Targeted Risk Assessment

User Guide (including addendum) for TRA Consumer Stand-alone Tool - Version 3.1

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PREFACE

The 3.2 version of the Integrated TRA tool did not introduce changes to the Consumer module. Therefore, version 3.1 of the Stand-alone Consumer tool remains the same. Nonetheless some of the text in this user guide was updated in September 2023 to remain relevant to newer versions of Excel and Windows and to be consistent with other ECETOC TRA User Guides.

1. ADDENDUM FOR VERSION 3.1

1.1 Introduction

This Addendum provides guidance for the use of the new applications introduced in version 3.1 of the ECETOC TRA Stand-alone Consumer tool. Therefore the Addendum is meant to be used in conjunction with the "User guide for the stand-alone consumer tool – version 3", **which comprises the remainder of this document**. Moreover, to understand the underlying science, assumptions, and limitations of the tool, refer to the ECETOC Technical Reports No. 93, No. 107, No 114, and the 2014 Addendum to 114, Technical Report No. 124.

1.2 New Applications in Consumer Tool Version 3.1

The new applications in version 3.1 of the consumer tool added to those in version 3 include:

A. Possibility of accounting for low frequency events when calculating exposure.
B. Possibility of introducing an inhalation transfer factor (similar to the oral and dermal transfer factors in version 3).
C. Application of "Indoor" or "Outdoor" scenarios when calculating inhalation exposure.
D. Possibility of selecting two additional body parts: "two fingertips" and "palm of one hand" when calculating dermal exposure

All these new applications are upgrades to the already existing tool needed for entering new product/article subcategories ("Add Subcategories" sheet). For a more in depth explanation of the preexisting system, see section 6 in page 24. The new implemented changes are all optional. An explanation on how to use the new features is briefly provided below.

The modifications in the TRA consumer module align with the Specific Consumer Exposure Determinants (SCED) concept developed across various industry sectors for their consumer applications and documented in SCED factsheets.

1.3 Accounting for Low Frequency Events

Version 3.1 of the consumer tool allows distinguishing among events depending on their frequency. In previous versions of the tool all events were assumed to occur daily (except for those that occurred several times per day). Version 3.1 considers four frequency categories and assigns an adjusting factor to the exposure estimate depending on the respective category chosen:

Table 1. Breakdown of frequency events

Frequency of Use	Definition	Proposed TRA Multiplier	Rationale for Multiplier
Frequent	Event occurs at least once a week	1	Equates to daily use
Occasional	Events occurs between once a week and once a month	0.2 (5x)	Exposure reduction factor reflects fact that average exposures expected to be at least one order less than daily exposure
Infrequent	Events occurs between once a month and once every 6 months	0.04 (25x)	Exposure reduction factor reflects fact that average exposures typically expected to be at least 50 fold less than daily exposures
Very Infrequent	Events occurs no more than once in 6 months	0.01 (100x)	Exposure reduction factor reflects fact that average exposures expected to be at least two orders less than daily exposures

To use this application, go to the "Add Subcategories" sheet. Then use the drop-down menu in column L to enter the frequency of use (as in above table) or a numerical value for the number of uses per day, as needed. The selected frequency will apply to all exposure routes relevant to the assessment of the respective sub-category.

1.4 Inhalation Transfer Factor

In order to use the Inhalation Transfer Factor (TF inhalation) first go to the "Add Subcategories" sheet in excel. Next, in column Y you can enter a value between 0 and 1 to define the "TF Inhalation".

This is an optional entry and the tool will default to 1 if no "TF inhalation" value is specified. Also note that the defined "TF Inhalation" is a separate value and as such it should be considered an additional adjustment perform on top of the normal ones the tool uses for non-spray products. This will take into account the saturated vapour concentration (SVC) of the substance (More information can be found below on Section 4 in page 17).

1.5 Indoor or Outdoor Inhalation Exposure

When calculating inhalation exposure, a user can choose between two options,

- an indoor (20 m^3 room volume; 0.6 air changes per hour),
- or outdoor (100 m^3 volume; 2.5 air changes per hour).

To do this go to column X in the “Add Subcategories” sheet and select either option on the drop-down menu. If no entry is selected the tool will default to the most conservative option of “indoor”.

1.6 Additional Body Part Selection for Dermal Exposure

Two additional selection options can be found in the drop-down list in column N on “Add Subcategories” (see example in screenshot below).

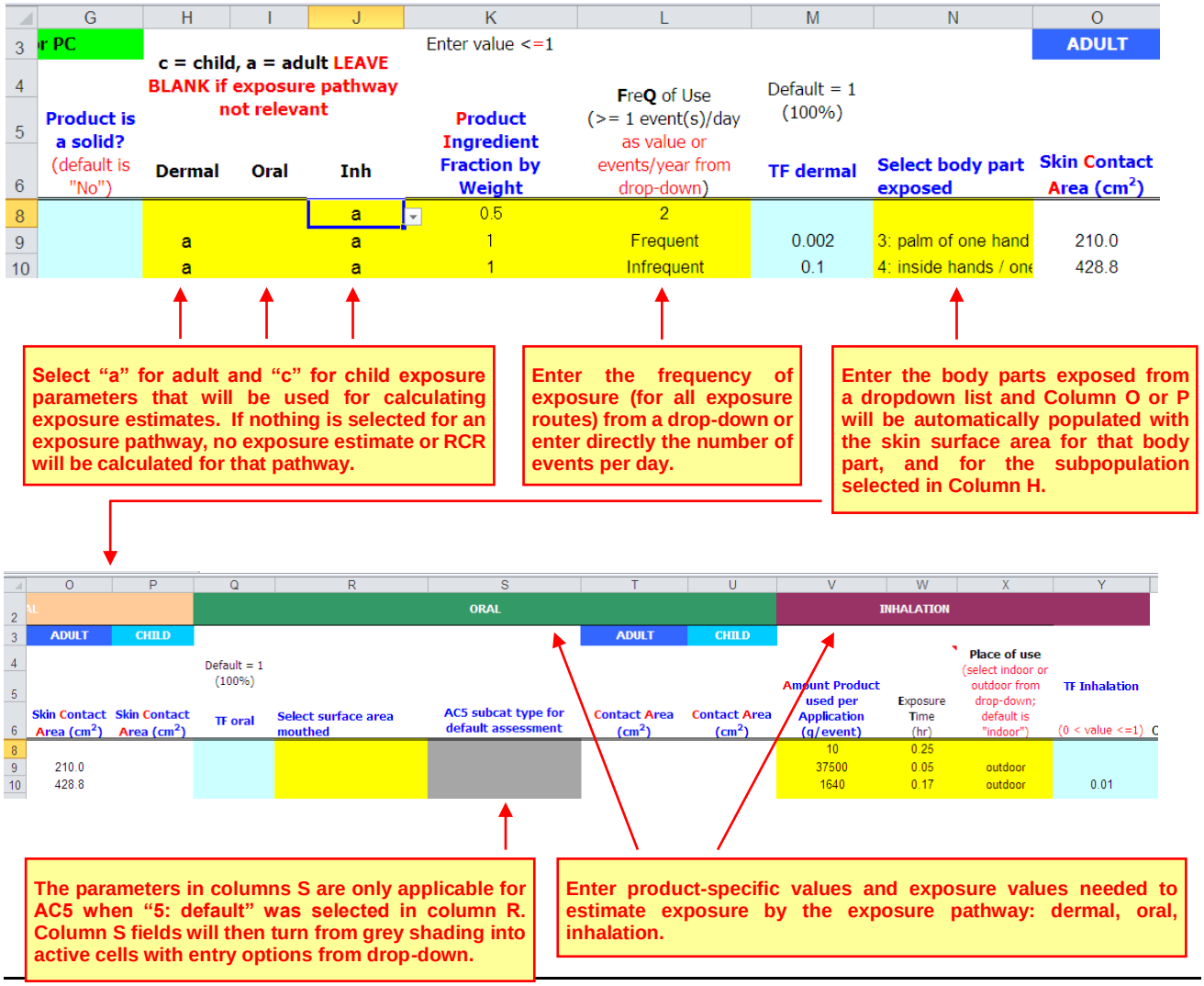

Figure 1. Examples for assessment parameters available in version 3.1

TARGETED RISK ASSESSMENT

USER GUIDE FOR THE STAND-ALONE CONSUMER TOOL

-VERSION 3

2. INTRODUCTION

The ECETOC TRA Consumer tool allows calculation of consumer exposures to substances that are present in preparations and articles used by consumers. The calculated exposures correspond to a tier 1 level of assessment based on simple models and limited data.

The tool calculates exposure via inhalation, dermal, and oral routes separately. It is available as a Stand-alone Excel tool, or as a module in the Integrated tool that combines worker, environmental, and consumer calculations. This User Guide provides guidance for working with version 3 of the Stand-alone Consumer tool, please refer to the Integrated tool User Guide if you are planning to use its consumer module. To understand the underlying science, assumptions, and limitations of the tool, refer to the ECETOC Technical Reports No. 93, No. 107, and the 2011 update of those reports.

2.1 Getting started

To begin please follow the instructions on the ECETOC website (https://www.ecetoc.org/tools/tra-main/tra-download/) and download the Stand-alone Consumer tool v3.1.

Once downloaded, first extract the file "ConsumerTRA_Ver31.zip" into a folder using WinZip or any other program capable of extracting .zip-files.

After extracting the file, the folder should look similarly to Figure 2.

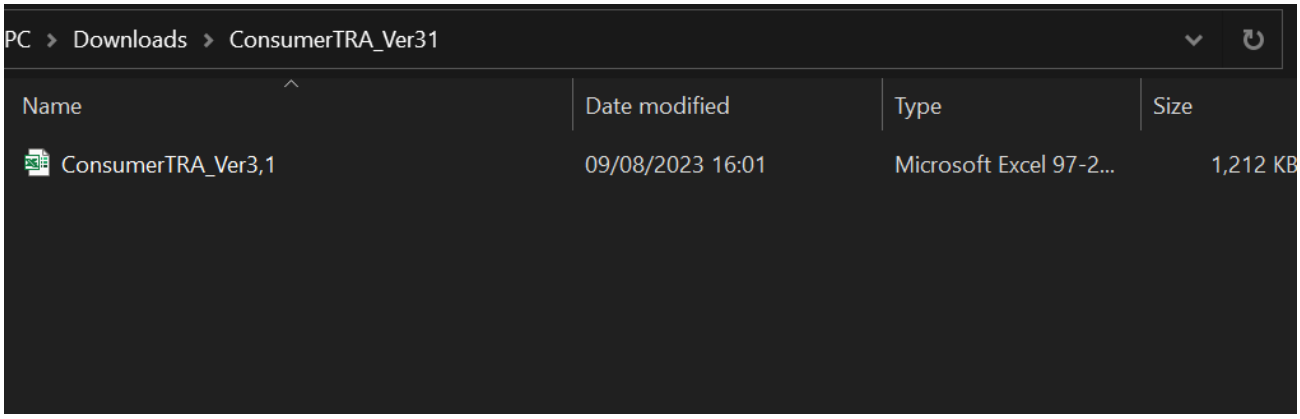

Figure 2. Extracted ECETOC TRA Stand-alone Consumer tool folder

Before you run the application, right-click on the excel file "ConsumerTRA_Ver3,1.xls" and go to properties. Under the General tab check the unblock security box at the bottom of the Properties window (Figure 3). This will unblock the tool and the macros of the worksheet.

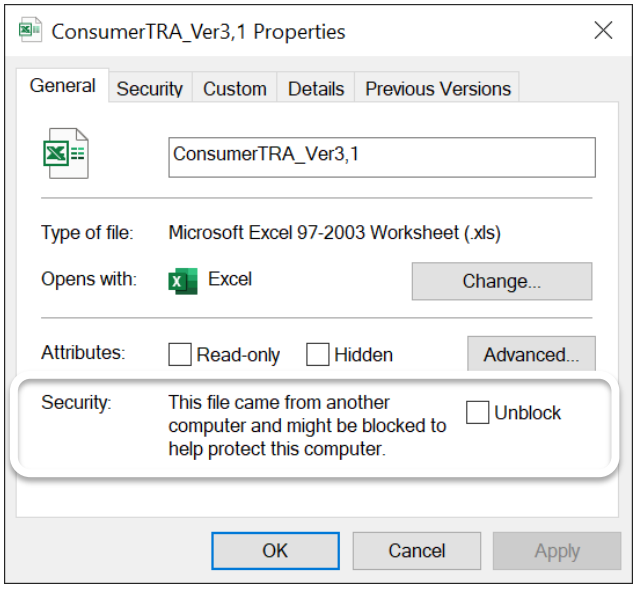

Figure 3. Unblock the TRA Consumer tool to enable Macros in Excel

Once this is done open "ConsumerTRA_Ver3,1.xls" as you would any other Excel file and the tool will start.

For Older versions of Excel and Windows

Upon opening the tool, the user will be presented with a Security Warning (Figure 4). To ensure the tool functions properly, select "Enable Macros". The screenshot below is for Microsoft Office Excel 2003 and lower.

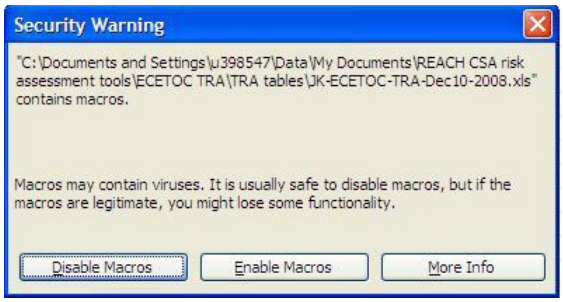

Figure 4. Excel 2003 security warning pop up message box

2.2 User Interface

The previous version of the Consumer TRA tool contained eight worksheets. A new worksheet has been added to Version 3, which allows users to add new product and article subcategories. Each of the worksheets can be navigated via the tabs at the bottom of the tool (Figure 5).

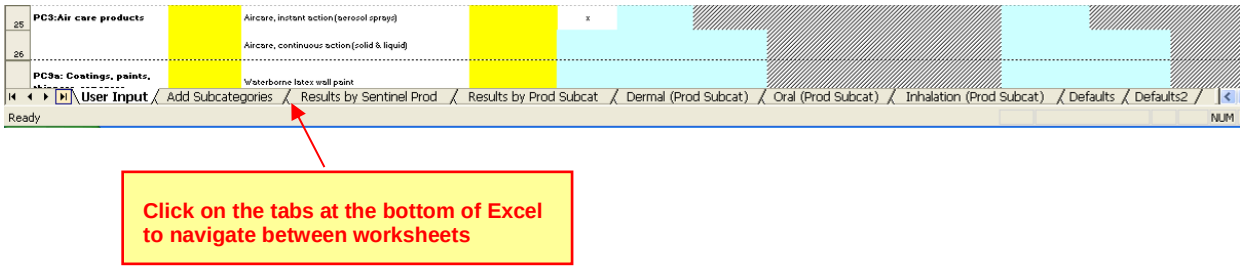

Figure 5. Navigation in the tool

Table 2 summarises these worksheets and explains the information provided within each sheet:

Table 2. Worksheets contained in the TRA Consumer Tool (Version 3)

Worksheet Name	Content
User Input	User-specific entries and selections are entered to generate exposure estimates and risk characterisation ratios (RCR).
Add Subcategories (**new for Version 3**)	Allows users to add new product and article subcategories if relevant specific data are available for the new subcategories.
Results by Sentinel Prod	Displays exposure estimates and RCRs for sentinel products[1] and shows route-specific algorithms and parameters used to calculate them.
Results by Prod Subcat	Displays exposure estimates and RCRs for product/article subcategories.
Dermal (Prod Subcat)	Displays dermal exposure estimates and RCRs for the product subcategories (including any new added ones) and shows the algorithm and parameters used to calculate them.
Oral (Prod Subcat)	Displays oral exposure estimates and RCRs for the product subcategories (including any new added ones) and shows the algorithm and parameters used to calculate them.
Inhalation (Prod Subcat)	Displays inhalation exposure estimates and RCRs for the product subcategories (including any new added ones) and shows the algorithm and parameters used to calculate them.
Defaults	Lists default exposure parameters and relevant exposure routes for each product/article.
Defaults2	Lists subpopulation-specific (child, adult) default parameters used to estimate exposure.

(1) The term "sentinel product" is used to describe a group of related product subcategories. An example is AC8 (paper products), which includes the following product subcategories: diapers, sanitary towels, tissues, and printed paper. Exposure estimates for sentinel products represent the most conservative (highest) values for all product subcategories within the group.

By default, upon opening the tool the "User Input" worksheet is shown. All of the user-required entries are done here. This worksheet contains colour-coded cells that identify inputs necessary for running the tool:

- Yellow cells are required information before the tool can generate results.
- Blue cells are optional if nothing is entered in these cells the tool automatically selects default parameters listed in the "Defaults" tab.
- Pink cells are automatically populated based on user made entries.

Changes can be made only in the yellow and blue cells. All other cells are locked to protect equations from being unintentionally deleted and to prevent users from over-riding default parameters set in the tool. Users can still format cells and rows and for better viewing. Columns cannot be formatted.

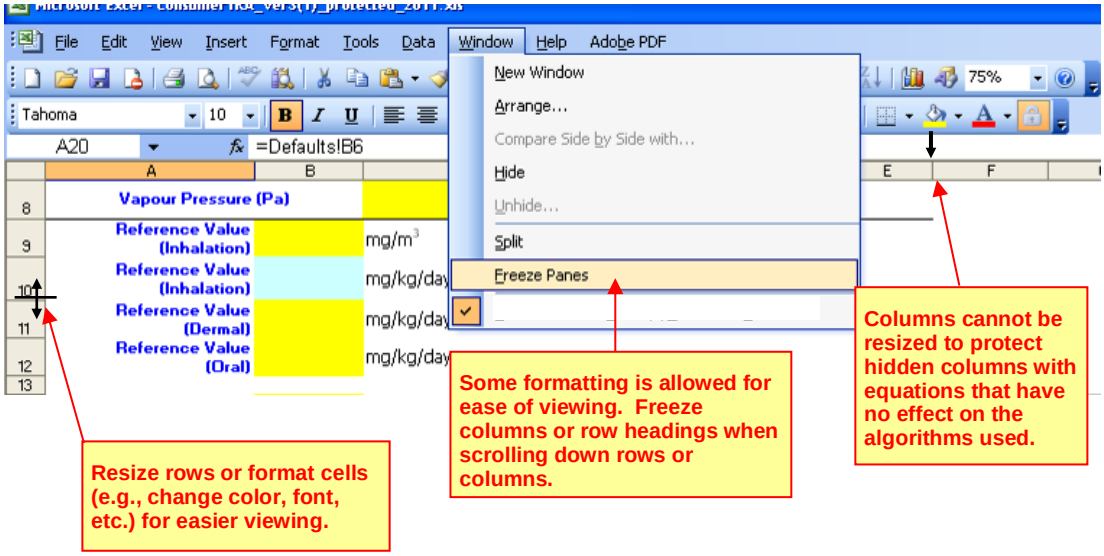

Figure 6. Formatting inside the tool

3. USING THE TOOL – DEFAULT PRODUCT AND ARTICLE TYPES

Exposure estimates and risk characterisation ratios (RCRs) can be calculated for a group of consumer products/articles (i.e. assessing sentinel products/articles of the PC/AC) or for individual product/article subcategories.

3.1 Selecting the default product/article types

First, identify which product or article to assess in the "User Input" worksheet. For sentinel products/articles, put an "x" in column B for the respective preparation or article listed in column A. Similarly, for a specific product/article subcategory (column C), put an "x" in column D of the respective product or article. More than one sentinel product/article and/or product/article subcategory can be evaluated simultaneously. There is no limit to the number of sentinel products/articles and subcategories that can be evaluated at the same time.

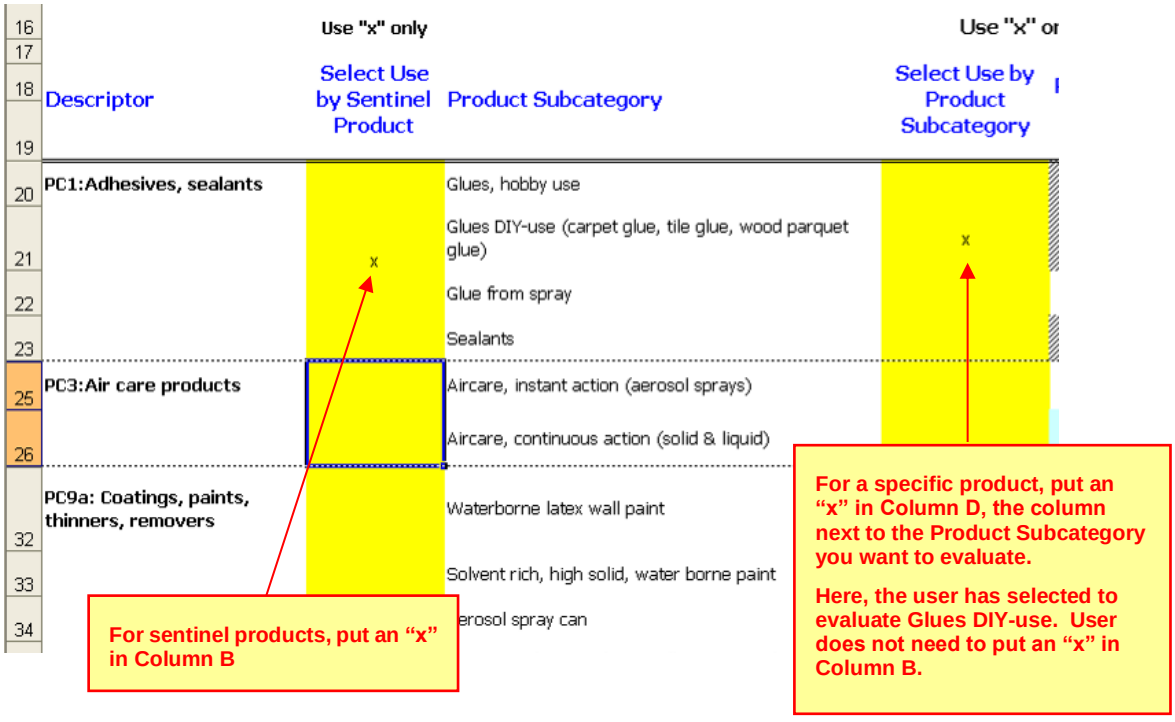

Figure 7. Use selection of products and articles

3.2 Entering reference values

Next, enter reference value(s) (e.g., DNEL) for the chemical being evaluated (Figure 8). The tool lists four reference values in total but only three reference values can be entered at once. This is a result of the user only being able to enter the inhalation reference value in either units of mg/m^3 or in units of mg/kg/day. When an inhalation reference value has already been entered and the user attempts to enter a second one with a different unit, an error message will be displayed, informing the user that only one inhalation reference value can be entered into the tool (Figure 8). When this occurs, select "cancel" to exit the error message box.

The tool does not convert the inhalation reference value from mg/m^3 to mg/kg/day; this will have to be calculated outside of the tool by using a general population inhalation rate and body weight. In some cases, the worst-case product subcategory for inhalation exposures may change depending on the units.

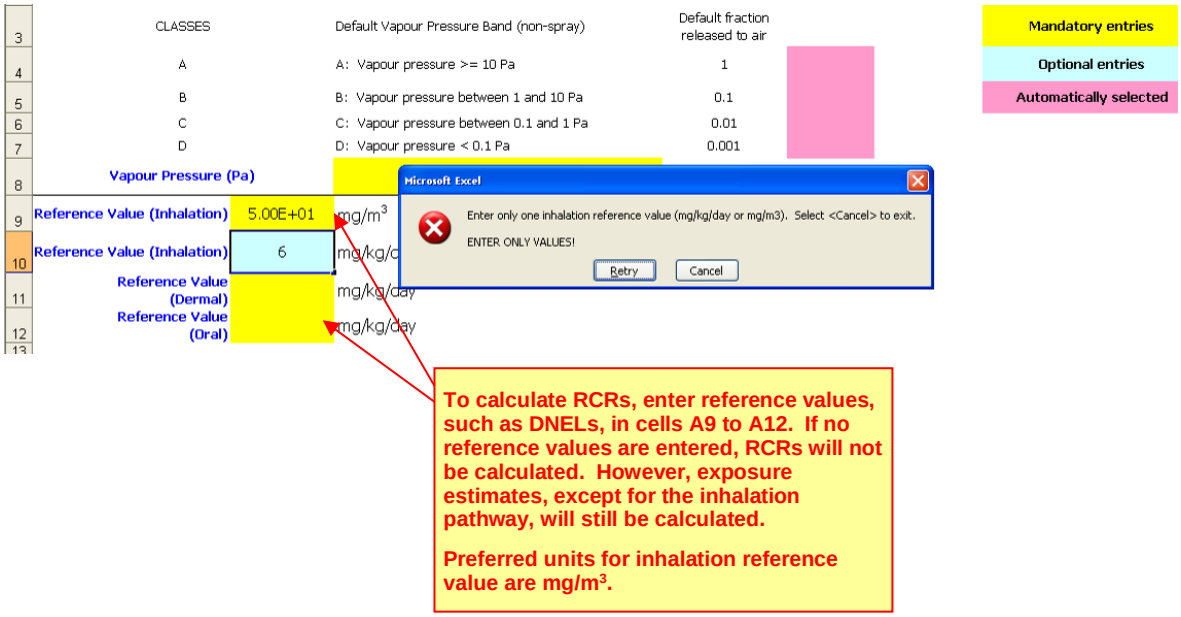

Figure 8. Entering reference values. Error message is displayed when inputting two different unit types for the inhalation reference value

A route-specific reference value is only needed if the exposure route is of significance for the selected product. Exposure routes included for a sentinel product or product subcategory can be viewed in the "Defaults" worksheet (Columns D to I). The simplest way to avoid error messages when viewing results is to enter reference values for all exposure routes.

3.3 Entering vapour pressure values

A vapour pressure is needed for inhalation exposures. Enter the vapour pressure, in units of Pascal (Pa), in cell C8 (Figure 9). The tool automatically selects the vapour pressure band that is used to assign a default fraction released to the air (cells C2 and E4-E7; Figure 8). The selected default fraction released to the air is only applicable for non-sprays and if inhalation is a significant exposure route associated with the use of the product/article. For sprays, the default fraction released to the air is always 1 and cannot be changed. Spray products are identified by an "x" marked in column E.

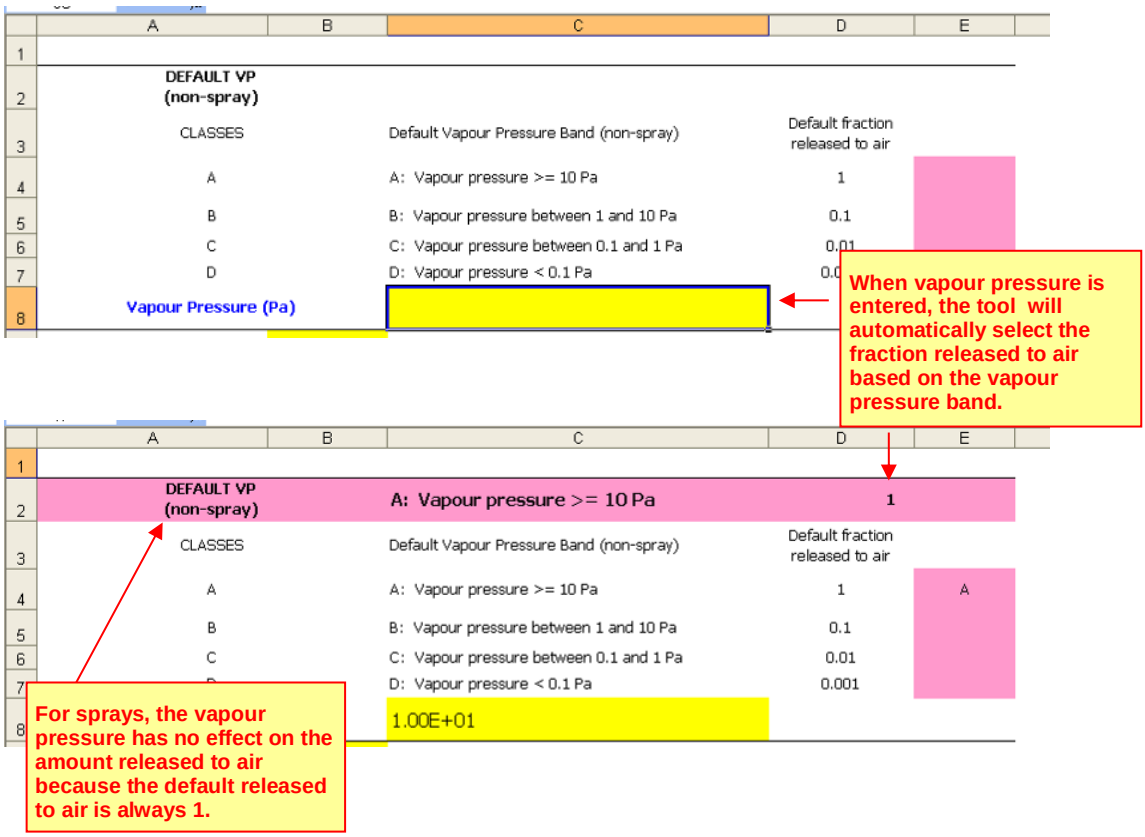

Figure 9. Entering vapour pressure values

For products and articles that are never sprays (e.g., finger paint, diapers), column E is hatched out and the user cannot change the default setting (Figure 10). However, the tool does allow users to determine whether or not some preparations are sprays. Cells in column E for these products are shaded blue, which means input is optional (Figure 10). Marking the product as a spray (i.e., putting an "x" in column E) assigns 1 as the fraction released to air. If this column is left blank, the tool assigns the default fraction released to air based on the substance's vapour pressure.

Note: For sentinel products, changing a product subcategory to a spray may change the worst-case product subcategory for inhalation exposures. This is a result of the tool calculating exposure estimates and RCRs by using the highest exposure estimate calculated for the product subcategories within each sentinel group. The worst-case product subcategory is not necessarily the same for all exposure routes.

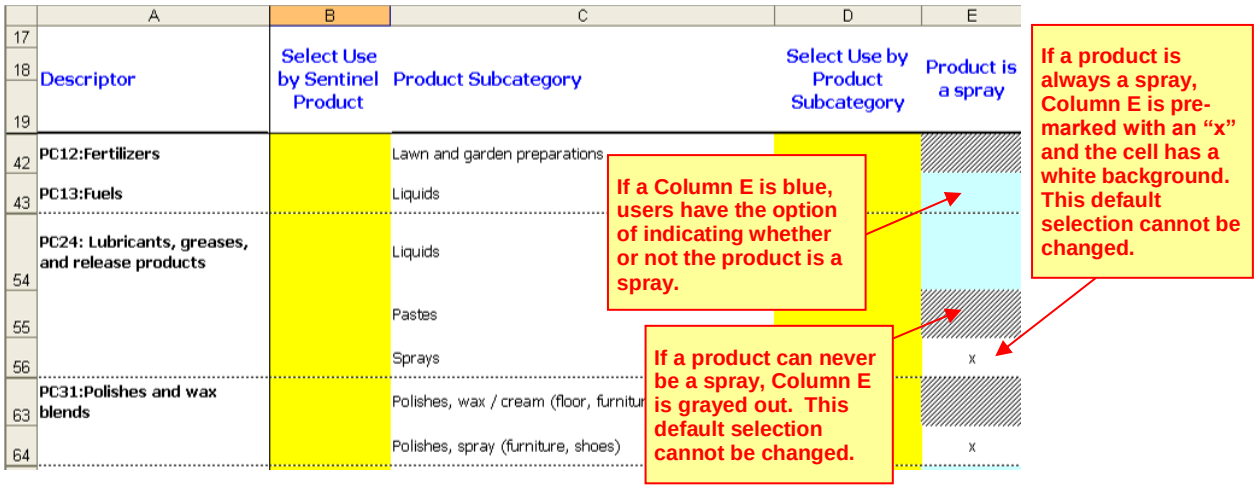

Figure 10. Explanation of the spray column

4. REFINING EXPOSURE ESTIMATES

4.1 Optional Change of Default Parameter Values for the Listed Categories and Subcategories

The user has the option to change default values for the "Product Ingredient Fraction by Weight", "Skin Contact Area" (dermal exposures), "Contact Area" (oral exposures) and the "Amount of Product used per Application" (inhalation exposure only), in columns F-K (Table 2). These modifiable parameters can be identified by the red letters highlighting the acronyms for the parameter in that algorithm. For example, the red letters in "skin **c**ontact **a**rea" define the parameter, CA, which is used in the equation for calculating dermal exposures. Note that although these changes are made at the product subcategory level, they could result in a change to the worst-case product subcategory used to estimate exposure for sentinel products.

New for Version 3, users can also enter transfer factors for the dermal and oral routes of exposure, in columns L-M (Table 3). Refer to the ECETOC Technical Report No. 114 for more information on transfer factors and how they can be used to refine exposure estimates.

If no values are entered in columns F to M, the tool automatically assigns default values listed in the "Defaults" worksheet. Transfer factors are not included in the "Defaults" worksheet, but are assigned default values of 100% (or fraction of 1).

Table 3. Parameters for which default values can be changed by the user

Parameter	Explanatory Note
Product **I**ngredient Fraction by Weight	Enter the fraction of substance (>0 to 1) in the product. This parameter is used to calculate exposure estimates for all three exposure pathways where applicable (inhalation, dermal, oral). Default values are listed in Column H of "Defaults" worksheet.
Skin **C**ontact Area (dermal exposure) (cm^2)	Enter different skin contact area in columns G or H, for the adult and child, respectively. The tool predetermines whether adult or child conditions are used, and therefore, the skin contact area can only be entered for either the adult or child, but not both. Although any value can be entered in columns G or H, user should refer to the contact areas listed in the "Defaults2" worksheet (rows 4 to 15 for dermal exposure).
Contact Area (oral exposure) (cm^2)	Enter different contact area in column J. Oral exposures are based on a child mouthing a surface or an area of skin. Therefore, the skin contact area should be based on child rather than adult values. Same as above, user should refer to the skin contact areas listed in rows 18-21 of the "Defaults2" worksheet.

Parameter	Explanatory Note
Amount Product used per Application (inhalation exposure) (g/event)	Enter a different value if more product-specific use information is available. This parameter only affects calculations for inhalation exposures. Default values are listed in column U of the "Defaults" worksheet.
Dermal Transfer Factor	Enter a fraction transferred (>0 to 1) from the product to the skin in Column L. As a conservative estimate, 100% is assumed. Note this value is not the same as the amount absorbed through the skin.
Oral Transfer Factor	Enter a fraction transferred (>0 to 1) from the product to the mouth during mouthing behaviour in Column M. As a conservative estimate, 100% is assumed. The oral transfer factor is not the same as the amount bioavailable once ingested.

4.2 Refining Inhalation Exposure Estimates

4.2.1 Saturated Vapour Concentration

New for Version 3, users have the option of refining inhalation exposure estimates by comparing them against the saturated vapour concentration (SVC) of the substance. If the estimated exposure value exceeds the SVC, the tool will use the SVC value. This was previously a separate refinement which users could apply outside of the TRA tool, discussed extensively in Appendix F of Technical Report No. 107. This option has now been incorporated into Version 3 of the tool.

The SVC is only calculated for non-sprays products and the comparison is triggered by entering the chemical's molecular weight in cell B14 in the "User Input" worksheet. Once the molecular weight is entered, the SVC is automatically calculated in cell B15 (pink cell) (Figure 11). When the user places the mouse over cell B15, which has a red triangle in the top right corner of the cell, a text box displays the equation and assumptions used to calculate the SVC.

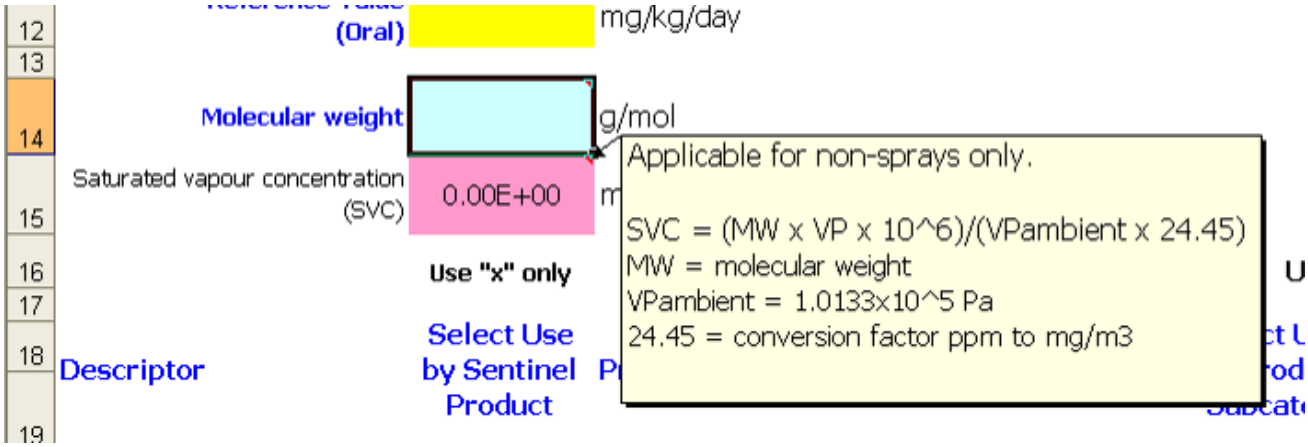

Figure 11. Equation and assumptions used to calculate SVC

To view whether the inhalation exposure estimate is based on the substance's SVC (Figure 12) you can either go into,

- the worksheet "Results by Sentinel Prod" in column AL
- or the worksheet "Inhalation (Prod Subcat)" in column R.

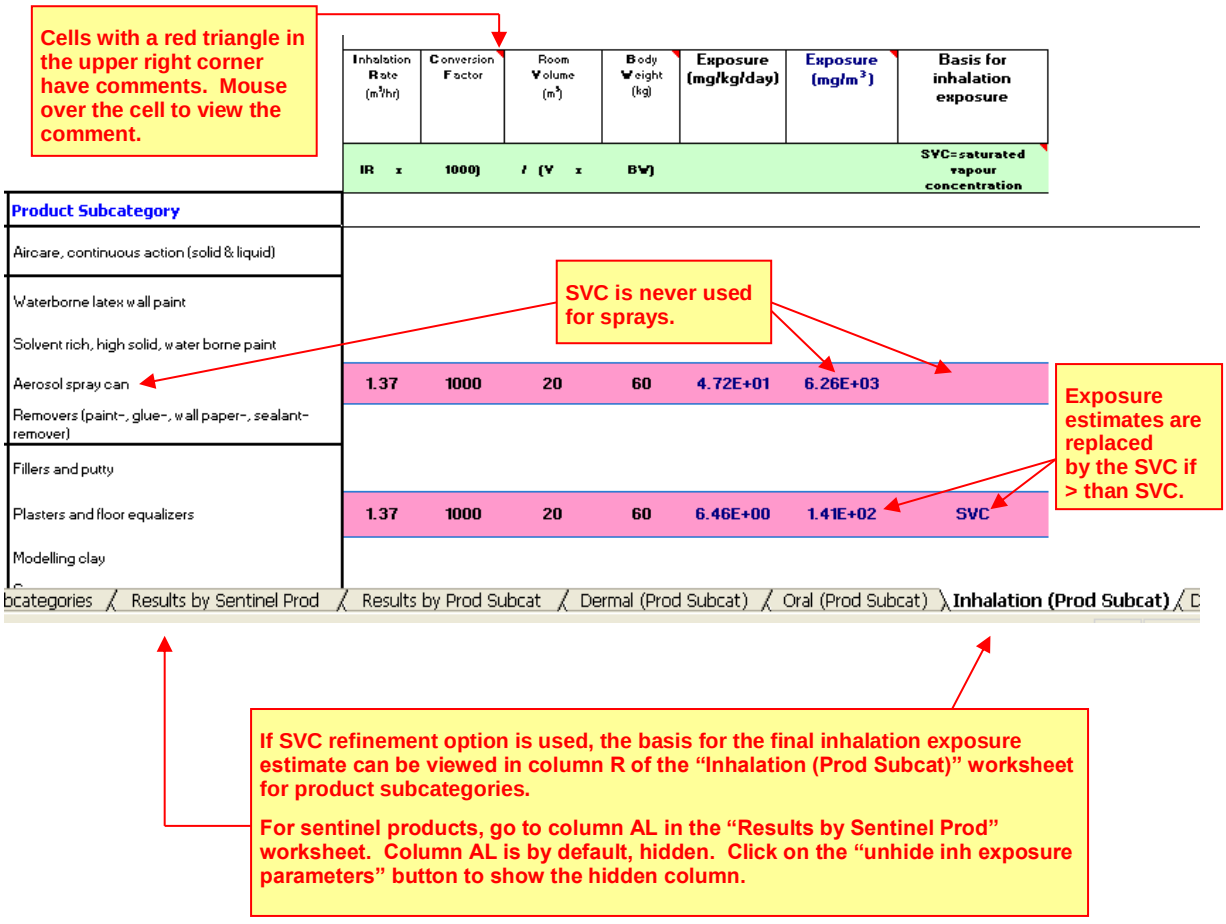

Figure 12. Location of the SVC refinements

4.2.2 Air Exchange Rate Dilution Factor:

The Dilution Factor (DF) has also been included in version 3 of the tool. In previous iterations the refinement was applied outside of the TRA tool (More information in Appendix F of Technical Report No. 107). This new addition can be found included in the algorithm for inhalation exposure calculations, which is shown in column I of the "Inhalation (Prod Subcat)" worksheet (Figure 13). The DF is calculated based on the duration of exposure (Exposure Time (hr)) and a conservative default value for air exchange.

The DF is included automatically by the tool without any intervention by the user. Refinement is achieved when users enter a specific value for the Exposure Time parameter.

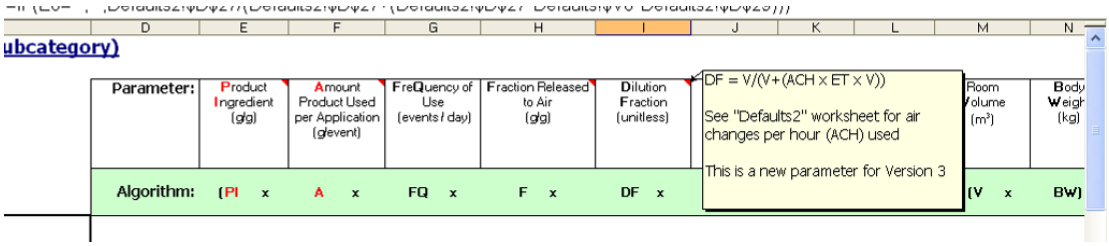

Figure 13. DF equation in the tool "Inhalation (Prod Subcat)"

A powerful additional alternative for refinement of exposure estimates is the building of new, tailor-made product subcategories (see Section 6 page 24 "Entering New Product Subcategories" in this guide). This is a new capability in version 3 of the tool and it requires knowledge by the user of data specific for the new subcategories.

5. VIEWING RESULTS

5.1 Sentinel Products

For sentinel products, refer to the "Results by Sentinel Prod" worksheet for both exposure and RCR estimates (Figure 14). By default, the algorithms and parameters used to calculate the exposure estimates are hidden from view and the only outputs displayed are: exposure estimates, and RCRs. To view the hidden algorithms and parameters, click on the buttons at the top of the worksheet (Figure 14).

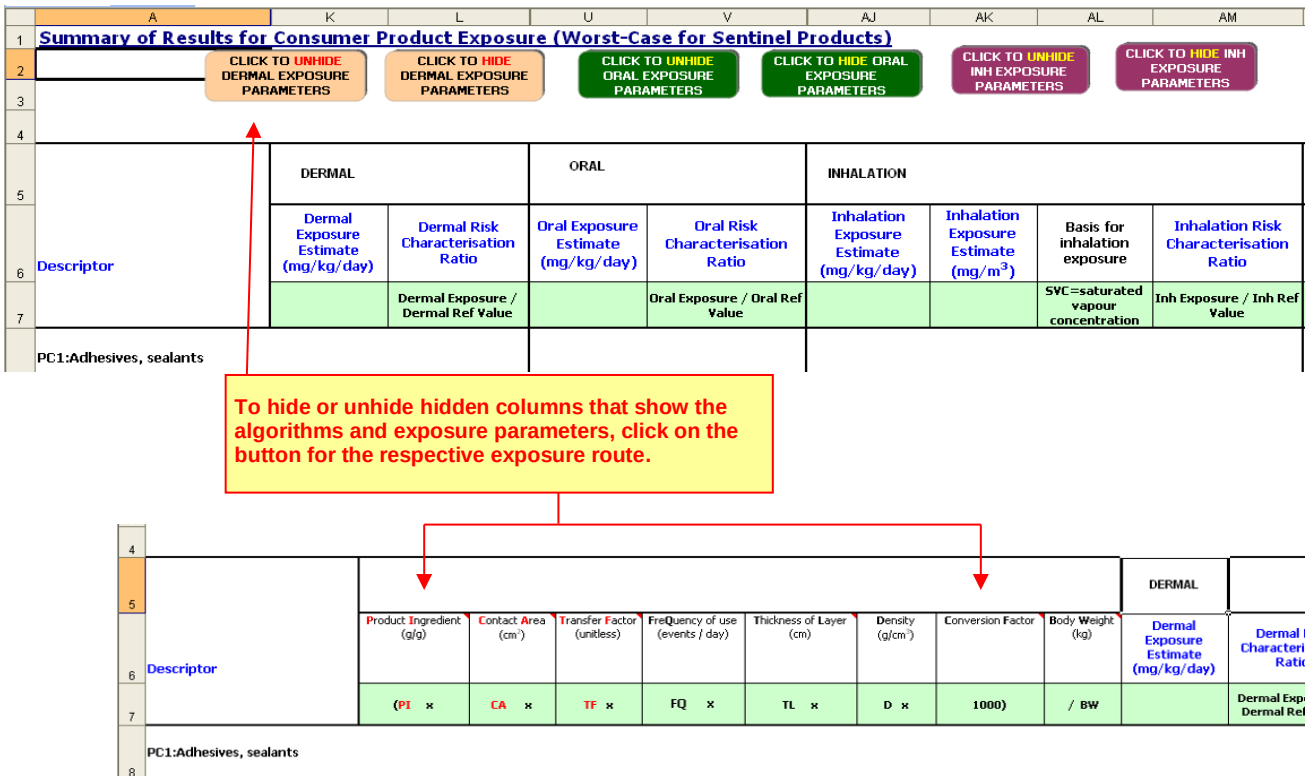

Figure 14. Results (exposure estimates and RCRs) for sentinel products, including buttons to hide/unhide exposure parameters

Rows for the sentinel products (previously selected in the "User Input" worksheet) are highlighted in pink (Figure 15). Risk characterisation ratios exceeding 1 are displayed in red. If no reference value or vapour pressure has been entered when such values are needed, error messages will be displayed, prompting the user to enter values in the "User Input" worksheet. The combined RCR value in column AN is the sum of the dermal, oral, and inhalation RCRs.

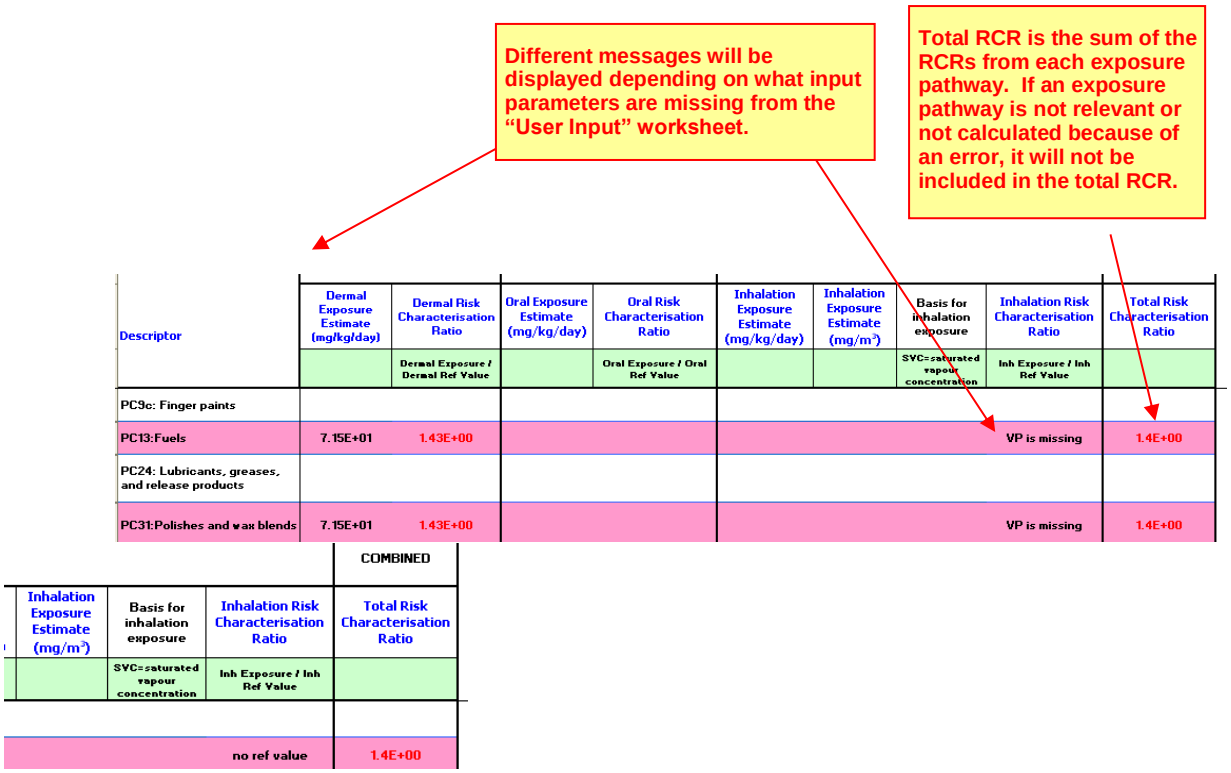

Figure 15. Results (exposure estimates and RCRs) for sentinel products, including error messages for missing input parameters

Note: To view exposure estimates for a specific exposure route only, enter a "dummy" reference value for that exposure route in the "User Input" worksheet (Cells B9 to B12). This will display the exposure concentration and not an error message that tells you the reference value is missing. You can ignore the RCRs generated using the "dummy" reference value.

5.2 Product Subcategories

Go to the "Results by Prod Subcat" worksheet to view results for product subcategories (previously selected in column D of the "User Input" sheet) (Figure 16). Only route-specific exposure estimates and RCRs (and also the combined RCR resulting from adding the RCRs from each route of exposure) are displayed in this sheet. To view the algorithms and parameters used to calculate route-specific exposure estimates, select either the "Dermal (Prod Subcat)", "Oral (Prod Subcat)", or "Inhalation (Prod Subcat)" tabs. These sheets are always locked to prevent accidental deletion or modification of equations, so users cannot change or edit values in these sheets. To change default parameter values you will need to go into the "User Input" sheet.

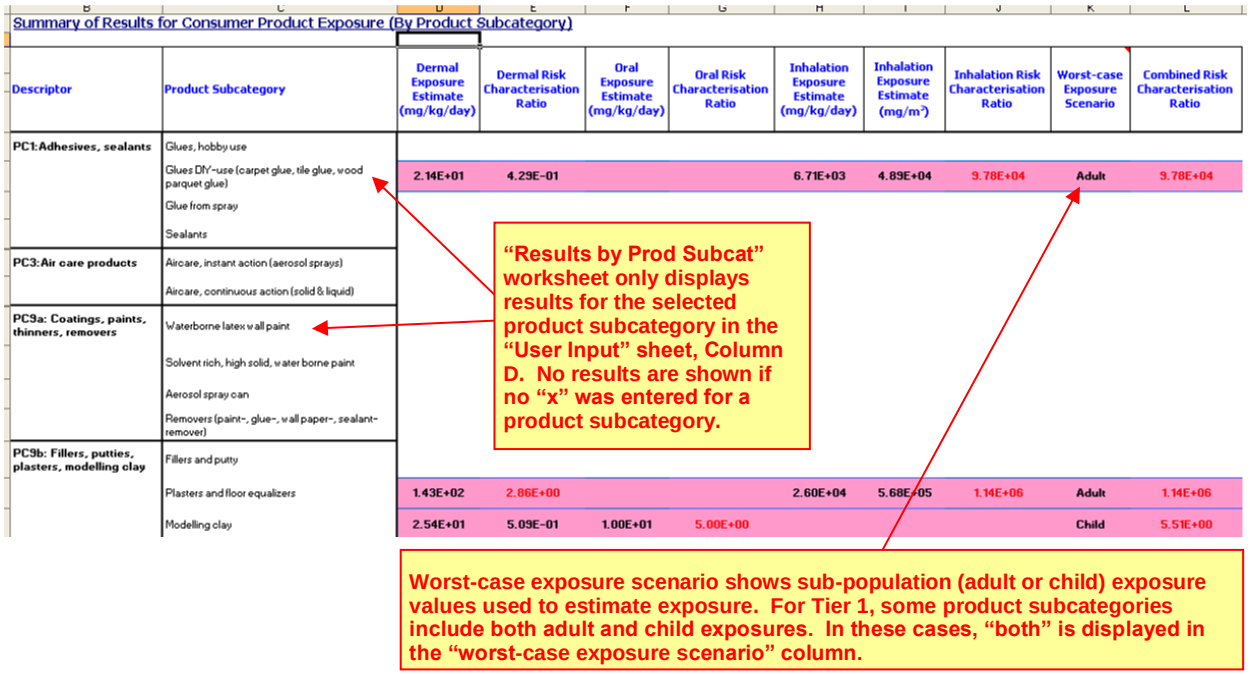

Figure 16. Results for product subcategories

6. ENTERING NEW PRODUCT SUBCATEGORIES

Users now have the option to add new product subcategories if product/article-specific information for a number of parameters is available for such subcategories.

Go to the "Add Subcategories" sheet to add a new product subcategory (Figure 17). Select the product type from a pre-populated dropdown list of PCs and ACs in Column B. This list contains both PCs and ACs already calculated with default input parameters. In Column D, enter the product subcategory name. Select the relevant exposure routes for the new subcategory in columns H, I, and J. At the same time, select adult or child exposure for the selected routes. This automatically selects sub-population specific exposure values (e.g., body weight, inhalation rate) that will be used to estimate exposure. For the inhalation exposure pathway, only adult exposure values can be selected at this time. This is based on the Tier 1 assumption that weighted exposure estimates, when taking into account body weight and inhalation rate, is higher for adult than for children.

As with the parameters in the "User Input" sheet, parameter values for yellow cells are required before the tool will calculate exposure estimates and RCRs. Blue cells contain pre-populated default values which will be used unless specific values are entered by the user. Enter the values for the parameters in yellow (required) and blue cells for each row. The parameters for which specific values can be selected include the following:

- Product Ingredient Fraction by Weight.
- Frequency of use (events per day).
- Transfer Factor dermal.
- Skin Contact area (cm^2). This value is automatically generated by selecting in column M the "body part exposed". The area value will show up in either column N or O depending on whether it corresponds to an adult or a child value.
- Transfer Factor oral.
- Contact area mouthed (cm^2): This value is generated by selecting in column Q the body part mouthed. The area value will show up in either column R or S depending on whether it corresponds to an adult or a child value. If no body part is chosen in column Q and "area of product mouthed" is chosen instead, users can enter a numerical value for the area of product mouthed in column S.
- Amount of Product used per Application (g/event).
- Exposure Time (hr).

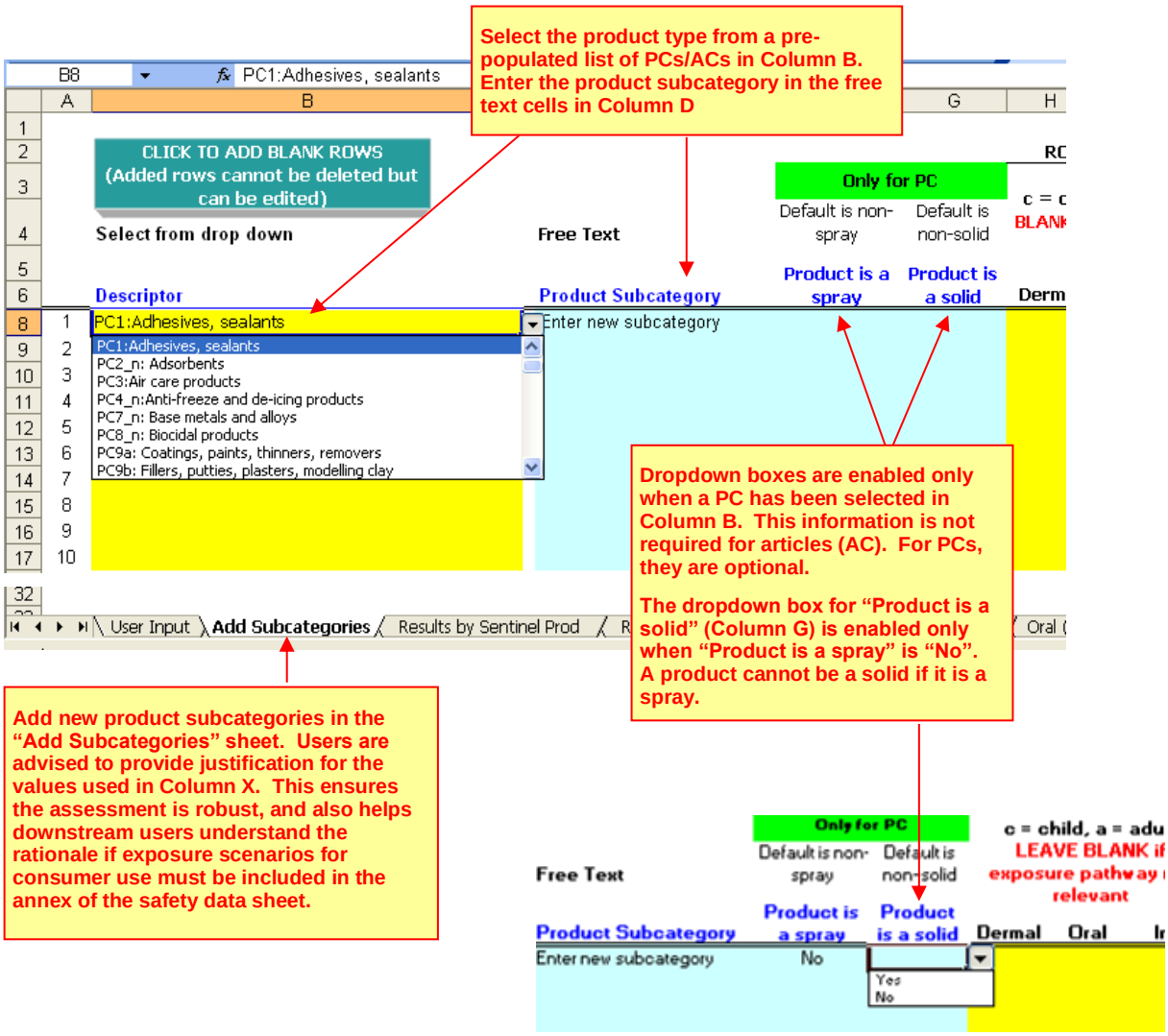

Figure 17. Entering new product subcategories in the "Add Subcategories" sheet

The sheet by default contains 10 editable entries that allow building up to ten new subcategories. To add more subcategories, click the "CLICK TO ADD BLANK ROWS" button on the top left of the worksheet (Figure 18). Macros must be enabled for the rows to be successfully added (see Section 2.1). Enter the number of new product subcategories you want to add in a text box that pops up after clicking the "add blank rows" button.

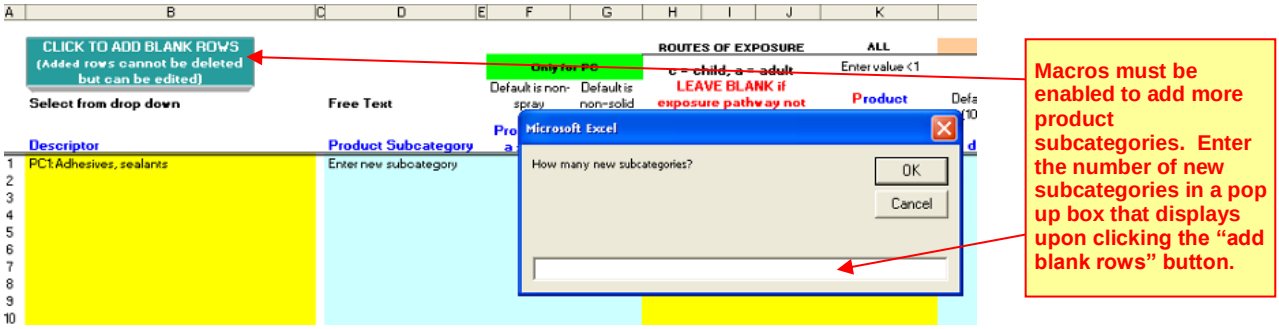

Figure 18. "Add Subcategories" sheet, add new blank rows

Note: Please refer to Section 1 in Page 5, for the context of the updated figure below.

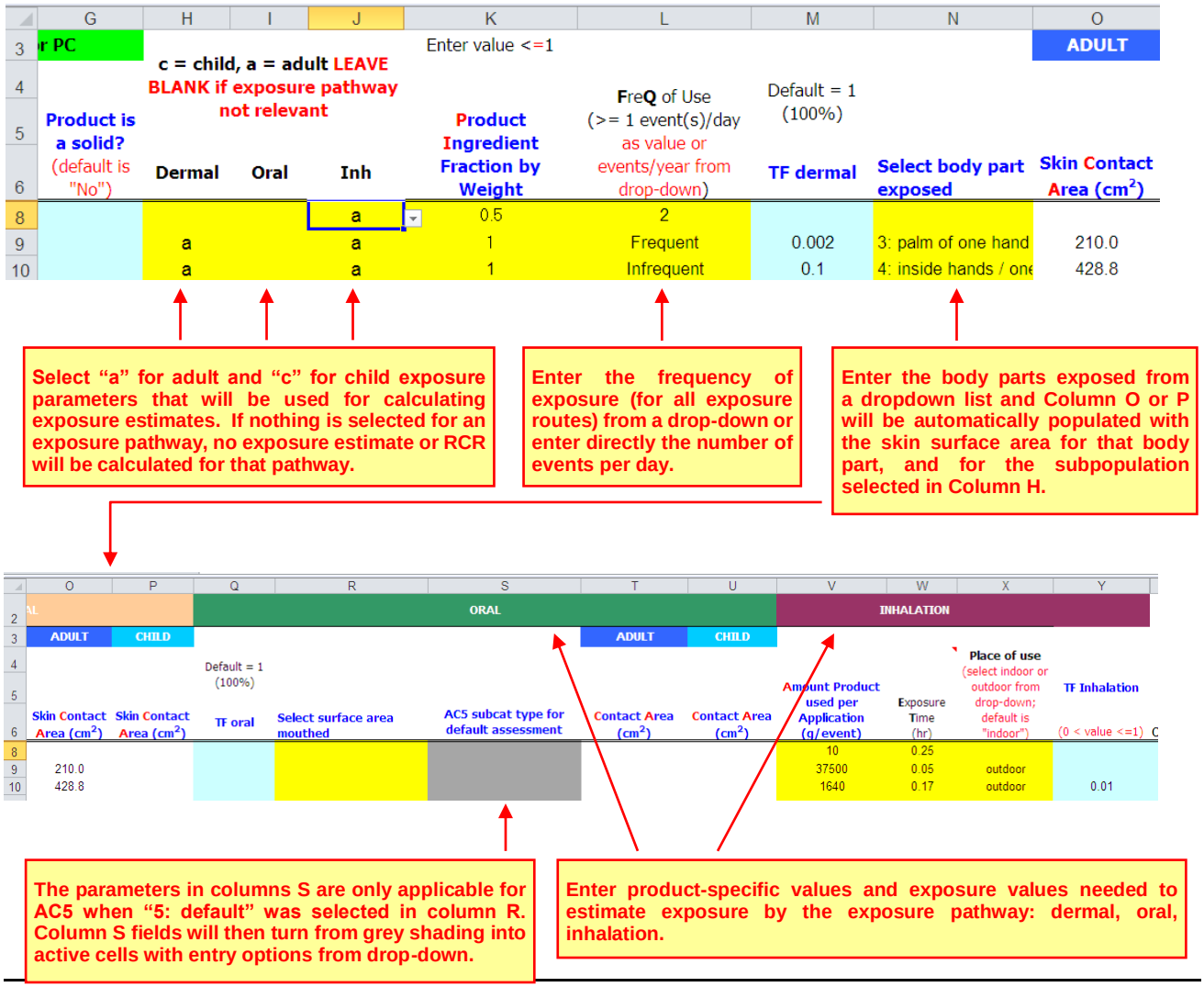

Figure 19. Updated v3.1"Add Subcategories" sheet

View results and exposure estimates following the same steps as discussed in Section 5 above. The only difference is that new product subcategories will not be used to calculate sentinel products. RCRs for the new product subcategories are displayed only in the "Results by Prod Subcat" sheet beginning from row 102 (Figure 20).

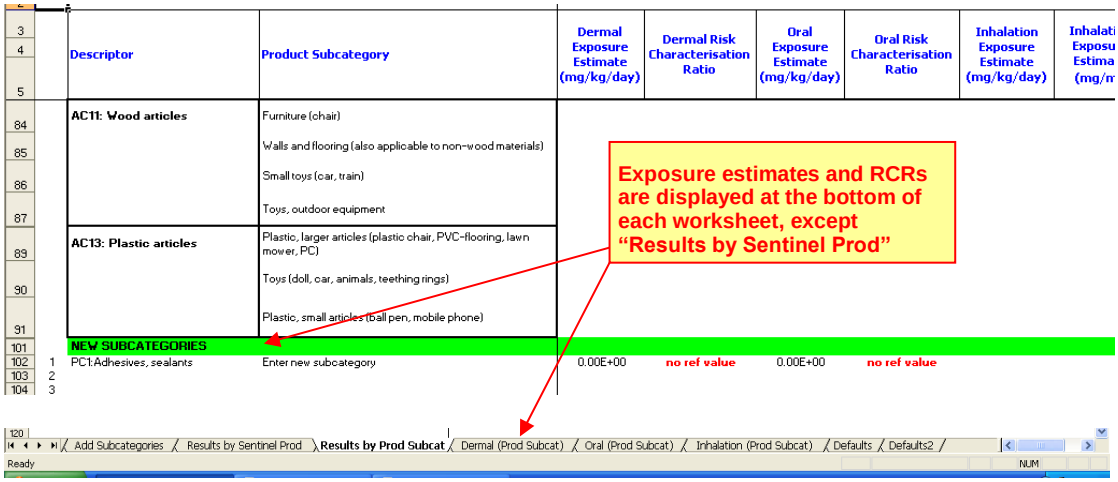

Figure 20. Results for new product subcategories in "Results by Prod Subcat" sheet

7. VIEWING DEFAULT PARAMETERS

Relevant routes of exposure and default parameters used in the exposure estimate calculations are listed in the “Defaults” and “Defaults2” worksheets (Figure 21). These worksheets are for information only and are therefore protected and cannot be changed by the user. Overriding of data, if appropriate, can only be done in the “User Input” worksheet or the “Add Subcategories” worksheet for new subcategories.

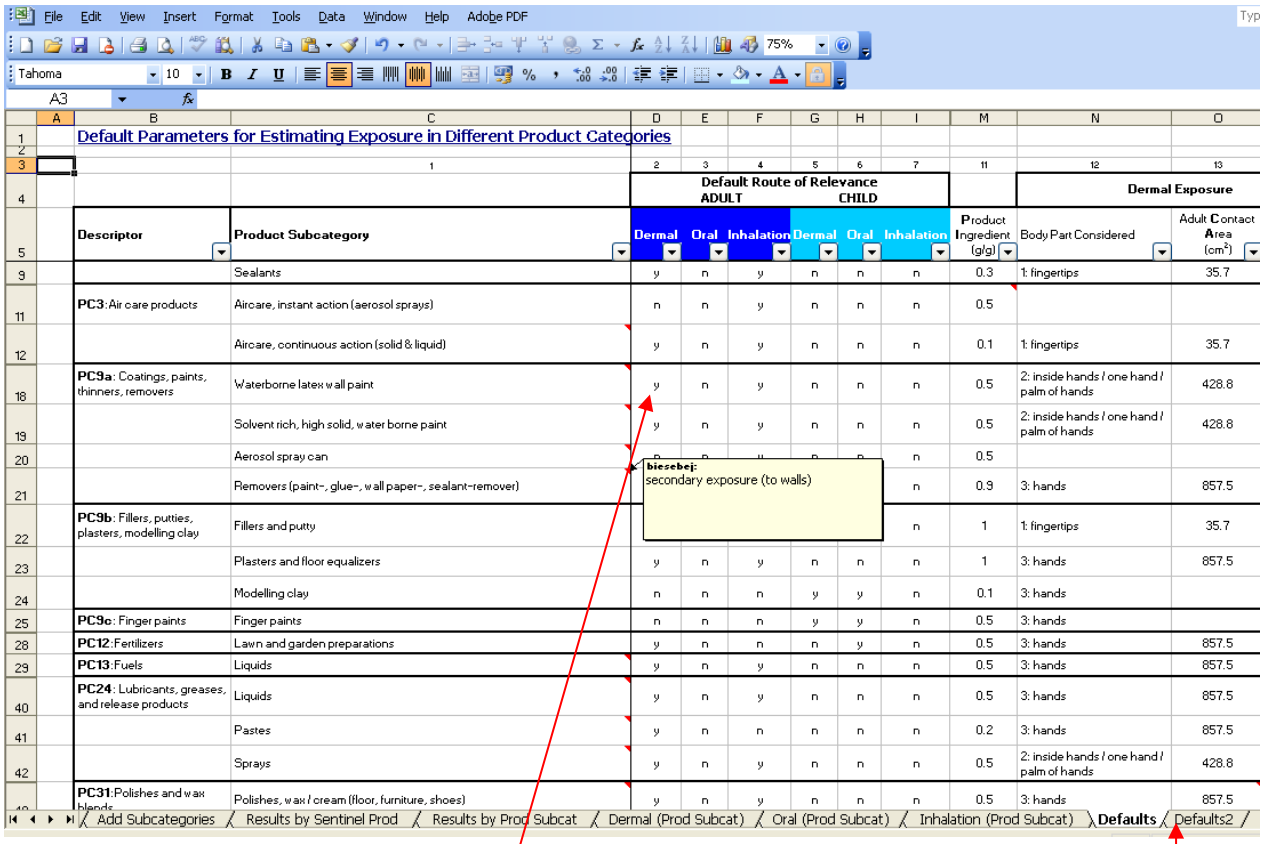

Figure 21. Relevant exposure pathways in “Default” and “Default2” worksheets