



TIP OF
THE
MONTH



Suitability Constraints

Suitability Constraints

Suitability Constraints are instructions or rules which can be set up for Parties, Regions, Customers or your own business to check compliance of polices for Raw Material use.

The rules can be applied in many different circumstances, to combinations of item types, single items, items in applications and relating to the application and dosage. When 'Suitability Check' is triggered the item is checked against all the rules that apply and a Suitability Report is generated for the User. Suitability checks can be undertaken during product development, selection and can also be linked to document production. This means ongoing compliance is possible to manage.

The key reasons to use Suitability checking are to:

- Ensure all formulations developed comply to internal or customer policies on ingredient use / non-use.
- Add rules to limit the hazards which would apply to a product used in an application at a specified dosage.
- Find matching items which meet customer restrictions, so non-compliant products are not submitted to customers
- Generate reports which show the reasons for non-compliance to aid formulation modification.
- Link the supply of documents to Suitability Checking, so product compliance is determined before issuing a document. This is a useful way of monitoring on going compliance.

Suitability is part of the Regulatory Module if you do not have this functionality and would like to add this feature please email support@formpak-software.com for more information.

Due to the recent increase in Cosmetic Allergens limiting the number that appear on the label has been a popular topic. The below example explains how this can be achieved by adding Suitability Constraints.

Add a New Suitability Constraint to Limit the number of Labelled Allergens

Navigate to Add a New Suitability Constraint.

Input the Party (This may be a Customer or a Party Group)

Comment You may want to leave a comment so you know what the Suitability Constraint is limiting.

For example: 'Leave-on Cosmetic applications Limit the number of labelled Allergens'

Choose the necessary Item Class if required or leave as All Item Types.

Select the Application(s). If you need help with adding Applications click [here](#) to view the relevant support article

To identify the required Items use Condition: 'Regulatory Items with Property At or Over Limit Count Maximum'.

Since we are looking for all Cosmetic Allergens use the Property AGNALL.

Select In Application.

The Limit is set to 0.001%. (Any allergen values below this level will be disregarded.)

Limit 2 defines the cut-off at, or over the maximum number of allergens, so in this case, 8 or more listed allergens results in a Suitability Fail.

A Constraint for Rinse-off Cosmetics with a limit of 0.01 should also be applied in a similar way to the below.

Add a New Suitability Constraint

On this page you can add a new suitability constraint.

Add a New Suitability Constraint

Party: EC [European Community]

Comment: []

Item Classes: All Item Types []

Application: COS_LEA001 [Leave-on Cosmetic]

Condition: Regulatory Item with Property At Or Ove []

Property: AGNALL [THIS IS/CONTAINS ALL COMMONLY REPORT]

Limit: 0.001 []

Limit 2: 8 []

In Application: Fixed Dosage: []

Apply to Direct Parties Belonged To Only:

Except Party:
Except Applications:
Except Items:

Using Suitability Checks

Navigate to Check Item Suitability.

Input the relevant Item.

the appropriate Party.

Select the relevant Item Class

Add the relevant Application(s) and Dosage(s).

Amend the TO and the format for reporting if required. Then Select 'Check Suitability'.

This will check the scenario, then give a message which indicates the Item either passed or failed the Suitability Check, with an option to 'Show Details'. Select 'Show Details' to access a PDF report with expanded information about the conditions of the check and the nature of the failed and / or passed checks.

Check Item Suitability | Check Suitability | Add from Basket | Print | View Details | Cancel | Help

On this page you can check the suitability of an Item.

Check Item Suitability

Item: DTH-FORM-MULTIF003 DTH Test Formulation - Multiflowers Dil

Party: European Community

Application: Body Butter 10 %

TO: Formpak Limited

Format: PDF

Item Name	Item Code	Application	Dosage(%)	Suitable
DTH Test Formulation - Multiflowers Dilution 0.5% in DPG	DTH-FORM-MULTIF003	Body Butter	10	✔

The report results indicates a pass with a tick and the statement 'Item conforms to the necessary Suitability Constraints' appears on the report.

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Suitability Check Report

Item Code	DTH-FORM-MULTIF003	Item Name	DTH Test Formulation - Multiflowers Dilution 0.5% in DPG
TO Code	DEFAULT	TO Name	Formpak Limited
Party Code	EC	Party Name	European Community
Application Name	Body Butter	Dosage(%)	10
Base Item Code		Base Item Name	

Expanded Parties

Name	Code
European Community	EC
Formpak Limited	DEFAULT
Global	GLOBAL
Requires compliance to IFRA Regulations	IFRA

Expanded Applications

Name	Dosage(%)
Body Butter	10
IFRA 49 Category 5A Applications	10
Leave-on Cosmetic	10

Item conforms to the necessary Suitability Constraints

Item does not violate any Suitability Constraints

Suitability Constraints Conformed

Conforms	Condition	Item/Property Name	Code	Limit	Limit 2	In Application	Value	Party	Applications
√	Regulatory Item with Property At Or Over Limit Count Maximum	THIS IS/CONTAINS ALL COMMONLY REPORTED ALLERGENS	AGNALL	0.001	8	In Application	4	European Community	Leave-on Cosmetic
	Items in the Composition	Eugenol	COMP-LM8786	Concentration(%)			0.012522	In Application(%)	0.00125220
		p-t-Butyl-alpha-methylhydrocinamic aldehyde	COMP-LM2478	Concentration(%)			0.01475	In Application(%)	0.0014750
		alpha-Hexylcinnamaldehyde	COMP-LM8773	Concentration(%)			0.019	In Application(%)	0.00190
		Tetramethyl acetyloctahydronaphthalenes	AGN23_STD_344	Concentration(%)			0.012	In Application(%)	0.00120
√	Exclusivity						-	European Community	

To demonstrate a failed Suitability Check, we change the concentration amount to 20%.

Check Item Suitability | Check Suitability | Add from Basket | Print | View Details | Cancel | Help

On this page you can check the suitability of an Item.

Check Item Suitability

Item: DTH-FORM-MULTIF003 DTH Test Formulation - Multiflowers Dil

Party: European Community

Application: Body Butter 20 %

TO: Formpak Limited

Format: PDF

Item Name	Item Code	Application	Dosage(%)	Suitable
DTH Test Formulation - Multiflowers Dilution 0.5% in DPG	DTH-FORM-MULTIF003	Body Butter	20	✘

The report then indicates a fail with a cross and the statement 'Item violates the necessary Suitability Constraints' appears on the report.

Suitability Check Report				Page 1 (2)
				Date 08/02/2024
Item Code	DTH-FORM-MULTIF003	Item Name	DTH Test Formulation - Multiflowers Dilution 0.5% in DPG	
TO Code	DEFAULT	TO Name	Formpak Limited	
Party Code	EC	Party Name	European Community	
Application Name	Body Butter	Dosage(%)	20	
Base Item Code		Base Item Name		

Expanded Parties		Expanded Applications	
Name	Code	Name	Dosage(%)
European Community	EC	Body Butter	20
Formpak Limited	DEFAULT	IFRA 49 Category 5A Applications	20
Global	GLOBAL	Leave-on Cosmetic	20
Requires compliance to IFRA Regulations	IFRA		

Item violates the necessary Suitability Constraints

Suitability Constraints Violated

Conforms	Condition	Item/Property Name	Code	Limit	Limit 2	In Application	Value	Party	Applications
x	Regulatory Item with Property At Or Over Limit Count Maximum	THIS IS/CONTAINS ALL COMMONLY REPORTED ALLERGENS	AGNALL	0.001	8	In Application	10	European Community	Leave-on Cosmetic
	Items in the Composition	Coumarin	COMP-LM4241	Concentration(%)			0.007	In Application(%)	0.00140
		Eugenol	COMP-LM8788	Concentration(%)			0.012522	In Application(%)	0.00250440
		Linalool	COMP-LM6825	Concentration(%)			0.0052297	In Application(%)	0.001045940
		p-t-Butyl-alpha-methylhydrocinnamic aldehyde	COMP-LM2478	Concentration(%)			0.01475	In Application(%)	0.00289500
		alpha-Hexylcinnamaldehyde	COMP-LM8773	Concentration(%)			0.019	In Application(%)	0.00380
		Camphor	AGN23_STD_331	Concentration(%)			0.008024	In Application(%)	0.00180480

The Suitability Check fails due to the limits set being exceeded. Ten allergenic components are listed, and the limit was 8 in application.

Mini Tip

SUITABILITY REPORT

Suitability Check Report Includes Item Sources Structure Report

You can now generate an Item Sources Structure Report when printing the Suitability Check if you have the necessary Regulatory Module on your system. This Report enables Users to understand the relationship between Component Items in the Suitability Check Report and the Formulation being checked.

To enable this function in the application, navigate to 'Manage Application Settings'.

Select Suitability Checking from the Category drop down menu.

Manage Application Settings - TEST (DB2 V10.3) Save

On this page you can modify the application settings.

Category: **Suitability Checking** (dropdown)

Setting	Description	Value
Item Count Warning Threshold		50
Item Count Error Threshold		250
Check Dilution Suitability		<input checked="" type="radio"/> Yes <input type="radio"/> No
Use Base Item in Suitability Checking for Dilutions		<input checked="" type="radio"/> Yes <input type="radio"/> No
Include Item Sources Structure Report in Suitability Check Report		<input checked="" type="radio"/> Yes <input type="radio"/> No

Select Yes 'Include Item Sources Structure Report in Suitability Check Report' and select Save.

Now navigate to 'Manage a User's Permissions on Operations' or 'Manage a Roles Permissions on Operations' (If you want to add this Permission to a Role)

Select the Operations Permission 'Print Item Sources Structure Report in Suitability Check Report' and select Save.

The screenshot shows a search interface for operations. At the top, there is a search bar with the text 'structure report'. Below the search bar are several filter options:

- Show Enabled Operations Only:
- Operation Type: Standard, Service
- License Level: A, B, C
- From: User, Role

Below the filters is a table with the following columns: Operation, Description, License Level, and All. The table contains one row with the following data:

Operation	Description	License Level	All
Print Item Sources Structure Report in Suitability Check Report		A	<input type="checkbox"/>