Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

A view on co-formulants – regulations and influence on formulation type

Content

Regulations on co-formulants (in Europe and Germany)

Influence on formulation type

Co-formulants = formulants = inerts

Any substance (or mixture of substances)

other than the active ingredient

that is intentionally included in a formulation.

Examples:

Solvents, emulsifiers, carriers, antifoaming agents, dyes …

Statistics

- **273** **active ingredients**
- **1450** **co-formulants (inerts)**
- **224** **adjuvants**

- **44** **formulation types (out of 63 defined)**

(January 2015)

Challenges

- **Co-formulants are difficult to handle for the regulation authorities**
  (often no detailed information / only SDS)
- **The applicants / formulators do not have all information in hand**
- **In general, the analytical determination of co-formulants is challenging**

Principles

US EPA

Approved inerts (food or non-food use)

Europe

Unacceptable co-formulants

Unacceptable co-formulants

A co-formulant should not be accepted where

- **Its residues have a harmful effect on human or animal health or on groundwater or environment,**
- **Its use has a harmful effect on human or animal health or on groundwater or environment,**

- **Unacceptable co-formulants will be included into Annex III of Regulation (EC) no 1107/2009,**

- **The Commission may review co-formulants at any time.**

Implementation

- **National provisions may be applied until June 2016**
- **After that each Member State may prohibit or restrict the use of a co-formulant for a specified time**

- **In March 2012 Commission asked Member States to notify unacceptable co-formulants**
- **Proposals were prepared by two Member States**

Criteria

Following criteria were proposed:

- **Restrictions according to the EU chemical legislation**
- **Cut-off criteria as given for active substances**
- **Classification as carcinogen, mutagen or toxic for reproduction category 2**
- **Classification for specific target organ toxicity after repeated exposure (STOT-RE) category 1, especially if a co-formulant shows other chronic effects or immunotoxicity or neurotoxicity**
- **Concerns within the assessment according to the Regulation (EC) No 1907/2006 (REACH) or No 1272/2008 (CLP),**
- **Co-formulants that contain impurities/additives/constituents of toxicological relevance above an established limit.**

Unacceptable co-formulants - Examples

Following substances are candidates for Annex III:

Solventnaphtha **64742-95-6**	**CARC 1B** **MUTA 1B**	**Destillates (mineral oil)** **64742-54-7** **64742-52-5** **64742-55-8** **64742-65-0** **64741-88-4** **64742-53-6**	**CARC 1B**
N-Methyl-2-pyrrolidone **872-50-4**	**REPR 1B**	**disodium tetraborate decahydrate, orthoboric acid, sodium salt** **1303-96-4**	**REPR 1B**
2-Methoxypropanol-1 **1589-47-5**	**REPR 1B**		

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- Restrictions according to the EU chemical legislation
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Unacceptable co-formulants - Examples

Content of impurities / additives / substances of toxicological relevance:

- **<u>oil-derived substances</u>**

  (benzene 0.1 %, 1,3-butadiene 0.1 %,

  benz(a)pyrene 0.005 %, DMSO extract 3 %,

  naphthalene 1 %, toluene 3 %),

- **quartz sand, kieselgur, diatomaceous earth, Al-silicates (crystalline silica 0.1 %),**

- **Attapulgite, talc (fibers > 5 µm).**

Expectations

- **Up to now Annex III is <u>empty</u>**
- **Low priority**

What will happen?

- ***transition rules***
- ***Rules apply for new applications***
- ***For existing authorisations, authorisation holders will be informed, with request for formulation change***

Unacceptable co-formulants - Germany

Ethoxyethanol, 2-= Ethylenglykolmonoethylether= Ethylglykol	110-80-5
Methoxyethanol, 2-= Ethylenglykolmonomethylether= Methylglykol	109-86-4
Methoxyethylacetat, 2-= Ethylenglykolmonoethyletheracetat= Methylglykolacetat	110-49-6
Methoxypropanol-1, 2-	1589-47-5
Ethoxyethylacetat, 2-= Ethylglykolacetat	111-15-9
Dimethylformamid, N,N-	68-12-2
Epichlorhydrin= Chlor-2,3-epoxypropan, 1-	106-89-8
Steinkohlenteeröle	
Benzol	71-43-2
Trichlorethan, 1,1,1-= Methylchloroform	71-55-6
Trichlorethan, 1,1,2-	79-00-5
Tetrachlorethan, 1,1,2,2-	79-34-5
Tetrachlorethan, 1,1,1,2-	630-20-6
Tetrachlormethan= Tetrachlorkohlenstoff	56-23-5
Pentachlorethan	76-01-7
Trichlorfluormethan (R 11)	75-69-4
Dichlordifluormethan (R 12)	75-71-8
Chlordifluormethan (R 22)	75-45-6
1-[(2-Methoxyphenyl)azo]-2-naphthol	1229-55-6
Nonylphenolethoxylate	009016-45-9 etc. 009036-19-5

Examples

Example: POE-Tallowamines

Wetting agent - mainly in formulations containing Glyphosate

First technical discussion in 2008

2014: last POE-Tallowamine containing glyphosate formulation

Other candidates:

Tetrahydrofurfuryl alcohol (THFA),	**CAS 97-99-4**	**(Repr. 2)**
N-methyl-2-pyrrolidone (NMP),	**CAS 872-50-4**	**(Repr. 1B)**

DC or SC

DC or SC?

SC A stable suspension of active ingredient(s) with water as the fluid, intended for dilution with water before use.

DC A liquid homogeneous formulation to be applied as a solid dispersion after dilution in water. (Note: there are some formulations which have characteristics intermediate between DC and EC).

A question of solvent…

EC - EW

How much water transforms an EC to an EW?

EW	A fluid, heterogeneous formulation consisting of a solution of pesticide in an organic liquid dispersed as fine globules in a continuous water phase.

Formulation containing 15 g/L water

Manufacturer stated it to be an EW.

Indeed it is a EC – for 1.5 % water may not form a continous phase!

→ **There is a FAO specification for EW requiring wet sieve test!**

SC, SE, EW or SL

Formulation:

active ingredient:	**25 g/L**
vegetable oil:	**200 g/L**
water:	**620 g/L**
other co-formulants:	**150 g/L**

Use concentration: **0,4 – 0,6 % v/v**

Concentration a.i. in spray tank: **ca. 125 mg/L**

SC, SE, EW or SL

Concentration a.i. in spray tank: ca. 125 mg/L

Water:	**ca. 40 mg/L**
Acetone	>250 g/L
Dichloroethane	250 g/L
Heptane	1 g/L
Ethyl acetate	250 g/L
2-Propanol	100 g/L
Xylene	50 g/L
Octanol	**100 g/L**
Toluol	50 g/L
Methanol	250 g/L

SC, SE, EW or SL

	Dissolved in water	Dissolved in oil	unsolved
formulation	25 mg = 0,1 %	20 g = 80 %	5 g = 20 %
Spray tank	40 mg = 30 %	100 mg = 80 %	0

SC	A stable suspension of active ingredient(s) with water as the fluid, intended for dilution with water before use.
SE	A fluid, heterogeneous formulation consisting of a stable dispersion of active ingredient(s) in the form of solid particles and of water-non miscible fine globules in a continuous water phase.
EW	A fluid, heterogeneous formulation consisting of a solution of pesticide in an organic liquid dispersed as fine globules in a continuous water phase.
SL	A clear to opalescent liquid to be applied as a solution of the active ingredient after dilution in water. The liquid may contain water-insoluble formulants.

SG or WG

Can a dispersing agent transform an SG to an WG?

Using a dispersing agent to accelerate the dispersion of the granules in a first step was the reason to denote the formulation initially as a water dispersible (WG) granule.

However, based on the water solubility of the active substance and the formulants compared to a maximum in use concentration, it can be also regarded as a water soluble granule (SG).

Thus the assignment of the formulation type depends on the interpretation of the definition of both, WG and SG.

Applicant must give information on co-formulants

Manufacturer of co-formulant:

Water:

GOD

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Ευχαριστώ !

Comments / questions ?

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