error messages;
- a warning message alerting a user making an application for mutual recognition if that product has already been authorised in the same market area; and
- new case types to support the implementation of Union authorisations in EEA countries and Switzerland.
- There are also new features aimed at assisting authorities using the tool, such as an email notification system.
  The new features in SPC Editor include:
- an effective comparison of SPCs for biocidal product families; and
- a more detailed outcome for the comparison of SPCs.

Borderline cases

1. Permetrine on living animals -permethrin used as a topical insecticide on livestock . A veterinary medicine product ???
2. Wolbachia trans-infected mosquitos used for vector control purposes : a biocide?
3. Pepper containing sprays to be used in case of attacks by aggressive dogs : a repellent? Mechanical or chemical action?

Union authorizations

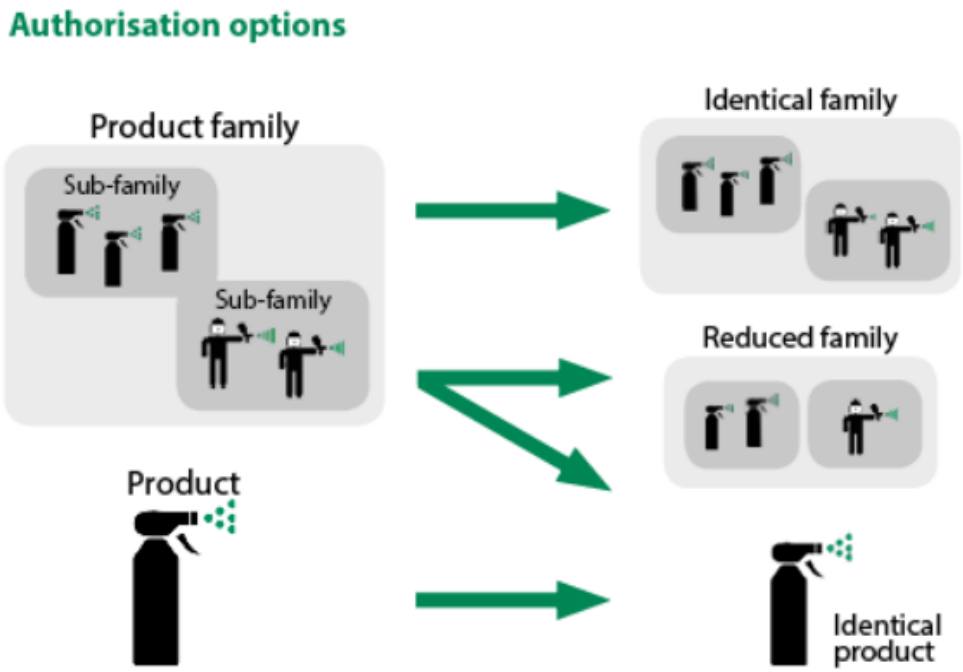
Table 1: Number of applications for Union authorisation submitted split by type of procedure, year of submission and type of authorisation sought.

	Year of submission						
	2015		2016		2017		
	Type of authorisation sought		**Type of authorisation sought**		**Type of authorisation sought**		
Type of procedure	Single biocidal product	Biocidal product family	Single biocidal product	Biocidal product family	Single biocidal product	Biocidal product family	Total by type of procedure
Article 43 of Regulation (EU) No 528/2012	0	12	5	12	5	36	70
Article 4 of Commission Implementing Regulation (EU) No 414/2013	0	2	1	8	9	25	45
Subtotal by type of authorisation/year	0	14	6	20	14	61	**TOTAL**
Total by year	14		26		75		**115**

Proposal on the “fast-track procedure” on Union authorisation

As for as certain degree of similarity is expected between the applications for products containing for example peracetic acid or hydrogen peroxide, it has been proposed to reconsider by the end of 2019 the possibility to establish a “fast track procedure” for Union authorisation in light of the experience acquired with time, in particular with the applications for products containing peracetic acid or hydrogen peroxide.

Biocide family authorizations



Brexit

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Brussels, 23 January 2018

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES ON BIOCIDAL PRODUCTS

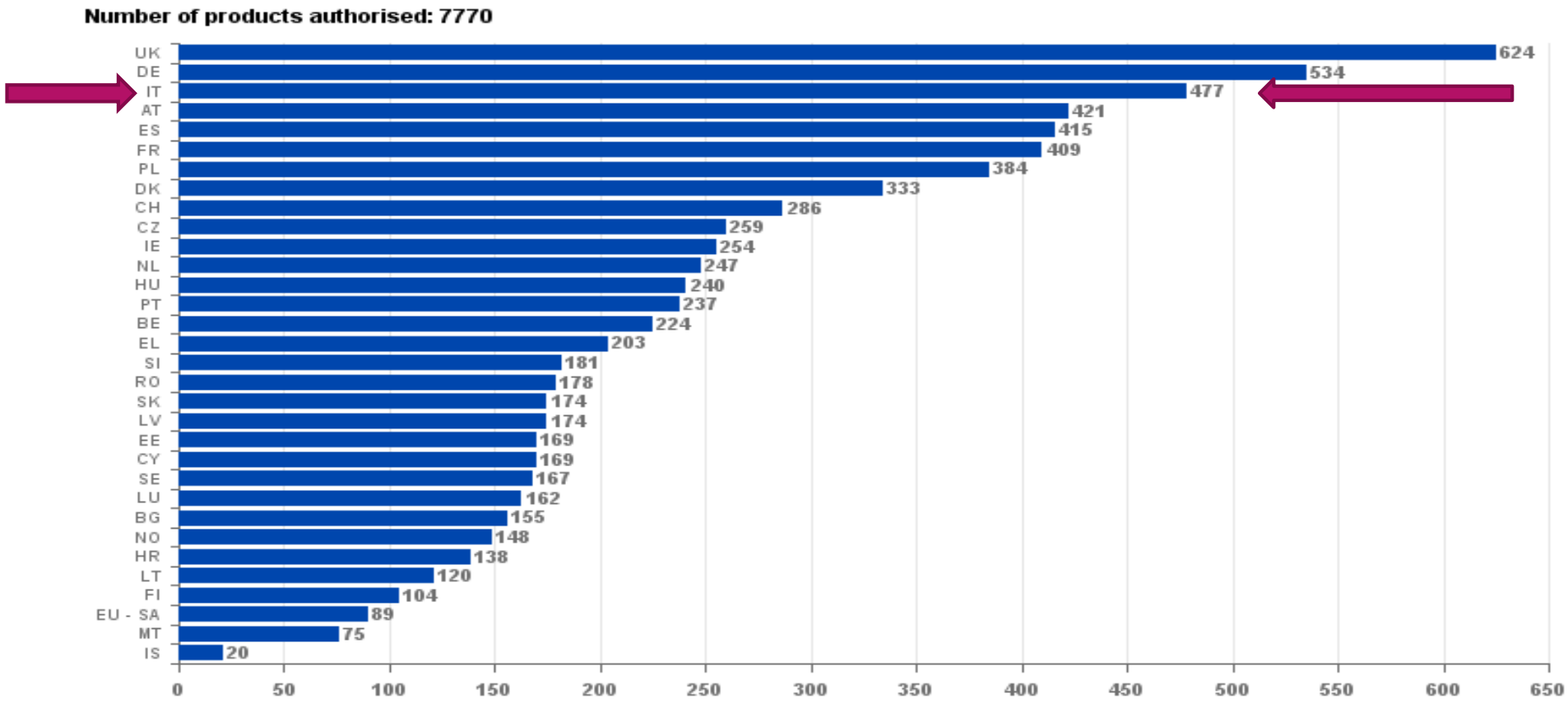
The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. This means that unless the withdrawal agreement[1] establishes another date, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET) ("the withdrawal date"). The United Kingdom will then become a 'third country'.

Preparing for the withdrawal is not just a matter for European and national authorities, but also for private parties.

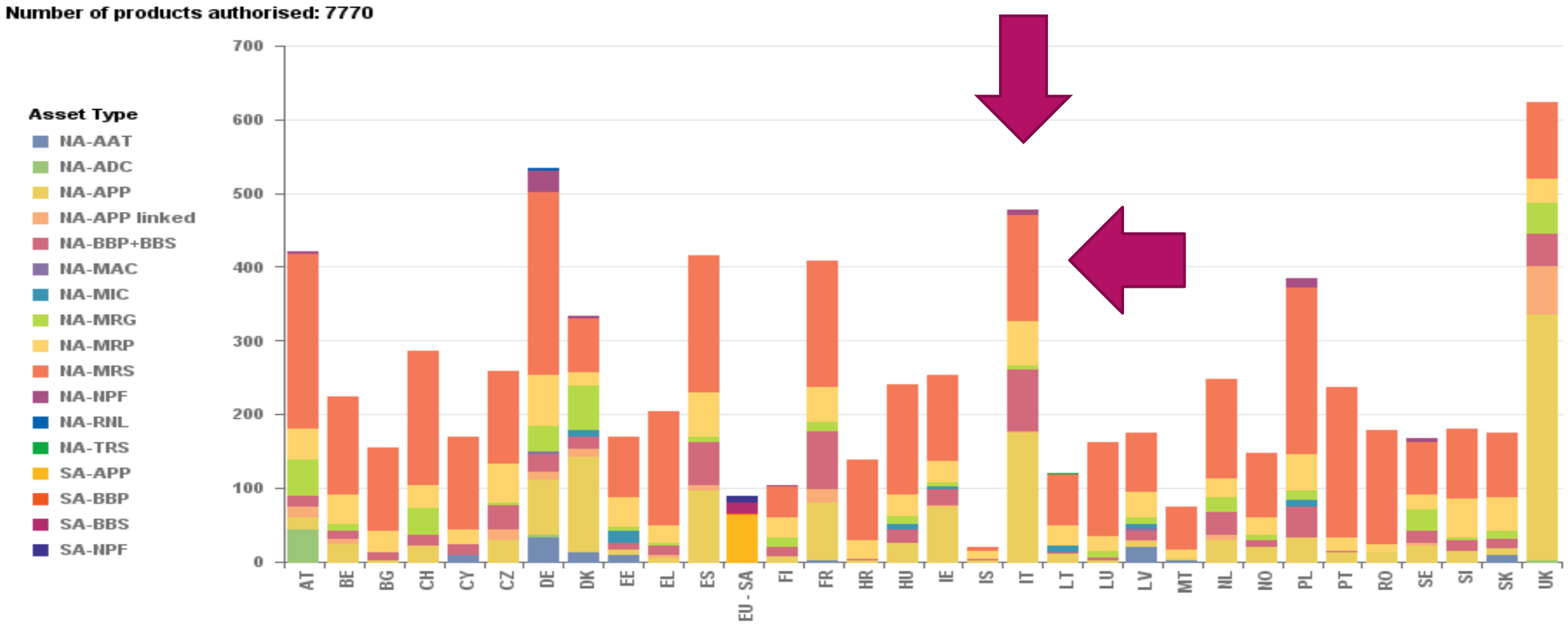
In view of the considerable uncertainties, in particular concerning the content of a possible withdrawal agreement, business operators involved in the activities falling under the scope of Regulation (EC) No 528/2012 concerning the making available on the market and use of biocidal products are reminded of certain legal repercussions stemming from currently applicable rules of Union law which need to be considered when the United Kingdom becomes a third country.

Subject to any transitional arrangement that may be contained in a possible withdrawal agreement, as of the withdrawal date, the EU rules in the field of biocidal products no longer apply to the United Kingdom. In particular, business operators should consider that, according to Union law, third countries cannot act as evaluating Member States or reference Member States[2].

Workload for MSs and Enterprises



Workload for MSs and Enterprises



Workload for MSs and Enterprises

	AT	BE	BG	CH	CY	CZ	DE	DK	EE	EL	ES	EU - SA	FI	FR	HR	HU	IE	IS	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK	Total
NA-AAT					8		33	13	8					1								20	2								8		**93**
NA-ADC	43						4																									1	**48**
NA-APP	17	23	2	22	1	29	74	128	8	5	97		7	78	1	25	75	1	174	11	2	7	4	29	19	33	12	12	21	15	10	335	**1277**
NA-APP linked	15	7				14	10	11		4	6			20		1	1		2			2		7					4			65	**169**
NA-BBP+BBS	14	11	11	15	14	33	25	17	9	13	59		12	77	3	18	22	2	85	2	4	12		32	9	41	3		17	13	12	44	**629**
NA-MIC							3															5											**8**
NA-MAC								9	16							7	4			9		4				9							**58**
NA-MRG	50	9		36		3	35	61	6	4	7		14	13		10	6		4		9	9		20	8	14			28	4	11	42	**403**
NA-MRP	42	40	28	31	21	54	70	18	40	22	61		26	48	24	30	28	11	61	27	20	36	10	25	24	48	18	11	20	53	47	32	**1026**
NA-MRS	237	134	114	182	125	126	248	72	82	155	185		43	172	110	149	117	6	145	69	127	79	59	134	88	227	204	155	72	96	86	104	**3902**
NA-NPF	3						29	4					2				1		6							12			5			1	**63**
NA-RNL							3																										**3**
NA-TRS																				2													**2**
SA-APP												63																					**63**
SA-BBP												2																					**2**
SA-BBS												14																					**14**
SA-NPF												10																					**10**
Total	**421**	**224**	**155**	**286**	**169**	**259**	**534**	**333**	**169**	**203**	**415**	**89**	**104**	**409**	**138**	**240**	**254**	**20**	**477**	**120**	**162**	**174**	**75**	**247**	**148**	**384**	**237**	**178**	**167**	**181**	**174**	**624**	**7770**

New classified biocidal active ingredients and coformulants

- 10 ATP has been published and will enter into force by December this year
- Some aass are heavily involved

Fipronil (10 ATP)

fipronil (ISO); (±)-5-ammino-1-(2,6-dicloro-α,α,α-trifluoro-para-tolil)-4-trifluorometil sulfinil-pirazol-3-carbonitrile	424-610-5	120068-37-3	Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H301 H311 H331 H372* H400 H410	GHS06 GHS08 GHS09 Dgr	H301 H311 H331 H372* H410

Terbutilazine (10 ATP)

613-323-00-2	terbutilazina (ISO); *N-terz*-butil-6-cloro-*N*′-etil-1,3,5-triazin-2,4-diammina	227-637-9	5915-41-3	Acute Tox. 4 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H302 H373 H400 H410	GHS07 GHS08 GHS09 Wng	H302 H373 H410

Linalole (10ATP)

603-235-00-2	linalolo; 3,7-dimetil-1,6-ottadien-3-olo; dl-linalolo; [1] coriandrolo; (S)-3,7-dimetil-1,6-ottadien-3-ol; d-linalolo; [2] licareolo; (R)-3,7-dimetil-1,6-ottadien-3-olo; l-linalolo [3]	201-134-4 [1] 204-810-7 [2] 204-811-2 [3]	78-70-6 [1] 126-90-9 [2] 126-91-0 [3]	Skin Sens. 1B	H317	GHS07 Wng	H317

2-methylisothiazol-3(2H)-one as preservative in biocides (12 ATP)

- At the 36th meeting of the Committee for Risk Assessment (RAC), an opinion on the Harmonized Classification and Labelling of 2-methylisothiazol-3(2H)-one (MIT, CAS no. 2682-20-4) was adopted.
- As part of the opinion, MIT was assigned an extreme potency categorisation for skin sensitisation and a recommendation for a **S**pecific **C**oncentration **L**imit (SCL) of 15 ppm was proposed, on the basis of data provided in the original CLH report and information provided during public consultation.
- Restriction threshold lowered for paints, detergents, PPPs, etc
- It will involve also MBIT, CMIT and others
- MBIT, CMIT and MIT are described as "product-type 6" biocides under the biocidal products Regulation (BPR); MBIT was approved as a new active substance last year.

12° ATP

613-326-00-9	2-metilisotiazol-3(2*H*)-one	220-239-6	2682-20-4	Acute Tox. 2 Acute Tox. 3 Acute Tox. 3 Skin Corr. 1B Eye Dam. 1 Skin Sens. 1 A Aquatic Acute 1 Aquatic Chronic 1	H330 H311 H301 H314 H318 H317 H400 H410	GHS05 GHS06 GHS09 Dgr	H330 H311 H301 H314 H317 H410	EUH071	Skin Sens. 1 A; H317: C ≥ 0,0015 % M = 10 M = 1»	

2-methyl-2H-isothiazol-3-one (12 ATP)

EC / List no.: 220-239-6 **CAS no.:** 2682-20-4 **Mol. formula:** C4H5NOS

Hazardclassification&labelling

Danger! Fatal if inhaled, is toxic if swallowed, is toxic in contact with skin, causes severe skin burns and eye damage, is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects and may cause an allergic skin reaction.

About this substance

This substance is manufactured and/or imported in the European Economic Area in 10 - 100 tonnes per year.
This substance is used by consumers, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.

Consumer Uses

This substance is used in the following products: treated articles, biocides, cosmetics and personal care products, fertilisers, plant protection products, perfumes and fragrances,inks.
Other release to the environment of this substance is likely to occur from: outdoor use as processing aid and indoor use as processing aid.

Article service life

ECHA has no public registered data on the routes by which this substance is most likely to be released to the environment. ECHA has no public registered data indicating whether or into which articles the substance might have been processed.

Widespread uses by professional workers

This substance is used in the following products: fertilisers, laboratory chemicals, plant protection products, perfumes and fragrances, cosmetics and personal care products and pH regulators and water treatment

2-methylisothiazol-3(2H)-one as preservative in cosmetics

- This means that such mixtures must be labelled when they contain more than 0.0015% of MIT – a limit value lowered from 1%.
- In addition, those mixtures must bear the warning "Contains methylisothiazolinone. May cause an allergic skin reaction.“ The decision amends Annex VI of the CLP Regulation, as part of the European Commission’s of next adaptation to technical progress.
- The Danish EPA’s has seen evidence of allergies to MIT "since the drug was allowed in cosmetics in 2005". There have also been several cases of MIT allergy directly related to paint
- The Commission’s ban on the use of MIT in cosmetic ‘leave-on’ products, such as deodorants and creams from February 2017. Meanwhile, a lower limit of MIT from 0.01% to 0.0015% in 'rinse-off' products, such as shampoo and soap, has been implemented since last April.
- The substance has been also restricted in toys for children under three years and toys intended to come into the mouth.

Conclusions

STAY UP-dated !!!!!!!!!!!!!!!!!!!!

GRAZIE PER L'ATTENZIONE

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