NEWSLETTER DECEMBER 2018

HOT TOPICS for 2019

Reach regulation

1. Remember to update the ***dossier quality*** mainly regarding tonnages levels

2. Check constantly the ***Candidate List*** for inclusion of further SVHC (Substance of Very High Concern)

3. Stay updated on ***Annex XIV*** (Authorization) and ***Annex XVII*** (Restriction) entries. A substance listed in such annexes will vary its regulatory status and a number of action are needed to keep it on the EU market or to use it as downstream user.

4. ***DMF restriction*** process expected to end by 2019. Check the status

5. ECHA/Member States ***Evaluation procedure***. Check the status

6. Other special points to be considered:

6.1 Companies to provide more information on nanomaterials (December 3, 2018)

A specific revision of the REACH information requirements for nanomaterials has now been adopted by the European Commission. The amendments clarify what information companies placing substances in nanoform on the market need to provide in their registration dossiers. The new rules apply as of 1 January 2020.

Nanomaterials are chemical substances in a particular form with special features at the nanoscale, between ***1 nm and 100 nm***. They can be used in many different ways, for example, in catalysts, electronics, solar panels and batteries and in materials science and biomedical applications. Similar to conventional forms of substances, some nanomaterials are hazardous and others are not. Scientific evidence shows that the toxicity of nanoforms as well as their effects on the environment may differ from the conventional substance.

The European Union Observatory for Nanomaterials (EUON) provides information about the safety, innovation, research and uses of nanomaterials on the EU market. It is funded by the European Commission and hosted and maintained by ECHA.

The new requirements given in the draft guideline will enable both companies and authorities to systematically assess the hazardous properties of nanomaterials, how they are used safely, and what risks they may pose to our health and the environment. This information will help authorities in the EU to identify if further risk management measures are needed.

Companies now have to assess whether the new information requirements apply to their substances. The changes are relevant for companies manufacturing or importing nanoforms of substances that fall within the scope of REACH. Nanoforms of substances are those covered by the European Commission's recommendation for a definition of a nanomaterial.

ECHA strongly encourages registrants of nanoform substances to familiarize themselves with the amendments and assess what action they need to take to comply. ECHA is also currently assessing the need to update existing guidance or issue new guidance to help registrants comply with the new requirements.

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nanomaterials are hazardous and others are not. Scientific evidence shows that the toxicity of nanoforms as well as their effects on the environment may differ from the conventional substance.

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6.2 ECHA's committees adopt 19 harmonised classification and labelling opinions and two restrictions (December 5, 2018)

The Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) agreed on two restriction proposals

9-C14 PFCAs, their salts and precursors

SEAC adopted its final opinion, in support of the proposal by Germany and Sweden, to **restrict** the manufacturing, use, placing on the market and import of C9-C14 PFCAs (PFNA; PFDA; PFUnDA; PFDoDA; PFTrDA; PFTDA), their salts and precursors. This restriction is intended to prevent a switch by industry using PFOA-based substances to longer-chain PFCAs to fulfill the same role in the end products after the restriction for PFOA, its salts and PFOA-related substances will become effective in 2020. PFOA has been used because of its special properties such as high friction resistance, dielectric properties, resistance to heat and chemical agents, low surface energy, and water, grease, oil, and dirt repellence. Alternatives to C9-C14 PFCAs, as well as to PFOA, are currently being used. SEAC reconfirmed that the proposed restriction is the most appropriate EU-wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its costs. Having considered the 15 comments received during the public consultation on the draft opinion agreed in September 2018, SEAC introduced a higher threshold for impurities in certain fluoropolymers and made some adjustments in the justification for its opinion.

Substances used in tattoo inks and permanent make-up

RAC adopted its final opinion, in support of ECHA's proposal (prepared in collaboration with Denmark, Italy and Norway) to **restrict** the placing on the market and use of tattoo inks and permanent make-up containing a wide range of chemicals, e.g. carcinogens, mutagens, reprotoxicants, sensitisers and irritating substances. SEAC agreed on its draft opinion on this restriction proposal. The public is invited to submit comments on the opinion between 12 December 2018 and 11 February 2019. After the consultation, SEAC will incorporate the comments and adopt its final opinion.

The Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) adopted three final authorization opinions.

The committees discussed and adopted one opinion on the application for authorization on the use of ***chromium trioxide*** to modify the properties of surfaces made of plastic, and two opinions on the review report for the use of PVC recyclate containing DEHP.

The Committee for Risk Assessment (RAC) adopted 19 opinions on harmonized classification and labeling

1. *Potassium (oxido-NNO-azoxy)cyclohexane; cyclohexylhydroxydiazene 1-oxide, potassium salt; [K-HDO]*

The substance K-HDO is an ***active substance used in biocidal products as a fungicide***. The substance has no existing entry in Annex VI to the CLP Regulation. RAC agreed to the proposal by Austria to classify the substance K-HDO for physical hazards as flammable solid category 1 (Flam. Sol. 1), as toxic if swallowed (Acute Tox. 3) with an acute toxicity estimate (ATE; oral) of 136 mg/kg bw for mixtures containing the substance; as a substance causing skin irritation and serious eye damage (Skin Irrit. 2 and Eye Dam. 1) and that may cause damage to liver through prolonged or repeated exposure (STOT RE 2). RAC also agreed to classify K-HDO for long-lasting aquatic hazards (Aquatic Chronic 2). Contrary to the proposal from Austria, RAC did not propose to include the gastrointestinal tract and kidney as target organs for repeated exposure toxicity classification.

2. *Bis(N-hydroxy-N-nitrosocyclohexylaminato-O,O')copper; bis(N-cyclohexyl-diazenium-dioxy)-copper; [Cu-HDO]*

The substance Cu-HDO is an active substance used in biocidal products. The substance has no existing entry in Annex VI to the CLP Regulation. RAC agreed to the proposal by Austria to classify the substance Cu-HDO for physical hazards as flammable solid category 1 (Flam. Sol. 1), as harmful if swallowed (Acute Tox. 4) with an acute toxicity estimate (ATE) of 360 mg/kg bw for mixtures containing the substance, as substance causing serious eye damage (Eye Dam. 1) and that may cause damage to liver through prolonged or repeated exposure (STOT RE 2). RAC also agreed to classify Cu-HDO for aquatic acute and chronic hazards (Aquatic Acute 1 and Aquatic Chronic 1) with multiplying factors of 1 for environmental hazards. Contrary to the proposal from Austria, RAC did not propose to include the gastrointestinal tract and kidney as target organs for repeated exposure toxicity classification.

3. *Thiencarbazone-methyl (ISO); methyl 4-[(4,5-dihydro-3-methoxy-4-methyl-5-oxo1H-1,2,4-triazol-1-yl)carbonylsulfamoyl]-5- methylthiophene-3-carboxylate*

The substance thiencarbazone-methyl (ISO) is an ***active substance used in plant protection products as a herbicide***. The substance has no existing entry in Annex VI to the CLP Regulation. RAC agreed to the proposal by the United Kingdom to classify the substance for hazards to aquatic environment as Aquatic Acute 1 and Aquatic Chronic 1 with multiplying factors of 1 000.

4. *2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate; [DOTE]*

The substance DOTE is as ***industrial chemical*** mostly used in articles, in formulation or re-packing, at industrial sites and in manufacturing. The substance has an existing entry in Annex VI to the CLP Regulation (Repr. 1B; H360D). RAC agreed to the proposal by Germany to classify DOTE as a substance that causes damage to immune system through prolonged or repeated exposure (STOT RE 1). Contrary to the proposal by Germany, RAC agreed to retain the existing classification for toxicity to reproduction (Repr. 1B; H360D) and to add classification for hazards to the aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1) without multiplying factors.

5. *Exythiazox (ISO); trans-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxo-3-thiazolidine-carboxamide*

The substance Hexythiazox (ISO) is an ***active substance used in plant protection products***. The substance has an existing entry in Annex VI to the CLP Regulation for hazards to the aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1). RAC agreed to the proposal by Finland to add multiplying factors of 1 to the environmental classification.

6. *Flurochloridone (ISO); 3-chloro-4-(chloromethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one*

The substance Flurochloridone (ISO) is an ***active substance used in plant protection products as a herbicide***. The substance has no existing entry in Annex VI to the CLP Regulation. RAC agreed to the proposal by Spain to classify Flurochloridone (ISO) as harmful if swallowed (Acute Tox. 4) and to assign an acute toxicity estimate (ATE) of 500 mg/kg bw for mixtures containing the substance, as a substance that may cause an allergic skin reaction (Skin Sens. 1), as a substance that may damage the unborn child and, contrary to the proposal by Spain to classify as a substance that may damage fertility, to instead classify as a substance suspected of damaging fertility (Repr. 1B; H360DF). RAC also agreed on the proposal to classify Flurochloridone for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1) with multiplying factors of 100.

7. *Iprovalicarb (ISO) isopropyl [(2S)-3-methyl-1-{[1-(4-methylphenyl)ethyl]amino}-1- oxobutan-2-yl]carbamate*

The substance iprovalicarb (ISO) is an ***active substance used in plant protection products as a fungicide***. The substance has no existing entry in Annex VI to the CLP Regulation. RAC agreed to the proposal by Ireland to classify the substance as suspected of causing cancer (Carc. 2; H351).

8. 2,4-dinitrophenol

The substance 2,4-dinitrophenol is an ***industrial chemical*** used as an intermediate in the manufacture of other chemicals and as an additive in the manufacture of textiles, leather and fur. Since the early 20th century, it has been used (without a formal authorization) as a weight loss agent, primarily for people who are attempting to lose fat but retain muscles. The substance has an existing entry in Annex VI to the CLP Regulation for acute toxicity through all routes of exposure and for repeated dose toxicity (Acute Tox. 3 and STOT RE 2). RAC agreed to the proposal by Germany to classify 2,4-dinitrophenol for acute toxicity through oral and dermal routes of exposure as fatal if swallowed and if in contact with skin and assigned acute toxicity estimates (ATEs) for mixtures containing the substance (ATE(oral)=30 mg/kg bw, ATE(dermal)=300 mg/kg bw). Contrary to the proposal by Germany, RAC agreed to classify 2,4-dinitrophenol as a substance that causes damage through prolonged or repeated exposure (STOT RE 1) without specifying the target organ or the route of exposure.

9. Phosphine

The substance phosphine is an ***active substance used in plant protection products as an insecticide*** and as an industrial chemical in semiconductor products and for the manufacture of electrical, electronic and optical equipment. The substance has an existing entry in Annex VI to the CLP Regulation for physical hazards as Press. Gas, Flam. Gas 1, for human health hazards for skin corrosion (Skin Corr. 1B), acute toxicity via the inhalation route of exposure (Acute Tox. 2*) and for hazards to aquatic environment (Aquatic Acute 1). RAC agreed to the proposal by France to modify the existing acute toxicity classification and classify phosphine as fatal if inhaled (Acute Tox. 1) with an acute toxicity estimate (ATE) of 10 ppm/Volume for gas.

10. Dibenzo[def,p]chrysene

The substance dibenzo[def,p]chrysene is an ***industrial chemical*** that belongs to the group of polycyclic aromatic hydrocarbons (PAHs). PAHs are contained in petroleum and coal streams, and potentially in material derived thereof. The substance has no existing entry in Annex VI to the CLP Regulation. RAC agreed to the proposal by Germany to classify dibenzo[def,p]chrysene as a substance suspected of causing genetic defects (Muta. 2; H341) and that may cause cancer (Carc. 1B; H350) with a specific concentration limit of 0.001 % for mixtures containing the substance.

11. 4,5-dichloro-2-octyl-2H-isothiazol-3-one [DCOIT]

The substance DCOIT (4,5-dichloro-2-octyl-2H-isothiazol-3-one) is ***an active substance used in biocidal products***. The substance has no existing entry in Annex VI to the CLP Regulation. RAC agreed to the proposal by Norway to classify DCOIT as a substance harmful if swallowed (Acute Tox. 4) with an acute toxicity estimate (ATE) of 567 mg/kg bw and to add a supplemental hazard information EUH071 for substances corrosive to the respiratory tract. In addition, in accordance with the proposal by Norway, RAC agreed to classify DCOIT as a substance that causes severe skin burns without sub-categorisation and eye damage (Skin Corr. 1) and that may cause an allergic skin reaction (Skin. Sens. 1A). Contrary to the proposal by Norway, RAC classified DCOIT as fatal if inhaled (Acute Tox. 2) with an ATE of 0.16 mg/L and set different specific concentration limits (SCL) for mixtures containing the substance (0.025% for skin irritation and 0.0015% for skin sensitisation). RAC further agreed to the proposal by Norway to classify the substance for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1) with multiplying factors of 100.

12. Octhilinone (ISO); 2-octyl-2H-isothiazol-3-one; [OIT]

The substance octhilinone (ISO) [OIT] is ***an active substance used in biocidal products***. The substance has an existing entry in Annex VI of the CLP Regulation – minimum classifications for acute toxicity through all routes of exposure (Acute Tox. 4* for oral route and Acute Tox. 3* for dermal and inhalation routes), for skin corrosion (Skin Corr. 1B) and skin sensitisation (Skin Sens. 1) with a specific concentration limit of 0.05% for mixtures containing the substance as well as for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1). RAC agreed to the proposal by the United Kingdom to modify the existing acute toxicity classifications as toxic if swallowed (Acute Tox. 3) with an acute

toxicity estimate (ATE) of 125 mg/kg bw, as toxic in contact with skin (Acute Tox. 3) with an ATE of 311 mg/kg bw and as fatal if inhaled (Acute Tox. 2) with an ATE of 0.27 mg/L (dust and mist) for mixtures containing the substance. RAC further agreed to the proposal by the United Kingdom to retain the existing classifications for eye damage and skin corrosion, to add a supplemental hazard information EUH071 for substances corrosive to respiratory tract and to add multiplying factors of 100 to the hazards for aquatic environment. Contrary to the proposal by the United Kingdom, RAC agreed to set a lower specific concentration limit for skin sensitisation (Skin Sens. 1A, SCL 0.0015 %) instead of 0.005%.

13. *Pirimiphos-methyl (ISO)*

The substance Pirimiphos-methyl (ISO) is ***an active substance used in plant protection products as an insecticide***. The substance has an existing entry in Annex VI of the CLP Regulation for Acute Tox. 4* and for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1). RAC agreed to the proposal by the United Kingdom to classify pirimiphos-methyl (ISO) as harmful if swallowed (Acute Tox. 4) and to assign an acute toxicity estimate (ATE) of 1 414 mg/kg bw for mixtures containing the substance, as a substance causing damage to the nervous system through prolonged or repeated exposure (STOT RE 1) and for hazards to aquatic environment (Aquatic Acute 1 and Aquatic chronic 1) with multiplying factors of 1 000.

14. *3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide; fluxapyroxad*

The substance Fluxapyroxad is an ***active substance used in plant protection products as a fungicide***. The substance has no existing Annex VI entry. RAC agree to the proposal by the United Kingdom to classify Fluxapyroxad for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1) with multiplying factors of 1. In addition, contrary to the proposal by the United Kingdom, RAC classified Fluxapyroxad as a substance that may cause harm to breast-fed children (Lact., H362).

15. *Oxathiapiprolin (ISO); 1-(4-{4-[5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]- 1,3-thiazol-2-yl}piperidin-1-yl)-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1- yl]ethanone*

The substance Oxathiapiprolin (ISO) is an ***active substance used in plant protection products as a fungicide***. The substance has no existing entry in Annex VI to the CLP Regulation. RAC agreed to the proposal by Ireland to classify Oxathiapiprolin (ISO) for hazards to the aquatic environment (Aquatic Chronic 1) with a multiplying factor of 1.

16. *m-bis(2,3-epoxypropoxy)benzene;*

Resorcinol diglycidyl ether Resorcinol diglycidyl ether is an ***industrial chemical*** used as an epoxy resin and as a reactive diluent in the production of other epoxy resins. The substance has an existing entry in Annex VI to the CLP Regulation for acute toxicity via oral and dermal routes of exposure (Acute Tox. 4), as a skin and an eye irritant (Skin Irrit. 2, Eye Irrit. 2) as a substance suspected of causing genetic defects (Muta. 2; H341) and carcinogenicity (Carc. 2; H351) and for hazards to aquatic environment (Aquatic Chronic 3). RAC agreed to the proposal by the Netherlands to confirm the classification for acute oral toxicity (Acute Tox. 4) and to modify the acute dermal toxicity (Acute Tox. 3), but contrary to the proposal by the Netherlands, RAC applied converted acute toxicity point estimate (ATEs) of ATE(oral)=500 mg/kg bw and ATE(dermal)=300 mg/kg bw. RAC further agreed to the proposal by the Netherlands to classify resorcinol diglycidyl ether as a substance that may cause cancer (Carc. 1B; H350).

17. *Silthiofam (ISO); N-allyl-4,5-dimethyl-2-(trimethylsilyl)thiophene-3-carboxamide*

The substance silthiofam (ISO) is ***an active substance used in plant protection products as a fungicide***. The substance has no existing entry in Annex VI to the CLP Regulation. RAC agreed to the proposal by Ireland to classify silthiofam (ISO) as a substance that may cause damage to organs through prolonged or repeated exposure (STOT RE 2) and for aquatic chronic hazards (Aquatic Chronic 2). Contrary to the proposal by Ireland, RAC did not classify silthiofam (ISO) for toxicity to reproduction.

18. *Hexyl 2-(1-(diethylaminohydroxyphenyl)methanoyl)benzoate; hexyl 2-[4-(diethylamino)-2-hydroxybenzoyl]benzoate (Uvinul A Plus)*

The substance Uvinul A Plus is an ***industrial chemical used in cosmetics and personal care products as a UV filter***. The substance has an existing entry in Annex VI to the CLP Regulation for environmental hazards as Aquatic Chronic 4. RAC did not agree to the proposal by Germany to change the environmental classification to category 1 as a substance that is very toxic to aquatic life with long-lasting effects. Instead, based on recent studies, RAC agreed that Uvinul A Plus does not warrant classification for hazards to the aquatic environment.

19. *Lead*

Lead has a large variety of uses. It has two entries in Annex VI to the CLP Regulation for massive and powder forms for toxicity to reproduction (Repr. 1A; H360FD). RAC agreed to the proposal by Denmark to classify lead as very toxic to aquatic life and as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1 and Aquatic Chronic 1) and to add multiplying factors of 10 to the classifications. This classification for hazards to the aquatic environment applies to both existing entries in Annex VI to the CLP Regulation.

CLP Regulation

1. Check and apply all new harmonized classification as described above, in your substances and products

2. Check Public consultation on harmonized classification and labeling proposals for:

desmedipham (ISO); ethyl 3-phenylcarbamoyloxyphenylcarbamate (EC 237-198-5; CAS 13684-56-5). Mainly used as an active substance in plant protection products used as non-systemic herbicides. It has an existing harmonized classification and labeling in Annex VI to CLP. Comments are invited on specific target organ toxicity - repeated exposure, carcinogenicity, reproductive toxicity and environmental hazard classes.

phenmedipham (ISO);methyl 3-(3-methylcarbaniloyloxy)carbanilate (EC 237-199-0; CAS 13684-63-4). Mainly used as an active substance in plant protection products used as herbicides. It has an existing harmonized classification and labeling in Annex VI to CLP. Comments are invited on specific target organ toxicity-repeated exposure, carcinogenicity, reproductive toxicity and environmental hazard classes.

triticonazole (ISO); (RS)-(E)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-methyl)cyclopentanol (EC: -; CAS: 138182-18-0). Mainly used as an active substance in plant protection products used as fungicides. It has an existing harmonized classification and labeling in Annex VI to CLP. Comments are invited on all human health and environmental hazard classes.

The deadline for comments is **15 February 2019**.

3. Give comments

New proposals to harmonize the classification and labeling have been submitted for:

4,4'-oxydi(benzenesulphonohydrazide) (EC 201-286-1, CAS 80-51-3);
toluene-4-sulphonohydrazide (EC 216-407-3, CAS 1576-35-8).

New intentions to harmonise the classification and labelling have been received for:

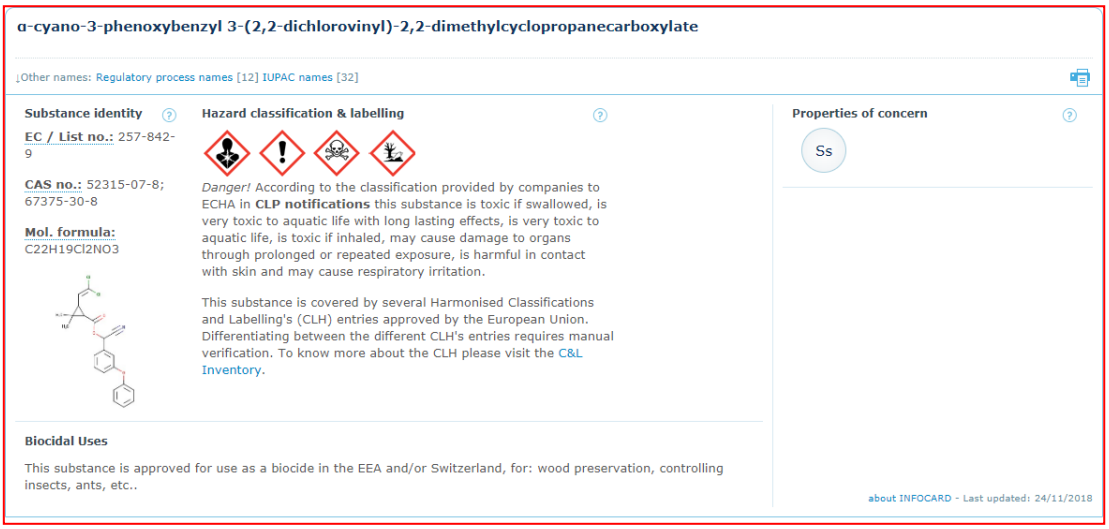
2,2-dimethylpropan-1-ol, tribromo derivative (EC 253-057-0, CAS 36483-57-5);
3-methylpyrazole (EC 215-925-7, CAS 1453-58-3); and
4,4'-sulphonyldiphenol (EC 201-250-5, CAS 80-09-1).

4. Check the publication of new ATPs (Adaptation to the Technical Progress)

Biocide regulation

1. Check and apply all new harmonized classification as described above, in your substances and related products

2. Check ***Cypermethryn*** (CAS n. 52315-07-8) regulatory status. *Be ready!!*



α-cyano-3-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate

↓Other names: Regulatory process names [12] IUPAC names [32]

Substance identity

EC / List no.: 257-842-9

CAS no.: 52315-07-8; 67375-30-8

Mol. formula: C22H19Cl2NO3

Hazard classification & labelling

Danger! According to the classification provided by companies to ECHA in **CLP notifications** this substance is toxic if swallowed, is very toxic to aquatic life with long lasting effects, is very toxic to aquatic life, is toxic if inhaled, may cause damage to organs through prolonged or repeated exposure, is harmful in contact with skin and may cause respiratory irritation.

This substance is covered by several Harmonised Classifications and Labelling's (CLH) entries approved by the European Union. Differentiating between the different CLH's entries requires manual verification. To know more about the CLH please visit the C&L Inventory.

Properties of concern

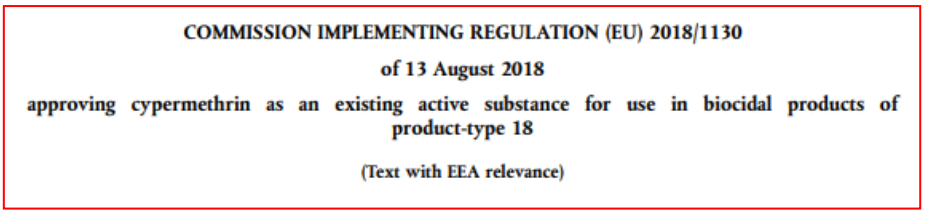
Ss

Biocidal Uses

This substance is approved for use as a biocide in the EEA and/or Switzerland, for: wood preservation, controlling insects, ants, etc..

about INFOCARD - Last updated: 24/11/2018

The substance will be approved as active substance in biocide product on June 01, 2020. The Implementing Regulation has been published on August 13, 2018 while a DAR /Draft Assessment Report) is not yet published.



COMMISSION IMPLEMENTING REGULATION (EU) 2018/1130

of 13 August 2018

approving cypermethrin as an existing active substance for use in biocidal products of product-type 18

(Text with EEA relevance)

3. Stay tuned on ADBAC/BKC and DDAC for use in Disinfectants (PT 3, and 4) as well as Icaridin as insects repellent (PT19)

Biocidal Products Committee concludes on a Union Authorization for disinfectants (December 18, 2018)

The committee also supported the approval of seven active substances for use in disinfectants, preservatives and insect repellents.

The Biocidal Products Committee (BPC) adopted an opinion supporting an application for Union authorisation for a biocidal product family based on **iodine** used in veterinary hygiene (product-type 3)

The BPC also supported the approval of the following active substances:

Silver zinc zeolite for use in disinfectants and preservatives (product-types 2, 7 and 9);
Silver zeolite for use in preservatives (product-type 9);
Silver copper zeolite for use in preservatives (product-type 9);
Silver sodium hydrogen zirconium phosphate for use in preservatives (product-type 9);
ADBAC/BKC for use in disinfectants (product-types 3 and 4);
DDAC for use in disinfectants (product-types 3 and 4);
Icaridin for use in insect repellents (product-type 19).

The evaluating Member States will need to assess the active substances against the new criteria for endocrine-disrupting properties before the Committee adopts its final opinions. The European Commission together with the EU Member States will take the final decision on the approval of the active substances and on the Union Authorisation of biocidal products. The committee met from 11 December to 14 December 2018. The opinions will be available on ECHA's website in the near future. The next meeting will be held in February 2019.

4. Get prepared and read the advice. Regulatory situation of **treated articles**

A new publication by ECHA (n. 18-B-11-EN) "What you need to know about treated articles" has been released by ECHA . It is very helpful for general criteria to determine a treated article or not.

5. Be aware. Biocidal Products Committee proposes not to approve ***three silver-containing active substances***:

- silver zeolite for product-types 2 and 7;
- silver copper zeolite for product-types 2 and 7; and
- silver sodium hydrogen zirconium phosphate for product-types 2 and 7.

The committee's opinion is that the active substances cannot be approved for product-types 2 and 7 because their efficacy is not sufficiently demonstrated.

The committee also discussed its draft opinions on the following active substances without reaching a conclusion:

- silver zinc zeolite for product-types 2, 4, 7 and 9;
- silver zeolite for product-types 4 and 9;
- silver copper zeolite for product-types 4 and 9; and
- silver sodium hydrogen zirconium phosphate for product-types 4 and 9.

The discussion on these opinions will continue in a forthcoming meeting.

6. Furthermore:

The BPC adopted a positive opinion on an application for Union Authorization for a teat disinfectant biocidal product family in veterinary hygiene (product-type 3). The committee also adopted an opinion addressing a request from the Commission on unresolved objections during the mutual recognition of a biocidal product family in insecticides (product-type 18) containing ***1R-trans phenothrin*** for use against ants. The committee was able to address the Commission's questions, which means that the Commission can now take a decision leading to the authorization of the biocidal product family.

The European Commission, together with the EU Member States, will take the final decision on the approval of the active substances and on the Union Authorization of biocidal products.

BREXIT, stay tuned on news!!!

Brexit milestones and expected timelines
23 June 2016 : the UK voted to leave the EU
29 March 2017 : UK's notification to leave the EU sent; 2 year negotiation period started
November 2018: Brexit negotiations to be finilised. EU Council to agree UK's EU Withdrawal Agreement and political declaration on future relationship framewor
By March 2019: EU and British Parliaments to ratify Withdrawal Agreement
29 March 2019: UK leaves the EU at 11pm (UK time)
30 March 2019: Transition period starts (if ultimately agreed) – UK remains in EU REACH
31 December 2020: Transition period ends. EU and UK to start a new economic and political relationship.

Pharma and Endocrine Disrupting Substances

On November 18, 2018 the EMA (European Medicine Agency) released the long expected updated "*Guideline on the Environmental Risk Assessment of medicinal product for human use" (EMA/CHMP/SWP/4447/00 Rev.1)*. Up to June 2019 a consultation period is open; final adoption is expected by end of 2019. The new guideline was introduced by the ***Concept Paper*** release in 2016 which posed the basis to this important revision of the fist EMEA guideline in 2006. Based on the experience of 12 years of application it's now the time to implement the old guideline. Many relevant changes are foreseen by the new guidance: among these three new requests seems to "harmonize" some criteria with the approaches used in the legislation for risk assessment on chemical substances. Indeed this behavior by Competent Authorities was in a way expected!

Secondary poisoning assessment. Secondary poisoning is a toxic effect on birds and mammalians resulting from a consumption of contaminated prey (fish or other contaminated organisms). It is relevant for compounds that accumulate through the food chain, mainly lipophilic compounds. When a Log Kow is > 3, the potential for secondary poisoning should be evaluated, firstly with the determination of the bioconcentration factor (BCF in fish) experimentally (OECD 305 study).

PBT assessment. It's prescribed in following the criteria of the chemicals. It has to be done for all active substance in specific cases by q preliminary approach and a definitive PBT assessment. vPvB (v=very) approach is also included.

ED (Endocrine properties) assessment. Such assessment is needed on the basis of the fact that some drug active substances may affect the reproduction of development of vertebrate or lower animals at concentration lower than 0.01 µg/L (guideline threshold limit) of even at much lower concentration (pg/L). The assessment of ED properties start with the application of "in vitro" and "in vivo" data which may be taken from the drug marketing authorization dossier or adding specific end-points studies. The focal point is to establish the ***MoA*** (Mechanism of Action) for the drug substance by studying its ***AOP*** (Adverse Outcome Pathway). The approach is consistent with that one described in the recent guideline for agrochemical and biocide active substances.

End of the Newsletter