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April 6, 2018

Via Certified Mail and Electronic Mail (quality@epa.gov)

USEPA Headquarters  
William Jefferson Clinton Federal Building  
1200 Pennsylvania Avenue, NW  
Mail Code: 2821T  
Washington, DC 20460

Subject: Request for Correction of "Anthraquinone, 9,10-" data  
- Screening levels for "Anthraquinone, 9,10-" in EPA's Regional  
Screening Level Tables displayed on EPA's website at  
<https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables-november-2017>  
- provisional screening values presented in Appendix A of "Provisional  
Peer-Reviewed Toxicity Values for 9,10-Anthraquinone (CASRN 84-65-1)", EPA/690/R-11/007F, Final 2-17-2011

Dear Sir or Madam:

This Request for Correction is submitted by Chemical Products Corporation (CPC), a Georgia corporation located at 102 Old Mill Road SE, Cartersville, GA 30120. CPC hereby petitions EPA to correct information disseminated in "Provisional Peer-Reviewed Toxicity Values for 9,10-Anthraquinone (CASRN 84-65-1)", EPA/690/R-11/007F, Final 2-17-2011 (PPRTV); and EPA's Regional Screening Level (RSL) Tables provided on EPA's website at <https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables-november-2017>.

The screening levels presented in EPA's RSL tables for the compound "Anthraquinone, 9,10-" are based upon the PPRTV which cites National Toxicology Program (NTP) Technical Report 494 (TR-494) as the principal study on which the provisional screening values presented in its Appendix A are based. TR-494 presents conclusions which are not

scientifically sound and do not comply with the U.S. Environmental Protection Agency's (EPA's) implementing guidelines (EPA Guidelines),<sup>1</sup> as a result, the "Anthraquinone, 9,10-" screening levels presented in EPA's Regional Screening Level (RSL) Tables do not reflect the "sound and objective scientific practices" required under the EPA Guidelines.

This Request for Correction is submitted under the Information Quality Act<sup>2</sup> and the EPA Guidelines, as well as the guidelines of the Office of Management and Budget (OMB)<sup>3</sup> and other applicable law.

CPC purchases 9,10-Anthraquinone as a 99% pure coarse powder and processes it into a fine-particle-size aqueous 50% solids suspension product which is sold primarily within the U.S. for use as a catalyst in the Kraft pulping process. The information in EPA's Regional Screening Level Tables disseminated to the public on EPA's website at <https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables-november-2017>. has harmed CPC by having an adverse effect on the sales of its product.

This Request for Correction will demonstrate that EPA should not consider the conclusions presented in National Toxicology Program Technical Report 494 (TR-494) to represent valid peer-reviewed toxicity values or sound science because peer reviewers were presented false information by NTP staff which prevented the Peer Review Panel from rendering a sound scientific judgment.

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1 EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (Oct. 2002).

2 Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, P.L. 106-554; 44 U.S.C. § 3516 (notes).

3 67 Fed. Reg. 8452 (Feb. 22, 2002).

There is no scientifically sound basis for considering non-mutagenic 9,10-Anthraquinone (AQ) likely to be carcinogenic to humans. There is no scientifically sound basis for concluding that non-mutagenic 9,10-Anthraquinone (AQ) caused cancers in the NTP TR494 animal studies. NTP unknowingly conducted animal testing with AQ contaminated by the potent mutagen 9-nitroanthracene. When the mutagenic contamination was discovered years after completion of animal testing, NTP staff presented false information to a subsequent peer review panel in order to achieve acceptance of the conclusions presented in TR-494: that AQ caused carcinogenicity in female F344/N rats and both male and female B6C3F1 mice and some evidence of carcinogenicity in male F344/N rats.

The PPRTV cited in EPA's RSL Summary Table as the basis for the screening levels presented in the table is "*Provisional Peer-Reviewed Toxicity Values for 9,10-Anthraquinone (CASRN 84-65-1)*"; Superfund Health Risk Technical Support Center; EPA/690/R-11/007F Final 2-17-2011. In this document, Table 2 on pages 5 through 7 identifies the principal study upon which the subchronic, chronic, and carcinogenic toxicity determinations are based as "NTP(2005b)"; the reference on Page 50 shows "NTP(2005b)" to be "NTP technical report on the toxicology and carcinogenesis studies of anthraquinone (CAS no. 84-65-1) in F344/N rats and B6C3F1 mice (feed studies). NTP TR 494; NIH Publication No. 05-3953. U.S. Department of Health and Human Services, Public Health Service, Research Triangle Park, NC. Available online at <http://ntp.niehs.nih.gov/files/TR494web1.pdf>. Accessed on 4/8/2010." Thus, the information disseminated by EPA regarding 9,10-Anthraquinone in both the PPRTV and the RSL Summary Tables derives solely from National Toxicology Program Technical Report 494. This Request for Correction provides documentation that Technical Report

494 does not represent sound science or the "sound and objective scientific practices" required under the EPA Guidelines.

#### Historical Background of NTP Technical Report 494

The AQ employed in the TR-494 animal testing was obtained by NTP in the early 1990s; animal testing was completed in 1997; mutagenic contamination in the AQ test article was discovered in 2000 and two separate aliquots of the TR-494 test article were tested and found to be mutagenic soon thereafter. In December 2004 NTP presented false information to peer reviewers to achieve acceptance of the conclusions that NTP's animal studies provided clear evidence that AQ caused carcinogenicity in female F344/N rats and both male and female B6C3F1 mice. A negative mutagenicity assay falsely ascribed to the TR-494 test article was employed at the third peer review of TR-494 to convince peer reviewers that contamination was not biologically significant.

9,10-Anthraquinone (AQ) is not mutagenic. NTP unknowingly obtained AQ contaminated with the potent mutagen 9-nitroanthracene in the early 1990s for its animal testing; this AQ was produced in Europe because there is no U.S. domestic production of AQ. In the 1980s European toxicologists had determined that mutagenicity found only in commercial AQ produced by the nitric acid oxidation of anthracene process resulted from contamination by the potent mutagen 9-nitroanthracene. The obsolete nitric acid oxidation of Anthracene process was discontinued by the mid 1990s (soon after NTP obtained the AQ employed for animal testing). The nitric acid oxidation of anthracene process for production of AQ is not practiced anywhere in the world. All of the commercially-available AQ around the world today is free of 9-nitroanthracene contamination and is not mutagenic.

At the time it was conducting animal testing, NTP also provided aliquots of its AQ test article to other laboratories for additional toxicological testing.<sup>4</sup>

In 1999, when contamination of NTP's AQ test article with the potent mutagen 9-nitroanthracene had not yet been discovered, a peer review panel accepted NTP's proposed conclusion that AQ was responsible for clear evidence of carcinogenicity in female F344/N rats and both male and female B6C3F1 mice and some evidence of carcinogenicity in male F344/N rats. This 1999 peer-reviewed TR-494 was withdrawn in 2003.

Chemical analysis of NTP's AQ test article discovered the presence of the potent mutagen 9-nitroanthracene in 2000. The TR-494 AQ test article, labeled "Anthraquinone, Lot #5893", has been stored under air at room temperature at Battelle Columbus Labs since completion of animal testing in 1997. The concentration of 9-nitroanthracene in the test article may have decreased as a result of decomposition by the time it was detected in 2000.

NTP had not previously performed mutagenicity testing on its TR-494 AQ test article and it did not perform mutagenicity testing on its TR-494 test article after the 9-nitroanthracene contamination was detected.

CPC had an aliquot of NTP's test article tested by Bioreliance Testing

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<sup>4</sup> Gibson, D.P., Brauninger, R., Shaffi, H.S., Kerckaert, G.A., LeBoeuf, R.A., Isfort, R.J., and Aardema, M.J. (1997). Induction of micronuclei in Syrian hamster embryo cells: Comparison to results in the SHE cell transformation assay for national toxicology program test chemicals. *Mutat. Res.* **392**, 61-70.

Laboratory in 2000 using the NTP test protocol and the aliquot was found to be mutagenic; this mutagenicity assay was reported to NTP.

Butterworth et al. also obtained an aliquot of NTP's AQ test article which was tested and was also found to be mutagenic.<sup>5</sup>

On September 8, 2003, Dr. Samuel H. Wilson, Deputy Director of NIEHS, withdrew the draft NTP Technical Report 494 which had been peer reviewed and accepted in 1999 because he determined that the presence of mutagenic contamination in non-mutagenic AQ had confounded interpretation of the NTP animal studies. Dr. Wilson informed CPC of the withdrawal of the 1999 peer-reviewed TR-494 in a letter which is included as Attachment 1.

Deputy Director Wilson's letter to CPC announcing the withdrawal of the 1999 TR-494 states in part:

*"Conclusions:* Following the process outlined above and after careful review of the information that I have described, I have reached the following conclusions:

1. The sample of anthraquinone used in the NTP 2-year study was contaminated with 9- nitroanthracene at a level of about 0.1%.
2. The presence of this contaminant raises doubt as to the effect(s) of anthraquinone itself, or its metabolites, and confounds interpretation of the NTP studies referenced in draft

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<sup>5</sup> Butterworth, B.E., Mathre, O.B., and Ballinger, K. (2001). The preparation of anthraquinone used in the National Toxicology Program cancer bioassay was contaminated with the mutagen 9-nitroanthracene. *Mutagenesis* **16**, 169-177.

TR-494. In addition, in view of imprecise statements in the text presented on the website, this abstract needs to have greater specificity than it presently has.

3. The abstract of draft TR-494 will immediately be removed from the NTP website."

The same conclusions which appeared in the 1999 draft TR-494 appear in the final 2005 TR-494.

The NTP peer review panel responsible for approving the conclusions in TR-494 met on December 9, 2004 and were presented "new information": a negative mutagenicity assay for "Sample A07496" which NTP staff alleged to be a mutagenicity assay of the TR-494 AQ test article, all of which is stored at Battelle Columbus Laboratories and identified as "Anthraquinone, Lot #5893". This negative mutagenicity assay for "Sample A07496" is included in the 2005 TR-494.

A 2009 paper, A Data-Based Assessment of Alternative Strategies for Identification of Potential Human Cancer Hazards, by eminent European toxicologist Alan R. Boobis<sup>6</sup> and co-authors contains the highly significant conclusion regarding the scientific validity of TR-494, "The data for anthraquinone are considered suspect

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<sup>6</sup> Professor Alan R. Boobis received the Order of the British Empire in 2003 for his contributions on the risk assessment of pesticides. He is an Honorary Member of EUROTOX, a Fellow of the British Toxicology Society, and a Fellow of the Institute of Biology.

because other carcinogenicity studies were negative, and the NTP carcinogenicity study used a batch of anthraquinone contaminated with the potent mutagen 9-nitroanthracene at a level of 1,200 ppm (Butterworth, Mathre, and Ballinger 2001). (A purified sample was negative in the Ames test.) Certainly, it can be said that the material used by the NTP was mutagenic...."<sup>7</sup> As stated earlier, European toxicologists identified and traced the source of mutagenicity in AQ produced by the nitric acid oxidation of anthracene to 9-nitroanthracene contamination (NTP's Kristine Witt confirmed in the email included in Attachment 2 that nitric acid oxidation of anthracene was the production method for the NTP TR-494 test article).

The following false information was presented to the December 9, 2004 NTP Board of Scientific Counselors Peer Review Panel which approved the conclusions in TR-494:

**1.** The negative mutagenicity assay of "Sample A07496" was presented as definitive proof that 9-nitroanthracene contamination in NTP's TR-494 AQ test article was not biologically significant. Documents obtained through Freedom of Information Act requests reveal that "Sample A07496" is not an aliquot of NTP's AQ test article.

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<sup>7</sup> Boobis, A.R. et al.; A Data-Based Assessment of Alternative Strategies for Identification of Potential Human Cancer Hazards; *Toxicologic Pathology* 2009; 37; 714.



The mutagenicity assay of "Sample A07496" was conducted by BioReliance Testing Laboratories in June 2004. Freedom of Information Act requests for information on shipments of AQ from Battelle Columbus Laboratories, the repository for all TR-494 AQ test article, to BioReliance Laboratories in the mid-2004 time period have not revealed any shipments of "Anthraquinone, Lot #5893" to BioReliance. Any aliquot of the TR-494 AQ test article shipped from Battelle would be labeled "Anthraquinone, Lot #5893".

When BioReliance Testing Laboratory reported the negative mutagenicity assay of "Sample A07496" to NTP, someone at NTP alleged, without providing any documentary evidence, that this was an aliquot of the TR-494 AQ test article "Anthraquinone, Lot #5893". Kristine Witt at NTP sought to verify the identity of "Sample A07496" by asking for confirmation from BioReliance Testing Laboratory that "Sample A07496" was an aliquot of "Anthraquinone, Lot #5893". Emails obtained through Freedom of Information Act requests are included as Attachment 2. Kristine Witt clearly states to Richard San at BioReliance that there is no documentation within NTP to demonstrate that "Sample A07496" is an aliquot of NTP's TR-494 AQ test article; she is forced to rely solely upon confirmation from BioReliance Testing Laboratory. Richard San at BioReliance emailed confirmation to Kristine Witt at NTP that "Sample A07496" was "Anthraquinone, Lot #5893" even though the BioReliance Test Article Receipt and Transfer Report demonstrates that no information existed within BioReliance Testing Laboratory to justify his confirmation.

The BioReliance Test Article Receipt and Transfer Report obtained through a Freedom of Information Act request shows that the sample in question was labeled only "Sample A07496" when it was received by BioReliance; BioReliance had no evidence that this sample was an aliquot of the TR-494 test article, "Anthraquinone, Lot #5893". The BioReliance Test Article Receipt and Transfer Report for "Sample A07496" is included as Attachment C.

Any aliquot of the TR-494 AQ test article would have been labeled "Anthraquinone, Lot #5893" when it was shipped from the Battelle Columbus Laboratories repository and when it was received by BioReliance Testing Laboratory. Someone at NTP arranged for the shipment of "Sample A07496" to BioReliance Testing Laboratories and authorized mutagenicity testing of a sample labeled "Sample A07496" by BioReliance with full knowledge that this AQ sample was not the TR-494 test article.

To sum, peer reviewers were under the false impression that the TR-494 AQ test article had been determined to be non-mutagenic when they approved the conclusions in TR-494, and TR-494 contains this false allegation. This false information would have been critical to their adjudication and renders their acceptance of the conclusions in TR-494 scientifically untenable.

**2.** During the December 9, 2005 peer review, a reviewer questioned whether mutagenic impurities might have decomposed during the roughly 8 year period between animal testing and the June 2004 negative mutagenicity assay; the possibility of decomposition of biologically significant mutagenic impurities in

the TR-494 test article over time confounds interpretation of a 2004 negative mutagenicity assay, even if the assay had been performed on an aliquot of the TR-494 test article. The Peer Review Panel was told by NTP's Cynthia Smith that the aliquot of the test article which underwent mutagenicity assay in June 2004 had been stored frozen under argon during the interval between animal testing and mutagenicity assay. Peer reviewers were provided false information; documents obtained under a Freedom of Information Act request showed that all TR-494 test article had been stored at room temperature under air for this 8 year period. In response to a Request for Correction, NTP opted to simply add an addendum paragraph after the last page of TR-494 rather than address the impact this false information had on peer reviewer's adjudication of the conclusions in TR-494.

In sum, peer reviewers were provided false information to prevent them from accurately evaluating the scientific validity of the conclusions presented in TR-494. The same conclusions that were approved in 1999 prior to discovery of mutagenic contamination in the TR-494 test article were approved on December 9, 2004 for inclusion in the final TR-494.

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The EPA Guidelines require "influential" scientific information to meet a "higher degree of quality."<sup>8</sup> In particular, EPA has established very rigorous standards for "influential scientific risk assessment information."<sup>9</sup> These stringent quality standards are applicable here.

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<sup>8</sup> EPA Guidelines at p. 19-20. Likewise, OMB has declared that: "The more important the information, the higher the quality standards to which it should be held." 67 Fed. Reg. At 8452.

<sup>9</sup> EPA Guidelines at pp. 20-23.

Other Required Information: The EPA Guidelines require Requests for Correction to include the name and contact information of the organization submitting the request, and to identify an individual to serve as a contact. For this Request, the name of the organization submitting the request is Chemical Products Corporation, a Georgia corporation, located at 102 Old Mill Road SE, Cartersville, GA 30120; and contact information is as follows:

Jerry A. Cook, Technical Director  
Chemical Products Corporation  
102 Old Mill Road SE  
P.O. Box 2470  
Cartersville, GA 30120

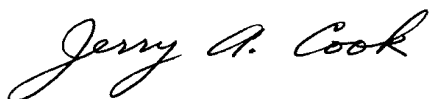
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Conclusion: For the reasons set forth above, CPC respectfully requests that:

- (1)** this Request for Correction be granted;
- (2)** "Anthraquinone, 9,10-" be immediately removed from EPA's Regional Screening Level Tables provided on EPA's website at <https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables-november-2017> pending revision of "Provisional Peer-Reviewed Toxicity Values for 9,10-Anthraquinone (CASRN 84-65-1)", EPA/690/R-11/007F, Final 2-17-2011 to provide toxicity values for 9,10-Anthraquinone which are based upon sound science;

**(3)** "Provisional Peer-Reviewed Toxicity Values for 9,10-Anthraquinone (CASRN 84-65-1)", EPA/690/R-11/007F, Final 2-17-2011 be immediately withdrawn and revised to provide toxicity values for 9,10-Anthraquinone which are based upon sound science rather than upon NTP Technical Report 494.

Very truly yours,



Jerry A. Cook  
Technical Director

Attachments – 12 pages

- Attachment 1 – 3 pages – contains Deputy Director Samuel H. Wilson letter to CPC announcing withdrawal of the peer-reviewed 1999 TR-494
- Attachment 2 – 6 pages – contains 2 emails from NTP's Kristine Witt to Richard San at BioReliance Testing Laboratory and 2 emails from Richard San to Kristine Witt.
- Attachment 3 – 3 pages – contains the Test Article Receipt and Transfer Report from BioReliance Testing Laboratory showing receipt of a sample labeled only "Sample A07496".

cc: **Via Certified Mail and Electronic Mail**

Dr. Tina Bahadori, Director  
EPA National Center for Environmental Assessment  
(Bahadori.tina@epa.gov)

## Attachment 1

Deputy Director Samuel H. Wilson's letter to CPC  
announcing withdrawal of the  
peer-reviewed 1999 TR-494  
after discovery of mutagenic contamination  
in the AQ test article



September 8, 2003

**National Institutes of Health  
National Institute of  
Environmental Health Sciences  
P.O. Box 12233  
Research Triangle Park, N.C. 27709  
Website: [www.niehs.nih.gov](http://www.niehs.nih.gov)**

Mr. Jerry A. Cook  
Technical Director  
Chemical Products Corporation  
Cartersville, Georgia 30120

Re: Request for Reconsideration submitted March 27, 2003

Dear Mr. Cook:

On behalf of the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), I am responding to your March 27, 2002, Request for Reconsideration submitted for the Chemical Products Corporation (CPC) under the NIH's "Guidelines for Ensuring the Quality of Information Disseminated to the Public" (NIH Guidelines). Your Reconsideration Request appealed the NIH's March 19, 2003, decision regarding the CPC's November 15, 2003, Request for Correction contained in the Abstract for Draft National Toxicology Program (NTP) Technical Report # TR-494. A summary of the background information on the study that culminated in draft TR-494, the process I used to consider the appeal, and my conclusions are provided as follows:

*Background:* The NTP conducted a 2-year carcinogenicity study in rodents on a batch of anthraquinone obtained commercially that was shown to be 99.9% pure; results of this study eventually led to a draft report termed TR-494. Once it was peer reviewed, the abstract of draft TR-494 was posted on the NTP website. On July 25, 2000, you sent a letter to Dr. Kenneth Olden, Director of the NTP, stating that the sample of anthraquinone tested contained a 0.1% contamination by 9-nitroanthracene, a mutagenic compound, and noting that the presence of this contaminant called the study interpretations into question. The NTP followed up on your letter, confirming that a contaminant in the anthraquinone sample at about the 0.1% level was indeed 9-nitroanthracene. The NTP then initiated the process, in September 2000, to assess the metabolism of the parent compound, anthraquinone, in rodents, and to assess the relative mutagenicity in an Ames test of anthraquinone, its two major urinary metabolites, the contaminant 9-nitroanthracene, and two isomers of 9-nitroanthracene. You subsequently filed an Information Quality Request for Correction on November 15, 2002, asking that the abstract be immediately removed from the NTP's website in view of errors or misleading statements in the material presented. On March 19, 2003, NIH sent you a response to your Request for Correction stating that additional information would be incorporated into the NTP web site to clarify the material in the abstract of draft TR-494 and informing you about ongoing follow-up studies of

anthraquinone. The NTP amended the abstract of draft TR-494 on April 1, 2003, on its website to include reference to the 9-nitroanthracene contaminant, and the NTP also made mention of ongoing studies to resolve whether or not this contaminant might have affected the 2-year study results. On March 27, 2003, you submitted a Request for Reconsideration to NIH.

*Process:* In the course of my review, I have reviewed the HHS and NIH Guidelines for Ensuring the Quality of Information Disseminated to the Public, read draft TR-494, and read Chemical Products Corporation's letters and the NTP's responses to those letters. I have consulted with NIH and HHS staff familiar with the Information Quality process. I also have reviewed data and ongoing tests with the staff of NIEHS' Environmental Toxicology Program who were responsible for the NTP studies and draft report. I have been assisted in these efforts by staff from the NIEHS Office of Policy, Planning and Evaluation.

*Conclusions:* Following the process outlined above and after careful review of the information that I have described, I have reached the following conclusions:

1. The sample of anthraquinone used in the NTP 2-year study was contaminated with 9-nitroanthracene at a level of about 0.1%.
2. The presence of this contaminant raises doubt as to the effect(s) of anthraquinone itself, or its metabolites, and confounds interpretation of the NTP studies referenced in draft TR-494. In addition, in view of imprecise statements in the text presented on the website, this abstract needs to have greater specificity than it presently has.
3. The abstract of draft TR-494 will immediately be removed from the NTP website.

Further studies are underway on the metabolism of anthraquinone in rodents and on the relative mutagenic potency of this compound, its major metabolites, the contaminant 9-nitroanthracene, and two isomers of 9-nitroanthracene. Additional information from this work will eventually be incorporated into a revised abstract and technical report which will be submitted for peer review and subsequent publication.

I appreciate your comments and hope that the actions that I have taken address your concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Samuel H. Wilson".

Samuel H. Wilson, M.D.  
Deputy Director

cc: Mary Wolfe, Ph.D.  
Director, NTP Liaison and Scientific Review Office



## Attachment 2

emails exchanged between NTP's Kristine Witt and Richard San at BioReliance Testing Laboratory about 3 months prior to the final peer review of TR-494

contains 2 emails from NTP's Kristine Witt to Richard San and 2 emails from Richard San to Kristine Witt

In Kristine Witt's first email she describes the TR-494 test article as  
" Anthraquinone, Lot #5893.  
This is from Zeneca Fine Chemicals.  
The Nitric Acid Oxidation manufacturing process"

In Kristine Witt's second email she states,  
"...without confirmation of the test article identities I'm uncertain as to what the results are telling us."

> **From:** Witt, Kristine (NIH/NIEHS[<mailto:witt@niehs.nih.gov>])  
> **Sent:** Friday, September 10, 2004 9:43 AM  
> **To:** San, Richard <[RSan@bioreliance.com](mailto:RSan@bioreliance.com)>  
> **Subject:** FW: question about aliquot number assignment

> Hello, Richard.

> Thank you for sending the preliminary results for the 4  
> Salmonella tests that were recently conducted at  
> BioReliance. The results were surprising to me, and  
> therefore, I need to make sure that your aliquot  
> assignment matches ours. Can you please confirm that the  
> aliquot numbers match the chemical samples described  
> below? If there is a discrepancy, please send me your list,  
> matching aliquot with test sample.

> Regarding the issue of money for the no-cost extension,  
> our contract officer is aware of the problem and he is  
> considering an approach to resolving the problem.

> Thanks for your help in understanding these test results.

> Best regards,  
> Kristine.

> > 4 aliquot numbers were assigned to 4 different samples of  
> > anthraquinone. They were:

> > A07496 1. Anthraquinone, Lot #5893. This is from  
> > Zeneca FineChemicals. The Nitric Acid Oxidation  
> > manufacturing process (78.82 kg).

> >

> > A40147 2. 9,10-Anthraquinone, Lot #2Y011. This is  
> > from Kawasaki Kasei Chemical LTD. The Diels-Alder  
> > manufacturing process (13.40 kg).

> >

> > A65343 3. 9,10-Anthraquinone, Lot # 64005. This is  
> > from Environmental Biocontrol Intl. The Diels-Alder  
> > manufacturing process.  
> > (23.20 g).

> >

> > A54984 4. 9,10-Anthraquinone, Lot # GSTU 2517770.  
> > This is from Environmental Biocontrol Intl. The Friedel-  
> > Crafts manufacturing process. (26.70 g).

> >

> > Kristine L. Witt  
> > Toxicology Operations Branch  
> > Environmental Toxicology Program  
> > National Institute of Environmental Health Sciences  
> > PO Box 12233, MD EC-32  
> > Research Triangle Park, NC 27709  
> > phone: 919-541-2761  
> > fax: 919-316-4511  
> > e-mail: [witt@niehs.nih.gov](mailto:witt@niehs.nih.gov)

> >

> >

>

>

> **From:** San, Richard <[RSan@bioreliance.com](mailto:RSan@bioreliance.com)>  
> **Sent:** Friday, September 10, 2004 4:44 PM  
> **To:** Witt, Kristine (NIH/NIEHS) <[witt@niehs.nih.gov](mailto:witt@niehs.nih.gov)>  
> **Subject: RE:** question about aliquot number assignment  
>  
> Hello, Kristine,>  
> Thanks for your e-mail. I have asked [*non-key employee*];  
> who has custody of the test article related documents, to  
> confirm the aliquot assignments. As soon as I hear from  
> him, I will let you know.  
>  
> Best regards,  
>  
> Richard  
>

**From:** Witt, Kristine (NIH/NIEHS) [<mailto:witt@niehs.nih.gov>]

**Sent:** Wednesday, September 15, 2004 3: 18 PM

**To:** San, Richard <[RSan@bioreliance.com](mailto:RSan@bioreliance.com)>

**Subject: RE:** question about aliquot number assignment

Hi, Richard.

Have you received word from [*non-key employee*] about the test article aliquot number assignments? We are having a meeting here Friday morning to review all the new data we've acquired on anthraquinone and try to understand what it means in terms of biological activity for some important commercial compounds. These data are key to that discussion, but without confirmation of the test article identities I'm uncertain as to what the results are telling us. Can you please let [*non-key employee*] know that the need for the information you requested is urgent?

Thanks,  
Kristine.

**Subject: RE: question about aliquot number assignment**

**Date:** Thursday, September 16, 2004 2:26 PM

**From:** San, Richard <[RSan@bioreliance.com](mailto:RSan@bioreliance.com)>

**To:** "Witt, Kristine (NIH/NIEHS)" <[witt@niehs.nih.gov](mailto:witt@niehs.nih.gov)>

**Conversation:** question about aliquot number assignment

Hello, Kritine,

[*non-key employee*] has confirmed that the test article aliquot number assignments are accurate as presented. Also, from a review of the study files, it is noted that we have a Material Safety Data Sheet only for A40147 from Kawasaki Kasei Chemical LTD.

Regards,

Richard

## Attachment 3

the Test Article Receipt and Transfer Report  
from BioReliance Testing Laboratory  
recording receipt of a sample  
labeled only  
"Sample A07496"

BioReliance reported a negative mutagenicity assay  
of this sample  
to NTP

BTL TEST ARTICLE RECEIPT AND TRANSFER  
REPORT

Compiled date 15-DEC-2006 01:30 PM

Lot, Sample: AA93WK.0001

Lot, Sample: AA93WK.0001

Test Article Name: A07496

Label ID: A07496

store at RT

No Exp Date given

Sieved 8 mesh

Lot/Batch No: NP

Expiration: N/A

Purity: NP

Storage Condition: Room Temperature

Stock Location: 15-30+RMS275B+CAN1/3C+BTL

Supplement Storage: protect from light/desiccate

Description: light yellow powder (per MSDS: light tan liquid)

Gross Weight: 32.32 g

Net Weight: NP

Unit of Measure: G

Handling: non-regulated

Condition on Receipt: GOOD

Receipt Date: 02-JUN-2004

Login By: [Non-User Contact Emp]

Logix Date: 04-JUN-2004

Comments:

received TA ambient with papers. Logged in TA late on 6/4/04 (received on 6/2/04) due to the fact that the Sponsor site in the Oracle Module was inactive. Changed location number because of change of RM#

From Subinv From Locator

# Units VOM Trx Date

System Date To Subinv To Locator

User

32.32 G 04-JUN-2004 04-JUN-2004 BTL-CINREP 3\*RT\*MCDDRM261\*3C

BTL-CINREP 3\*RT\*MCDDRM261\*3C

600.00 MG 16-JUN-2004 16-JUN-2004 BTL-GAMES

BTL-CINREP 3\*RT\*MCDDRM261\*3C

100.00 MG 16-JUN-2004 16-JUN-2004 BTL-GAMES

[Non-User Contact Emp]



MANIFESTLANKPBR.rtf V3.0

BTL TEST ARTICLES RECEIPT AND TRANSFER  
REPORT

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Compiled date 15-DEC-2006 01:30 PM

Lot Sample: AA93WK.0001

FROM Subinv FROM Locator	# Units UOM	Vtx Date	System Date To Subinv	To Locator	User
BTL-CHMRP 3*RT*MCDDRM261*3C	480.00	MG	16-JUN-2004	16-JUN-2004	BTL-GAMES
BTL-CHMRP 3*RT*MCDDRM261*3C	200.00	MG	15-JUL-2004	15-JUL-2004	BTL-GAMES
BTL-CHMRP 3*RT*MCDDRM261*3C	30.94	G	20-OCT-2005	20-OCT-2005	BTL-CHMRP 15-30*RM5275B-CAB/3C

Run-7  
Kitt  
Conduct  
[Employee]