INSTRUCTIONS FOR THE
BIOCIDAL PRODUCT FAMILY (BPF) OVERVIEW

VERSION 2.0

Document history

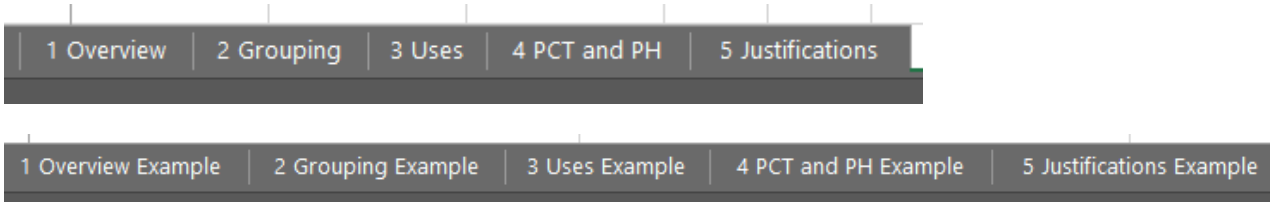
Version	Changes	Date
1.0	First edition (original unnumbered version)	26 November 2020 at CG-44
2.0	Changes in the document: • in Grouping (2nd worksheet), clarification on how to enter information and replacement of screenshots of the previous BPF overview template; • addition of section 2.10 Annex – Explanation and examples regarding grouping.	24 November 2021 at CG-49

1. Introduction

In order to allow the applicant to make sure that the group of BPs fulfil the definition of a BPF and in order to ensure that the application is manageable for the CA a well-structured overview needs to be provided. Please note, the excel file is a template which can and must be adapted to the applicant's needs (columns, lines etc. can be added, deleted as needed).

1.1. Workbook – BPF_Overview.xlsx

The corresponding excel file (workbook) includes five worksheets: Overview, Grouping, Uses, PCT and PH as well as Justifications (see upper box in Screenshot 1). The file is available on the ECHA homepage.[A] In one extra file also an example is included in additional worksheets (see lower box in Screenshot 1).

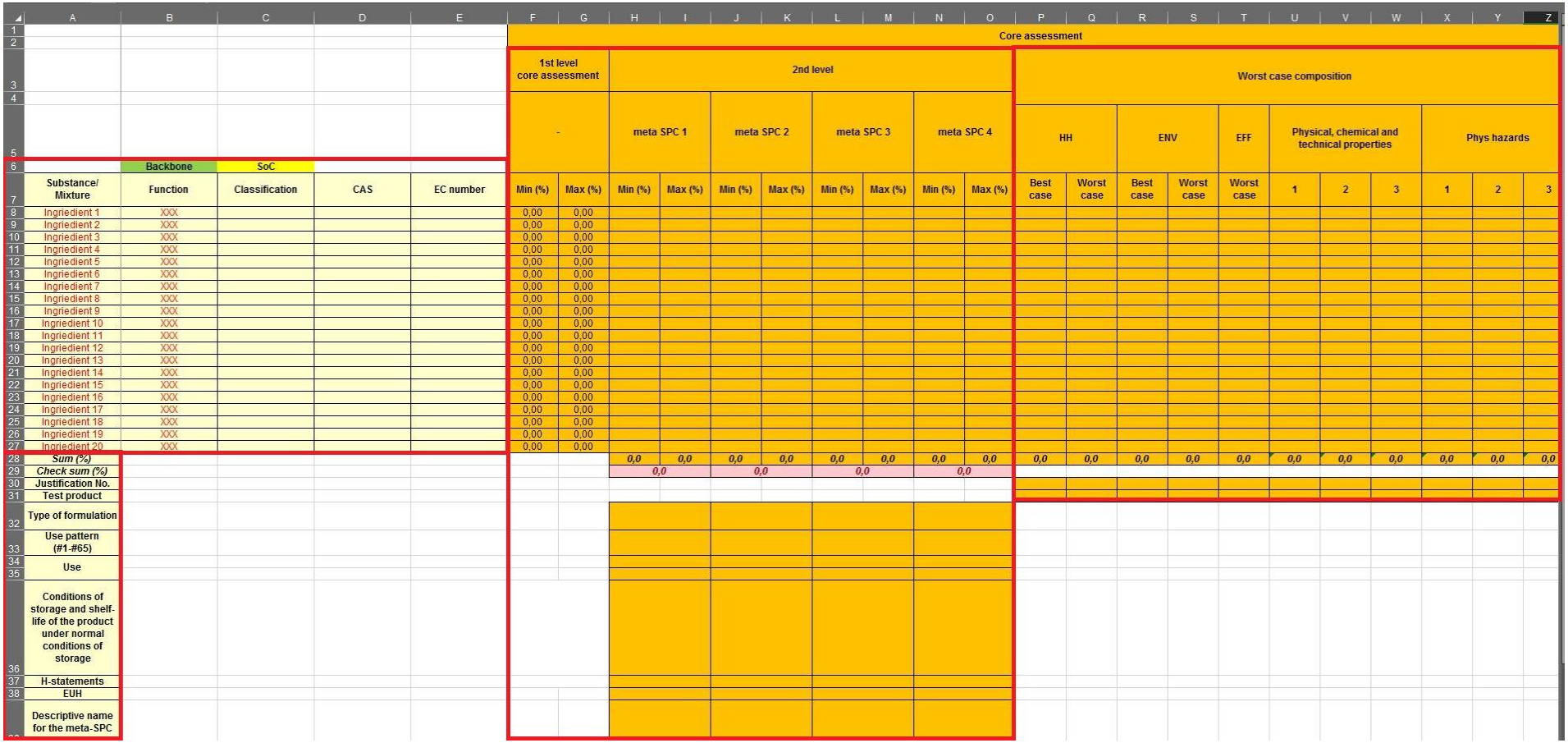


Screenshot 1 (Empty template includes four worksheets; Example includes four additional worksheets).

A https://echa.europa.eu/support/dossier-submission-tools/r4bp/supporting-documents

1.2. Worksheet – Overview

In the worksheet “Overview” the ingredients of the BPF need to be listed, the backbone and SoCs need to be identified (see upper left red box in Screenshot 2 and details in chapter 2.1). Furthermore, the formulation type, a list of the uses, storage conditions and classification (of the ingredients as well as of the BPF) needs to be provided (see lower left red box in Screenshot 2 and details in chapter 2.2). The information requirements listed on the left need to be provided per meta SPC. In addition to the information provided per meta SPC (see large red box in the middle of Screenshot 2) information on the worst case composition needs to be provided, too (see right red box in Screenshot 2).



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z
1						Core assessment																				
2						1st level core assessment		2nd level								Worst case composition										
3						-		meta SPC 1		meta SPC 2		meta SPC 3		meta SPC 4		HH		ENV		EFF	Physical, chemical and technical properties			Phys hazards		
4		Backbone	SoC																							
5	Substance/ Mixture	Function	Classification	CAS	EC number	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)	Best case	Worst case	Best case	Worst case	Worst case	1	2	3	1	2	3
6	Ingriedient 1	XXX				0,00	0,00																			
7	Ingriedient 2	XXX				0,00	0,00																			
8	Ingriedient 3	XXX				0,00	0,00																			
9	Ingriedient 4	XXX				0,00	0,00																			
10	Ingriedient 5	XXX				0,00	0,00																			
11	Ingriedient 6	XXX				0,00	0,00																			
12	Ingriedient 7	XXX				0,00	0,00																			
13	Ingriedient 8	XXX				0,00	0,00																			
14	Ingriedient 9	XXX				0,00	0,00																			
15	Ingriedient 10	XXX				0,00	0,00																			
16	Ingriedient 11	XXX				0,00	0,00																			
17	Ingriedient 12	XXX				0,00	0,00																			
18	Ingriedient 13	XXX				0,00	0,00																			
19	Ingriedient 14	XXX				0,00	0,00																			
20	Ingriedient 15	XXX				0,00	0,00																			
21	Ingriedient 16	XXX				0,00	0,00																			
22	Ingriedient 17	XXX				0,00	0,00																			
23	Ingriedient 18	XXX				0,00	0,00																			
24	Ingriedient 19	XXX				0,00	0,00																			
25	Ingriedient 20	XXX				0,00	0,00																			
26	*Sum (%)*							*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*
27	*Check sum (%)*							*0,0*		*0,0*		*0,0*		*0,0*												
28	Justification No.																									
29	Test product																									
30	Type of formulation																									
31	Use pattern (#1-#65)																									
32	Use																									
33	Conditions of storage and shelf-life of the product under normal conditions of storage																									
34	H-statements																									
35	EUH																									
36	Descriptive name for the meta-SPC																									

Screenshot 2 (Information on composition, formulation type, uses, storage, labelling and worst case composition)

1.3. Worksheet – Grouping

Applicants are allowed to group co-formulants having the same function (See “Guidance note on BPF concept” (CA-July19-Doc.4.2-), page 7.). Accordingly, also a group of substances/mixtures can be listed as an ingredient (see row 10 in Screenshot 7). Detailed information on the grouped substances/mixtures is to be provided in the separate worksheet “grouping” (see Screenshot 3 and chapter

Grouping 2.3).

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
1																				
2																				
3											Core assessment									
											meta SPC 1		meta SPC 2		meta SPC 3		meta SPC 4			
4	Group no.	Common name	IUPAC name	Function	CAS number	EC number	Classification	Have the same impact on the classification (i.e. resulting in the same hazard and safety statements) for the whole formulation	Have the same impact on the level of risk and efficacy of the formulation.	Groupable ?	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)
5																				
6																				
7																				
8																				
9																				
10																				

Screenshot 3 (Template for overview of grouped ingredients)

1.4. Worksheet – Uses

Generally, every use of a BPF applied for needs to be assessed. However, for each use it should be checked whether it is already covered by another use previously assessed. Therefore, the applicant is strongly encouraged to structure and present the uses applied for in one table in order to minimise the overall workload. Unfortunately, the SPC editor does not allow for an export into an excel file. Therefore, the excel table needs to be filled in manually. This detailed information on the uses applied for is to be provided in the separate worksheet “uses” (see Screenshot 4 and chapter 2.3).

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Use pattern (#1-#65)	Use no.	meta SPC	Name of the use	PT	Where relevant, an exact description of the authorised use	Target organism(s)	Field(s) of use	Application method(s)	Application rate(s) and frequency If relevant incl.: Dilution and concentration a.s. in diluted product	Category(ies) of users	Pack sizes and packaging material	No assessment necessary (covered by assessment of use no.)
2													
3													
4													
5													
6	The similarity of uses is visualised in form of a matrix. This matrix can be found … here												

Screenshot 4 (Template for detailed overview of uses applied for)

1.5. Worksheet - PCT and PH

In the past applicants had problems to provide an overview which test products were used in order to generate data on physical, chemical and technical (PCT) properties as well as physical hazards and respective characteristics (PH) of the BPF.

After having identified and justified a number of relevant test products (see chapter 2.7) this worksheet can be used in order to list which test product(s) were used in order to generate data for a given data requirement (see chapter 2.8).

	A	B	C
1	**3. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES**	**Data provided based on study with test product:**	**Justification**
2			
3	3.1. Appearance (at 20 °C and 101,3 kPa)	---	---
4	3.1.1. Physical state (at 20 °C and 101,3 kPa)		
5	3.1.2. Colour (at 20 °C and 101,3 kPa)		
6	3.1.3. Odour (at 20 °C and 101,3 kPa)		
7	3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4---10		
8	3.3. Relative density (liquids) and bulk, tap density (solids)		
9	3.4. Storage stability, stability and shelf---life	---	---
10	3.4.1. Storage stability tests		
11	3.4.1.1. Accelerated storage test		
12	3.4.1.2. Long term storage test at ambient temperature		
13	3.4.1.3. Low temperature stability test (liquids)		
14	3.4.2. Effects on content of the active substance and technical characteristics of the biocidal product		
15	3.4.2.1. Light		
16	3.4.2.2. Temperature and humidity		
17	3.4.2.3. Reactivity towards container material		

Screenshot 5 (Template)

1.6. Worksheet - Justifications

Longer justifications (e.g. for the back-bone identified, regarding grouping, the worst case composition and the similarity of uses) should be provided here. The other worksheets should include only references to the “worksheet – justifications” in order to ensure the readability of the information provided in the tables.

2. How to enter information

2.1. Overview (1st worksheet) - Ingredients of the core

a) List all the ingredients of the core in the upper left corner

	A	B	C	D	E
6		Backbone	SoC		
7	Substance/ Mixture	Function	Classification	CAS	EC number
8	Ingriedient 1	XXX			
9	Ingriedient 2	XXX			
10	Ingriedient 3	XXX			

Screenshot 6 (Template)

b) One ingredient per line, give the function, the classification of the ingredient, the CAS and EC number (only for substances)

c) Mark the function field in green if the corresponding ingredient is a part of the backbone[B] of the BPF.

d) The justification why the product compositions should be considered as similar/the rational for the back bone identified are to be entered in the worksheet “5 Justifications”

If applicable:

e) Mark the classification field in yellow if the corresponding ingredient is a SoC

f) Instead of a single ingredient, also a group of substances/mixtures can be listed (see row 10 in Screenshot 7). Detailed information on the grouped substances/mixtures is to be provided in a separate worksheet (see chapter 1.1 above).

g) For BPFs including more than 20 ingredients, please copy the necessary number of rows and add these complete rows before the line “Sum”

	A	B	C	D	E
6		Backbone	SoC		
7	Substance/ Mixture	Function	Classification	CAS	EC number
8	Active substance	Active substance	XYZ	123	123
9	Solvent 1	Solvent	None	123	123
10	Group 1	Complexing agent	None	123	123
11	Group 2	Binder	None	123	123
12	Group 3	Colourant	XYZ	-	-

Screenshot 7 (Example)

B See “Guidance note on BPF concept” (CA-July19-Doc.4.2- Final – Guidance note on BPF concept_rev2.), chapter 3.2.2.

2.2. Overview (1st worksheet) - Meta SPCs of the core

a) Give composition variations for meta SPC(s)
b) If applicable: Give reasons for the creation of additional meta SPCs in the worksheet "5 Justifications".

	A	F	G	H	I	J	K	L	M	N	O
1											Core
2											
3		1st level core assessment		2nd level							
4											
5		-		meta SPC 1		meta SPC 2		meta SPC 3		meta SPC 4	
6											
7	Substance/ Mixture	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)
8	Ingriedient 1	0,00	0,00								
9	Ingriedient 2	0,00	0,00								
10	Ingriedient 3	0,00	0,00								
28	*Sum (%)*			*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*
29	*Check sum (%)*			*0,0*		*0,0*		*0,0*		*0,0*	

Screenshot 8 (Template)

c) Enter composition variations for each meta SPC for each ingredient.
d) Please note, the information regarding "Min (%)" and "Max (%)" is automatically filled in.
e) "Min (%)" and "Max (%)" are added up in the row "Sum". These two sums are added up in the row "Check sum".
f) Please note, if the check sum is not "200.0" (e.g.J/K30 below) the numbers entered above need to be checked. Example (see Screenshot 9): If you go from meta 1 (without variations) to meta 2 (variation of active substance) than a second ingredient needs to vary too (see solvent 1 in meta 3) because otherwise you cannot reach 100 % when choosing the lower value for the active substance. Please note, the check sum is considered as a helpful tool and not as a hard criterion.
g) Please note, regarding the worst and best case compositions to be identified the row "Sum" must not necessarily give 100.

	A	F	G	H	I	J	K	L	M
1									
2									
3		1st level core assessment		2nd level					
4		-		meta SPC 1		meta SPC 2		meta SPC 3	
7	Substance/ Mixture	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)
8	Active substance	4,00	5,00	5,00	5,00	4,00	5,00	4,00	5,00
9	Solvent 1	90,00	91,00	90,00	90,00	90,00	90,00	90,00	91,00
10	Group 1	0,50	0,50	0,50	0,50	0,50	0,50	0,50	0,50
11	Group 2	4,50	4,50	4,50	4,50	4,50	4,50	4,50	4,50
12	Group 3	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
29	*Sum (%)*			*100,00*	*100,00*	*99,00*	*100,00*	*99,00*	*101,00*
30	*Check sum (%)*			*200,00*		*199,00*		*200,00*	

Screenshot 9 (Example)

If applicable:

a) For every additional meta SPC the reason why the corresponding products could not be included in meta SPC 1 needs to be entered. Information regarding acceptable reasons for the creation of an additional meta SPC can be found in the “Guidance note on BPF concept” (CA-July19-Doc.4.2-), chapter 3.2.4 Similar levels of risk and efficacy: Definition of the core.

b) For an ingredient belonging to the core but which is not relevant for a given meta SPC you have to enter the min. and max. content "0" (see Screenshot 9 “Group 3” in meta SPC 1 above).

c) Enter the following per meta SPC of the core (see Screenshot 10 below)

i) <u>One</u> formulation type
ii) Conditions of storage and shelf-life of the product under normal conditions of storage
iii) H-statements
iv) EUH
v) Descriptive name for the meta-SPC

	A	F	G	H	I	J	K
1							
2							
3		1st level core assessment		2nd level			
4		-		meta SPC 1		meta SPC 2	
23	Type of formulation			Liquid solvent based		See meta 1	
24	Use pattern (#1-#65)			#39 (PT8)		#39 (PT8)	
25	Use no.			1		1	
26				2		2	
27				3		3	
28	Conditions of storage and shelf-life of the product under normal conditions of storage			Ambient temp. Protect from sunlight. 12 month.		See meta 1	
29	H-statements			H319 (eye irritation) H272 (oxidiser)		H318 (eye damage) H272 (oxidiser)	
30	EUH			-		-	
31	Descriptive name for the meta-SPC			Lower overall range of Co-F1+2		Higher overall range of Co-F1+2	

Screenshot 10 (Example)

d) How to enter redundant information

i) If information is redundant please do not re-enter the information but refer to the meta SPC where the information was already entered (see line 23 and 28 in Screenshot 11 below).

ii) The advantage is an advanced readability and the information that e.g. the conditions of storage are the same for all the meta SPCs is available at first glance (see line 28 in Screenshot 11 below).

iii) Contrary to this the information that also the H-statements are the same for all the meta SPC is not available at first glance (see line 29 in Screenshot 11 below).

	A	F	G	H	I	J	K
1							
2							
3		1st level core assessment		2nd level			
4		-		meta SPC 1		meta SPC 2	
23	Type of formulation			Liquid solvent based		See meta 1	
24	Use pattern (#1-#65)			#39 (PT8)		#39 (PT8)	
25	Use no.			1		1	
26				2		2	
27				3		3	
28	Conditions of storage and shelf-life of the product under normal conditions of storage			Ambient temp. Protect from sunlight. 12 month.		See meta 1	
29	H-statements			H200 H202 H208 H220 H335 H336 H312+332 H400 H413 H420		H200 H202 H208 H220 H335 H336 H312+332 H400 H413 H420	
30	EUH			-		-	
31	Descriptive name for the meta-SPC			Lower overall range of Co-F1+2		Higher overall range of Co-F1+2	

Screenshot 11 (Example)

2.3. Grouping (2nd worksheet)

a) The concept of "grouping" [C] was developed in order to allow applicants to reduce the number of potential products to be taken into account by the MSCAs by applying more precisely for the actually intended composition variations. In order to really reduce the complexity of applications instead of only triggering different questions it is necessary to consider the inherent complexity of grouping. Therefore, the template is prefilled with lines which allow enter grouped substances/mixtures easily and correctly.

b) In the following the terms, formats and formulas used in the template are explained:
   i) Every group consists of several lines. One bold line per **group** (line 5, 9 and 13 below) and one additional line per grouped substance/mixture.
   ii) It is possible to use the grouped substances/mixtures alternatively (or), in combination (and) or both (and/or).
   iii) For each group **AND** grouped substance/mixture a min. and max. content must be given.

c) The values can be chosen quite freely. A lot of flexibility is possible. In the end the BPF overview is a flexible template and not a fixed form. This means it can (and sometimes has to) be adapted to the users needs. However, depending on the type of logical operator chosen ("or", "and", "and/or") there are certain constrains or automatisms for the numbers to be entered. Therefore the template to be filled in looks as follows (see Screenshot 12 and Screenshot 13 below) For more examples and explanation, please consider the Annex - Explanation and examples regarding grouping.

C See "Guidance note on BPF concept" (CA-July19-Doc.4.2-), page 7.

	A	B	C	D	E	F	G	H	I	J
1										
2										
3										
4	**Group no.**	**Common name**	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Classification**	**SAME impact on the classification (i.e. resulting in the same hazard and safety statements) for the whole formulation?**	**SAME impact on the level of risk and efficacy of the formulation?**	***Groupable? (For MSCA)***
5	**1**	**Group A (or)**	---		---	---	---	---	---	**---**
6	1	Grouped A1		Same?				Same?	Same?	*Yes/No?*
7	1	Grouped A2		Same?				Same?	Same?	*Yes/No?*
8	1	Grouped A3		Same?				Same?	Same?	*Yes/No?*
9	2	**Group B (and)**	---		---	---	---	---	---	**---**
10	2	Grouped B1		Same?				Same?	Same?	*Yes/No?*
11	2	Grouped B2		Same?				Same?	Same?	*Yes/No?*
12	2	Grouped B3		Same?				Same?	Same?	*Yes/No?*
13	3	**Group C (and/or)**	---		---	---	---	---	---	**---**
14	3	Grouped C1		Same?				Same?	Same?	*Yes/No?*
15	3	Grouped C2		Same?				Same?	Same?	*Yes/No?*
16	3	Grouped C3		Same?				Same?	Same?	*Yes/No?*

Screenshot 12 (Template)

d) Having listed one or more groups of substances/mixtures as ingredient (see row 10-12 in Screenshot 7 above) the following detailed information is to be provided as follows (see Screenshot 12 above and Screenshot 13 below):

i) Copy the template for the different types of grouping (block of four lines with the needed logical operator (or, and, and/or)) as often as necessary.

ii) Delete the templates not needed.

iii) For each group copy in additional lines or delete lines in order to adjust it to the number of substances to be grouped.

iv) If in a cell "###" is displayed the formula behind got corrupted when adjusting the number of lines and now needs to be corrected manually.

v) Number the groups consecutively (see column A above).

vi) Name the groups but do not delete the logical operator (see column B above).

vii) Enter the common name of the grouped substances (see column B above).

viii) Enter the IUPAC name of the grouped substances (see column C above).

ix) Enter the function for each group and the grouped substances/mixtures within (see column D above). The function of the group and all grouped substances/mixtures within the group must be the same.

x) Enter CAS number, EC number and classification (see column E, F and G above).

xi) Column H and I are more a reminder for the applicant and a place where a reference to the corresponding justification can be made. The justifications are to be entered in the worksheet "5 Justifications".

xii) Column J is for use by the MSCA. If a grouped substance/mixture does not fulfil all the criteria (column D, H and I) it cannot be part of the authorisation.

	A	B	K	L	M	N	O	P	Q	R	S	T
1			Core assessment									
2												
3					meta SPC 1		meta SPC 2		meta SPC 3		meta SPC 4	
4	Group no.	Common name	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)
5	1	Group A (or)	0,00	0,00		0,00		0,00		0,00		0,00
6	1	Grouped A1	0,00	0,00	0,00		0,00		0,00		0,00	
7	1	Grouped A2	0,00	0,00	0,00		0,00		0,00		0,00	
8	1	Grouped A3	0,00	0,00	0,00		0,00		0,00		0,00	
9	2	Group B (and)	0,00	0,00	0,00		0,00		0,00		0,00	
10	2	Grouped B1	0,00	0,00		0,00		0,00		0,00		0,00
11	2	Grouped B2	0,00	0,00		0,00		0,00		0,00		0,00
12	2	Grouped B3	0,00	0,00		0,00		0,00		0,00		0,00
13	3	Group C (and/or)	0,00	0,00								
14	3	Grouped C1	0,00	0,00	0,00		0,00		0,00		0,00	
15	3	Grouped C2	0,00	0,00	0,00		0,00		0,00		0,00	
16	3	Grouped C3	0,00	0,00	0,00		0,00		0,00		0,00	

Screenshot 13 (Template)

xiii) Enter composition variations for each group and of each grouped substances/mixtures for each meta-SPC (see columns M to T Screenshot 13 above).

xiv) Please note, the information regarding “Min (%)” and “Max (%)” is automatically filled in (see columns K and L Screenshot 13 above).

xv) For groups which allow for alternative use (or, and/or) of grouped substances/mixtures

(1) only the min. value for the group itself must be entered. The min. value for the grouped substances/mixtures is always “0,0”. This min. value is mandatory. A substance/mixture which is always present in the BPs is simply not used alternativly and therefore needs to be presented outside of such a group.

(2) the max. value for the group cannot be larger than the sum of the maxima of the grouped substances/mixtures. While choosing the latter would not be wrong it would not reduce the number of potential BPs in the BPF.

xvi) For groups which allow for a use of grouped substances/mixtures in combination (and)

(1) the min. value for the group is automatically filled in (sum of all the min. values of the grouped substances/mixtures).

(2) the max. value for the grouped substances/mixtures is automatically filled in (upper limit for the group entered by the applicant minus all the minimum vales of the other grouped substances/mixtures in the group).

	A	B	C	D	E	F	G	K	L	M	N	O	P
1								Core assessment					
2													
3										meta SPC 1		meta SPC 2	
4	**Group no.**	**Common name**	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Classification**	**Min (%)**	**Max (%)**	Min (%)	Max (%)	Min (%)	Max (%)
5	1	**Group A (and)**	---	**Complexing agent**	---	---	---	**0,50**	**1,00**	**0,50**	**1,00**	**0,50**	**1,00**
6	1	Complexing agent 1	XYZ	Complexing agent	123	123	None	0,25	0,75	0,25	0,75	0,25	0,75
7	1	Complexing agent 2	XYZ	Complexing agent	123	123	None	0,25	0,75	0,25	0,75	0,25	0,75
8	**2**	**Group B (or)**	---	**Binder**	---	---	---	**4,50**	**9,00**	**4,50**	**9,00**	**4,50**	**9,00**
9	2	Binder 1	XYZ	Binder	123	123	None	0,00	9,00	0,00	9,00	0,00	9,00
10	2	Binder 2	XYZ	Binder	123	123	None	0,00	9,00	0,00	9,00	0,00	9,00
11	3	**Group C (and/or)**	---	**Colourant**	---	---	---	**1,00**	**2,00**	**0,00**	**2,00**	**0,00**	**2,00**
12	3	Colourant 1	XYZ	Colourant	123	123	XYZ	0,00	2,00	0,00	2,00	0,00	2,00
13	3	Colourant 2	XYZ	Colourant	123	123	XYZ	0,00	2,00	0,00	2,00	0,00	2,00
14	3	Colourant 3	XYZ	Colourant	123	123	XYZ	0,00	2,00	0,00	2,00	0,00	2,00

Screenshot 14 (Example)

e) Due to the above mentioned inherent complexity of grouping itself and example of a filled in template is provided here and explained in the following:

i) A BPF includes the complexing agents 1 and 2 (Group A lines in green). Each of them with 0,25 to 0,75 % but every BP in the BPF includes overall 0,5 to 1 %. In this example grouping of co-formulants which are used in combination („and“) is used in order to exclude BP which include overall more than 1 %. Otherwise the MSCA would have to take BPs into account which include overall 0,5 to 1,5 % complexing agents. The applicant is of course free to enter a value lower than the 0,75 % calculated.

ii) A BPF includes the binders 1 or 2 (Group B lines in blue). Either 0 to 9 % of binder 1 or 0 to 9 % of binder 2 but every BP in the BPF includes overall 4,5 to 9 % binder. In this example grouping of co-formulants which are used alternatively („or“) is used in order to exclude BP which include less than 4,5 % and more than 9 % binder. Otherwise the MSCA would have to take BPs into account which include overall 0 to 18 % binders.

iii) A BPF includes the colourants 1, 2 and/or 3 (Group C lines in brown). This allows for every combination of the colourants. Every BP in the BPF includes overall 1 to 2 % colourants. In this example grouping of co-formulants which are used in combination or alternatively („and/or“) is used in order to exclude BP which include less than 1 and more than 2 % colourant. Otherwise the MSCA would have to take BPs into account which include overall 0 to 6 % colourants. For more examples and explanation, please consider the Annex - Explanation and examples regarding grouping.

2.4. Uses (3rd worksheet) - Detailed information on the uses

a) Enter the “Use pattern(s) (#1-#65)” to which a use belongs to (e.g. #38 = Wood preservatives[D], see Screenshot 15 column A below).
b) Number the uses consecutively (see column B below)
c) List the meta-SPCs (plural) to which the use belongs to (see column C below)
d) Name the use (see column D below)
e) Enter the PT (singular) the use belongs to (see column E below)
f) Where relevant (e.g. if PT 19 you enter “Attractant” or “Repellent”), enter an exact description of the use (see column F below)
g) Enter the target organism(s) (see column G below)
h) Enter the field(s) of use (see column H below)
i) Enter the application method(s) (see column I below)
j) Enter application rate(s) (etc.) (see column J below)
k) Enter the user category(ies) (see column K below)
l) Enter pack sizes and packaging material (see column L below)
m) Enter the corresponding use no. if a use needs no assessment because it is covered by a use previously assessed (see column M below)

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Use pattern (#1-#65)	Use no.	meta SPC	Name of the use	PT	Where relevant, an exact description of the authorised use	Target organism(s)	Field(s) of use	Application method(s)	Application rate(s) and frequency If relevant incl.: Dilution and concentration a.s. in diluted product	Category(ies) of users	Pack sizes and packaging material	No assessment necessary (covered by assessment of use no.)
2	#39	1	1, 2	Brushing	8	-	X	Indoor	Brushing	X	Professional	X	-
3	#39	2	1, 2	Spraying	8	-	Y	Indoor	Spraying	Y	Professional	Y	-
4	#39	3	1, 2	Brushing and Spraying	8	-	X, Y	Indoor	Brushing, spraying	X, Y	Professional	X, Y	1 and 2
5													
6	The similarity of uses is visualised in form of a matrix. This matrix can be found ... here												

Screenshot 15 (Example)

n) In order to check whether the uses can be considered as similar please refer to the relevant guidance. Please enter the listed “use patterns” in the automated tool provided by ECHA[E] and create the corresponding matrix.
o) Please, enter a reference to the matrix below the table.
p) Justifications why a pair of uses (use patterns) should be considered as similar are to be entered in the worksheet “5 Justifications”.

D See “Guidance note on BPF concept” (CA-July19-Doc.4.2-)”, chapter 3.2.3 Similarity of uses.
E See“Matrix.xls”.

2.5. Overview (1st worksheet) – List of uses

a) Take over the following information from the worksheet "uses" (see chapter 2.3 above).

i) "Use pattern (#1-#65)"

ii) "Use no." (consecutively)

iii) meta-SPCs to which the use belongs to

	A	F	G	H	I	J	K	L	M	N	O
1											
2											Core
3		1st level core assessment		2nd level							
4		-		meta SPC 1		meta SPC 2		meta SPC 3		meta SPC 4	
34	Use pattern (#1-#65)			#38		#38					
35	Use no.			1							
36				2		2					
37						3					

Screenshot 16 (Example)

If applicable:

b) For BPFs including more than one "Use pattern (#1-#65)", please copy the block of rows "use pattern (#1-#65)" AND "Use no." (see Screenshot 16 line 34 to 37) and add these complete rows below (see Screenshot 17).

c) Having entered this information one has an excellent overview of the uses applied for (see Screenshot 17). Although the underlying information is included in the xml SPC file the following information would not be available from the "linear" SPC:

i) Meta SPC 1 includes the uses 1 and 2 both belonging to the use pattern #XX

ii) Furthermore, meta SPC 1 includes the uses 3 and 4 both belonging to the use pattern #YY.

iii) While meta SPC 2 does not include use 1 it does include use 2 and additionally use 5.

iv) Furthermore, meta SPC 2 does not include use 3 but it does include use 4 and additionally use 6.

	A	F	G	H	I	J	K
1							
2							
3		1st level core assessment		2nd level			
4							
5		-		meta SPC 1		meta SPC 2	
6							
24	Use pattern (#1-#65)			#XX		#XX	
25	Use no.			1		-	
26				2		2	
27						5	
28	Use pattern (#1-#65)			#YY		#YY	
29	Use no.			3		-	
30				4		4	
31						6	

Screenshot 17 (Example)

2.6. Overview (1st worksheet) - Worst case composition

a) Enter the worst and best case composition per area[F]

b) For every ingredient (see cells A8-A10 in Screenshot 18) one value must be entered in the corresponding cells (see cells P8-T10 in Screenshot 18)

	A	B	C	F	G	H	I	J	K	P	Q	R	S	T
1				Core assessment										
2														
3				1st level core assessment		2nd level				Worst case composition				
4														
5				-		meta SPC 1		meta SPC 2		HH		ENV		EFF
6		Backbone	SoC											
7	Substance/ Mixture	Function	Classification	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)	Best case	Worst case	Best case	Worst case	Worst case
8	Ingriedient 1	XXX		0,00	0,00									
9	Ingriedient 2	XXX		0,00	0,00									
10	Ingriedient 3	XXX		0,00	0,00									
28	*Sum (%)*					*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*
29	*Check sum (%)*					*0,0*		*0,0*						
30	Justification No.													
31	Test product													

Screenshot 18 (Template)

c) Generally the following values should be taken into account:
   i) Best/Worst case:
      (1) Lowest/Highest AS content
      (2) Lowest/Highest content of relevant SoCs
   ii) For <u>human/animal health (HH)</u> generally the following values should be taken into account:
      (1) Best/Worst case:
         (a) Lowest/Highest content of substances influencing dermal absorption
   iii) For <u>environment (ENV)</u> generally the following values should be taken into account:
      (1) Best/Worst case:
         (a) Lowest/Highest content of substances influencing entry into the environment (e.g. binders in wood protection products).
   iv) For efficacy (EFF) generally the following values should be taken into account:
      (1) Worst case:
         (a) Lowest AS content
         (b) Lowest content of substances influencing leaching (e.g. binders in wood protection products).

d) Please note, regarding the worst and best case compositions to be identified the row “Sum” must not necessarily give 100.

F Generally it will not be possible to enter one worst case composition per BPF but it will be necessary to enter one per area: HH = Human/Animal health; ENV = Environment; EFF = Effectivity.

e) For each composition chosen a justification needs to be provided. The justifications are to be entered in the worksheet “5 Justifications”. From the justification it should become clear why the composition chosen is sufficient to cover the whole range of specified variations applied for.

f) For each composition chosen the corresponding test product should be named: Either a reference to a product being part of the BPF applied for should be made (to level 3 info e.g. BP 17 of BPF applied for) or a reference to a list with separate test products should be made.

	A	B	C	F	G	H	I	J	K	L	M	N	O	P
1				Core assessment										
2														
3				1st level core assessment		2nd level				Worst case composition				
4														
5				-		meta SPC 1		meta SPC 2		HH		ENV		EFF
6		Backbone	SoC											
7	Substance/ Mixture	Function	Classification	Min (%)	Max (%)	Min (%)	Max (%)	Min (%)	Max (%)	Best case	Worst case	Best case	Worst case	Worst case
8	Active Substance 1	Active Substance	1 Acute toxicity	5,00	10,00	5,00	10,00	5,00	10,00	**5,00**	**10,00**	**5,00**	**10,00**	**5,00**
9	Co-formulant 1	X	2 Serious eye damage	1,00	4,00	1,00	2,00	2,01	4,00	**1,00**	**4,00**	*1,00*	*1,00*	*1,00*
10	Co-formulant 2	X	2 Serious eye damage	1,00	4,00	1,00	2,00	2,01	4,00	**1,00**	**4,00**	*1,00*	*1,00*	*1,00*
11	Co-formulant 3	X	3 STOT	1,00	2,00	1,00	2,00	1,00	2,00	*1,00*	*1,00*	*1,00*	*1,00*	*1,00*
12	Co-formulant 4	X	3 STOT	1,00	2,00	1,00	2,00	1,00	2,00	*1,00*	*1,00*	*1,00*	*1,00*	*1,00*
13	Co-formulant 5	Acid	4 Skin corrosion	2,50	5,00	2,50	5,00	2,50	5,00	**2,50**	**5,00**	*2,50*	*2,50*	*2,50*
14	Group 1	Binder	See Grouping	4,00	4,00	4,00	4,00	4,00	4,00	*4,00*	*4,00*	**4,00**	**4,00**	**4,00**
15	Group 2	PPD	See Grouping	1,00	1,00	1,00	1,00	1,00	1,00	*1,00*	*1,00*	*1,00*	*1,00*	*1,00*
16	Group 3	Anti-dripping agent	See Grouping	1,00	1,00	1,00	1,00	1,00	1,00	*1,00*	*1,00*	*1,00*	*1,00*	*1,00*
17	Co-formulant 6	Catalyst	6 Oxidiser	1,00	2,00	1,00	2,00	1,00	2,00	**1,00**	**2,00**	*1,00*	*1,00*	*1,00*
18	Co-formulant 7	Solvent	7 Flammable liquid	65,00	81,50	69,00	81,50	65,00	79,48	81,50	67,00	*81,50*	*76,50*	81,50
19	***Sum (%)***					***87,50***	***112,50***	***85,52***	***114,48***	***100,00***	***100,00***	***100,00***	***100,00***	***100,00***
20	***Check sum (%)***					***200,00***		***200,00***						
21	**Justification No.**									1	1	2	2	3
22	**Test product**									1	2	3	4	1

Screenshot 19 (Example)

2.7. Overview – Composition of test products used for generation of PCT and PH data

a) Having identified the worst and best case compositions for human health (HH), environment (ENV) and efficacy (EFF) one has a good idea of products representative for the composition range of the BPF applied for (e.g. test products 1 and 2 in Screenshot 19 above).

b) These representative products and e.g. the average product in between are natural candidates for test products in order to generate data on physical, chemical and technical (PCT) properties as well as physical hazards and respective characteristics (PH) of the BPF.

c) Information on the composition of test products which were used in order to generate data on physical, chemical and technical (PCT) properties as well as physical hazards and respective characteristics (PH) of the BPF has to be entered in columns Q to V (see Screenshot 20 below).

d) For each composition chosen a justification needs to be provided. The justifications are to be entered in the worksheet “5 Justifications”.

e) For each composition chosen the corresponding test product should be named: Either a reference to a product being part of the BPF applied for should be made (to level 3 info e.g. BP 17 of BPF applied for) or a reference to a list with separate test products should be made.

	A	B	C	L	M	N	O	P	Q	R	T	U	V
1				Core assessment									
2													
3				Worst case composition									
4													
5				HH		ENV		EFF	Physical, chemical and technical		Phys hazards		
6		Backbone	SoC										
7	Substance/ Mixture	Function	Classification	Best case	Worst case	Best case	Worst case	Worst case	Lowest solvent content	Highest solvent content	oxidiser worst case	oxidiser and flamm-ability best case	corrosivity to metal worst case
8	Active Substance 1	Active Substance	1 Acute toxicity	5,00	10,00	5,00	10,00	5,00	10,00	5,00	5,00	5,00	5,00
9	Co-formulant 1	X	2 Serious eye damage	1,00	4,00	1,00	1,00	1,00	4,00	1,00	1,00	1,00	1,00
10	Co-formulant 2	X	2 Serious eye damage	1,00	4,00	1,00	1,00	1,00	4,00	1,00	1,00	1,00	1,00
11	Co-formulant 3	X	3 STOT	1,00	1,00	1,00	1,00	1,00	2,00	1,00	1,00	1,00	1,00
12	Co-formulant 4	X	3 STOT	1,00	1,00	1,00	1,00	1,00	2,00	1,00	1,00	1,00	1,00
13	Co-formulant 5	Acid	4 Skin corrosion	2,50	5,00	2,50	2,50	2,50	5,00	2,50	2,50	2,50	5,00
14	Group 1	Binder	See Grouping	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00
15	Group 2	PPD	See Grouping	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00
16	Group 3	Anti-dripping agent	See Grouping	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00
17	Co-formulant 6	Catalyst	6 Oxidiser	1,00	2,00	1,00	1,00	1,00	2,00	1,00	2,00	1,00	2,00
18	Co-formulant 7	Solvent	7 Flammable liquid	81,50	67,00	81,50	76,50	81,50	65,00	81,50	80,50	81,50	78,00
19	*Sum (%)*			*100,00*	*100,00*	*100,00*	*100,00*	*100,00*	*100,00*	*100,00*	*100,00*	*100,00*	*100,00*
20	*Check sum (%)*												
21	Justification No.			1	1	2	2	3	4	4	5	6	7
22	Test product			1	2	3	4	1	5	1	6	1	7

Screenshot 20 (Example)

2.8. PCT and PH (4th worksheet)

a) For each data requirement, please list the test product(s) used in order to generate data.
b) If the general justification provided before (see chapter 2.7 above) is not sufficient, please provide a specific justification for the corresponding data requirement in column C. From the justification it should become clear why the test products used and the data generated are sufficient to cover the whole range of specified variations applied for.

	A	B	C
1	**3. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES**	**Data provided based on study with test product:**	**Justification why this test product(s) was/were chosen**
2			
3	3.1. Appearance (at 20 °C and 101,3 kPa)	---	---
4	3.1.1. Physical state (at 20 °C and 101,3 kPa)	6	XYZ
5	3.1.2. Colour (at 20 °C and 101,3 kPa)	6	XYZ
6	3.1.3. Odour (at 20 °C and 101,3 kPa)	6	XYZ
7	3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4---10	Waiver	---
8	3.3. Relative density (liquids) and bulk, tap density (solids)	6	XYZ
9	3.4. Storage stability, stability and shelf---life	---	---
10	3.4.1. Storage stability tests	1, 2	XYZ
11	3.4.1.1. Accelerated storage test	1, 2	XYZ
12	3.4.1.2. Long term storage test at ambient temperature	1, 2	XYZ
13	3.4.1.3. Low temperature stability test (liquids)	1, 2	XYZ

Screenshot 21 (Example)

2.9. Justifications (5th worksheet)

The onus is on the applicant to prove that the group of biocidal products fulfils the definition of a biocidal product family and that any potential product within the family fulfils the authorisation criteria.

Having prepared the dossier for years all the reasons for the family structure chosen are obvious for the applicant. However, given the complexity of a family dossier they are not obvious for the CA.

Therefore, comprehensible in depth justifications must be provided in order to ensure a timely and if possible positive decision.

If you have provided an in depth justification of several pages already in a different document (e.g. your PAR) you can enter a reference to this document instead of repeating the justification in the worksheet.

DISCLAIMER: The worksheet “5 Justifications Example” is an example only and there is no claim of completeness or guaranteed acceptance by eCAs. MS can demand a different line of argumentation or level of detail.

2.10. Annex – Explanation and examples regarding grouping

Purpose of grouping

As written in the BPF guidance (CA-July19-Doc.4.2- Final – Guidance note on BPF concept_rev2.docx see (36)) it is crucial to make clear which variations in composition are applied for because according to Article 19 (6) BPR the MS are obliged to consider "the whole potential range of products" within the BPF when assessing it. Therefore, the purpose of grouping is to narrow down the number of potential BP within the BPF to the BP the company actually wants to place on the market.

Explanation of terminology used

	Min	**Max**	**Notes**
Group A	**X %**	**Y %**	
Grouped A1	*X1 %*	*Y1 %*	
Grouped A2	*X2 %*	*Y2 %*	
and/or			
Grouped A3	*X3 %*	*Y3 %*	

The three substances/mixtures A1, A2, A3 are grouped and thereby form Group A.

Depending on whether they are used alternatively (or), in combination (and) or both (and/or) the corresponding logical operator has to be chosen.

Min. and max. content must be given for the group as a whole ($Group_{Min}$ = X % and $Group_{Max}$ = Y %).

Min. and max. content must be given for each grouped substance/mixture ($Grouped_{Min}$ = X1/X2/X3 % and $Grouped_{Max}$ = Y1/Y2/Y3 %).

"Max of $Grouped_{Max}$" means maximum of Y1/Y2/Y3 %.

"$Group_{Min} = \sum Grouped_{Min}$" means $Group_{Min}$ results from sum of all three $Grouped_{Min}$ values (Y1+Y2+Y3 %).

Examples concerning co-formulants <u>in combination</u> ("and"):

<u>Concrete</u> example (example 1):

	Min	**Max**	**Notes**
Group C	**1 %**	**3 %**	In order to make clear that the complexing agents 1 and 2 are used in combination and that every BP in the BPF includes at least 0.4 and 0.6 % of these but never more than 3 % overall one can group the complexing agents and link them with a logical "and". Without this grouping the BPF would include BPs with 1-5 % complexing agent (Complexing agent 1 0.4-2.4 % and Complexing agent 2 0.6-2.6 %) and the CA would have to take these potential BPs into account for the assessment.
Complexing agent 1	0.4 %	2.4 %	
and			
Complexing agent 2	0.6 %	2.6 %	
To be taken into account for the worst (and best) case composition: • Since they are used in combination all the co-formulants. • All the $Grouped_{Min}$ values. • The relevant max values must be identified and justified by the applicant.			

<u>Abstract</u> example (example 2):

	Min	**Max**	**Notes**
Group C	**1 %**	**3 %**	$Group_{Min} = \sum Grouped_{Min}$
Grouped C1	0.4 %	2.4 %	$Grouped_{Max} = Group_{Max} - \sum \underline{Other}\ Grouped_{Min}$
and			Grouping of co-formulants which are used in combination („and") is useful in order to exclude BP which include more than $Group_{Max}$ % of the grouped co-formulants (e.g. more than 3 % complexing agent in example 1).
Grouped C2	0.6 %	2.6 %	See note regarding Grouped C1
To be taken into account for the worst (and best) case composition: • Since they are used in combination all the co-formulants. • All the $Grouped_{Min}$ values. • The relevant max values must be identified and justified by the applicant.			

Examples concerning co-formulants <u>used alternatively</u> ("or"):

<u>Concrete</u> example (example 3):

	Min	**Max**	**Notes**
Binder	**10 %**	**30 %**	In order to make clear that the binders 1 and 2 are used alternatively and that every BP in the BPF includes 10-30% binder one can group the binders and link them with an logical "or". Without this grouping the BPF would include BPs with 0-50 % binder (Binder 1 0-30 % and Binder 2 0-20 %) and the CA would have to take these potential BPs into account for the assessment.
Binder 1	0 %	30 %	
or			
Binder 2	0 %	20 %	

<u>Abstract</u> example (example 4):

	Min	**Max**	**Notes**
Group B	**10 %**	**30 %**	• $Group_{Min}$ can be chosen between 0 and $Group_{Max}$ • $Group_{Max}$ = Max of $Grouped_{Max}$
Grouped B1	0 %	30 %	• $Grouped_{Min}$ = 0 (because the BPs of the BPF include 0 or X % Grouped…) • $Grouped_{Max}$ can be chosen above 0 and up to $Group_{Max}$
or			• Grouping of co-formulants which are used alternatively („or") is useful in order to exclude BP which do not include at least GroupMin % of the grouped co-formulants (e.g. below 10 % Binder in example 3).
Grouped B2	0 %	20 %	See note regarding Grouped B1

Examples concerning co-formulants <u>in combination or alternatively</u> ("and/or"):

<u>Concrete</u> example (example 5):

	Min	**Max**	**Notes**
Group D	**0.5 %**	**2 %**	In order to make clear that the driers 1, 2 and 3 are used in combination or alternatively and that every BP in the BPF includes 0.5-2 % binder one can group the binders and link them with a logical "and/or". Without this grouping the BPF would include BPs with 0-3.5 % drier (Drier 1 0-2 %, Drier 2 0-1 % and Drier 3 0-0.5 %) and the CA would have to take these potential BPs into account for the assessment.
Drier 1	*0 %*	*2 %*	
Drier 2	*0 %*	*1 %*	
and/or			
Drier 3	*0 %*	*0.5 %*	

<u>Abstract</u> example (example 6):

	Min	**Max**	**Notes**
Group D	**0.5 %**	**2 %**	• $Group_{Min}$ can be chosen between 0 and $Group_{Max}$ • Largest <u>possible</u> $Group_{Max} = \sum Grouped_{Max}$
Grouped D1	*0 %*	*2 %*	• $Grouped_{Min} = 0$ (because the BPs of the BPF include 0 or X % Grouped…) • For GroupedMax a value larger than 0 and up to GroupMax has to be chosen
and/or			• Grouping of co-formulants which are used in combination or alternatively („and/or") is useful in order to exclude on the one hand BP which include more than $Group_{Max}$ % (e.g. more than 2 % drier in example 5) and on the other hand do not include at least GroupMin % of the grouped co-formulants (e.g. less than 0.5 % drier in example 5).
Grouped D2	*0 %*	*1 %*	See note regarding Grouped D1
Grouped D3	*0 %*	*0.5 %*	