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To Whom It May Concern:

Evonik Corporation is submitting information regarding four studies under TSCA FYI for Isobornyl Acrylate (2-Propenoic acid, 1,7,7-trimethylbicyclol[2.2.1]hept-2-yl ester, exo) CAS no. 5888-33-5. The studies include the results from Acute Toxicity Fish (96h), NOEC Daphnia magna (21 d), EC50 Algae (72h), and a LLNA report. The study summaries and results are attached.

With kind regards,

Tiana M. Rosamilia

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1 Summary

The *Daphnia magna* Reproduction Test (semi-static, 21 d) of the test item Isobornyl acrylate (batch number: 1210180017) was conducted according to OECD 211 (2008) from 2012-09-26 to 2012-10-19, with the definitive exposure phase from 2012-09-26 to 2012-10-17, at DR.U.NOACK-LABORATORIEN, Käthe-Paulus-Str. 1, 31157 Sarstedt, Germany.
Test species was *Daphnia magna* STRAUS (Clone 5). Ten daphnids, individually held, were used per concentration level and control. At the start of the exposure phase, the daphnids were 2 to 24 hours old. The study was carried out under semi-static conditions with a daily renewal of the test solutions in sealed glass flasks to reduce contact with oxygen.
Aim of the Daphnia Reproduction Test over 21 days was to assess effects on the reproduction capacity and other test item-related effects or parameters such as intrinsic rate of natural increase, time of production of first brood, occurrence of aborted eggs and stillborn juveniles, adult mortality, and body length of the parental daphnids.
Nominal concentrations of Isobornyl acrylate were selected as follows: 0.100 - 0.320 - 1.00 - 3.20 - 10.0 mg/L.
The tested concentration levels of the test item Isobornyl acrylate and the control were analytically verified by GC-MS of samples taken on days 0, 7, 14 (fresh media, 0 hours) and on days 1, 8, 15 (old media, 24 hours). Details of the analytical method are presented in part 11.
In the fresh media (0 h), the measured concentrations of the test item Isobornyl acrylate were in the range of 82 to 118 % of the nominal values. The measured test item concentrations in the old media (24 hours) were in the range of 74 to 103 % of the nominal values. Therefore, all effect values given are based on the geometric mean measured concentrations of test item Isobornyl acrylate, calculated as follows: 0.0920 - 0.277 - 0.838 - 2.94 - 8.89 mg/L, which corresponds to mean recovery rates of 84 to 92 % of the nominal values. The analytical results are presented in Table 11 to Table 13.

- The average number of living juveniles per parent alive at the end of the test after 21 days was 97 in the control group. A statistically significant reduction of the **reproductive output** alive in comparison to the control was determined at the concentration levels of 0.277 and 0.838 mg/L (One Way Analysis of Variance, DUNNETT'S method, $p = 0.059$). At the concentration levels of 2.94 and 8.89 mg/L, no juveniles occurred due to 100 % mortality of the daphnids.

- The reduction of the reproductive output was the most sensitive effect in this study. The No Observed Effect Concentration (**$NOEC_{Reproduction}$**) after 21 days was assessed at 0.0920 mg/L. The Lowest Observed Effect Concentration (**$LOEC_{Reproduction}$**) was assessed at 0.277 mg/L.
  The EC_{50}-value for the reduction of the reproductive output was calculated to be 0.537 mg/L (95 % confidence limits: 0.453 – 0.647 mg/L). The EC_{10}-value was < 0.0920 mg/L. For details see Table 1, Table 4, Figure 1 and Figure 2.

- The coefficient of variation of the **number of living offspring** produced per parent was 10 % in the control. In the concentration levels 0.0920 and 0.277 mg/L the coefficient of variation was 9 and 19 %. A coefficient of variation of more than 25 % is regarded to be biologically significant. The coefficient of variation of 64 % in the concentration level of 0.838 mg/L is biologically significant (Table 1 and Table 4).

- The **intrinsic rates of natural increase (IR)** of the surviving parent animals accounting for generation time and number of offspring were used for calculation of population growth and maintenance. The mean IR of the surviving daphnids of the treatment groups were compared to the control by One Way Analysis of Variance, DUNNETT'S method ($p < 0.05$). There was a statistical significance at the concentration level of 0.838 mg/L in comparison to the control. For the concentration levels of 2.94 and 8.89 mg/L, no IR were calculated, because no offspring occurred due to 100 % mortality of the daphnids (see Table 1, Table 5 and Figure 3).

- The **first brood** was released till day 9 by all parent animals of the control and the concentration level of 0.0920 mg/L. At the concentration levels of 0.277 and 0.838 mg/L, several daphnids released its first brood on day 10 and later, which is regarded to be significantly delayed. These daphnids released also a lower number of broods (1 to 3 broods) than the control and the concentration level of 0.0920 mg/L during the exposure period. In the tested concentration level of 0.0920 mg/L and in the control 4 to 5 broods were produced by the adult daphnids. In the concentration levels of 2.94 and 8.89 mg/L all daphnids died before producing juveniles (Table 6).

- No **stillborn juveniles** and one **aborted egg** were produced by the control group during the exposure period of 21 days. Related to the total number of produced juveniles (dead + alive), the fraction of dead juveniles (sum of stillborn juveniles and aborted eggs) was 5 % in the concentration level of 0.0920 mg/L, 10 % in the concentration level of 0.277 mg/L and 67 % in the concentration level of 0.838 mg/L during the exposure period of 21 days. For details see Table 8.

- The test item induced biologically significant **adult mortality** in concentration levels of 0.838 mg/L (30%), 2.94 mg/L (100 %) and 8.89 mg/L (100%) after 21 days. In the concentration levels 0.0920 and 0.277 mg/L and in the control all parental daphnids survived till the end of the test after 21 days.
  The EC_{10}-value for the adult mortality was calculated by sigmoidal dose-response regression to be 0.760 mg/L (95 % confidence limits: 0.277 – 2.94 mg/L). The EC_{50}-value was calculated accordingly to be 0.900 mg/L (95 % confidence limits: 0.277 – 2.94 mg/L). For details see Table 1 Table 9 and Figure 4.

- The mean **body length** of the surviving parental daphnids in the concentration levels of 0.0920 to 0.838 mg/L were in the range of 4.86 to 5.50 mm per daphnid and 5.50 mm per daphnid in the control group. The mean **dry body weight** was in the range of 0.900 to 1.26 mg per daphnid in the concentration levels of 0.0920 to 0.838 mg/L and 1.15 mg per daphnid in the control (Table 1 and Table 10).

A summary of all test item related effects and the assessed effect levels for reproduction and adult mortality is given in Table 1.

Table 1: **Test Item Related Effects (NOEC, LOEC, EC_{10}, EC_{50} and EC_{100})**
(based on the geometric mean measured concentrations of Isobornyl acrylate)

Effects	Geometric Mean Measured Concentration of Isobornyl acrylate [mg/L]					
	Control	0.0920	0.277	0.838	2.94	8.89
Mean Number of Living Juveniles per Producing Parent (Reproduction Rate ± SD)	97 ± 10	86 ± 8	**81 ± 16**[1)]	**15 ± 10**[1)]	---	---
Coefficient of Variation of the Mean Number of Juveniles per Producing Parent [%]	10	9	19	**64**[2)]	---	---
Percentage of Dead Juveniles Related to the Total Number of Juveniles [%]	0	5	10	67	---	---
Mean Intrinsic Rates of Natural Increase	0.47	0.44	0.43	0.32[3)]	---	---
Appearance of First Brood [Mean Day]	8.0	8.4	9.4[4)]	10.1[4)]	---	---
Mean Number of Broods	4.00	4.10	3.7[5)]	2.14[5)]	---	---
$NOEC_{Reproduction}$	**0.0920 mg/L**					
$LOEC_{Reproduction}$	**0.277 mg/L**					
EC_{10} Reproduction	**< 0.0920 mg/L**					
EC_{50} Reproduction	**0.524 mg/L (95 % confidence limits: 0.277 – 0.838 mg/L)**					
Adult Mortality after 21 Days [%]	0	0	0	**30**[6)]	**100**[6)]	**100**[6)]
Parent Animals: Mean Dry Weight [mg]	1.15	1.18	1.26	0.900	---	---
Parent Animals: Mean Body Length [mm]	5.50	5.38	5.50	4.86	---	---
EC_{10} Adult Mortality	**0.783 mg/L (95 % confidence limits: 0.277 – 2.94 mg/L)**					
EC_{50} Adult Mortality	**0.874 mg/L (95 % confidence limits: 0.277 – 2.94 mg/L)**					
EC_{90} Adult Mortality	**2.94 mg/L**					

SD = Standard deviation
1) = Statistical significance (One Way Analysis of Variance, DUNNETT'S method, p = 0.059)
2) = Significant variation between the test replicates (Coefficient of variation > 25 %)
3) = Statistical significance (One Way Analysis of Variance, DUNNETT'S method, p < 0.05)
4) = 1st brood significantly delayed (after day 10) at several daphnids
5) = Less than four broods released by several daphnids
6) = Significant adult mortality (> 20 %)
--- = Not applicable, due to 100 % mortality of the daphnids.

- No **males** and **ephippia** (winter eggs) were observed in the control or in the test groups.

- **Water quality parameters** as pH-value, dissolved oxygen, water hardness and temperature were within the acceptable limits.

- In order to prove the **validity of the test system** and test conditions at the test facility, an acute immobilization test according to DIN 38412 L 11 is carried out with **potassium dichromate** as reference item once per month.
  The EC_{50} of the reference item at 1.44 mg/L (95% confidence limits: 1.29 - 1.52 mg/L) after 24 hours is within the prescribed concentration range of 1.0 - 2.5 mg/L of quality criteria according to AQS P 9/2 (05/1996) for daphnids clone 5 cultured in Elendt M4 medium. The EC_{50}-value of the reference item is also within the recommended range of 0.6 - 2.1 mg/L according to OECD-Guideline 202. For details see part 4.3.

6 SUMMARY

In the study the test item Isobornyl acrylate dissolved in acetone:olive oil (4+1 v/v) was assessed for its possible skin sensitising potential.

For this purpose a local lymph node assay was performed using test item concentrations of 5, 10, and 25% (w/w). The highest concentration tested was the highest concentration that could be achieved whilst avoiding systemic toxicity and excessive local skin irritation as confirmed by a pre-experiment.

The animals did not show any signs of systemic toxicity or local skin irritation during the course of the study and no cases of mortality were observed.

A test item is regarded as a sensitizer in the LLNA if exposure to one or more test item concentrations results in a 3-fold or greater increase in incorporation of ^{3}HTdR compared with concurrent controls, as indicated by the Stimulation Index (S.I.). The estimated test item concentration required to produce a S.I. of 3 is referred to as the EC3 value.

In this study Stimulation Indices (S.I.) of 4.07, 14.07 and 22.84 were determined with the test item at concentrations of 5, 10, and 25% (w/w) in acetone:olive oil (4+1 v/v), respectively. A clear dose response was observed. Since the S.I. values of all treatment groups were above the threshold value of 3, the EC3 value could not be calculated.

The test item Isobornyl acrylate was **found to be a skin sensitizer** under the test conditions of this study.

1 Summary

The toxicity of Isobornyl acrylate (Batch no.: 1210180017) to the unicellular freshwater green alga *Pseudokirchneriella subcapitata* was determined according to the principles of OECD 201 from 2012-10-22 to 2012-10-26 with the definitive exposure phase from 2012-10-22 to 2012-10-25 at DR.U.NOACK-LABORATORIEN in 31157 Sarstedt, Germany. The aim of the study was the determination of NOEC, LOEC, EC_{10} - , EC_{20} - and EC_{50} - values of growth rate and yield over a period of 72 hours.

The study was conducted under static conditions with an initial cell density of 5089 cells/mL. With regard to the volatility of the test item glass flasks without headspace were used to reduce losses of test item. Seven concentrations were tested in a geometrical series with a dilution factor of 3.16 (nominal): 0.00500 - 0.0158 - 0.0500 - 0.158 - 0.500 - 1.58 - 5.00 mg/L, corresponding to geometric mean measured test item concentrations of 0.00467 - 0.0153 - 0.0445 - 0.153 - 0.405 - 1.36 - 4.39 mg/L.

The environmental conditions were determined to be within the acceptable limits.

The concentrations of Isobornyl acrylate was determined in the fresh media (0 hours) and old media (72 hours) of all tested concentration levels and the control via GC-FID. For results see Table 8. Details of the analytical method are presented in part 9. The measured concentrations of Isobornyl acrylate in the fresh media (0 hours) were in the range of 97 – 121 % of the nominal concentrations. After 72 hours they were in the range of 67 – 80 % of the nominal values at all tested concentration levels. All effect values given are based on the nominal and geometric mean measured concentrations of the test item Isobornyl acrylate.

The inhibition values are given in Table 1.

Table 1: **NOEC, LOEC, EC-Values and 95 % Confidence Intervals of Isobornyl acrylate (0-72 hours)**
based on nominal and geometric mean measured test item concentrations [mg/L]

	Inhibition of Growth Rate	
	Nominal	Geometric mean measured
NOEC	0.500	0.405
LOEC	1.58	1.36
E_rC_{10}	0.528 (0.453 – 0.604)	0.444 (0.383 – 0.509)
E_rC_{20}	0.900 (0.823 – 0.976)	0.763 (0.696 – 0.831)
E_rC_{50}	2.29 (2.12 – 2.48)	1.98 (1.83 – 2.15)
	Inhibition of Yield	
NOEC	0.158	0.153
LOEC	0.500	0.405
E_yC_{10}	0.260 (0.209 – 0.315)	0.224 (0.183 – 0.268)
E_yC_{20}	0.351 (0.294 – 0.411)	0.299 (0.254 – 0.346)
E_yC_{50}	0.720 (0.626 – 0.840)	0.596 (0.517 – 0.701)

1 Summary

The acute toxicity of the test item Isobornyl acrylate (batch no.: 1210180017) to fish (zebrafish), was determined according to OECD-Guideline for Testing of Chemicals No. 203 (1992) from 2012-07-20 to 2012-06-15 with the definitive exposure phase from 2012-09-24 to 2012-09-28, at DR.U.NOACK-LABORATORIEN, 31157 Sarstedt, Germany.
A semi-static test with daily renewal of the test media was conducted with the nominal test item concentrations of 0.155 – 0.341 – 0.751 – 1.65 – 3.64 – 8.00 mg/L (factor 2.2) corresponding to geometric mean test item concentrations of 0.073 – 0.159 – 0.431 – 1.15 – 2.63 – 6.28 mg/L. Duration of the test was 96 hours. 7 test organisms were exposed to each test concentration and control. Water quality parameters temperature, pH-value and O_2-saturation measured at 0, 24, 48, 72 and 96 hours were within the acceptable limits.
The determination of the concentrations of the test item Isobornyl acrylate was carried out via GC-FID from freshly prepared media after 0 and 72 h, and from the corresponding 24 h old test media after 24 and 96 h.
The measured concentrations of Isobornyl acrylate in freshly prepared media were in the range of 35 - 101 % of the nominal values and 30 – 72 % in 24 h aged test media. For details of the analytical results please refer to part 9. All effect levels are given based on the geometric mean concentrations of the test item Isobornyl acrylate (see Table 1).

Table 1: **LC-Values with 95 % Confidence Intervals (0 – 96 hours)**

Based on geometric mean test item concentrations [mg/L]
Due to only one partial response the LC10 and LC20 values have been given as a range. For the same reason no calculation of confidence intervals was carried out for the LC50 value.

Test duration [hours]	LC_{10} (p = 95 %)	LC_{20} (p = 95 %)	LC_{50} (p = 95 %)
24	$1.19 < LC_{10} < 3.03$	$1.19 < LC_{20} < 3.03$	2.66 (2.63 – 6.28)
48	$1.19 < LC_{10} < 3.03$	$1.19 < LC_{20} < 3.03$	1.74 (1.15 – 2.63)
72	$0.431 < LC_{10} < 1.15$	$0.431 < LC_{20} < 1.15$	1.11 (0.431 – 1.15)
96	$0.431 < LC_{10} < 1.15$	$0.431 < LC_{20} < 1.15$	0.704 (0.431 – 1.15)
LC_0 = Highest test item concentration with 0 % mortality after 96 hours	0.431		
LC_{100} = Lowest test item concentration with 100 % mortality after 96 hours	1.15		

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