Committee for Risk Assessment

RAC

Opinion Development Document

proposing harmonised classification and labelling
at EU level of

Chlorsulfuron (ISO);
2-chloro-N-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]benzenesulphonamide

EC number: 265-268-5
CAS number: 64902-72-3

CLH-O-0000001412-86-48/F

Adopted

4 December 2014

04 December 2014

CLH-O-0000001412-86-48/F

OPINION OF THE COMMITTEE FOR RISK ASSESSMENT ON A DOSSIER PROPOSING HARMONISED CLASSIFICATION AND LABELLING AT EU LEVEL

In accordance with Article 37 (4) of Regulation (EC) No 1272/2008, the Classification, Labelling and Packaging (CLP) Regulation, the Committee for Risk Assessment (RAC) has adopted an opinion on the proposal for harmonised classification and labelling (CLH) of:

Chemicals name: **Chlorsulfuron (ISO); 2-chloro-N-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]benzenesulphonamide**

EC number: **265-268-5**

CAS number: **64902-72-3**

The proposal was submitted by **Poland** and received by the RAC on **19 February 2014.**

In this opinion, all classifications are given in the form of CLP hazard classes and/or categories.

PROCESS FOR ADOPTION OF THE OPINION

Germany has submitted a CLH dossier containing a proposal together with the justification and background information documented in a CLH report. The CLH report was made publicly available in accordance with the requirements of the CLP Regulation at ***http://echa.europa.eu/harmonised-classification-and-labelling-consultation*** on **20 May 2014**. Concerned parties and Member State Competent Authorities (MSCA) were invited to submit comments and contributions by **4 July 2014**.

ADOPTION OF THE OPINION OF THE RAC

Rapporteur, appointed by RAC: **Marian Rucki**

Co-rapporteur, appointed by RAC: **-**

The opinion takes into account the comments provided by MSCAs and concerned parties in accordance with Article 37(4) of the CLP Regulation. The comments received are compiled in Annex 2.

The RAC opinion on the proposed harmonised classification and labelling was reached on **4 December 2014**.

The RAC opinion was adopted by **consensus**.

OPINION OF RAC

RAC adopted the opinion that **Chlorsulfuron** should be classified and labelled as follows:
Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-121-00-4	chlorsulfuron (ISO); 2-chloro-N-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]benzene sulphonamide	265-268-5	64902-72-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410			
Dossier submitters proposal	613-121-00-4	chlorsulfuron (ISO); 2-chloro-N-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]benzene sulphonamide	265-268-5	64902-72-3						Add M=1000 M=100	
RAC opinion	613-121-00-4	chlorsulfuron (ISO); 2-chloro-N-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]benzene sulphonamide	265-268-5	64902-72-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1000 M=100	
Resulting Annex VI entry if agreed by COM	613-121-00-4	chlorsulfuron (ISO); 2-chloro-N-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]benzene sulphonamide	265-268-5	64902-72-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1000 M=100	

SCIENTIFIC GROUNDS FOR THE OPINION

HUMAN HEALTH HAZARD ASSESSMENT

RAC general comment

During public consultation several Member States proposed the (re)evaluation of human health hazard classes. Since they were not addressed by the dossier submitter they were not subject to evaluation by RAC.

RAC evaluation of environmental hazards

Summary of the Dossier submitter's proposal

Chlorosulfuron is a herbicide and is listed in Annex VI of CLP Regulation since 2008. The dossier submitter (DS) reviewed classification for environmental hazards to include the 2nd ATP changes and proposed that the current classification (Aquatic Acute 1 - H400 and Aquatic Chronic 1 - H410) should be kept, and an acute M-factor of 1000 and a chronic M-factor of 100 should be added to the entry.

The DS concluded that chlorosulfuron is not readily biodegradable. It was also considered as very toxic to algae and aquatic plants, the latter being the most sensitive species in both acute and chronic tests as was confirmed by two studies on *Lemna gibba*. In the first GLP experiment (Boeri *et al.*, 2002), the inhibition values on frond count after 14 days of exposure were the following: EC_{50} = 0.00035 mg/L and NOEC = 0.00024 mg a.s./L. In the second GLP experiment (Porch *et al.*, 2010a), chlorosulfuron toxicity was tested after four periods of exposure (4, 8, 24, and 48 hours), each with six nominal concentrations ranging from 0.033 to 500 μg a.s./L. The lowest NOEC based on frond count was equal to 0.00036 mg a.s./L.

In conclusion, the DS proposed to add an acute M-factor of 1000 and a chronic M-factor of 100 to the current Annex VI entry.

Comments received during public consultation

Two Member States agreed with the proposed M-factors, but requested further information on the studies or had minor comments on the data presented. Two member states, suggested to recalculate data from the Boeri *et al.* (2002) study and for classification purposes to use the 7-day E_rC_{50} and NOEC and the 14-day E_rC_{50} and corresponding NOEC.

Assessment and comparison with the classification criteria

All available studies on fate and behaviour of chlorsulfuron in the environment were performed under GLP and according to US EPA, OECD or equivalent guidelines.

Degradability

Hydrolysis

Chlorsulfuron is essentially stable at pH 7 and pH 9. At pH 5 chlorfsulfuron hydrolyses significantly with a calculated first-order half-life of ~23 days at 25 °C (Dietrich, 1989).

Aqueous photolysis

Photolysis is not considered a major degradation process for chlorsulfuron at pH 5, pH 7, or pH 9 at 25 °C (Dietrich, 1989).

Soil photolysis

Chlorsulfuron degrades in dry irradiated alkaline soil with DT_{50} and DT_{90} values of 62.2 and 207 days and is relatively stable in non irradiated systems (Hawkins, 1990).

Biodegradation
Not readily biodegradable according to the criteria of OECD 301B (Barnes, 2001).

Aerobic water/sediment
Chlorsulfuron degrades in an alkaline aerobic sediment system with DT_{50} and DT_{90} values of 21 and 69 days in the water phase and 26 and 87 days in the total system.

In conclusion, RAC agrees with the DS that chlorsulfuron should be considered not rapidly degradable according to CLP.

Aquatic bioaccumulation
The only available information on bioaccumulation potential was the measured log K_{ow}, which is below the trigger value of ≥ 4 (pH = 7: log K_{ow} = 0.102). RAC agrees with the DS that chlorsulfuron has a low potential for bioaccumulation.

Aquatic Toxicity
Both acute and chronic toxicity tests were conducted for three trophic levels. The 96 hour acute LC_{50} values for two species of fish (*Oncorhynchus mykiss* and *Lepomis macrochirus*) are greater than 122 mg a.s./L and 128 mg a.s./L, respectively. The flow-through 77 day chronic fish test resulted in a NOEC of 32 mg a.s./L.

The 48 hour EC_{50} for aquatic invertebrates (*Daphnia magna*) is greater than 112 mg a.s./L with a chronic 21 day NOEC = 12 mg a.s./L.

Two species of algae were tested with the most sensitive endpoint belonging to *Selenastrum capricornutum*. The E_rC_{50} for cell count is 0.068 mg a.s./L.

The most sensitive species is *Lemna gibba* (Boeri *et al.*, 2002) with a 7 day E_rC_{50}, a 7 day NOE_rC, a 14 day E_rC_{50}, and a 14 day NOE_rC for average specific growth rate, based on nominal and geometric mean concentrations, which are presented in Table 1.

Table 1. 7 and 14 day E_rC_{50} and NOE_rC values based on growth rate

	Exposure Initiated: Day 0:		**Exposure Ended: Day 14:**						**Nominal Chlorsulfuron Concentration µg/L**
	Count (Fronds) by Test Day								
Rep.	**0**	**1**	**4**	**6**	**8**	**11**	**13**	**14**	
1	15	22	86	134	240	415	482	529	**Blank Control**
2	15	22	80	143	322	710	812	1018	
3	15	20	80	152	359	584	716	965	
	15	21	82	143	307	570	670	837	**Mean**
	0	1	3	9	61	148	170	268	**Std. Dev.**
	0.0	5.4	4.2	6.3	19.8	26.0	25.3	32.0	**Coeff. of Variation**
1	15	22	66	119	214	344	432	493	**0.06**
2	15	23	100	167	333	607	756	784	
3	15	20	81	125	235	395	520	594	
	15	22	82	137	261	449	569	624	**Mean**
	0	2	17	26	64	139	168	148	**Std. Dev.**
	0.0	7.1	20.7	19.1	24.4	31.1	29.4	23.7	**Coeff. of Variation**
	0	-2	0	4	15	21	15	26	**% Inhibition**
1	15	21	81	150	320	597	712	1059	**0.12**
2	15	25	80	151	268	434	548	576	
3	15	21	72	129	231	407	516	546	

	15	22	78	143	273	479	592	727	**Mean**
	0	2	5	12	45	103	105	288	**Std. Dev.**
	0.0	10.3	6.4	8.7	16.4	21.4	17.8	39.6	**Coeff. of Variation**
	0	-5	5	0	11	16	12	13	**% Inhibition**
1	15	26	88	144	284	445	576	625	
2	15	19	75	134	244	433	592	608	**0.24**
3	15	21	79	145	259	446	536	562	
	15	22	81	141	262	441	568	598	**Mean**
	0	4	7	6	20	7	29	33	**Std. Dev.**
	0.0	16.4	8.3	4.3	7.7	1.6	5.1	5.4	**Coeff. of Variation**
	0	-3	2	1	15	23	15	29	**% Inhibition**
1	15	19	31	44	62	109	206	273	
2	15	23	32	50	61	116	196	238	**0.48**
3	15	21	36	49	84	206	350	414	
	15	21	33	48	69	144	251	308	**Mean**
	0	2	3	3	13	54	86	93	**Std. Dev.**
	0.0	9.5	8.0	6.7	18.8	37.7	34.4	30.2	**Coeff. of Variation**
	0	2	60	67	78	75	63	63	**% Inhibition**
1	15	18	22	34	29	31	31	30	
2	15	18	24	26	37	40	37	38	**0.96**
3	15	17	28	31	39	41	40	43	
	15	18	25	30	35	37	36	37	**Mean**
	0	1	3	4	5	6	5	7	**Std. Dev.**
	0.0	3.3	12.4	13.3	15.1	14.8	12.7	17.7	**Coeff. of Variation**
	0	17	70	79	89	93	95	96	**% Inhibition**

In toxicity studies for algal and aquatic plants, E_rC_{50} and NOE_rC values at concentrations $\leqslant$ 1 mg a.s./L were observed. In addition, chlorsulfuron is not readily biodegradable, and is unlikely to bio-accumulate in aquatic organisms (log Kow < 4). As a consequence, and according to the CLP Regulation, due to its acute effects on algae and aquatic plants at concentrations < 1 mg a.s./L and its low degradability, RAC confirms the current chlorsulfuron classification, i.e. Aquatic Acute 1 and Aquatic Chronic 1.

RAC agrees with the DS proposal of an **acute M-Factor of 1000** based on the following criteria:

- A 14 day static study conducted on *Lemna gibba*, with a calculated 7 day E_rC_{50} of 0.60 µg a.s./L (0.0006 mg/L) (7 day calculation based on frond count data collected on day 6 and day 8, (Boeri *et al.*, 2002). Calculations were conducted outside of study report, see also Supplemental Information – In depth analysis by RAC).
- The CLP Regulation states that an M-factor of 1000 is to be used if the acute toxicity is in the range of $0.0001 < EC_{50} \leqslant 0.001$ (mg/L).

RAC agrees with the DS proposal of a **chronic M-Factor of 100** based on the following criteria:

- A 14 day static study conducted on *Lemna gibba*, with a calculated 7 and 14 day NOEC value, based on growth rate, of 0.24 µg a.s./L (0.00024 mg/L) (Boeri *et al.*, 2002, additional calculations conducted outside of study report, see also Supplemental Information – In depth analysis by RAC).
- Chlorsulfuron is not ready biodegradable, determined from the results of a modified Sturm Test, according to the criteria of OECD 310B, and summarized in Barnes (2001).
- The CLP Regulation states that an M-factor of 100 is to be used if the chronic toxicity for non-readily biodegradable substances is in the range of $0.0001 < NOEC \leqslant 0.001$ (mg/L).

In conclusion in agreement with DS proposal, RAC recommends that Chlorsulfuron should be classified as:

Aquatic Acute 1; H400, M-factor = 1000,
Aquatic Chronic 1; H410, M-factor = 100

according to CLP (Regulation (EC) No. 1272/2008).

Supplemental information - In depth analyses by RAC

Analyses

L. GIBBA FROND COUNT DATA
Original *L. gibba* frond count data for Chlorsulfuron
The frond count data from day 0 to day 14 by treatment group and replicate, as presented in Boeri *et al.* (2002), are provided in Table 2.

Table 2. *L. gibba* frond count data from Boeri *et al.* (2002)

	Exposure Initiated: Day 0:		**Exposure Ended: Day 14:**						**Nominal Chlorsulfuron Concentration µg/L**
	Count (Fronds) by Test Day								
Rep.	**0**	**1**	**4**	**6**	**8**	**11**	**13**	**14**	
1	15	22	86	134	240	415	482	529	**Blank Control**
2	15	22	80	143	322	710	812	1018	
3	15	20	80	152	359	584	716	965	
	15	21	82	143	307	570	670	837	**Mean**
	0	1	3	9	61	148	170	268	**Std. Dev.**
	0.0	5.4	4.2	6.3	19.8	26.0	25.3	32.0	**Coeff. of Variation**
1	15	22	66	119	214	344	432	493	**0.06**
2	15	23	100	167	333	607	756	784	
3	15	20	81	125	235	395	520	594	
	15	22	82	137	261	449	569	624	**Mean**
	0	2	17	26	64	139	168	148	**Std. Dev.**
	0.0	7.1	20.7	19.1	24.4	31.1	29.4	23.7	**Coeff. of Variation**
	0	-2	0	4	15	21	15	26	**% Inhibition**
1	15	21	81	150	320	597	712	1059	**0.12**
2	15	25	80	151	268	434	548	576	
3	15	21	72	129	231	407	516	546	
	15	22	78	143	273	479	592	727	**Mean**
	0	2	5	12	45	103	105	288	**Std. Dev.**
	0.0	10.3	6.4	8.7	16.4	21.4	17.8	39.6	**Coeff. of Variation**
	0	-5	5	0	11	16	12	13	**% Inhibition**
1	15	26	88	144	284	445	576	625	**0.24**
2	15	19	75	134	244	433	592	608	
3	15	21	79	145	259	446	536	562	
	15	22	81	141	262	441	568	598	**Mean**
	0	4	7	6	20	7	29	33	**Std. Dev.**
	0.0	16.4	8.3	4.3	7.7	1.6	5.1	5.4	**Coeff. of Variation**
	0	-3	2	1	15	23	15	29	**% Inhibition**

1 2 3	15 15 15	19 23 21	31 32 36	44 50 49	62 61 84	109 116 206	206 196 350	273 238 414	**0.48**
	15	21	33	48	69	144	251	308	**Mean**
	0	2	3	3	13	54	86	93	**Std. Dev.**
	0.0	9.5	8.0	6.7	18.8	37.7	34.4	30.2	**Coeff. of Variation**
	0	2	60	67	78	75	63	63	**% Inhibition**
1	15	18	22	34	29	31	31	30	
2	15	18	24	26	37	40	37	38	**0.96**
3	15	17	28	31	39	41	40	43	
	15	18	25	30	35	37	36	37	**Mean**
	0	1	3	4	5	6	5	7	**Std. Dev.**
	0.0	3.3	12.4	13.3	15.1	14.8	12.7	17.7	**Coeff. of Variation**
	0	17	70	79	89	93	95	96	**% Inhibition**

Calculated growth rate by test interval

The mean frond count is determined using the number of fronds observed in a test beaker on a given observation day.

Growth rate is calculated for each treatment group and control group based on frond count (or biomass). Growth rate is calculated in this analysis using frond count data and the following formula:

$$\mu = \frac{\ln N_n - \ln N_0}{t_n}$$

where:

μ = Average specific growth rate

N_0 = Number of fronds (or biomass) at the beginning of the test

N_n = Number of fronds (or biomass) at t_n

t_n = Time of nth measurement after beginning of test (days).

Inhibition is calculated for each treatment group as the percent reduction in mean frond count and mean growth rates relative to the respective control means. The following formula was used:

$$\% I = \frac{C - T}{C} \times 100$$

where:

C = Control mean frond count or growth rate

T = Treatment group mean frond count or growth rate

The results are presented in Table 3.

TABLE 3. CALCULATED GROWTH RATE BY TEST INTERVAL BASED ON FROND COUNTS
5.0

Nominal Chlorsulfuron Concentration µg/L	Rep.	Exposure Initiated:Day 0: Exposure Ended:Day 14: Growth Rate Based on Count (Fronds) by Test Day						
		Day 0-1	**Day 0-4**	**Day 0-6**	**Day 0-8**	**Day 0-11**	**Day 0-13**	**Day 0-14**
Blank Control	1	0.3830	0.4366	0.3650	0.3466	0.3018	0.2669	0.2545
	2	0.3830	0.4185	0.3758	0.3833	0.3507	0.3070	0.3013
	3	0.2877	0.4185	0.3860	0.3969	0.3329	0.2974	0.2974
Mean		0.3512	0.4245	0.3756	0.3756	0.3285	0.2904	0.2844
Std. Dev.		0.0550	0.0105	0.0105	0.0260	0.0247	0.0209	0.0260
Coeff. of Variation		15.7	2.5	2.8	6.9	7.5	7.2	9.1
0.06	1	0.3830	0.3704	0.3452	0.3322	0.2848	0.2585	0.2495
	2	0.4274	0.4743	0.4017	0.3875	0.3364	0.3015	0.2826
	3	0.2877	0.4216	0.3534	0.3439	0.2973	0.2728	0.2628
Mean		0.3660	0.4221	0.3668	0.3545	0.3062	0.2776	0.2650
Std. Dev.		0.0714	0.0520	0.0305	0.0291	0.0269	0.0219	0.0167
Coeff. of Variation		19.5	12.3	8.3	8.2	8.8	7.9	6.3
% Inhibition		-4	1	2	6	7	4	7
0.12	1	0.3365	0.4216	0.3838	0.3825	0.3349	0.2969	0.3041
	2	0.5108	0.4185	0.3849	0.3604	0.3059	0.2768	0.2606
	3	0.3365	0.3922	0.3586	0.3418	0.3001	0.2722	0.2568
Mean		0.3946	0.4108	0.3758	0.3616	0.3136	0.2820	0.2738
Std. Dev.		0.1006	0.0162	0.0149	0.0204	0.0186	0.0131	0.0263
Coeff. of Variation		25.5	3.9	4.0	5.6	5.9	4.7	9.6
% Inhibition		-12	3	0	4	5	3	4
0.24	1	0.5500	0.4423	0.3770	0.3676	0.3082	0.2806	0.2664
	2	0.2364	0.4024	0.3650	0.3486	0.3057	0.2827	0.2644
	3	0.3365	0.4153	0.3781	0.3561	0.3084	0.2751	0.2588
Mean		0.3743	0.4200	0.3734	0.3574	0.3074	0.2795	0.2632
Std. Dev.		0.1602	0.0204	0.0073	0.0096	0.0015	0.0039	0.0039
Coeff. of Variation		42.8	4.8	1.9	2.7	0.5	1.4	1.5
% Inhibition		-7	1	1	5	6	4	7
0.48	1	0.2364	0.1815	0.1794	0.1774	0.1803	0.2015	0.2072
	2	0.4274	0.1894	0.2007	0.1754	0.186	0.1977	0.1974
	3	0.3365	0.2189	0.1973	0.2153	0.2382	0.2423	0.2370
Mean		0.3334	0.1966	0.1925	0.1894	0.2015	0.2138	0.2139
Std. Dev.		0.0955	0.0197	0.0114	0.0225	0.0319	0.0247	0.0206
Coeff. of Variation		28.7	10.0	5.9	11.9	15.8	11.6	9.6
% Inhibition		5	54	49	50	39	26	25
0.96	1	0.1823	0.0957	0.1364	0.0824	0.0660	0.0558	0.0495
	2	0.1823	0.1175	0.0917	0.1129	0.0892	0.0695	0.0664
	3	0.1252	0.1560	0.1210	0.1194	0.0914	0.0754	0.0752
Mean		0.1633	0.1231	0.1164	0.1049	0.0822	0.0669	0.0637
Std. Dev.		0.0330	0.0305	0.0227	0.0198	0.0141	0.0101	0.0131
Coeff. of Variation		20.2	24.8	19.5	18.8	17.1	15.0	20.5

% Inhibition		54	71	69	72	75	77	78

Results
Statistical analyses are reported based on nominal concentrations and were conducted using SAS Version 9.4. The 7 and 14 day E_rC_{50} values (and 95% confidence intervals) for growth rate based on frond count and nominal concentrations were obtained with the 3-parameter exponential model (1 of 5 models used for toxicity experiments advocated by Slob (2002)).

Determination of the 7 and 14 day E_rC_{50} and NOEC values
A complication in this analysis was that no observations of effects were measured at day 7. Instead, measures were made at 6 and 8 days of exposure. However, since there was consistency in results from 6 and 8 days exposure, it was possible to obtain meaningful NOEC determinations and E_rC_{50} estimates for 7 days of exposure from the data available.

The E_rC_{50} estimates for day 6 and day 8 were 0.6067 and 0.5868 µg a.s./L, with 95% confidence intervals of (0.4884, 0.7250) and (0.4760, 0.6975), respectively. Consequently, the E_rC_{50} estimate for 7 days of exposure is the geometric mean of the day 6 and day 8 estimates. The calculated 7 day E_rC_{50} = 0.5967 µg a.s./L, with approximate 95% confidence intervals of (0.4760, 0.7250).

The 14 day E_rC_{50} based on average specific growth rate has been recalculated previously (McKelvey, 2011) and resulted in an E_rC_{50} = 0.69 µg/L. The 14 day E_rC_{50} calculated in this analysis was determined to be 0.71 µg/L. The difference observed in these two values is not significant, and is most likely due to differences in rounding of the raw data.

FIGURE 1. 6 DAY GROWTH RATE DOSE RESPONSE CURVE

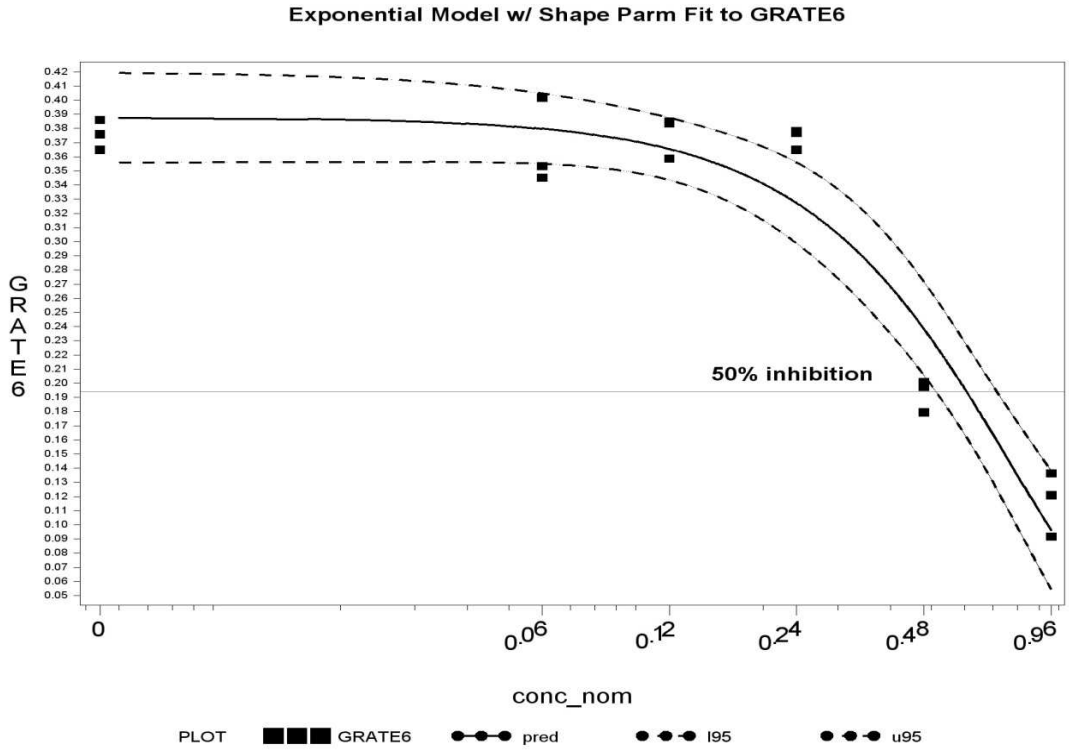


FIGURE 2. 8 DAY GROWTH RATE DOSE RESPONSE CURVE

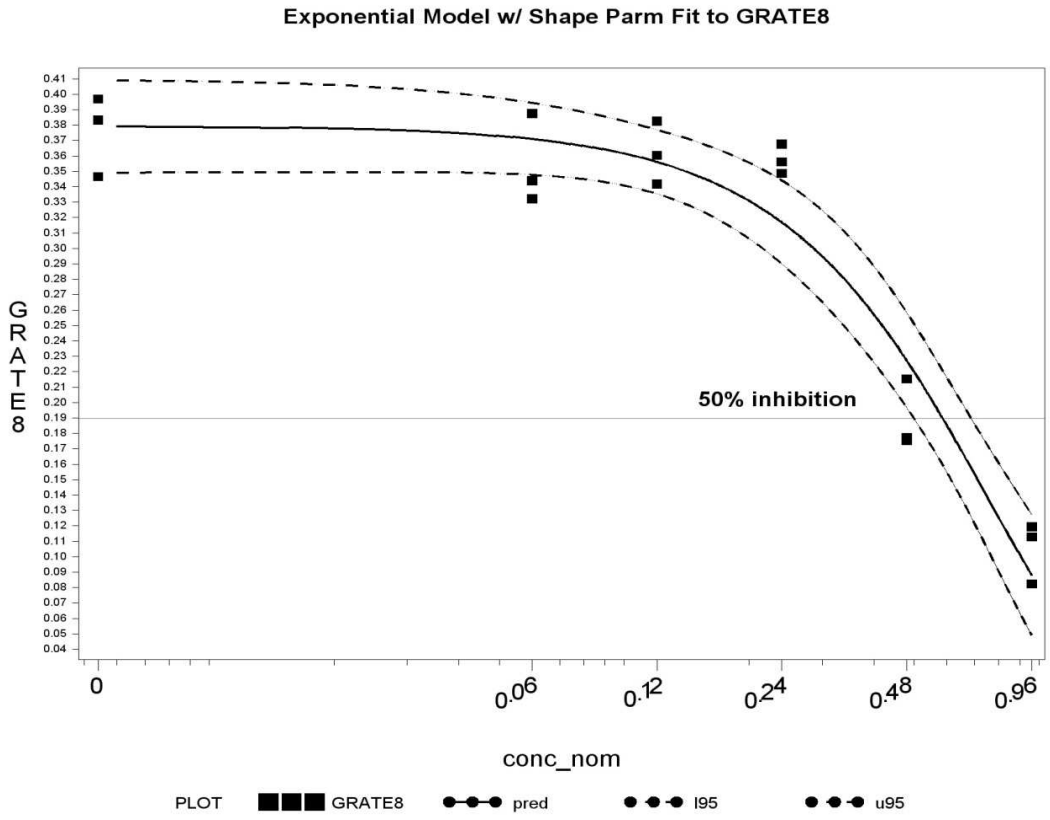
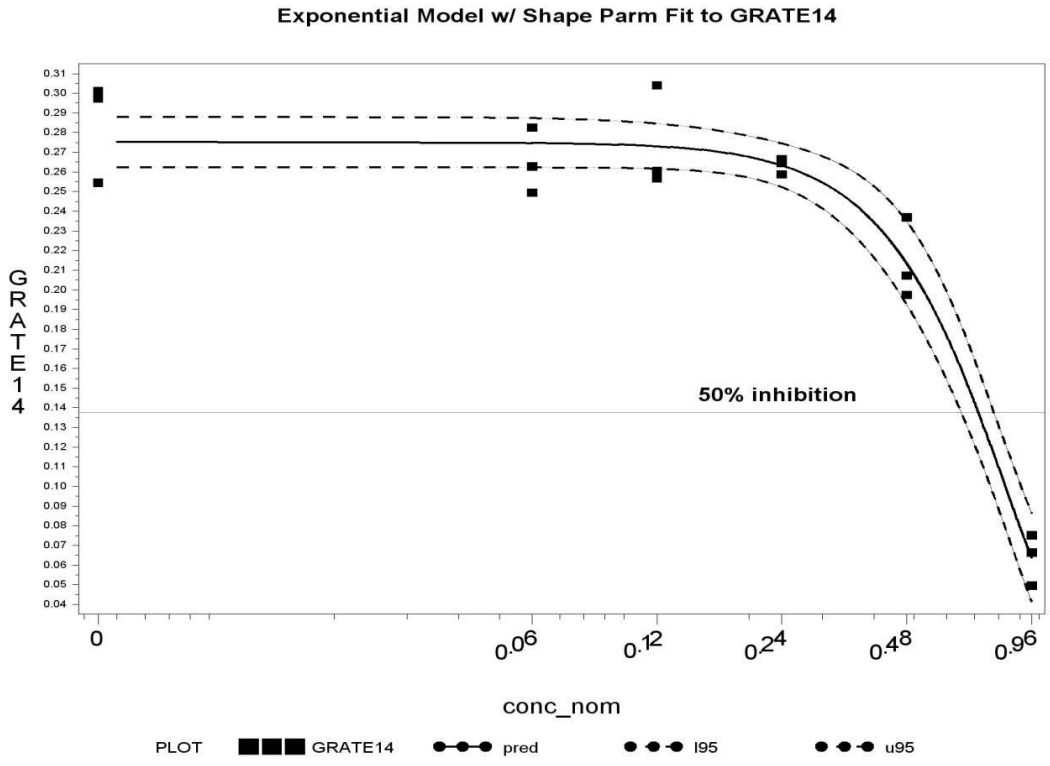


FIGURE 3. 14 DAY GROWTH RATE DOSE RESPONSE CURVE



Recalculation of 7 and 14 day E_rC_{50} and NOEC values based on geometric mean concentration

The E_rC_{50} and NOEC for *Lemna Giba* growth rate endpoint based on the geometric mean of initially measured concentrations and one half of LOQ (LOQ for chlorsurfuron is equal to 0.0132 µg/L) were recalculated (Table 4). The results for 14 days test are the following: The E_rC_{50} is 0.064 µg/L and the NOEC is 0.04 µg/L. There are no available measured test concentrations on the days 6 and 8, the recalculation of E_rC_{50} and NOEC based on geometric mean of initial concentrations and half of LOQ is rather speculative. Despite the recalculation was performed and the resulting values for 7 days test were the following: E_rC_{50} equal to 0.0595 µg/L and the NOEC to 0.04 µg/L.

Table 4. 7 and 14 day E_rC_{50} and NOEC Values Based on Growth Rate

Response	Day	NOE_rC (µg/L)	Concentrations	E_rC_{50} (µg/L)	95% Confidence Intervals
Growth rate	7	0.24	Nominal	0.5967	(0.4760, 0.7250)
	14	0.24	Nominal	0.715[a]	(0.6438, 0.7857)

[a] Previously calculated to be 0.69 µg/L (McKelvey, 2011)

Details of Douglas *et al*. (1988) study

(DAR 07, Vol 3, Annex B, part 5, B.9)

Test Substance: DPX-W4189 technical, purity: 98.5%
Test organism: *Lemna minor*
Medium: algal nutrient medium pH = 5
GLP: Yes
Medium renewed on days 2, 5, 7, 9, 12
14-day E_rC_{50} = 0.11 µg/L
14-day NOE_rC = 0.04 µg/L

Regarding the Douglas *et al.* (1988) study, the endpoints are based on the growth rate. The NOE_rC for 14-day test duration was 0.04 µg/L and is the same as NOEC derived from recalculated data of the Boeri *et al.* (2002) study. In RAC's opinion, both NOEC results are derived from methods which are designed for compounds not stable in the test solution. On contrary, chlorsulfuron stability was proved during 21 day test period; the compound is not ready biodegradable and bioaccumulation is not expected because of the low log K_{ow} (at pH 7, log Kow = -0.99). The very low concentration (below the LOQ) at the end of the 14 days study could be explained by uptake of the test compound to the test organism. Unfortunately this hypothesis cannot be verified since no information on the chlorsulfuron concentration in the test organisms is available.

Additional references

SAS Version 9.4 (2014). SAS Institute Inc. NC 27513-2414.

Slob, W., (2002). Dose-response Modeling of Continuous endpoints. *Toxicol. Sci.* 66: 298-312.

McKelvey, R., (2011). Chlorsulfuron: Calculation of Average Specific Growth Rate for *Lemna gibba* Based on Data Presented in DuPont-4468. E.I. du Pont de Nemours and Company, Wilmington, Delaware. DuPont-33183.

ANNEXES:

Annex 1 Background Document (BD) gives the detailed scientific grounds for the opinion. The BD is based on the CLH report prepared by the Dossier Submitter; the evaluation performed by RAC is contained in RAC boxes.

Annex 2 Comments received on the CLH report, response to comments provided by the Dossier Submitter and by RAC (excl. confidential information).