



**COUNCIL OF  
THE EUROPEAN UNION**

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**COVER NOTE**

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From:	European Commission
date of receipt:	20 January 2014
To:	General Secretariat of the Council
Subject:	Commission Decision of XXX amending Decisions 2011/263/EU, 2011/264/EU, 2011/382/EU, 2011/383/EU, 2012/720/EU and 2012/721/EU in order to take account of developments in the classification of substances

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Delegations will find attached document D030637/02.

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Encl.: D030637/02

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**ANNEXES I-VI****ANNEX I**

The Annex to Decision 2011/263/EU is amended as follows:

(1) In Criterion 2, point (b), fifth paragraph, the table of derogations is replaced by the following table:

"

Surfactants in total concentrations < 25 % in the final product	H400: Very toxic to aquatic life	R50
Surfactants in total concentrations < 25 % in the final product (*)	H412: Harmful to aquatic life with long-lasting effects	R52-53
Biocides used for preservation purposes (**)	H410: Very toxic to aquatic life with long-lasting effects	R50-53
	H411: Toxic to aquatic life with long-lasting effects	R51-53
	H412: Harmful to aquatic life with long-lasting effects	R52-53
Fragrances	H412: Harmful to aquatic life with long-lasting effects	R52-53
Enzymes (***)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
NTA as an impurity in MGDA and GLDA (****)	H351: Suspected of causing cancer	R40

(\*) This derogation is applicable provided that they are ready degradable and anaerobically degradable.

(\*\*) Referred to in criterion 2(e). This derogation is applicable provided that biocides' bioaccumulation potentials are characterised by log Pow (log octanol/water partition coefficient) < 3,0 or an experimentally determined bioconcentration factor (BCF) ≤ 100.

(\*\*\*) Including stabilisers and other auxiliary substances in the preparations.

(\*\*\*\*) In concentrations lower than 1,0 % in the raw material as long as the total concentration in the final product is lower than 0,10 %

”;

(2) In Criterion 2, point (b) the following paragraph is added to the *Assessment and verification* text:

”

For derogated surfactants meeting the criteria for classification with the hazard classes H412, the applicant shall provide documentation for their degradability making reference to the DID list. For surfactants not included in the DID list, reference shall be done to the relevant information from literature or other sources, or appropriate test results, as described in Appendix I.

”.

## ANNEX II

The Annex to Decision 2011/264/EU is amended as follows:

(1) In Criterion 4, point (b), fifth paragraph, the table of derogations is replaced by the following table:

”

Surfactants in total concentrations < 25 % in the final product	H400: Very toxic to aquatic life	R50
Surfactants in total concentrations < 25 % in the final product (*)	H412: Harmful to aquatic life with long-lasting effects	R52-53
Biocides used for preservation purposes (**)	H410: Very toxic to aquatic life with long-lasting effects	R50-53
	H411: Toxic to aquatic life with long-lasting effects	R51-53

	H412: Harmful to aquatic life with long-lasting effects	R52-53
Fragrances	H412: Harmful to aquatic life with long-lasting effects	R52-53
Enzymes (***)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
Bleach catalysts (***)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
NTA as an impurity in MGDA and GLDA (****)	H351: Suspected of causing cancer	R40
Optical brighteners (only for heavy duty laundry detergent)	H413: May cause long lasting effects to aquatic life	R53

(\*) This derogation is applicable provided that they are ready degradable and anaerobically degradable.

(\*\*) Referred to in criterion 4(e). This derogation is applicable provided that biocides' bioaccumulation potentials are characterised by log Pow (log octanol/water partition coefficient) < 3,0 or an experimentally determined bioconcentration factor (BCF) ≤ 100.

(\*\*\*) Including stabilisers and other auxiliary substances in the preparations.

(\*\*\*\*) In concentrations lower than 1,0 % in the raw material as long as the total concentration in the final product is lower than 0,10 %.

”;

(2) In Criterion 4, point (b) the following paragraph is added to the *Assessment and verification* text:

”

For derogated surfactants meeting the criteria for classification with the hazard classes H412, the applicant shall provide documentation for their degradability making reference to the DID list. For surfactants not included in the DID list, reference shall be done to the relevant information from literature or other sources, or appropriate test results, as described in Appendix I.

”.

**ANNEX III**

The Annex to Decision 2011/382/EU is amended as follows:

(1) In Criterion 3, point (c), fourth paragraph, the table of derogations is replaced by the following table:

”

Surfactants in total concentrations < 25 % in the final product (*)	H400: Very toxic to aquatic life	R50
Surfactants in total concentrations < 25 % in the final product (**)	H412: Harmful to aquatic life with long-lasting effects	R52-53
Surfactants in total concentrations < 2,5 % in the final product (**)	H411: Toxic to aquatic life with long-lasting effects	R51-53
Fragrances	H412: Harmful to aquatic life with long-lasting effects	R52-53
Enzymes (***)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
NTA as an impurity in MGDA and GLDA (****)	H351: Suspected of causing cancer	R40

(\*) The percentage must be divided by the M-factor established in accordance with the Regulation (EC) No 1272/2008.

(\*\*) This derogation is applicable provided that they are ready degradable and anaerobically degradable.

(\*\*\*) Including stabilisers and other auxiliary substances in the preparations.

(\*\*\*\*) In concentrations lower than 1,0 % in the raw material as long as the total concentration in the final product is lower than 0,10 %.

”.

(2) In Criterion 3, point (c) the following paragraph is added to the *Assessment and verification* text:

"

For derogated surfactants meeting the criteria for classification with the hazard classes H412 and/or H411, the applicant shall provide documentation for their degradability making reference to the DID list. For surfactants not included in the DID list, reference shall be done to the relevant information from literature or other sources, or appropriate test results, as described in Appendix I.

".

#### ANNEX IV

The Annex to Decision 2011/383/EU is amended as follows:

(1) In Criterion 3, point (c), fourth paragraph, the table of derogations is replaced by the following table:

"

Surfactants in total concentrations < 25 % in the final product (*)	H400: Very toxic to aquatic life	R50
Surfactants in total concentrations < 25 % in the final product (**)	H412: Harmful to aquatic life with long-lasting effects	R52-53
Fragrances	H412: Harmful to aquatic life with long-lasting effects	R52-53
Enzymes (***)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
NTA as an impurity in MGDA and GLDA (****)	H351: Suspected of causing cancer	R40

(\*) The percentage must be divided by the M-factor established in accordance with the Regulation (EC) No 1272/2008.

(\*\*) This derogation is applicable provided that they are ready degradable and anaerobically degradable.

(\*\*\*) Including stabilisers and other auxiliary substances in the preparations.

(\*\*\*\*) In concentrations lower than 1,0 % in the raw material as long as the total concentration in the final product is lower than 0,10 %.

”;

(2) In Criterion 3, point (c) the following paragraph is added to the *Assessment and verification* text:

”

For derogated surfactants meeting the criteria for classification with the hazard classes H412, the applicant shall provide documentation for their degradability making reference to the DID list. For surfactants not included in the DID list, reference shall be done to the relevant information from literature or other sources, or appropriate test results, as described in Appendix I.

”.

### ANNEX V

The Annex to Decision 2012/720/EU is amended as follows:

(1) In Criterion 3, point (b), sixth paragraph, the table of derogations is replaced by the following table:

”

Surfactants in total concentrations < 15 % in the final product	H400: Very toxic to aquatic life	R50
Surfactants in total concentrations < 25 % in the final product	H412: Harmful to aquatic life with long-lasting effects	R52-53
Biocides for preservation purpose (*) (only for liquids)	H331: Toxic if inhaled	R23
	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43

with pH between 2 and 12 and maximum 0,10 % w/w of active material )	H400: Very toxic to aquatic life	R50
Enzymes (**)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
	H400: Very toxic to aquatic life	R50
NTA as an impurity in MGDA and GLDA (***)	H351: Suspected of causing cancer	R40

(\*) Derogation is only for criterion 3(b). Biocides shall comply with criterion 3(d).

(\*\*) Including stabilisers and other auxiliary substances in the preparations.

(\*\*\*) In concentrations lower than 1,0 % in the raw material as long as the total concentration in the final product is lower than 0,10 %

”;

(2) In Criterion 3, point (b) the following paragraph is added to the Assessment and verification text:

”

For derogated surfactants meeting the criteria for classification with the hazard classes H412, the applicant shall provide documentation for their degradability making reference to the DID list. For surfactants not included in the DID list, reference shall be done to the relevant information from literature or other sources, or appropriate test results, as described in Appendix I.

”.

## ANNEX VI

The Annex to Decision 2012/721/EU is amended as follows:

(1) In Criterion 4, point (b), sixth paragraph, the table of derogations is replaced by the following table:

”

Surfactants in	H400: Very toxic to aquatic life	R50
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total concentrations < 20 % in the final product		
Surfactants in total concentrations < 25 % in the final product (*)	H412: Harmful to aquatic life with long-lasting effects	R52-53
Biocides for preservations purposes (**)  (only for liquids with pH between 2 and 12 and maximum 0,10 % w/w of active material )	H331: Toxic if inhaled	R23
	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
	H400: Very toxic to aquatic life	R50
Enzymes (***)	H400: Very toxic to aquatic life	R50
	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
Bleach catalysts (***)	H400: Very toxic to aquatic life	R50
NTA as an impurity in MGDA and GLDA (****)	H351: Suspected of causing cancer	R40

(\*) This derogation is applicable provided that surfactants comply with criterion 3(a) and they are anaerobically degradable.

(\*\*) Derogation is only for criterion 4(b). Biocides shall comply with criterion 4(e).

(\*\*\*) Including stabilisers and other auxiliary substances in the preparations.

(\*\*\*\*) In concentrations lower than 1,0 % in the raw material as long as the total concentration in the final product is lower than 0,10 %.

”;

(2) In Criterion 4, point (b) the following paragraph is added to the *Assessment and verification* text:

"

For derogated surfactants meeting the criteria for classification with the hazard classes H412, the applicant shall provide documentation for their degradability making reference to the DID list. For surfactants not included in the DID list, reference shall be done to the relevant information from literature or other sources, or appropriate test results, as described in Appendix I.

".