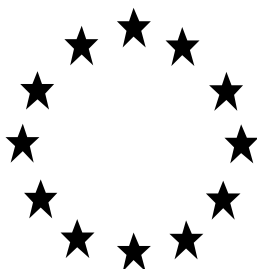


Draft Renewal Assessment Report  
under Regulation (EC) 1107/2009



**FORAMSULFURON**  
**Volume 3 – B.2 (PPP) –**  
**foramsulfuron+isoxadifen-ethyl OD 45**  
**(22.5+22.5 g/L)**

Rapporteur Member State: Finland  
Co-Rapporteur Member State: Slovakia

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## **B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT FORAMSULFURON + ISOXADIFEN-ETHYL OD 45 (22.5+22.5 G/L)**

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 opaque liquid with an aromatic odour. It is not explosive, has no oxidizing properties. It has a self-ignition temperature of 350°C. In aqueous solution, it has a pH value around 5.6. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/PA or HDPE/EVOH is expected. Its technical characteristics are acceptable for an OD formulation.

The intended concentration of use is 0.2% to 1.6%.

The following batches have been used in the physico-chemical studies:

1. Specification 102000011304-06, batch EFKM002442; 2.33 % w/w foramsulfuron, 2.29 % w/w isoxadifen-ethyl.
2. AE F130360 01 1K05 A3, batch AE F130360 01 1K05 A304; 2.42 % w/w foramsulfuron, 2.44 % w/w isoxadifen-ethyl.
3. AEF130360 01 1K05 A3, batch AE F130360 01 1K05 A802, 2.22 % w/w foramsulfuron, 2.30 % w/w isoxadifen-ethyl.

The accelerated storage stability was fully assessed in HDPE/EVOH & HDPE/PA packaging. These packaging materials have an internal barrier layer (see point 4.4). The shelf life storage was fully assessed on an older version of the formulation, in HDPE/PA packaging. The shelf life storage study on the actual version of the formulation is running in HDPE/PA & HDPE/EVOH packaging.

Short codes for the active substances:

FSN = foramsulfuron

IDF=isoxadifen-ethyl

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
<b>B.2.1. APPEARANCE</b>						
Physical state and colour B.2.1/01	USEPA OCSPP 830.6302 830.6303 830.6304	102000011304-06, batch EFKM002442	Physical state: opaque liquid Colour: beige Odour: aromatic, weakly sweetish	Acceptable	Y	KCP 2.1 /04; Rexer, K.; 2013; M-470556-01-1

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
<b>B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES</b>						
<b>Explosive properties B.2.2/01</b>	92/69/EEC, Annex Part A, A14	AEF130360 1K05 A304	No danger of explosion	Acceptable	Y	KCP 2.2 /01; Smeykal, H.; 1999; M-192780-01-1
<b>Oxidizing properties B.2.2/02</b>	92/69/EEC, Annex Part A, A17	AEF130360 01 1K05 A304	The preparation does not contain any oxygen compounds which might have an oxidising effect on combustible materials and does not react exothermically in the range from 25 to 450°C. The decomposition energy is lower than 500 J/g	Acceptable	Y	KCP 2.2 /02; Sixl, F.; Rexer, K.; 2000; M-194573-01-1
<b>B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY</b>						
<b>Flash point of the liquids formulations B.2.3/01</b>	92/69/EEC, Annex Part A, A9	AEF130360 1K05 A304	> 100°C (closed)	Acceptable	Y	KCP 2.3 /01; Bittner, P.; Rexer, K.; 1999;M-192873-01-1
<b>Flammability of solid formulations B.2.3/02</b>			Not relevant for an OD formulation			
<b>Self-heating of formulation B.2.3/03</b>	92/69/EEC, Annex Part A, A15	AEF130360 1K05 A304	Self-ignition temperature: 350°C	Acceptable	Y	KCP 2.3 /02; Smeykal, H.; 1999;M-192779-01-1
<b>B.2.4. ACIDITY/ALKALINITY AND pH VALUE</b>						
<b>pH of the neat aqueous formulation B.2.4/01</b>			pH undiluted not relevant for an OD formulation			
<b>pH of a 1 % dilution of the solid or non-aqueous formulation B.2.4/02</b>	CIPAC MT 75.3 (electrometric determination)	102000011304-06, batch EFKM002442	1 % dilution in distilled water pH = 5.6	Acceptable	Y	KCP 2.1/04 Rexer, K.; 2013; M-470556-01-1
<b>Acidity / Alkalinity B.2.4/03</b>			Acidity/alkalinity not required as the preparation is neither strongly acidic (pH < 4) nor strongly alkaline (pH > 10).			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
<b>B.2.5. VISCOSITY AND SURFACE TENSION</b>						
<b>Kinematic viscosity of the liquid formulation</b> <b>B.2.5/01</b>	OECD 114 CIPAC MT 192	102000011304-06, batch EFKM002442	Calculation of the kinematic viscosity at 40 °C from the dynamic viscosity values and the density. $\nu = 18 \cdot 10^{-6} \text{ m}^2/\text{s}$ at 20 °C $\nu = 14 \cdot 10^{-6} \text{ m}^2/\text{s}$ at 100 °C	Acceptable. However, this ppp needs to be classified as an aspiration hazardous compound (according to CLP), because one of its co-formulants is classified in Category 1 (see Volume 4), the formulation contains > 10% of it, and the kinematic viscosity of the formulation at 40 °C is < 20.5 mm <sup>2</sup> /s. <b>Classification „H304 May be fatal if swallowed and enters airways,, will be required</b>	Y	KCP 2.1/04; Rexer, K.; 2013; M-470556-01-1
<b>Dynamic viscosity of the liquid formulation</b> <b>B.2.5/02</b>	OECD 114 CIPAC MT 192	102000011304-06, batch EFKM002442	Rotating viscometer: 26·10 <sup>-3</sup> Pa.s at 20 °C, at 20 1/s 25·10 <sup>-3</sup> Pa.s at 20 °C, at 100 1/s 17·10 <sup>-3</sup> Pa.s at 40 °C, at 20 1/s 14·10 <sup>-3</sup> Pa.s at 40 °C, at 100 1/s	Acceptable	Y	KCP 2.1/04; Rexer, K.; 2013; M-470556-01-1
<b>Surface tension of the formulation</b> <b>B.2.5/03</b>	92/69/EEC A.5 OECD 115	102000011304-06, batch EFKM002442	32 mN.m <sup>-1</sup> at a dilution of 1 g/L (20°C) 33 mN.m <sup>-1</sup> undiluted (25 °C)	Acceptable. The product is surface active.	Y	KCP 2.1/04; Rexer, K.; 2013-; M-470556-01-1
<b>B.2.6. RELATIVE DENSITY AND BULK DENSITY</b>						
<b>Relative density of the liquid formulation</b> <b>B.2.6/01</b>	OECD 109 EC A3 OPPTS 830.7300	102000011304-06, batch EFKM002442	D <sub>4</sub> <sup>20</sup> = 0.960 at 20 °C D <sub>4</sub> <sup>40</sup> = 0.946 at 40 °C	Acceptable	Y	KCP 2.1/04; Rexer, K.; 2013; M-470556-01-1
<b>Bulk density (pour and tap) of powder or granules</b> <b>B.2.6/02</b>			No study provided since this is only required for a solid formulation			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results					Comments (Acceptable / Non acceptable)	GLP	Reference																				
B.2.7. STORAGE STABILITY AND SHELF-LIFE: EFFECTS OF TEMPERATURE ON TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT																														
Stability after accelerated storage (54°C during 14 days, 8 weeks at 40°C, 12 weeks at 35°C or 18 weeks at 30°C) B.2.7/01	CIPAC MT46	102000011304-06, batch EFKM002442	Stable throughout the test period of 14 days at 54 °C except degradation of foramsulfuron see below (tested parameters: active substance contents, water content, appearance, pH, persistence of foam, suspensibility, wet sieving, dispersion stability, pourability).  Packaging material: HDPE/PA, HDPE/EVOH  Please refer to Tables 2.7-1 and 2.7.2 for detailed results					Acceptable  Content of foramsulfuron decreased by 7.2%; degradation products are identified	Y	KCP 2.7 /03; Rexer, K.; 2013; M-470580-02-1; Amended: 2013-12-11																				
								Content of foramsulfuron decreased by 6.8%; degradation products are identified		KCP 2.7 /04; Rexer, K.; 2013;M-470568-02-1; Amended: 2013-12-11																				
Accelerated Storage Stability: other storage conditions B.2.7/02	CIPAC MT46	102000011304-06, batch EFKM002442	Stable throughout the test periods of 8 weeks at 40 °C (tested parameters: active substance contents, water content, appearance, pH, persistence of foam, suspensibility, wet sieving, dispersion stability, pourability).  Packaging material: HDPE/PA, HDPE/EVOH  Please refer to Tables 2.7-1 and 2.7.2 for detailed results					Acceptable	Y	KCP 2.7 /03; Rexer, K.; 2013; M-470580-02-1; Amended: 2013-12-11																				
										KCP 2.7 /04; Rexer, K.; 2013;M-470568-02-1; Amended: 2013-12-11																				
AS content after accelerated storage B.2.7/03	AM021113MF1	102000011304-06, batch EFKM002442	<table><tr><td></td><td>FSN (g/L)</td><td>IDF (g/L)</td><td>Degradation rate FSN (%)</td><td>Degradation rate IDF (%)</td></tr><tr><td>Initial</td><td>22.2</td><td>22.3</td><td>-</td><td>-</td></tr><tr><td>14 Days 54 °C</td><td>20.6 (20.7)</td><td>22.4 (22.2)</td><td>7.2(6.8)</td><td>-0.44 (0.45)</td></tr><tr><td>8 weeks 40 °C</td><td>21.4 (21.2)</td><td>21.8 (21.8)</td><td>3.6 (4.5)</td><td>2.24 (2.24)</td></tr></table>						FSN (g/L)	IDF (g/L)	Degradation rate FSN (%)	Degradation rate IDF (%)	Initial	22.2	22.3	-	-	14 Days 54 °C	20.6 (20.7)	22.4 (22.2)	7.2(6.8)	-0.44 (0.45)	8 weeks 40 °C	21.4 (21.2)	21.8 (21.8)	3.6 (4.5)	2.24 (2.24)	Acceptable. However, the degradation rate of foramsulfuron is above the maximum recommended value of 5% at 54 °C.	Y	KCP 2.7 /03; Rexer, K.; 2013; M-470580-02-1; Amended: 2013-12-11
				FSN (g/L)	IDF (g/L)	Degradation rate FSN (%)	Degradation rate IDF (%)																							
			Initial	22.2	22.3	-	-																							
			14 Days 54 °C	20.6 (20.7)	22.4 (22.2)	7.2(6.8)	-0.44 (0.45)																							
			8 weeks 40 °C	21.4 (21.2)	21.8 (21.8)	3.6 (4.5)	2.24 (2.24)																							
HDPE/PA (HDPE/EVOH)																														

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference												
						KCP 2.7 /04; Rexer, K.; 2013;M-470568-02-1; Amended: 2013-12-11												
Effect of low temperature on stability of liquid formulation B.2.7/04	CIPAC MT 39	102000011304-06, batch EFKM002442	Stable throughout the test period of 7 days at 0 °C (tested parameters:, suspensibility, wet sieving, dispersion stability). Please refer to Table 2.7-3 for detailed results	Acceptable	Y	KCP 2.7 /04; Rexer, K.; 2013;M-470568-02-1; Amended: 2013-12-11												
Shelf life following storage at ambient temperature B.2.7/05	CIPAC MT46	AE F130360 1K05 A3, batch AE F130360 1K05 A304	Tested parameters: active substance contents, appearance, pH, foam, wet sieving, suspensibility, spontaneity of dispersion, pourability. Please refer to Table 2.7-4 for detailed results. Packaging material: HDPE/ PA. <table><tr><td></td><td>FSN</td><td>IDF</td></tr><tr><td>Initial:</td><td>2.42 %</td><td>2.44 %</td></tr><tr><td>2 years ambient:</td><td>2.26 %</td><td>2.35 %</td></tr><tr><td>Degr. rate:</td><td>6.6 %</td><td>3.7 %</td></tr></table> A new study is running on specification 102000011304-06, batch EFKM002442 (in HDPE/PA & HDPE/EVOH)		FSN	IDF	Initial:	2.42 %	2.44 %	2 years ambient:	2.26 %	2.35 %	Degr. rate:	6.6 %	3.7 %	Content of foramsulfuron decreased by 6.6%; no major changes in the tested physical properties were detectable. The results are acceptable.  The applicant has been contacted and asked about the timetable of the test. According to the answer, the 2- year storage stability studies will be available by end of year 2015. Thus the shelf life test is considered as a data gap.	N	KCP 2.7 /05; Sixl, F.; Rexer, K.; 2001;M-206624-01-1
	FSN	IDF																
Initial:	2.42 %	2.44 %																
2 years ambient:	2.26 %	2.35 %																
Degr. rate:	6.6 %	3.7 %																



Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
<b>B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT</b>						
<b>B.2.8.1. Wettability</b>						
Wettability of solid formulation B.2.8.1/01			No study provided since this is only required for a solid formulation			
<b>B.2.8.2. Persistence foaming</b>						
Persistence of foaming of the diluted formulation B.2.8.2/01	CIPAC MT 47.2	102000011304-06, batch EFKM002442	After 1 min. in CIPAC D water. dilution: 1.6% 5 mL	Acceptable	Y	KCP 2.1/04; Rexer, K.; 2013;M-470556-01-1
<b>B.2.8.3. Suspensibility</b>						
Suspensibility of water dispersible formulation B.2.8.3/01	CIPAC MT184 + AM021113MF1	102000011304-06, batch EFKM002442	In CIPAC D water. dilution: 0.2% FSN        IDF 100 %     100 % dilution: 1.6% FSN        IDF 99%        100 %	Acceptable	Y	KCP 2.1/04; Rexer, K.; 2013;M-470556-01-1
Spontaneity of dispersion of water dispersible formulation B.2.8.3/02			No study provided since this is not required for an OD formulation			
Dispersion stability of SE, OD or EG formulation B.2.8.3/03	CIPAC MT180	102000011304-06, batch EFKM002442	The stability of the emulsion was assessed in CIPAC water D and A and at two concentrations (dose: 0.2% & dose: 1.6%). The results were identical for all tests as shown below: Dispersion after: 0 min            complete 30 min           no sediment, no oil, max 0.20 mL cream Re-dispersibility after:	Acceptable	Y	KCP 2.1/04, Rexer, K.; 2013;M-470556-01-1

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			24 h complete 24.5 h no sediment, no oil, max 0.25 mL cream			
<b>B.2.8.4. Degree of dissolution and dilution stability</b>						
Degree of dissolution of water soluble formulation B.2.8.4/01			No study provided since this is not required for an OD formulation			
Dilution stability of water soluble formulation B.2.8.4/02			No study provided since this is not required for an OD formulation			
<b>B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability</b>						
<b>B.2.8.5.1. Particle size distribution</b>						
Wet sieve test of water dispersible formulation B.2.8.5.1/01	CIPAC MT185	102000011304-06, batch EFKM002442	0.012 % residue on a 75 µm sieve	Acceptable	Y	KCP 2.1/04; Rexer, K.; 2013;M-470556-01-1
Size distribution of particles of powder or suspension concentrate formulation B.2.8.5.1/02	CIPAC MT187	102000011304-06, batch EFKM002442	Laser diffraction d (0.1) = 1.04 µm d (0.5) = 3.04 µm d (0.9) = 10.41 µm	Acceptable	Y	KCP 2.1/04 Rexer, K.; 2013;M-470556-01-1
Nominal size range of granule B.2.8.5.1/03			No study provided since this is only required for granular formulations			
<b>B.2.8.5.2. Dust content</b>						
Dust content of granular formulation B.2.8.5.2/01			No study provided since this is only required for granular formulations			
<b>B.2.8.5.3. Attrition</b>						
Attrition characteristics of granules and tablets B.2.8.5.3/01			No study provided since this is only required for granular formulations			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
<b>B.2.8.5.4. Hardness and integrity</b>						
Hardness of tablets B.2.8.5.4/01			No study provided since this is only required for tablets formulations			
Integrity of tablets B.2.8.5.4/02			No study provided since this is only required for tablets formulations			
<b>B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability</b>						
Emulsifiability, emulsion stability and re-emulsifiability of formulation B.2.8.6/01			No study provided since this is not required for an OD formulation			
<b>B.2.8.7. Flowability, pourability and dustability</b>						
Flowability of granular formulation B.2.8.7/01			No study provided since this is only required for granular formulations			
Pourability of suspensions B.2.8.7/02	CIPAC MT 148	102000011304-06, batch EFKM002442	Residue: 0.71% Rinsed residue: 0.16%	Acceptable	Y	KCP 2.1/04; Rexer, K.; 2013;M-470556-01-1
Dustability of dustable powders after accelerated storage B.2.8.7/03			Only for dustable powders			
<b>B.2.9. PHYSICAL AND CHEMICAL COMPATIBILITY WITH OTHER PRODUCTS INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED</b>						
Physical and chemical compatibility of tank mixtures B.2.9/01		AEF130360 1K05 A304	Physical and chemical compatibility is given for the tank mixtures with Lido SC, Gardobuc, Terano, Certrol B, Buctril, Emblem/Saxo, Mikado, Zintan fluessig pack, Stentan, Eclat, Pendimox, Banvel 4S, Harpun, Tactril Pack, Frontier, Lentagran 600, Basfoliar 36 extra, Basfoliar 34, Basfoliar 12+4+6 and Solubor DF. Mixtures with Certrol B and Duogranol are evaluated to have a limited physical compatibility	Acceptable	N	KCP 2.9 /01; Jacob, T.; Rexer, K.; 2000;M-194594-01-1

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			Where relevant please refer to local recommendations.			
<b>B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS</b>						
Distribution and adhesion to seeds B.2.9.10/01			No study provided since this is only required for seed treatment formulations			
<b>B.2.11. OTHER STUDIES</b>						
			No other studies			

Table 2.7-1: Detailed results: Accelerated storage stability study(ies) in HDPE/PA

Test/Method	Initial	14 days at 54°C	8 weeks at 40°C
<b>Content of active (analytical method AM021113MF1)</b>	22.2 g/L	20.6 g/L	21.4 g/L
foramsulfuron			
<b>Content of degradation product (analytical method AM020213MF1)</b>			
AE F092944	0.0094%	0.0467%	Not required
AE F153745	0.0118%	0.0532%	Not required
AE F130619	0.0053%	0.0066%	Not required
<b>Content of active (analytical method AM021113MF1)</b>	22.3 g/L	22.4 g/L	21.8 g/L
Isoxadifen-ethyl			
<b>Water content CIPAC MT 30.5</b>	0.12%	0.13%	0.13%
<b>Stability of packaging material OCSPP 830.6320</b>	Not applicable	No deterioration of the packaging material and no adverse interaction with the formulation were observed.	No deterioration of the packaging material and no adverse interaction with the formulation were observed.
Change in weight	Not applicable	-0.005%	+0.006%
Deformation	None	Slight signs of panelling.	Slight signs of panelling.
Leakage	None	No leaking	No leaking
Effect on closure	None	Leak proof	Leak proof
<b>Packaging/preparation interaction</b>	Not applicable	Approximately 15% reversible sedimentation, no claying.	Approximately 12% reversible sedimentation, no claying.
<b>Colour OCSPP 830.6302</b>	Beige	Beige	Beige
<b>Odour OCSPP 830.6304</b>	Aromatic, weakly sweetish	Aromatic	Aromatic
<b>Physical state OCSPP 830.6303</b>	Opaque liquid	Opaque liquid	Opaque liquid
<b>Acidity/alkalinity CIPAC MT 191</b>	The determination was not required as the pH value was between 4.0 and 10.0		
<b>pH value CIPAC MT 75.3 OCSPP 830.7000</b>	1% in deionised water		
	5.6	5.6	5.3
<b>Persistent foaming CIPAC MT 47.3</b>	1.6% w/w (2.6 L/ha in 150 L/ha) in CIPAC standard water D		
Foam after 10s	7 mL	7 mL	5 mL
Foam after 1 min	5 mL	5 mL	4 mL
Foam after 3 min	5 mL	5 mL	4 mL
Foam after 12 min	4 mL	4 mL	4 mL
<b>Suspensibility CIPAC MT 184</b>	0.2% w/w (1.0 L/ha in 400 L/ha) in CIPAC standard water D		
foramsulfuron	100%	100%	100%
isoxadifen-ethyl	100%	100%	100%
<b>Suspensibility CIPAC MT 184</b>	1.6% w/w (2.6 L/ha in 150 L/ha) in CIPAC standard water D		
foramsulfuron	99%	99%	99%
isoxadifen-ethyl	100%	100%	100%
<b>Wet sieve test CIPAC MT 187</b>	Residue on 75 µm		
	0.012%	0.004%	

<b>Particle size distribution</b> CIPAC MT 180	d(0.1) 1.04 µm d(0.5) 3.04 µm d(0.9) 10.41 µm	d(0.1) 1.14 µm d(0.5) 3.20 µm d(0.9) 10.91 µm	d(0.1) 1.12 µm d(0.5) 3.09 µm d(0.9) 9.89 µm
<b>Dispersion stability</b> CIPAC MT 180	0.2% w/w (1.0 L/ha in 400 L/ha) in CIPAC standard water A		
Initial dispersibility	Completely	Completely	Completely
Separation after 30 min	None	None	None
Re-dispersibility after 24 h	Completely	Completely	Completely
Separation after further 30 min	No sediment, less than 0.05 mL top-cream, no oil	None	None
<b>Dispersion stability</b> CIPAC MT 180	0.2% w/w (1.0 L/ha in 400 L/ha) in CIPAC standard water D		
Initial dispersibility	Completely	Completely	Completely
Separation after 30 min	None	None	None
Re-dispersibility after 24 h	Completely	Completely	Completely
Separation after further 30 min	No sediment, less than 0.05 mL top-cream, no oil	None	None
<b>Dispersion stability</b> CIPAC MT 180	1.6% w/w (2.6 L/ha in 150 L/ha) in CIPAC standard water A		
Initial dispersibility	Completely	Completely	Completely
Separation after 30 min	No sediment 0.20 mL top-cream, no oil	No sediment 0.05 mL top-cream, no oil	No sediment < 0.05 mL top-cream, no oil
Re-dispersibility after 24 h	<b>Completely</b>	Completely	Completely
Separation after further 30 min	No sediment 0.25 mL top-cream, no oil	No sediment 0.05 mL top-cream, no oil	No sediment < 0.05 mL top-cream, no oil
<b>Dispersion stability</b> CIPAC MT 180	1.6% w/w (2.6 L/ha in 150 L/ha) in CIPAC standard water D		
Initial dispersibility	Completely	Completely	Completely
Separation after 30 min	No sediment 0.15 mL top-cream, no oil	No sediment < 0.05 mL top-cream, no oil	No sediment < 0.05 mL top-cream, no oil
Re-dispersibility after 24 h	Completely	Completely	Completely
Separation after further 30 min	No sediment 0.20 mL top-cream, no oil	No sediment < 0.05 mL top-cream, no oil	No sediment < 0.05 mL top-cream, no oil
<b>Pourability</b>			
Residue	0.71%	0.76%	0.64%
Rinsed residue	0.16%	0.19%	0.15%

Table 2.7-2: Detailed results: Accelerated storage stability study(ies) in HDPE/PEVOH

Test/Method	Initial	14 days at 54°C	8 weeks at 40°C
<b>Content of active (analytical method AM021113MF1)</b> foramsulfuron	22.2 g/L	20.7 g/L	21.2 g/L
<b>Content of degradation product (analytical method AM020213MF1)</b>			
AE F092944	0.0094%	0.0467%	Not required
AE F153745	0.0118%	0.0532%	Not required
AE F130619	0.0053%	0.0066%	Not required
<b>Content of active (analytical method)</b>	22.3 g/L	22.2 g/L	21.8 g/L

<b>AM021113MF1)</b>			
Isoxadifen-ethyl			
<b>Water content</b> CIPAC MT 30.5	0.12%	0.12%	0.12%
<b>Stability of packaging material</b> OCSPP 830.6320	Not applicable	No deterioration of the packaging material and no adverse interaction with the formulation were observed.	No deterioration of the packaging material and no adverse interaction with the formulation were observed.
Change in weight	Not applicable	-0.008%	-0.000%
Deformation	None	No ballooning, no panelling.	No ballooning, no panelling..
Leakage	None	No leaking	No leaking
Effect on closure	None	Leak proof	Leak proof
Packaging/preparation interaction	Not applicable	Approximately 15% reversible sedimentation, no claying.	Approximately 9% reversible sedimentation, no claying.
<b>Colour</b> OCSPP 830.6302	Beige	Beige	Beige
<b>Odour</b> OCSPP 830.6304	Aromatic, weakly sweetish	Aromatic	Aromatic
<b>Physical state</b> OCSPP 830.6303	Opaque liquid	Opaque liquid	Opaque liquid
<b>Acidity/alkalinity</b> CIPAC MT 191	The determination was not required as the pH value was between 4.0 and 10.0		
<b>pH value</b> CIPAC MT 75.3 OCSPP 830.7000	1% in deionised water		
	5.6	5.7	5.3
<b>Persistent foaming</b> CIPAC MT 47.3	1.6% w/w (2.6 L/ha in 150 L/ha) in CIPAC standard water D		
Foam after 10s	7 mL	7 mL	5 mL
Foam after 1 min	5 mL	5 mL	4 mL
Foam after 3 min	5 mL	5 mL	4 mL
Foam after 12 min	4 mL	4 mL	4 mL
<b>Suspensibility</b> CIPAC MT 184	0.2% w/w(1.0 L/ha in 400 L/ha) in CIPAC standard water D		
foramsulfuron	100%	100%	100%
isoxadifen-ethyl	100%	100%	100%
<b>Suspensibility</b> CIPAC ?T 184	1.6% w/w (2.6 L/ha in 150 L/ha) in CIPAC standard water D		
foramsulfuron	99%	99%	99%
isoxadifen-ethyl	100%	100%	100%
<b>Wet sieve test</b> CIPAC MT 187	Residue on 75 µm		
	0.012%	0.004%	0.002%
<b>Particle size distribution</b> CIPAC MT 180	d(0.1) 1.04 µm d(0.5) 3.04 µm d(0.9) 10.41 µm	d(0.1) 1.14 µm d(0.5) 3.20 µm d(0.9) 10.91 µm	d(0.1) 1.12 µm d(0.5) 3.09 µm d(0.9) 9.89 µm
<b>Dispersion stability</b> CIPAC MT 180	0.2% w/w(1.0 L/ha in 400 L/ha) in CIPAC standard water A		
Initial dispersibility	Completely	Completely	Completely
Separation after 30 min	None	None	None
Re-dispersibility after 24 h	Completely	Completely	Completely
Separation after further 30 min	No sediment < 0.05 mL top-cream, no oil	None	None
<b>Dispersion stability</b> CIPAC MT 180	0.2% w/w(1.0 L/ha in 400 L/ha) in CIPAC standard water D		

Initial dispersibility	Completely	Completely	Completely
Separation after 30 min	None	None	None
Re-dispersibility after 24 h	Completely	Completely	Completely
Separation after further 30 min	No sediment < 0.05 mL top-cream, no oil	None	None
<b>Dispersion stability</b> CIPAC MT 180	1.6% w/w (2.6 L/ha in 150 L/ha) in CIPAC standard water A		
Initial dispersibility	Completely	Completely	Completely
Separation after 30 min	No sediment 0.20 mL top-cream, no oil	No sediment 0.05 mL top-cream, no oil	No sediment < 0.05 mL top-cream, no oil
Re-dispersibility after 24 h	<b>Completely</b>	Completely	Completely
Separation after further 30 min	No sediment 0.25 mL top-cream, no oil	No sediment 0.05 mL top-cream, no oil	No sediment < 0.05 mL top-cream, no oil
<b>Dispersion stability</b> CIPAC MT 180	1.6% w/w (2.6 L/ha in 150 L/ha) in CIPAC standard water D		
Initial dispersibility	Completely	Completely	Completely
Separation after 30 min	No sediment 0.15 mL top-cream, no oil	No sediment < 0.05 mL top-cream, no oil	No sediment < 0.05 mL top-cream, no oil
Re-dispersibility after 24 h	Completely	Completely	Completely
Separation after further 30 min	No sediment 0.20 mL top-cream, no oil	No sediment < 0.05 mL top-cream, no oil	No sediment < 0.05 mL top-cream, no oil
<b>Pourability</b>			
Residue	0.71%	0.76%	0.64%
Rinsed residue	0.16%	0.19%	0.15%

Table 2.7-3: Detailed results: Cold stability study

<b>Test/Method</b>	<b>Initial</b>	<b>7 days 0°C</b>
<b>Suspensibility</b> CIPAC 184	0.2% w/w (1.0 L/ha in 400 L/ha) in CIPAC standard water D	
foramsulfuron	100%	100%
isocadifen-ethyl	100%	100%
<b>Suspensibility</b> CIPAC 184	1.6% w/w (2.6 L/ha in 150 L/ha) CIPAC standard water D	
foramsulfuron	99%	99%
isocadifen-ethyl	100%	100%
<b>Wet sieve test</b> CIPAC MT 185	Residue on 75 µm	
	0.012%	0.004%
<b>Dispersion stability</b> CIPAC MT 180	0.2% w/w(1.0 L/ha in 400 L/ha) in CIPAC standard water A	
Initial dispersibility	Completely	Completely
Separation after 30 min	None	None
Re-dispersibility after 24 h	Completely	Completely
Separation after further 30 min	No sediment < 0.05 mL top-cream, no oil	No sediment < 0.05 mL top-cream, no oil
<b>Dispersion stability</b> CIPAC MT 180	0.2% w/w(1.0 L/ha in 400 L/ha) in CIPAC standard water D	
Initial dispersibility	Completely	Completely
Separation after 30 min	None	None
Re-dispersibility after 24 h	Completely	Completely
Separation after further 30 min	No sediment < 0.05 mL top-cream, no oil	No sediment < 0.05 mL top-cream, no oil
<b>Dispersion stability</b> CIPAC MT 180	1.6% w/w(2.6 L/ha in 150 L/ha) in CIPAC standard water A	
Initial dispersibility	Completely	Completely



Separation after 30 min	No sediment 0.20 mL top-cream, no oil	No sediment 0.15 mL top-cream, no oil
Re-dispersibility after 24 h	Completely	Completely
Separation after further 30 min	No sediment 0.25 mL top-cream, no oil	No sediment 0.20 mL top-cream, no oil
<b>Dispersion stability</b> CIPAC MT 180	1.6% w/w(2.6 L/ha in 150 L/ha) in CIPAC standard water D	
Initial dispersibility	Completely	Completely
Separation after 30 min	No sediment 0.15 mL top-cream, no oil	No sediment 0.10 mL top-cream, no oil
Re-dispersibility after 24 h	Completely	Completely
Separation after further 30 min	No sediment 0.20 mL top-cream, no oil	No sediment 0.15 mL top-cream, no oil

Table 2.7-4: Detailed results: Ambient storage stability study

<b>Test</b>	<b>Initial</b>	<b>2 years ambient</b>
<b>Content of active substance</b> method AL007/98	2.42% w/w foramsulfuron	2.26% w/w foramsulfuron
<b>Content of active substance</b> method AL007/98	2.44% w/w isoxadifen-ethyl	2.35% w/w isoxadifen-ethyl
<b>Appearance</b> visual estimation at room temperature	beige liquid, no sedimentation	beige liquid, no sedimentation
<b>pH value</b> CIPAC MT 75	5.2	5.3
<b>Persistence of foam</b> CIPAC 47.2	in CIPAC C water 0.1% dilution: no foam after 1 min 1.0% dilution: 2 mL foam after 1 min	in CIPAC C water 0.1% dilution: no foam after 1 min 1.0% dilution: 2 mL foam after 1 min
<b>Spontaneity of dispersion</b> CIPAC MT 160	108% (CIPAC C water)	110% (CIPAC C water)
<b>Wet sieve test</b> CIPAC MT 167	no residue on a 75 µm sieve	no residue on a 75 µm sieve
<b>Pourability</b> CIPAC MT 148	Residue: 2.02% Rinsed residue: 0.42%	Residue: 1.37% Rinsed residue: 0.36%

## B.2.12. REFERENCES RELIED ON

Studies KCP 2.1/01; 2.1/02; 2.1/03; KCP 2.4/01; KCP 2.5/01; 2.5/02; KCP 2.6/01; KCP 2.7/01; 2.7/02; KCP 2.8.2/01; 2.8.3/01; 2.8.3/02; 2.8.5/01; 2.8.5.1/01 and 2.8.7/01 were replaced with studies done with new batches reflecting the changes in formulation (specification 102000011304-06, batch EFKM002442), all relevant information are included in the new studies. Studies and results used for re-approval are acceptable.

Amended ambient storage stability study (HDPE/PA packaging) shows decrease in content of foramsulfuron

by 6.6%; degradation products are identified, formation of hazardous degradation compounds can be excluded. No loss of biological efficacy will occur. No major changes in the tested physical properties were detectable. The results are acceptable.

New ambient storage stability studies in HDPE/PA and HDPE/EVOH packaging are ongoing.

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
B.2.1/01 B.2.4/02 B.2.5/01 B.2.5/02 B.2.5/03 B.2.6/01 B.2.2.2/01 B.2.8.3/01 B.2.8.3/03 B.2.8.5.1/01 B.2.8.5.1/02 B.2.8.7/02 KCP 2.1/04	Rexer, K.	2013	Physical, chemical and technical properties of foramsulfuron+ isoxadifen-ethyl OD 45 (22.5+22.5 g/L) Final report Bayer CropScience, Report No.: FF0048(PCF00)G01, Edition Number: <a href="#">M-470556-01-1</a> Date: 2013-11-21 GLP/GEP: yes, unpublished ...also filed: KCP 2.4 /02 ...also filed: KCP 2.5 /03 ...also filed: KCP 2.6 /02 ...also filed: KCP 2.8.2 /02 ...also filed: KCP 2.8.3 /03 ...also filed: KCP 2.8.5.1 /03 ...also filed: KCP 2.8.7 /02	N	Y	New data required due to change in specification	Bayer CropScience	Submitted for the purpose of renewal
B.2.2/01 KCP 2.2 /01	Smeykal, H.	1999	Explosive properties AE F130360 + AE F122006 oil flowable 22.5 + 22.5 g/L Code: AE F130360 01 1K05 A304 Aventis Research & Technologies GmbH & Co KG, Analytical Technologies, Frankfurt, Germany Report No.: C005844, Edition Number: <a href="#">M-192780-01-1</a> Date: 1999-10-26 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001

**Foramsulfuron Volume 3 – B.2 (PPP) - foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L)**

<b>Annex point / reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
B.2.2/02 KCP 2.2 /02	Sixl, F.; Rexer, K.	2000	Determination of the oxidizing properties AE F130360 + AE F122006 oil flowable 22.5 + 22.5 g/L Code: AE F 130360 01 1K05 A304 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: C006756, Edition Number: <a href="#">M-194573-01-1</a> Date: 2000-01-11 GLP/GEP: no, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001
B.2.3/01 KCP 2.3 /01	Bittner, P.; Rexer,	1999	Determination of the flash point closed AE F130360 + AE F122006 oil flowable 22.5 + 22.5 g/L Code: AE F130360 01 1K05 A304 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: C005890, Edition Number: <a href="#">M-192873-01-1</a> Date: 1999-10-28 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001
B.2.3/03 KCP 2.3 /02	Smeykal, H.	1999	Auto-flammability (determination of the temperature of self- ignition of volatile liquids and of gases) AE F130360 + AE F122006 oil flowable 22.5 + 22.5 g/L Code: AE F130360 01 1K05 A304 Aventis Research & Technologies GmbH & Co KG,  Analytical Technologies, Frankfurt, Germany Report No.: C005843 Edition Number: <a href="#">M-192779-01-1</a> Date: 1999-10-26 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001

**Foramsulfuron Volume 3 – B.2 (PPP) - foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L)**

<b>Annex point / reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
B.2.7/01 B.2.7/02 B.2./7/03 KCP 2.7/03	Rexer, K.	2013	Storage stability at elevated temperature of foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) - Packaging material: COEX/PA - Final report (8 weeks) Bayer CropScience, Report No.: FF0048(ACF02)N01, Edition Number: <a href="#">M-470580-02-1</a> Date: 2011-03-15 ...Amended: 2013-12-11 GLP/GEP: yes, unpublished	N	Y	New data required due to change in specification	BayerCropScience	Submitted for the purpose of renewal
B. 2.7/01 B.2.7/02 B.2./7/03 B.2.7/04 KCP 2.7/04	Rexer, K.	2013	Storage stability at elevated temperature and cold stability of foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) - Packaging material: COEX/EVOH - Final report (8 weeks) Bayer CropScience, Report No.: FF0048(ACF03)N01, Edition Number: <a href="#">M-470568-02-1</a> Date: 2011-11-25 ...Amended: 2013-12-11 GLP/GEP: yes, unpublished	N	Y	New data required due to change in specification	Bayer CropScience	Submitted for the purpose of renewal
B. 2.7/05 KCP 2.7/05	Sixl, F.; Rexer, K.	2001	Determination of the storage stability (Two years shelf life at room temperature) AE F130360 + AE F122006 oil flowable 22.5 + 22.5 g/L Code: AE F130360 01 1K05 A304 Aventis CropScience GmbH, Frankfurt am Main, Germany Report No.: C014445, Edition Number: <a href="#">M-206624-01-1</a> Date: 2001-07-09 GLP/GEP: no, unpublished	N	N	Not relevant	Bayer CropScience	Submitted for the purpose of renewal
B.2.9/01 KCP 2.9 /01	Jacob, T.; Rexer	2000	F130360 + AE F122006 oil flowable 22.5 + 22.5 g/L Code: AE F130360 01 1K05 A304 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: C006770, Edition Number: <a href="#">M-194594-01-1</a> Date: 2000-01-11 GLP/GEP: no, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001