REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: 102000007779

Product name: Flufenacet SC 508.8 G

Active substance: Flufenacet 508.8 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorization)

Applicant: Bayer Crop Science Division

Submission date: 30 June 2021

MS Finalisation date: February 2022 (initial Core Assessment)

June 2023 (final Core Assessment)

Version history

When	What
June 2021	Original Bayer Crop Science Division submission
February 2022	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
June 2023	Final report (National Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance.

Noticed data gaps are:
- Ambient temperature study is currently ongoing, and should be provided upon completion.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

This section of the draft registration report is a core document and as such will be submitted in all countries where the product will be registered. Since the legal name of the applicant may vary depending on the country this information is provided in the National document (Part A, point 1.1, Application background). The registration holder will be either Bayer or one of its' legal entities in the countries.

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Name:	Bayer S.A.S.
Address:	16, rue Jean-Marie Leclair CS 90106 69266 Lyon Cedex 09 France
Contact:	xxx
Telephone number:	xxx
E-mail:	xxx

Location of the production site
CONFIDENTIAL information - data provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Please send all correspondence to:

Bayer AG	Person to contact:	xxx
Alfred-Nobel-Straße 50	Position:	xxx
40789 Monheim am Rhein	Telephone No.:	xxx
Germany	E-mail:	xxx

Location of the production site
CONFIDENTIAL information - data provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Flufenacet

Flufenacet	min. 950 g/kg There is no relevant impurity

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name:	Please refer to Registration Report Part A

Company code number: Flufenacet SC 508.8 (508.8 g/L)
FFA SC 508.8 G
102000007779
UVP: 05559022

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

The formulation FFA SC 508.8 G was not the representative formulation for the inclusion of the active substance flufenacet into Annex I of Directive 91/414/EEC.

Table 1.4-1: Active substance and variants of the active substance

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max) (g/L or g/kg)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Flufenacet	508.8	483.8 - 533.8	535.6	44.63

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers
** Based on the density of the formulation = 1.20 g/cm^3

The formulation FFA SC 508.8 G doesn't contain any safener and synergists.

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
none	-

1.4.2 Information on the active substance (KCP 1.4.2)

Table 1.4-3: Information on substance

Type	Flufenacet
ISO common name	Flufenacet
CAS No.	142459-58-3
EC No.	Not allocated
CIPAC No.	588

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

The formulation FFA SC 508.8 G doesn't contain any safener and synergists.

Co-formulants: CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type : Aqueous Suspension concentrate [Code: SC]

1.6 Function (KCP 1.6)

Herbicide.

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a beige liquid, with no odour. It is not explosive, has no oxidising properties. The product has no flash point up to the boiling point. It has a self-ignition temperature of 417°C. In aqueous solution, it has a pH value around 5.9 at ambient temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed (HDPE). The 2 years storage stability is still on going and will be submitted upon finalization.

The intended concentration of use is:
0.24 L/ha in 100 L/ha - 400 L/ha = 0.06% - 0.24%
0.48 L/ha in 100 L/ha - 400 L/ha = 0.12% - 0.48%

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Reference:	**KCP Section 12/01**
Title:	Flufenacet SC 508.8 (508.8 g/L)
Report:	Anon.; 2021; M-761606-01-1
Authority registration No:	--
Guideline(s):	--
Deviations:	--
GLP/GEP:	Not applicable
Acceptability:	Yes
Duplication (if vertebrate study):	--

Reference:	**KCP Section 12/02**
Title:	Flufenacet TC
Report:	Anon.; 2019; M-359892-05-1
Authority registration No:	--
Guideline(s):	--
Deviations:	--
GLP/GEP:	Not applicable
Acceptability:	Yes
Duplication (if vertebrate study):	--

Notifier Proposals for Risk and Safety Phrases (KCP 12)

There is no specific proposal linked to the physical chemical part.

Hazard pictograms:	
Signal word:	**Warning**

Hazard statements

H302	Harmful if swallowed
H373	May cause damage to organs (Nervous system) through prolonged or repeated exposure if swallowed.
H410	Very toxic to aquatic life with long lasting effects

EUH208	Contains Flufenacet, 1,2-benzisothiazolin-3-one, 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one. May produce an allergic reaction
EUH401	To avoid risks to human health and the environment, comply with the instructions for use.

Precautionary statements

P260	Do not breathe gas/ mist/vapours/ spray.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P308 + P311	IF exposed or concerned: Call a POISON CENTER/ doctor/ physician.
P391	Collect spillage.
P501	Dispose of contents/container in accordance with local regulation.

Compliance with FAO specifications:

The product FFA SC 508.8 G complies with FAO specifications for a SC formulation type.

Formulation used for tests

The following batches have been used in the physico-chemical studies:
102000007779, Batch 2020-010174; 511.0 g/L flufenacet

Composition of all these batches are described in Part C

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	USEPA OCSPP 830.6302 830.6303 830.6304	102000007779 Batch: 2020-010174	Physical state: liquid, opaque Colour: beige Odour: odourless	Y	Hoppe, M. 2021 M-770211-01-1	Accepted.
Explosive properties (KCP 2.2.1)	UN-MTC Appendix 6, point A6.3 US EPA OCSPP 830.6316 DIN 51007	102000007779 Batch: 2020-010174	Not explosive The total heat release of the exothermic effects during the screening DSC measurement is below the threshold of 500 J/g.	Y	Heinz, U. 2021 M-767061-01-1	Accepted. FFA SC 508.8 G has no explosive properties.
Oxidizing properties (KCP 2.2.2)	UN O.2	102000007779 Batch: 2020-010174	The test item is to be classified to have no oxidizing properties according to UN-MTC.	Y	Heinz, U. 2021 M-767061-01-1	Accepted. FFA SC 508.8 G has no oxidising properties.
Flash point (KCP 2.3.1)	EC A:9	102000007779 Batch: 2020-010174	No flash point up to 95°C	Y	Heinz, U. 2021 M-767061-01-1	Accepted.
Flammability (KCP 2.3.2)	-	-	Not required as the formulation is not a solid nor a gas.	-	-	-
Self-heating (KCP 2.3.3)	EC A15 (liquids) DIN EN 14522 DIN EN ISO/IEC 80079-20-1	102000007779 Batch: 2020-010174	The Auto-ignition temperature has been found to be 417°C.	Y	Heinz, U. 2021 M-767061-01-1	Accepted.
	UN-MTC Appendix 6, point A6.5.1 US EPA OCSPP 830.6316 DIN 51007	102000007779 Batch: 2020-010174	The test item has no self-reactive behavior. The total heat release of the exothermic effects during the screening DSC measurement is below the threshold of 300 J/g.	Y	Heinz, U. 2021 M-767061-01-1	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT191 pH undiluted: CIPAC MT75.3 OCSPP830.7000	102000007779 Batch: 2020-010174	Acidity/alkalinity not required as the preparation is neither strongly acidic (pH < 4) nor strongly alkaline (pH > 10). pH = 6.1 (undiluted at 25 °C ± 5 °C)	Y	Hoppe, M. 2021 M-770211-01-1	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT75.3 OCSPP830.7000	102000007779 Batch: 2020-010174	In de-ionised water pH = 5.9 (1 % in de-ionised water at 25 °C ± 5 °C)	Y	Hoppe, M. 2021 M-770211-01-1	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Viscosity (KCP 2.5.1)	CIPAC MT 192 OECD 114 OCSPP 830.7100	102000007779 Batch: 2020-010174	**Dynamic viscosity:** at 20°C 623·10^{-3} Pa·s at shear rate 20 1/s 302·10^{-3} Pa·s at shear rate 100 1/s at 40°C 470·10^{-3} Pa·s at shear rate 20 1/s 202·10^{-3} Pa·s at shear rate 100 1/s **kinematic viscosity:** at 20°C 515·10^{-6} m²/s at shear rate 20 1/s 250·10^{-6} m²/s at shear rate 100 1/s at 40°C 392·10^{-6} m²/s at shear rate 20 1/s 168·10^{-6} m²/s at shear rate 100 1/s	Y	Hoppe, M. 2021 M-770211-01-1	Accepted.
Surface tension (KCP 2.5.2)	OECD115 EC A.5	102000007779 Batch: 2020-010174	1 g/L in Milli-Q Water at 20°C: 41 mN/m Undiluted at 25°C: 37 mN/m	Y	Hoppe, M. 2021 M-770211-01-1	Accepted.
Relative density (KCP 2.6.1)	OECD 109 EC A.3 OCSPP 830.7300	102000007779 Batch: 2020-010174	D_4^{20} = 1.208 D_4^{40} = 1.199	Y	Hoppe, M. 2021 M-770211-01-1	Accepted.
Bulk density (KCP 2.6.2)	-	-	No study provided since this is only required for a solid formulation.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT46.3 OCSPP 830.6317	102000007779 Batch: 2020-010174	Stable throughout the test period of 14 days at 54°C with respect to active substance content, appearance, pH, relative density, spontaneity of dispersion, suspensibility, wet sieving, particle size distribution, pourability, persistent foaming and packaging stability. Packaging material: HDPE For detailed results refer to Table 2-1 below.	Y	Hoppe, M. 2021 M-770211-01-1	The product showed no significant physical changes after accelerated storage. Taking in to account the results of the pourability test triple rinsing with tap water is recommended. No significant changes were observed in the HDPE packaging and therefore it can be concluded that the test item was not corrosive to the container material. No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE.
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	The formulated is stable throughout the test period of 14 days at 54°C. Please refer to KCP 2.7.1.	-	-	The formulated is stable throughout the test period of 14 days at 54°C. Please refer to KCP 2.7.1.
Minimum content after heat stability testing (KCP 2.7.3)	analytical method AM036120MF1	102000007779 Batch: 2020-010174	The active substance content did not decline to less than 95% of the content prior to the test. (packaging material: HDPE).	Y	Hoppe, M. 2021 M-770211-01-1	Accepted.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT39.3	102000007779 Batch: 2020-010174	Stable throughout the test period of 7 days at 0 °C with respect to wet sieving and suspensibility. For detailed results refer to Table 2-1 below.	Y	Hoppe, M. 2021 M-770211-01-1	Accepted.
Ambient temperature shelf life (KCP 2.7.5)	-	-	The two-year shelf-life study is still ongoing and will be submitted upon finalization.	-	-	The final Ambient temperature study is currently ongoing, and should be provided upon completion.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not required as shelf life at ambient temperature is expected to be stable at least 24 months.	-	-	Ambient temperature study is currently ongoing, and should be provided upon completion.
Wettability (KCP 2.8.1)	-	-	No study provided since this is only required for a solid formulation	-	-	-
Persistence of foaming (KCP 2.8.2)	CIPAC MT47.3	102000007779 Batch: 2020-010174	**0.01% v/v** in CIPAC D water: after 10 sec 17 mL after 1 min 12 mL after 3 min 11 mL after 12 min 10 mL **0.3% v/v** in CIPAC D water: after 10 sec 52 mL after 1 min 47 mL after 3 min 42 mL after 12 min 40 mL	N	Hoppe, M. 2021 M-770211-01-1	Accepted.
Suspensibility (KCP 2.8.3.1)	CIPAC MT184.1 analytical method AM036120MF1	102000007779 Batch: 2020-010174	**0.01% v/v** in CIPAC D water: Flufenacet: 99% **0.3% v/v** in CIPAC D water: Flufenacet: 99%	N	Hoppe, M. 2021 M-770211-01-1	Accepted.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT160 (SC) analytical method AM036120MF1	102000007779 Batch: 2020-010174	CIPAC D water Flufenacet: 92%	N	Hoppe, M. 2021 M-770211-01-1	Accepted.
Dispersion stability (KCP 2.8.3.3)	-	-	No study provided since this is only required for SE / OD formulations	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	No study provided since this is only required for water soluble formulations	-	-	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	102000007779 Batch: 2020-010174	d(0.1): 1.15 µm d(0.5): 2.85 µm d(0.9): 6.05 µm	Y	Hoppe, M. 2021 M-770211-01-1	Accepted.
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	102000007779 Batch: 2020-010174	On a 75 µm sieve: < 0.01%	N	Hoppe, M. 2021 M-770211-01-1	Accepted.
Dust content (KCP 2.8.5.2.1)	-	-	No study provided since this is only required for granular formulations.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Particle size of dust (KCP 2.8.5.2.2)	-	-	No study provided since this is only required for granular formulations.	-	-	-
Attrition (KCP 2.8.5.3)	-	-	No study provided since this is only required for granular formulations.	-	-	-
Hardness and integrity (KCP 2.8.5.4)	-	-	No study provided since this is only required for tablet formulations.	-	-	-
Emulsifiability (KCP 2.8.6.1)	-	-	No study provided since this is only required for formulations forming emulsions.	-	-	-
Emulsion stability (KCP 2.8.6.2)	-	-	No study provided since this is only required for formulations forming emulsions.	-	-	-
Re-emulsifiability (KCP 2.8.6.3)	-	-	No study provided since this is only required for formulations forming emulsions.	-	-	-
Flowability (KCP 2.8.7.1)	-	-	No study provided since this is only required for granular formulations.	-	-	-
Pourability (KCP 2.8.7.2)	CIPAC MT148	102000007779 Batch: 2020-010174	Residue: 5.87% First rinsed residue: 0.93% Second rinsed residue: 0.22%	N	Hoppe, M. 2021 M-770211-01-1	Accepted. Taking in to account the results of the pourability test triple rinsing with tap water is recommended.
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Only for dustable powders.	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Where relevant please refer to local recommendations.	-	-	-
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Where relevant, please refer to local recommendations.	-	-	-
Adhesion to seeds (KCP 2.10.1)	-	-	No study provided since this is only required for seed treatment formulations.	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	No study provided since this is only required for seed treatment formulations.	-	-	-
Other/special studies (KCP 2.11)	-	-	There is no other / special study.	-	-	-

Results referring to the point KCP 2.7.1: Storage stability after 14 days at 54 °C

Test	Initial	14 days at 54°C
Content of active flufenacet method AM036120MF1 For a full validation details please refer to the Section 5.	42.3% w/w 511.0 g/L	42.1% w/w 508.6 g/L
Packaging stability (HDPE) OCSPP 830.6320	No negative effects observed	No negative effects observed
Weight change	-	< 0.1% no significant change
Deformation of packaging	no panelling, no ballooning	no panelling, no ballooning Immediately after removal from storage of the sample, the bottom of the bottle was flat. After cooling to ambient temperature for 24 hours the bottom of the bottle was in original form. Stable standing of the bottle was given at any time.
Leakage	no leakage	no leakage
Effect on closure	leak proof	leak proof
Packaging/preparation interaction	no claying, no sedimentation	no claying, no sedimentation
Appearance	Physical state: liquid, opaque Colour: beige Odour: odourless	Physical state: liquid, opaque Colour: beige, light Odour: odourless
pH-value (at 25 °C ± 5 °C) CIPAC Handbook MT 75.3 OCSPP 830.7000	Undiluted	
	6.1	6.0
	1% in de-ionised water	
	5.9	5.7
Relative density EC A.3 OECD 109 OCSPP 830.7300	D_4^{20} 1.208	D_4^{20} 1.208
Persistence of foam CIPAC Handbook MT 47.3	0.01% v/v in CIPAC standard water D	
Foam after 10 s Foam after 1 min Foam after 3 min Foam after 12 min	17 mL 12 mL 11 mL 10 mL	21 mL 15 mL 13 mL 11 mL
Persistence of foam CIPAC Handbook MT 47.3	0.3% v/v in CIPAC standard water D	
Foam after 10 s Foam after 1 min Foam after 3 min Foam after 12 min	52 mL 47 mL 42 mL 40 mL	51 mL 43 mL 38 mL 33 mL
Suspensibility CIPAC Handbook MT 184.1 method AM036120MF1	0.01% v/v in CIPAC standard water D	
	99.0%	98%
	0.3% v/v in CIPAC standard water D	
	99%	89%

Test	Initial	14 days at 54°C
Spontaneity of dispersion CIPAC Handbook MT 160	92%	95%
Wet sieving CIPAC Handbook MT 160	<0.01% residue on a 75 µm sieve	0.04% residue on a 75 µm sieve
Particle size distribution CIPAC Handbook MT 187	d(0.1): 1.15 µm d(0.5): 2.85 µm d(0.9): 6.05 µm	d(0.1): 1.50 µm d(0.5): 5.80 µm d(0.9): 13.7 µm*
Pourability CIPAC Handbook MT 148 Residue First rinsed residue Second rinsed residue	 5.87% 0.93%** 0.22%	 4.77% 0.60%** 0.15%

* It is normal for particle size to change over time and therefore an aged stressed sample may not be within existing manufacturing limits. The stability of the formulation is not affected as the other data show.
**According to guidelines an acceptable limit would be maximal 0.25% rinsed residue. The increased value for rinsed residue according to CIPAC MT 148 can be neglected due to the fact that the rinsed residue was carried out with an additional second rinsing process to demonstrate that the triple rinse procedure, which is well established in practice, will lead to acceptable results.

Results referring to the point KCP 2.7.4: cold storage stability 7 days at 0 °C

Test	Initial	After 7 Days at 0 °C and three hours warming up to room temperature
Suspensibility CIPAC Handbook MT 184 method AM036120MF1	0.01% v/v in CIPAC standard water D	
	99.0%	98%
	0.3% v/v in CIPAC standard water D	
	99.0%	99%
Wet Sieving CIPAC Handbook MT 185	< 0.01% residue on a 75 µm sieve	0.02% residue on a 75 µm sieve

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

The nature and characteristics of the packaging: information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproffness, resistance to normal transport and handling, resistance to and compatibility with the contents of the packaging, have been submitted, evaluated and are considered to be acceptable.

Comments of zRMS:	Ambient temperature study is currently ongoing, will be provided upon completion. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Extrapolation from HDPE to HDPE/EVOH and HDPE/PA is acceptable.

Table 4.1-1: Packaging information for 1 litre bottle

Type	Description
Material:	HDPE or coex HDPE/EVOH
Shape/size:	cylindrical / 88.5 x 244.5 mm
Opening:	45 mm inner diameter
Closure:	Screw cap
Seal:	HF seal, Foam Disc
Manner of construction	extruded

Type	Description
UN/ADR	compliant

Table 4.1-2: Packaging information for 3 litres bottle

Type	Description
Material:	HDPE or coex HDPE/PA
Shape/size:	rectangular / 190 x 140 x 236 mm
Opening:	57.8 mm inner diameter
Closure:	Screw cap
Seal:	HF seal, Foam Disc
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information for 5 litres bottle

Type	Description
Material:	HDPE or coexHDPE/PA
Shape/size:	rectangular / 190 x 140 x 309 mm
Opening:	57.8 mm inner diameter
Closure:	Screw cap
Seal:	HF seal, Foam Disc
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information for 10 litres bottle

Type	Description
Material:	HDPE or coexHDPE/PA
Shape/size:	rectangular / 226 x 186 x 370 mm
Opening:	57.8 mm inner diameter
Closure:	Screw cap
Seal:	HF seal, Foam Disc
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 15 litres bottle

Type	Description
Material:	HDPE or coexHDPE/PA
Shape/size:	rectangular / 245 x 225 x 404 mm
Opening:	57.8 mm inner diameter
Closure:	Screw cap
Seal:	HF seal,
Manner of construction	extruded
UN/ADR	compliant

Complying with CropLife International recommendation for one way agrochemical packaging design criteria for liquids and solids [Guidelines for the safe formulation and packaging of crop protection products (Guideline 6)].

Resistance of the packaging material:
The material proposed for use (High Density Polyethylene – HDPE, Coex HDPE/PA and Coex HDPE/EVOH) are known from experience to be compatible with water-based formulations and are resistant to the influences of chemicals. However, the resistance of the packaging material to its contents has been tested in the accelerated storage stability studies in accordance with CropLife International Technical Monograph No 17 (June 2009). The results show that no detrimental effects were noted thus demonstrating the acceptability of the packaging material.

4.2 Procedures for Cleaning Application Equipment

4.2.1 Effectiveness of the cleaning procedures

Comments of zRMS:	Taking in to account the results of the accelerated storage study (storage stability after 14 days at 54°C) triple rinsing with tap water is recommended.

Reference:	**KCP 4.2/01**
Title:	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000 – 2008.
Report:	Friessleben, R.; 2008; M-357166-01-1
Authority registration No:	--
Guideline(s):	not specified
Deviations:	--
GLP/GEP:	not applicable
Acceptability:	Yes
Duplication (if vertebrate study):	--

The report summarizes the results of trials on tank cleaning realized in the years 2000 - 2008. These trials were carried out because registration of crop protection products requires specific information on the cleaning of sprayer tanks to avoid damages during subsequent treatments.
During this period, 72 studies were conducted, in which a total of 60 active substances (16 fungicides, 33 herbicides, 3 safeners, 7 insecticides and 1 growth regulator) were tested. All tests were done with the same spraying equipment and under the same test protocol, thus the differences found in the results reflect the different behavior of active substances and formulation systems.

Within this report it has been shown that cleaning efficacy does not depend on chemical or formulation related parameters and therefore a global statement on tank cleaning efficacy is justified. The results can be summarized as follows:
1. The established cleaning procedure, including two rinsing processes and the careful cleaning of all filters, is able to remove or reduce active substances leftover down to neglectable quantities.
2. By following the tank cleaning recommendation product groups (herbicides, fungicides, insecticides, and growth regulators), formulations and concentrations differ only quantitatively. The cleaning success follows an exponential function of the general formula $y = a\, e^{-bx}$. From one cleaning step to the next one, the initial concentration is reduced by at least one order of magnitude.
3. After filling the tank with fresh water, the active substance concentrations in all trials are either below the Limit of Quantification or are not relevant as far as biological effects during follow-up treatments are concerned.
4. According to the extensive number of results available, the recommendations on the product label regarding tank cleaning can apply equally to all products.

As a conclusion it can be proposed that no further studies for individual formulations need to be performed.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 2.1 / 01 **... also filed:** **2.4.1 / 01** **2.4.2 / 01** **2.5.1 / 01** **2.5.2 / 01** **2.6.1 / 01** **2.7.1 / 01** **2.7.3 / 01** **2.7.4 / 01** **2.8.3.1 / 01** **2.8.3.2 / 01** **2.8.5.1.1 / 01** **2.8.5.1.2 / 01** **KCP 2.8.2 / 01** **KCP 2.8.7 / 01**	Hoppe, M.	2021	Storage stability at elevated temperature and cold stability of flufenacet SC 508.8 (508.8 g/L) - Packaging material: HDPE - Final report (14 days). Report No.: FM0415(PKF01)G01, Edition Number: M-770211-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
2.2.1 / 01 **... also filed:** **2.2.2 / 01** **2.3.1 / 01** **2.3.3 / 01**	Heinz, U.	2021	Safety-relevant data of flufenacet SC 508.8 (508.8 g/L) Report No.: 2021/00068, Edition Number: M-767061-01-1 Bayer AG, Leverkusen, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP Section 12 / 01	Anon.	2021	Flufenacet SC 508.8 (508.8 g/L) Report No.: M-761606-01-1 Bayer AG, Leverkusen, Germany GLP/GEP: n.a. unpublished	No	-public data-
KCP Section 12 / 02	Anon.	2019	Flufenacet TC Report No.: M-359892-05-1 Bayer AG, Leverkusen, Germany GLP/GEP: n.a. unpublished	No	-public data-
KCP 4.2 / 01	Friessleben, R.	2008	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000 - 2008 Report No.: M-357166-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: n.a. unpublished	No	Bayer

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Please note that all data mentioned as part of DAR, RAR, or EFSA journals are considered as relied on.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Flufenacet

Not relevant for this submission.