Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

to the Opinion proposing harmonised classification and labelling at EU level of

1,2-epoxybutane

EC number: 203-438-2
CAS number: 106-88-7

CLH-O-0000002824-72-02/A2

Adopted

11 September 2013

ANNEX 1 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1,2-EPOXYBUTANE (2-ETHYLOXIRANE)

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COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in this table as submitted by the webform. Please note that only the comments provided in the commenting boxes are published. Supportive information submitted as attachments not included in the table below.

ECHA accepts no responsibility or liability for the content of this table.

Substance name: 1,2-epoxybutane (2-ethyloxirane)
EC number: 203-438-2
CAS number: 106-88-7

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
22.03.2013	France		MemberState	1
Comment received				
FR is in accordance with the classification proposal: 1,2-epoxybutane reveals no need to classify the substance for the environment.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Thank you for the opinion.				

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
13.03.2013	Finland		MemberState	2
Comment received				

Biodegradability:
We agree with the comments presented by the Netherlands that the conclusion of rapid degradability cannot be supported by the information available in the CLH report. We also agree with the NL comments that further information should be submitted concerning the OECD 301C and ISO 14593 biodegradability tests and that a better justification for the conclusion is needed.

In addition, we present the following comments:

1) Concerning the ISO 14593 test, a 8-day adaptation phase is mentioned in the registration dossier. However, in the CLH report it is mentioned that "As it is required for ready tests the used inoculum was not adapted in all three cases". Therefore, it should be clarified whether the inoculum was adapted to test substance or not. This information is needed to evaluate whether this test can be considered a ready biodegradability test or not.

2) Concerning the OECD301A test we would like to point out that the conclusion of this test should be "not readily biodegradable" because the requirement concerning the 10-day window was not fulfilled. Moreover, the OECD301A test should be better described in the report (including the modifications used, because this guideline is not meant for volatile substances).

3) In the beginning of page 15 it is said: "In both studies with closed flasks (ISO 14593 and

OECD 301A) abiotic controls where performed to assess volatilization processes.". It should be clarified whether the OECD 301C test was conducted with closed flasks or open flasks.

4) The conclusion on degradability should be better justified. Particularly, if the different biodegradability tests are deemed valid and show conflicting results, it should be carefully documented how the conclusion was derived.

Aquatic toxicity:
There are only acute aquatic toxicity studies available. The test results are based on nominal concentrations and no analytical monitoring of the test concentrations has been done. Due to volatility potential of 1,2-epoxybutane (Henry's law constant of 21.48 Pa.m3/mol) it is impossible to evaluate the validity of the tests with the information given. Therefore, we do not support the removal of current entry in Annex VI: Aquatic Chronic 3; H412, R52-53 based on the information available in the CLH report.

Dossier Submitter's Response

Biodegradability:

Finland agrees with the comments presented by the Netherlands that the conclusion of rapid degradability cannot be supported by the information available in the CLH report.

In the currently discussed case of 1,2-epoxybutane three well documented guideline studies on ready biodegradability are available (OECD 301 A, OECD 301C and ISO 14593 – equal to OECD 310). All three studies are reliable and the results of the three studies show only differences in terms of their kinetics, whereas the pass level was reached in all three cases. These differences in the kinetic are the point of discussion, since in one study (OECD 301 A) the relevant 'ten-day-time window criterion' is missed and in case of the other study (ISO 14593 – equal to OECD 310) the test design, with 7 days measuring intervals complicates the proof of the 'ten-day-time window criterion' (more details are reported in the CLH report). Nevertheless the third test according to OECD 301C is excluded from the 'ten-day-time window' requirement. Hence the MITI I study on its own is sufficient to prove the ready biodegradable of 1,2-epoxybutane.

Regarding the comments of "Finland" point 1):

The described test according to ISO 14593 was conducted with non-adapted activated sludge. The wording "8-day adaptation phase" describes the lag phase, at which 10% degradation was reached. Commonly the wording adaptation phase is used equivalent to lag phase. To exclude further misunderstanding, we suggest to replace "8-day adaptation phase" with the term lag phase.

Regarding the comments of "Finland" point 2):

The DOC-Die-Away test (OECD 301A) is usually prepared in an open test system. In case of testing 1,2-epoxybutane, the DOC-Die-Away test (OECD 301A) was exceptionally prepared in a closed test system. Therefore specially designed 1 liter shake flasks were used, which were filled with 500 mL mineral medium and a sufficient amount of test substance. After closing the test flasks the remaining space results into a headspace volume of air. At the end of the DOC-Die-away test the degradation exceeds 90%, but missed the 10-day-time window.

Regarding the comments of "Finland" point 3):

The cited test was conducted on behalf of the Japanese government authority according to their standard procedure. The MITI I test (OECD 301C) is commonly prepared in closed test vessels, since the consumption of oxygen is determined by measuring the change in volume or pressure in the apparatus. In the described MITI I test a control measurement carried out (test substance solution without inoculum), to proof the loss of test substance during the 28 days test duration. At the end of the test 94% recovery of the test substance was determined in the control flask, based on DOC measurement. Furthermore, in all three parallels (test substance with inoculum) of the MITI I test, biodegradation rates of 88 – 91% were determined. Since the biodegradation rates were estimated from the oxygen consumption, a parameter which is directly correlated with the metabolism, significant abiotic losses of test item can be excluded.

Regarding the comments of "Finland" point 4):

In general it can be assumed that the results of biodegradability tests vary, since different inocula are used. Therefore and based on the stringent test conditions of ready biodegradability tests, the guidance documents declare: "Realising that ready biodegradability tests may sometime fail because of the stringent test conditions, in general, and the differences among the individual tests in terms of their stringency, consistent positive test results from test(s) should generally supersede negative test results" (ECHA Guidance on information requirements and chemical safety assessment Chapter R. 7b, 2012). In the currently discussed case of 1,2-epoxybutane the results of all three available ready biodegradability tests (OECD 301 A, OECD 301C and ISO 14593 – equal to OECD 310) show only small differences in terms of their kinetics, whereas the pass level was reached in all three cases. Therefore it can be concluded that the three tests show no conflicting results.

Aquatic toxicity:

"Finland" states that there are only acute aquatic toxicity studies available and that no analytical monitoring of the test concentration has been done, in respect to a volatile potential:

Acute aquatic toxicity:

All acute aquatic studies (fish, daphnia, algae) were performed 1988, according to former guideline standards. Therefore we evaluate them as valid with deficiencies (Klimisch score 2). Since the substance shows a moderate potential to evaporate from the water surface into the atmosphere (Henry's law constant of 21.48 Pa.m3/mol) and the tests are performed without analytical monitoring, we are not able to prove, whether the test substance got lost during the 2–4 day of test duration. We expect only negligible losses of test item. This indicates the sterile control of the biodegradation study (headspace of the DOC-Die-Away test) in which no DOC removal was observed during the 28 days of test duration. Nevertheless, we suggest to follow the comment of the "Netherland" to support the test results with QSAR-calculations. For the acute aquatic toxicity we calculate the following effect values with EpiSuite (ECOSAR v1.11):

ECOSAR v1.11 Class-specific Estimations

	Organism	Duration	End Pt	mg/L (ppm)
Epoxides, mono	: Fish	96-hr	LC50	30.124
Epoxides, mono	: Daphnid	48-hr	LC50	106.794
Epoxides, mono	: Green Algae	96-hr	EC50	154.647
Neutral Organic SAR (Baseline Toxicity)	: Fish	96-hr	LC50	621.516
	: Daphnid	48-hr	LC50	317.739
	: Green Algae	96-hr	EC50	153.358

Based on the measured data, the lowest acute effect value was determined with an EC50 (48h) of 70 mg/L (*Daphnia magna*), whereas the lowest acute effect value based on QSAR calculation is 30mg/L (fish LC50(96h)). Therefore measured and calculated data resulted in the same range (EC/LC50 values >10<100 mg/L). Hence it can be concluded that 1,2-epoxybutane is acutely harmful to aquatic organisms.

Chronic aquatic toxicity:
In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms.
Due to the fact, that 1,2-epoxybutane is ready biodegradable, the substance does not persist in the environment. Hence, long-term exposure of organisms is not expected. Furthermore, release of 1,2-epoxybutane to the environment is negligible, due to its use as monomer in polymers. The life cycle of 1,2-epoxybutane includes only a few steps, such as production, formulation, use as intermediate and use as monomer in polymerisation processes. All this uses are industrial processes in closed systems, with negligible releases. This confirms an exposure estimation, which was conducted in connection with the REACh registration of 1,2-epoxybutane. The exposure estimation shows that all the identified uses of 1,2-epoxybutane are safe (RCR<1).
Therefore, and for reasons of animal welfare, long-term toxicity studies are not required.

RAC's response

RAC agrees with the MS that in the CLH report there is not sufficient information to conclude on rapid degradation. RAC also agrees with the MS on the conclusion on aquatic toxicity: without measured concentrations, the reliability of the test cannot be evaluated.
However, more information has been provided by the Dossier Submitter in the responses to the public consultation comments. This information is useful and is discussed further in the opinion.

Date	Country	Organisation	Type of Organisation	Comment number
08.03.2013	Netherlands		MemberState	3

Comment received

Biodegradability
The proposed declassification is based on the results of a MITI study (OECD 301C) from

1997. However, no robust study summary is included for this study and only the final result is reported. Without additional information, it is very difficult to agree with the interpretation of the data. More information about the OECD 301C study is needed, including but not limited to the amount of epoxybutane used in the test, test conditions, results at each day of oxygen consumption measurement, the results from the positive control, results from toxicity and negative controls if included.

Further, Table 12 and section 5.1.2.2 state that epoxybutane is ready biodegradable in an ISO 14593 test. We doubt whether this conclusion can be drawn based on this test method. We do not have access to ISO 14593 but test guideline OECD 302D is based on the standard. OECD method 302D is a test for inherent aerobic biodegradability of organic substances but not a ready biodegradability screening test. According to the Guidance (II.2.3.4), inherent tests are generally not used to draw a conclusion on ready biodegradability. The conclusion that can be drawn from this study is that epoxybutane is inherently biodegradable.

Due to the limited information provided on biodegradability, we cannot support the conclusion that the 1,2-epoxybutane is rapidly degradable. Detailed descriptions of the key studies and a better justification need to be provided.

Aquatic toxicity
No chronic aquatic toxicity studies are provided. There are serious concerns about the validity of the acute aquatic toxicity studies due to possible/likely decrease in epoxybutane concentrations over the study duration that would underestimate the aquatic toxicity. The vapour pressure and Henrys constant indicate that evaporation of 1,2-epoxybutane must be taken into account when testing the substance. However, the CLH report does not mentioned whether epoxybutane was tested in open or closed vessels, or whether the studies were carried out under static or flow-through conditions. Also, no analytical monitoring was carried out. Despite of this, the results from the aquatic acute studies are reported as nominal concentrations.

The CLH report states that the concentrations of epoxybutane were constant in sterile controls in the biodegradation studies and thus, the concentrations are also expected to be constant in the aquatic toxicity studies. However, the biodegradability studies are said to be conducted in closed systems whereas open systems seem to have been used for the acute aquatic toxicity studies. Based on the available information, it cannot be assumed that the test substance concentrations were between 80-120% of nominal throughout the study. Without further information, these studies cannot be considered reliable.

We note that 1,2-epoxybutane has been evaluated in the OECD HPV chemical assessment program where it is stated that the aquatic toxicity studies were performed in open systems (http://webnet.oecd.org/HPV/UI/handler.axd?id=583dac2a-efeb-4a70-af91-546c74fa69ec). The SIAR also contains an ECOSAR prediction of the aquatic acute toxicity for 1,2-epoxybutane but no estimation for the chronic aquatic toxicity. We have included a copy of ECOSAR predictions for 1,2-epoxybutane. We believe that epoxybutane falls within the applicability domain of the models, however, documentation needs to be provided. The predictions for short-term toxicity show higher toxicity than is reported in the CLH report.

Of interest is that the ChV value for fish is predicted to be < 1 mg/L suggesting that 1,2-epoxybutane may have chronic aquatic toxicity effects in fish. The ChV is defined as the geometric mean of the no observed effect concentration (NOEC) and the lowest observed effect concentration (LOEC). This can be mathematically represented as ChV = 10^([log (LOEC x NOEC)]/2).

Due to the limited information provided on the conditions of the aquatic toxicity studies, we have serious doubts about the reliability of the aquatic toxicity studies. More clarity on the conditions and thus the reliability needs to be provided. If the studies were conducted in open vessels without analytical monitoring, they cannot be considered realiable and additional data, for example QSAR data, should be added to the data set for a better assessment of the aquatic toxicity.

ECOSAR predictions

SMILES : CCC1CO1
MOL FOR: C4 H8 O1
MOL WT : 72.11
Log Kow: 0.68 (User entered)
Melt Pt: -129.50 deg C
Wat Sol: 8.68E+004 mg/L (measured)

ECOSAR v1.00 Class(es) Found

Epoxides, mono
Predicted

ECOSAR Class	Organism	Duration	End Pt	mg/L (ppm)
Epoxides, mono:	Fish	96-hr	LC50	37.177 mg/L
Epoxides, mono:	Fish	14-day	LC50	23.459 mg/L
Epoxides, mono:	Daphnid	48-hr	LC50	138.904 mg/L
Epoxides, mono:	Green Algae	96-hr	EC50	143.771 mg/L
Epoxides, mono:	Fish		ChV	0.016 mg/L
Epoxides, mono:	Daphnid		ChV	13.653 ! mg/L
Epoxides, mono:	Green Algae		ChV	89.296 mg/L

Note: ! = exclamation designates: The toxicity value was determined from a predicted SAR using established acute-to-chronic ratios and ECOSAR regression techniques which are documented in the supporting Technical Reference Manual. When possible, this toxicity value should be considered in a weight of evidence approach.

Epoxides, mono:

For Fish (96-h) and Daphnid Acute Toxicity Values: If the log Kow of the chemical is greater than 5.0, or if the compound is solid and the LC50 exceeds the water solubility by 10X, no effects at saturation are predicted for these endpoints.

For Fish 14-day LC50 Toxicity Values: If the log Kow of the chemical is greater than 6.0, or if the compound is solid and the LC50 exceeds the endpoints.

For Green Algae Acute Toxicity Values: If the log Kow of the chemical is greater than 6.4, or if the compound is solid and the EC50 exceeds the water solubility by 10X, no effects at saturation are predicted for these endpoints.

For All Chronic Toxicity Values: If the log Kow of the chemical is greater than 8.0, or if the

compound is solid and the ChV exceeds the water solubility by 10X, no effects at saturation are predicted for these endpoints.

ECOSAR v1.00 SAR Limitations:

Maximum LogKow: 5.0 (Fish 96-h LC50, Daphnid LC50)
Maximum LogKow: 6.0 (Fish 14-day)
Maximum LogKow: 6.4 (EC50)
Maximum LogKow: 8.0 (ChV)
Maximum Mol Wt: 1000

Dossier Submitter's Response

Biodegradability:

The "Netherlands" request more detailed information on the MITI I study.
Therefore we provide some more information (including the degradation curves). Here an overview of the main aspects:

- amount of epoxybutane used in the test: 100 mg/L
- amount of reference substance: 100 mg/L
- activated sludge: 30 mg/L
- kinetic based on oxygen consumption:

	Degradation % (BOD)			
	day 7	day 14	day 21	day 28
reference control (1): sludge + aniline	69.1	101.5	111.7	112.1
sterile controle (2): water + test substance	0	0	0	0
test vessel (3): sludge + test substance	5.4	38.8	68.5	88.9
test vessel (4): sludge + test substance	12.0	39.0	69.6	89.7
test vessel (5): sludge + test substance	12.4	40.6	70.9	91.5
control blank (6)	3.3	6.7	9.4	10.7

The "Netherlands" asked, whether the test guideline ISO 14593 describes a ready biodegradability test, since they recognized that the test guideline OECD302D is based on this standard.

The ISO 14593 describes the headspace method, which was the origin of the ready biodegradability test according to OECD 310 as well as of the inherent biodegradability test according to OECD 302D. The OECD guidelines 310 and 302D differ mainly in the concentration and the adaptation of the used inoculum, whereas the test design is quite similar. In the discussed study on 1,2-epoxybutane 34 mg/L test substance was added to the test vessels, which corresponds to 19 mg C/L. This concentration is in accordance to the OECD guideline 310, where a concentration of test substance is postulated to be between 2 and 40 mg C/L, preferably 20 mg C/L. Furthermore, a concentration of 4 mg/L (dry substance) non-adapted activated sludge was used as inoculum, which is also in accordance with OECD guideline 310. Therefore it can be concluded that the described biodegradation test according to ISO 14593 is conducted equal to OECD guideline 310, which represents a

standard guideline for testing ready biodegradability.

Aquatic toxicity:

Due to missing analytical clarifications of the test concentrations during the aquatic tests, the "Netherlands" suggest using additional data, for example QSAR data, for a better assessment of the aquatic toxicity.

Acute aquatic toxicity:
All acute aquatic studies (fish, daphnia, algae) were performed 1988, according to former guideline standards. Therefore we evaluate them as valid with deficiencies (klimish score 2). Since the substance shows a moderate potential to evaporate from the water surface into the atmosphere (Henry's law constant of 21.48 Pa.m3/mol) and the tests are performed without analytical monitoring, we are not able to prove, whether the test substance got lost during the 2–4 day of test duration. We expect only negligible losses of test item. This indicates the sterile control of the biodegradation study (headspace of the DOC-Die-Away test) in which no DOC removal was observed during the 28 days of test duration. Nevertheless, we suggest to follow the comment of the "Netherland" to support the test results with QSAR-calculations. For the acute aquatic toxicity we calculate the following effect values with EpiSuite (ECOSAR v1.11):

ECOSAR v1.11 Class-specific Estimations

	Organism	Duration	End Pt	mg/L (ppm)
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Epoxides, mono	: Green Algae	96-hr	EC50	154.647
Neutral Organic SAR	: Fish	96-hr	LC50	621.516
(Baseline Toxicity)	: Daphnid	48-hr	LC50	317.739
	: Green Algae	96-hr	EC50	153.358

Based on the measured data, the lowest acute effect value was determined with an EC50 (48h) of 70 mg/L (*Daphnia magna*), whereas the lowest acute effect value based on QSAR calculation is 30mg/L (fish LC50(96h)). Therefore measured and calculated data resulted in the same range (EC/LC50 values >10<100 mg/L). Hence it can be concluded that 1,2-epoxybutane is acutely harmful to aquatic organisms.

Chronic aquatic toxicity:
In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms.
Due to the fact, that 1,2-epoxybutane is ready biodegradable, the substance does not persist in the environment. Hence, long-term exposure of organisms is not expected. Furthermore, release of 1,2-epoxybutane to the environment is negligible, due to its use as monomer in polymers. The life cycle of 1,2-epoxybutane includes only a few steps, such as production, formulation, use as intermediate and use as monomer in polymerisation processes. All this uses are industrial processes in closed systems, with negligible releases. This confirms an exposure estimation, which was conducted in connection with the REACh

registration of 1,2-epoxybutane. The exposure estimation shows that all the identified uses of 1,2-epoxybutane are safe (RCR<1).
Therefore, and for reasons of animal welfare, long-term toxicity studies are not required.

RAC's response

See response to comment number 1. RAC agrees that the QSAR calculations are a good option for evaluating the toxicity of the substance in the absence of valid ecotoxicity data. RAC agrees that the substance falls within the applicability domain of the models. More details can be found in the opinion. The DS has explained that chronic aquatic toxicity studies are not proposed for several reasons that are not, however, classification related. In the CLH process all available information is used and no further testing is required.

Date	Country	Organisation	Type of Organisation	Comment number
21.03.2013	Belgium		MemberState	4

Comment received

Biodegradation :
As biodegradation, in this case, is the key point whether or not to classify the substance for the environment, it would have been preferable if more detailed info was given on the validity and procedure of the tests performed, controls, reference substance, biodegradation curve, ...

The headspace test is considered the key study for ready biodegradation of 1,2-epoxybutane. The OECD310 Headspace test demonstrates that the test substance is readily biodegradable under aerobic conditions when biodegradation >60% ThC02 within the 10-d window. The percentage reached after 28 days may be used directly for assessment of ready biodegradability when no information on the 10-d window is available.
Based on the concise info given in the CLH report, the fact that records were made during 7 days intervals and 80-90% of the substance is degraded after 28d, it can be assumed that the substance is readily biodegradable. However info is available indicating that it was not definitely been proved that the 10-d window was met. Can this be closely examined by means of the degradation curve?
Also in the DOC-die away study the substance was readily degradable, but failing the 10-d window.
When more degradation data are available for the same substance, data of the highest quality and the best documentation should be used for determining the ready biodegradability of the substance.
Indeed, the 10-d window concept does not apply to the MITI method, however this test is considered as supporting study with a klimish score 2.

Dossier Submitter's Response

"Belgium" argues that biodegradation is the key point, whether or not to classify the substance for the environment, so they prefer to get more detailed information on it.

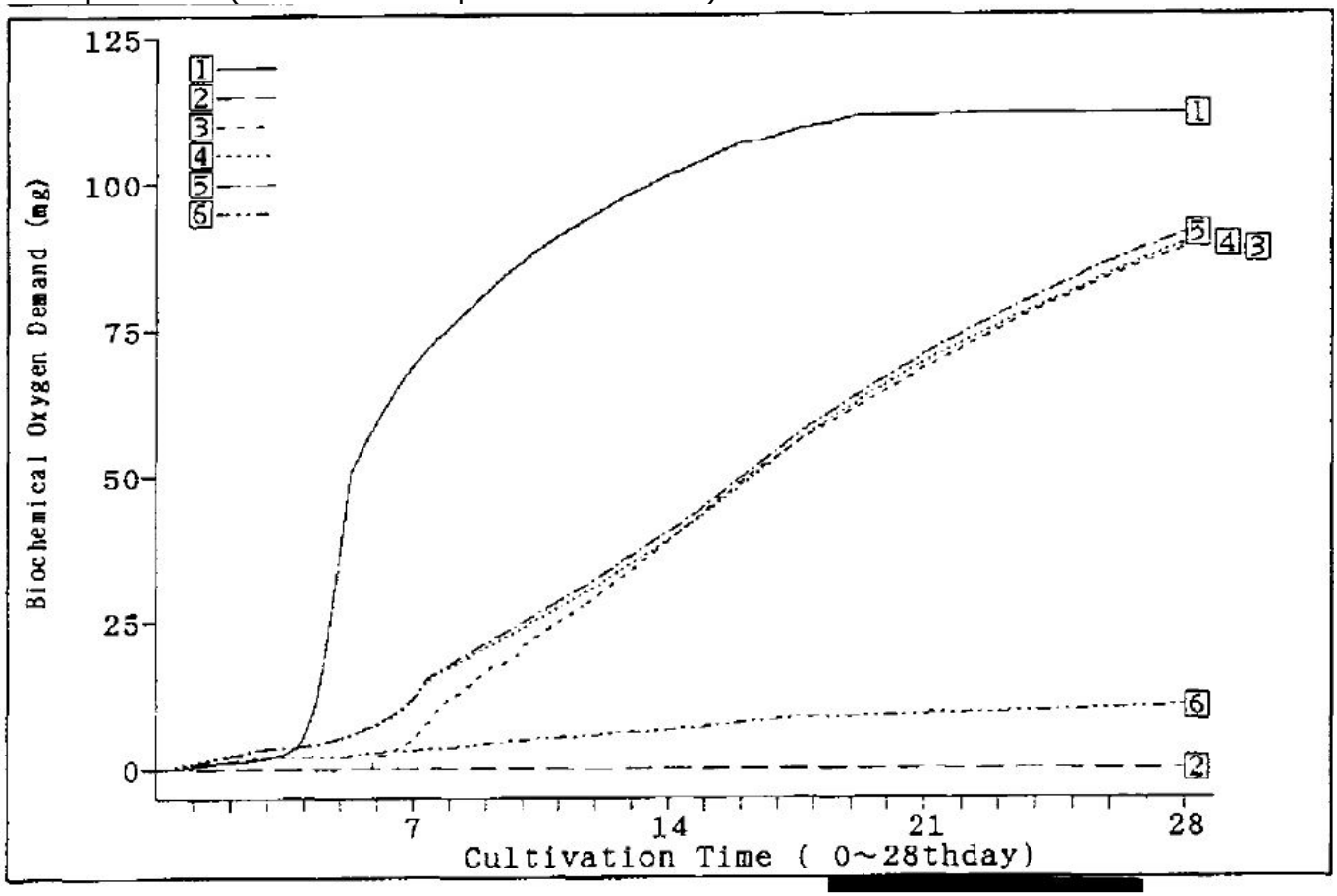
Therefore we provide more important information on the MITI study in the IUCLID.
Here an overview of the main aspects:

- amount of epoxybutane used in the test: 100 mg/L
- amount of reference substance: 100 mg/L
- activated sludge: 30 mg/L

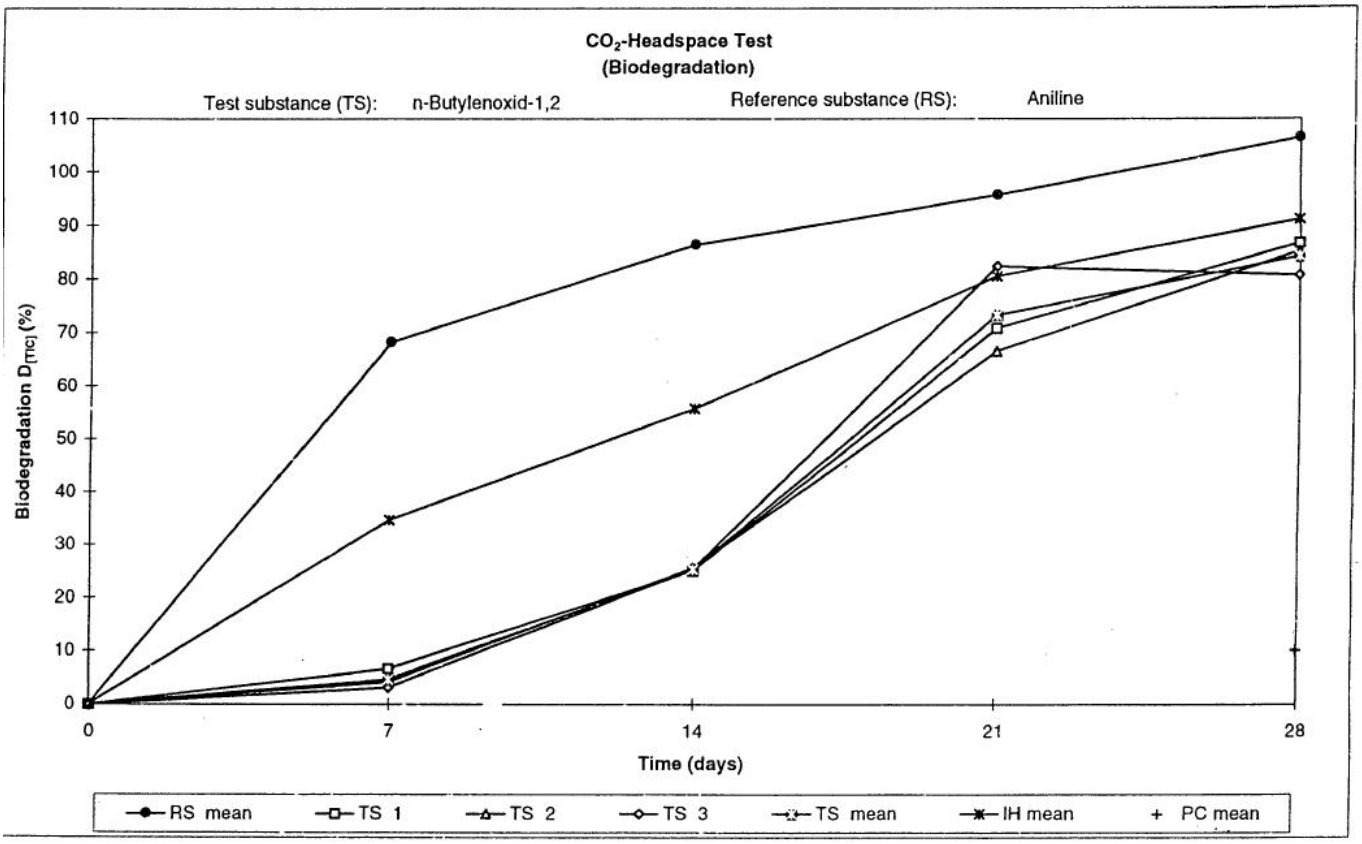
- kinetic based on oxygen consumption:

	Degradation % (BOD)			
	day 7	day 14	day 21	day 28
reference control (1): sludge + aniline	69.1	101.5	111.7	112.1
sterile controle (2): water + test substance	0	0	0	0
test vessel (3): sludge + test substance	5.4	38.8	68.5	88.9
test vessel (4): sludge + test substance	12.0	39.0	69.6	89.7
test vessel (5): sludge + test substance	12.4	40.6	70.9	91.5
control blank (6)	3.3	6.7	9.4	10.7

Please find also the following degradation curves of the MITI I test as well as for the headspace test (ISO 14593 - equal to OECD 310).



MITI I Test according to OECD guideline 301C: reference control, sludge + aniline (1) / sterile controle (2), water + test substance / test vessel (3) (4) (5) / control blank (6)



CO2 -Headspace test (ISO 14593 - equal to OECD 310)

<u>"Belgium" notes, if more than one degradation study is available, data of the highest quality and the best documentation should be used for determining the ready biodegradability of the substance.</u>

In the currently discussed case of 1,2-epoxybutane three well documented guideline studies on ready biodegradability are available (OECD 301 A, OECD 301C and ISO 14593 – equal to OECD 310). All three studies are reliable and the results of the three studies show only differences in terms of their kinetics, whereas the pass level was reached in all three cases. These differences in the kinetic are the point of discussion, since in one study (OECD 301 A) the relevant 'ten-day-time window criterion' is missed and in case of the other study (ISO 14593 – equal to OECD 310) the test design, with 7 days measuring intervals complicates the proof of the 'ten-day-time window criterion' (more details are reported in the CLH report). Nevertheless the third test according to OECD 301C is excluded from the 'ten-day-time window' requirement. Hence the MITI I study on its own is sufficient to prove the ready biodegradable of 1,2-epoxybutane.

We agree with "Belgium", that data of the highest quality and the best documentation should be used for determining the ready biodegradability of the substance. In the past we flagged the headspace test (ISO 14593 – equal to OECD 310) as key study, due to the fact that the test report of the MITI I test was not available, at the time of dossier preparation. Meanwhile we received the full test report of the MITI I test and can state that the study is reliable without deficient. Therefore we suggest to flag the MITI I test as key study with Klimisch score 1, and the headspace test (ISO 14593 – equal to OECD 310) as supporting study.

RAC's response
See response to comment number 1 on degradation.